ACI

Brand Name: Cartilex® Plus
Generic: Glucosamine sulfate & Chondroitin sulfate
Dosage Form: Tablet
Strength: Glucosamine sulfate 750mg & Chondroitin sulfate 600mg
Indications: Osteoarthritis, Rheumatoid arthritis & Sports injuries

Brand Name: Coufix®
Generic: Dextromethorphan Hydrobromide + Guaifenesin + Menthol
Dosage Form: Syrup
Strength: Each 5ml contains Dextromethorphan Hydrobromide BP 15mg, Guaifenesin BP 200mg & Menthol USP 15mg
Indications: Cough with phlegm, Chest congestion & Sore throat

Brand Name: Acical®-MX
Generic: Calcium + Vitamin D3 + Minerals
Dosage Form: Effervescent Tablet
Strength: 600mg + 500 IU + Minerals (Mg, Cu, B, Zn, Mn)
Indication: Osteoporosis, Eclampsia, Pre-eclampsia, Premenstrual Syndrome, Calcium Deficiency

Brand Name: Glitin® M
Generic: Linagliptin + Metformin Hydrochloride
Dosage Form: Tablet
Strength: 2.5mg + 500mg; 2.5mg + 850mg; 2.5mg + 1000mg
Indication: Type 2 diabetes mellitus

Brand Name: Cilocab®
Generic: Cilnidipine INN
Dosage Form: Tablet
Strength: 5mg & 10mg
Indication: Hypertension

Brand Name: Bepost®
Generic: Bepotastine Besilate
Dosage Form: Eye drop
Strength: Bepotastine Besilate 1.5%
Indication: Allergic conjunctivitis

Brand Name: Testoren®
Generic: Testosterone
Dosage Form: Injection
Strength: 250mg/ml
Indications: Testosterone replacement therapy for primary and secondary hypogonadal disorders, including after castration, eunochoidism, hypopituitarism, endocrine impotence, infertility due to spermatogenic disorders, decreased libido and decreased feeling of wellbeing and fitness, osteoporosis & masculinization of female to male transsexuals

Brand Name: D3®
Generic: Colecalciferol
Dosage Form: Capsule & Tablet
Strength: 40000IU, 20000IU & 2000IU
Indications: For the prevention and treatment of vitamin D deficiency diseases like osteoporotic fracture, osteomalacia, back pain, low bone mineral density, during pregnancy and breastfeeding, pre-eclampsia, menopause, diabetics, depression

Brand Name: Fosfocin®
Generic: Fosfomycin Trometamol
Dosage Form: Powder for Oral Solution
Strength: 3g
Indication: Uncomplicated Urinary Tract Infection (Acute Cystitis)

Brand Name: Lynotril®
Generic: Lynestrenol
Dosage Form: Tablet
Strength: 5mg
Indications: Primary & secondary Amenorrhea, Oligomenorrhea, Polymenorrhea.

ACME

Brand Name: Glifo
Generic Name: Empagliflozin INN
Dosage Form: Powder
Strength: Glifo 10- Each film coated tablet contains Empagliflozin INN 10mg.
Glifo 25- Each film coated tablet contains Empagliflozin INN 25 mg.
Indications: Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus and to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Brand Name: Trizidim
Generic Name: Ceftazidime
Dosage Form: Injection
Strength: 250 mg IM/IV, 500 mg IM/IV and 1 g IM/IV

Indications: Lower respiratory tract infections, Skin & skin structure infections, Urinary tract infections, Bacterial septicemia, Bone & joint infections, Gynecological infections, Intra-abdominal infections, Central nervous system infections, Infections associated with haemo-and peritoneal dialysis and with continuous ambulatory peritoneal dialysis (CAPD).

Aristopharma

Brand Name: Cilnipin
Generic Name: Cilnidipine
Dosage Form: Tablet
Strength: 5mg & 10mg
Indications: For the management of hypertension

Brand Name: Aristo D_3
Generic Name: Cholecalciferol
Dosage Form: Tablet
Strength: 2000 IU
Indications: To treat vitamin D_3 deficiency & related diseases

Brand Name: Aristo D_3
Generic Name: Cholecalciferol
Dosage Form: Capsule
Strength: 20000 IU
Indications: To treat vitamin D_3 deficiency & related diseases

Brand Name: Aristo D_3
Generic Name: Cholecalciferol
Dosage Form: Capsule
Strength: 40000 IU
Indications: To treat vitamin D_3 deficiency & related diseases

Brand Name: Arthanib & Arthanib XR
Generic Name: Tofacitinib
Dosage Form: Tablet
Strength: 5mg & 11mg
Indications: For the treatment of rheumatoid arthritis, psoriatic arthritis and ulcerative colitis.

Asiatic

Brand Name: Asibalin
Generic Name: Pregabalin INN
Dosage Form: Capsule
Strength: 25mg
Indications: Diabetic Neuropathy, Low Back Pain, Fibromyalgia, Spinal Cord Injury, Partial Onset Seizure.

Brand Name: Asibalin
Generic Name: Pregabalin INN
Dosage Form: Capsule
Strength: 50mg
Indications: Diabetic Neuropathy, Low Back Pain, Fibromyalgia, Spinal Cord Injury, Partial Onset Seizure.

Brand Name: Asibalin
Generic Name: Pregabalin INN
Dosage Form: Capsule
Strength: 75mg
Indications: Diabetic Neuropathy, Low Back Pain, Fibromyalgia, Spinal Cord Injury, Partial Onset Seizure.

Beximco

Brand Name: Tigel
Generic Name: Ticagrelor
Dosage Form: Tablet
Strength: 90mg
Indication: To reduce the risk of CV death, MI and Stroke during the first year of ACS event.

Brand Name: Onriva Plus Bexicap
Generic Name: Indacaterol & Glycopyrronium
Dosage Form: Dry Powder Inhaler (DPI)
Strength: 110mcg & 50mcg
Indications: Fast-acting once-daily LABA/LAMA combination for COPD patients.

Brand Name : Turboclav®
Generic Name: Cefuroxime + Clavulanic Acid
Dosage Form: Tablet
Strength: 250mg + 62.5mg and 500 mg + 125mg
Indications: Tonsillopharyngitis, Tonsillectomy, Acute Suppurative Otitis Media (ASOM), Chronic Suppurative Otitis Media (CSOM), Sinusitis, Cellulitis & Abscess, Cystitis, Pyelonephritis, Complicated UTIs, Dentoalveolar Abscess & Infections, Diabetic Foot Infections, Bone & Joint Infections, Osteomyelitis, Acute Exacerbation of Chronic Bronchitis (AECB) & Community Acquired Pneumonia (CAP).

Brand Name: Vomix® DR
Generic Name: Doxylamine Succinate & Pyridoxine HCl
Dosage Form: Tablet
Strength: 10mg + 10mg
Indications: Nausea & Vomiting in Pregnancy.

Eskayef

Brand Name: Memanto
Generic Name: Memantine hydrochloride
Dosage Form: Film coated tablet
Strength: 5mg & 10mg
Indications: Moderate to severe dementia of Alzheimer's disease and Vascular dementia.

Brand Name: Emazid
Generic Name: Empagliflozin
Dosage Form: Tablet
Strength: 10mg & 25mg
Indications: Type 2 Diabetes Mellitus

Brand Name: Ostiban
Generic Name: Ibandronic Acid
Dosage Form: Tablet (film coated)
Strength: 150mg
Indications: Prevention and treatment of osteoporosis

Brand Name: Palosis Injection
Generic Name: Palonosetron Hydrochloride
Dosage Form: Intravenous injection
Strength: 0.075mg/ 1.5mL
Indications: Prevention of acute nausea and vomiting associated with initial and repeat courses of moderately and highly emetogenic cancer chemotherapy, Prevention of delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy and Postoperative nausea and vomiting.

Brand Name: Cardobis M
Generic Name: Bisoprolol & Amlodipine
Dosage Form: Tablet
Strength: 2.5mg & 5mg
Indications: Hypertension and Stable Coronary Artery disease.

Brand Name: Gemtor
Generic Name: Gemcitabine
Dosage Form: Lyophilized Powder for Injection
Strength: 1gm & 200mg
Indications: Advanced Breast Cancer, Advanced Ovarian Cancer, Advanced non-small cell Lung Cancer and Advanced Pancreatic Cancer.

Euro Pharma

Brand Name: Axipime
Generic Name: Cefipime
Dosage Form: Injection
Strength: 1gm IV
Indications: Renal and urinary tract infections, Gonococcal infections, Lower respiratory tract infections particularly pneumonia, Skin and soft tissue, Bone and joint infections, Bacterial meningitis, Serious bacterial infections e.g. septicemia, ENT infections, Infections in cancer patient, Typhoid/Enteric fever, Prevention of postoperative infection, Preoperative prophylaxis of infections associated with surgery

Brand Name: Oropem
Generic Name: Meropenem
Dosage Form: Injection
Strength: 1gm IV
Indications: Pneumonias and Nosocomial Pneumonias, Septicaemia, Urinary Tract Infections, Empiric treatment for presumed infections in adult patients with febrile neutropenia and other polymicrobial infections, Gynaecological Infections such as endometritis, Intra-abdominal Infections, Meningitis, Skin and Skin Structure Infections.

Brand Name: Nixamid
Generic Name: Nitazoxanide
Dosage Form: Tablet
Strength: 500mg
Indications: Protozoal diarrhoea caused by *Cryptospordium parvum*, *Giardia strains* (lamblia/ intestinalis) and *Entamoeba histolytica*, Diarrhoea caused by rota virus, Wide range of helminth/ worm infections; Helminthiasis, Diarrhoea caused by Giardia strains that are resistant to other drugs

Brand Name: Clepam
Generic Name: Clonazepam
Strength: 0.5mg & 2mg
Dosage Form: Tablet
Indications: Panic disorder, Anxiety disorders (Generalized & Phobic disorders), Insomnia & severe sleeping disorder, prolonged depression, Hypertension, Peri and Post-menopausal anxiety (Anxiety in middle aged women), Postoperative anxiety disorder, Tension Headache, Seizure disorders: Partial seizures, generalized seizures

Brand Name: Nenvit
Generic Name: Vitamin B_1 + B_6 + B_{12}
Dosage Form: Tablet
Strength: 100mg+200mg+200mcg
Indications: Polyneuropathy of any origin such as-Diabetic, Alcoholic etc, Neuritis, Neuralgia, Cervical Syndrome, Shoulder-arm syndrome, Lumbago, Sciatica, Myalgia, Intercostal, Neuralgia, Herpes-Zoster, Trigeminal Neuralgia, Supportive treatment in facial paresis.

Brand Name: Vita AZ Gold
Generic Name: Multivitamin & Multimineral
Dosage Form: Tablet
Indications: Tablet helps preventing and treatment of vitamin &-mineral deficiencies in adult, It stimulates appetite and improves digestion, Promotes healthy hair, skin and nails, good vision, strong bones and healthy teeth, Increases resistance against coughs, colds, chest and bronchial troubles, Helps maintain healthy muscles and nervous system

Brand Name: Dofolin
Generic Name: Doxofylline
Dosage Form: Tablet
Strength: 200mg & 400mg
Indications: Asthma, Chronic Obstructive Pulmonary Disease (COPD), Bronchospasm

Brand Name: Eteen
Generic Name: Ebastine
Dosage Form: Tablet
Strength: 10mg
Indication: Seasonal and perennial allergic rhinitis, Allergic skin disorders, Chronic idiopathic urticarial.

General

Brand Name: Nebipres
Generic Name: Nebivolol
Dosage Form: Tablet
Strength: 2.5mg & 5mg
Indications: Hypertension: Nebivolol is indicated for the treatment of hypertension, to lower blood pressure. Nebivolol may be used alone or in combination with other antihypertensive agents. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions. Chronic heart failure: Treatment of mild to moderate chronic heart failure in patients over 70 years.

Brand Name: Emfogen
Generic Name: Empagliflozin
Dosage Form: Tablet
Strength: 10mg & 25mg
Indication: Emfogen is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus and also to reduce the risk of cardiovascular death in adult patients with type 2 diabetes mellitus and established cardiovascular disease.

Hamdard

Brand Name: Vitorist
Generic Name: Balarista
Dosage Form: Syrup
Indications: General debility, Malnutrition, Indigestion, Paralysis, Hand tremors, Deafness, Dysarthria & Rheumatism.

Brand Name: Nervonic
Generic Name: Aswagandharista
Dosage Form: Syrup
Indications: Epilepsy, Swooning, Apoplexy, Insanity, Arthritis, Insomnia and General decay.

Brand Name: SUDYS
Generic Name: Mustakarista
Dosage Form: Syrup
Indications: Dyspepsia, Indigestion, Diarrhoea, Cholera, Puerperal sickness & IBS.

Brand Name: GHITIKA
Generic Name: Gheekowar
Dosage Form: Syrup
Indications: Constipation, Weakness of stomach & liver, Inflammatory conditions of liver.

Kumudini

Brand Name: Myospa
Generic Name: Baclofen BP
Dosage Form: Tablet
Strength: 10mg
Indications: Baclofen is indicated for Spasm & Spasticity, Low back pain, Spinal cord injury/disease.

NIPRO JMI

Brand Name: D-Star 20000
Generic Name: Colecalciferol
Dosage Form: Capsule
Strength: 20000 IU
Indications: Vit Treatment & prevention of vitamin D deficiency addition to specific therapy for osteoporosis.

Brand Name: D-Star 40000
Generic Name: Colecalciferol
Dosage Form: Capsule
Strength: 40000 IU
Indications: Treatment & prevention of vitamin D deficiency addition to specific therapy for osteoporosis.

Brand Name: Visnil Syrup
Generic Name: Tiemonium Methylsulphate
Dosage Form: Syrup
Strength: 10mg/ 5ml
Indication: Visceral pain reliever

Opsonin

Brand Name: Trilock® Oral Granules Sachet
Generic Name: Montelukast USP
Dosage Form: Tablet
Strength: 10mg, 4mg, 5mg & 4mg
Indications: Asthma & allergic rhinitis.

Brand Name: Finix ®
Generic Name: Rabeprazole Sodium
Dosage Form: Capsule
Strength: 20 mg
Indications: GERD, Ulcer & NSAID Induced Ulcer etc.

Brand Name: Bislol® Max
Generic Name: Bisoprolol fumarate & Amlodipine
Dosage Form: Tablet
Strength: 2.5/5mg
Indications: Hypertension, Angina Pectoris & Stable chronic heart failure.

Brand Name: Xolamid® T
Generic Name: Brinzolamide USP 1% + Timolol BP 0.5%
Dosage Form: Eye Drops
Strength: 1%+0.5%
Indications: Open Angle Glaucoma or Ocular Hypertension.

Brand Name: Sitadus®-M
Generic Name: Sitagliptin INN + Metformin USP
Dosage Form: Tablet
Strength: 50/500 + 50/1000mg
Indication: Type-2 Diabetic Mellitus

Brand Name: Finix®
Generic Name: Rabeprazole Sodium
Dosage Form: Capsule
Strength: 10mg
Indications: Pediatric GERD & Hyperacidity Management.

Popular

Brand Name: Fatisol
Generic Name: IV Fat Emulsion 10%
Dosage Form: Glass Bottle
Strength: 250ml & 500ml
Indications: Fatisol is a source of calories & essential fatty acids for patients requiring parenteral nutrition for extended periods of time (usually for > 5 days). It is a source of essential fatty acids when a deficiency occurs. Part of the intravenous diet in all parenteral nutrition indications including:

- Preoperative & postoperative nutritional disturbances where an improved nitrogen balance is required.
- Failing intestinal absorption caused by tumors in the GIT & acute or chronic intestinal diseases e.g. peritonitis. Burns & prolonged unconsciousness.
- Impaired renal function where a concentrated source of energy may be indicated to reduce protein breakdown.
- Cachexia & patients with essential fatty acid deficiency who cannot maintain or restore a normal essential fatty acid pattern by oral intake.

Brand Name: Obecol
Generic Name: Obeticholic Acid
Dosage Form: Tablet
Strength: 5mg
Indications: Obecol is indicated for the treatment of primary biliary cholangitis (PBC) in combination with Ursodeoxycholic Acid (UDCA) in adults with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA, cho-

lestatic liver disease & non-alcoholic fatty liver disease (NAFLD) including non-alcoholic steatohepatitis (NASH).

Renata

Brand Name: Angela
Generic Name: Drospirenone and Estradiol
Dosage Form: Oral Tablet
Strength: 0.5mg and 1mg
Indications: Angela is an HRT which reduces the menopausal symptoms (hot flush, night sweating, palpitation etc.) without increasing body weight, prevents osteoporosis, provides endometrial protection, offers beneficial effects on cardiovascular parameters and lipid profile in Post-menopausal women only with intact Uterus.

Brand Name: Antogin ER
Generic Name: Ranolazine
Dosage Form: Tablet
Strength: 500mg
Indications: It is indicated for the treatment of chronic angina. Ranolazine may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors and angiotensin receptor blockers.

Brand Name: Azisan Plus
Generic Name: Azilsartan Medoxomil INN and Chlorthalidone USP
Dosage Form: Tablet
Strength: 40mg and 12.5mg
Indications: For the treatment of hypertension, to lower blood pressure.

Brand Name: Bigmet XR
Generic Name: Metformin Hydrochloride BP
Dosage Form: Tablet
Strength: 500mg
Indications: It is used in the management of non-insulin dependent diabetes mellitus.

Brand Name: Pulmino
Generic Name: Doxofylline
Dosage Form: Oral Tablet
Strength: 400mg
Indications: Asthma, COPD, Chronic Bronchitis.

Brand Name: Erpen
Generic Name: Ertapenem
Dosage Form: IM/IV Injection
Strength: 1g
Indications: Complicated intra-abdominal infections, Complicated skin and skin-structure, infections, Community-acquired pneumonia, Complicated urinary tract infections and Acute pelvic infections.

Brand Name: Glinta
Generic Name: Linagliptin
Dosage Form: Tablet
Strength: 5mg
Indications: It is indicated in the treatment of type II diabetes mellitus to improve glycemic control in adults.

Brand Name: Oxyton DS
Generic Name: Oxytocin
Dosage Form: Injection
Strength: 10 IU
Indications: An uterotonic agent indicated for Induction of labor, Stimulation of uterine contraction, Post-partum hemorrhage and To stimulate lactation (only if advised by gynecologist).

Sharif

Brand Name: Calcibost-D
Generic Name: Calcium Carbonate + Vitamin D3
Dosage Form: Tablet
Strength: 500mg+ 200 IU
Indications: Used as Dietary calcium supplement and also in Pregnancy & lactation, Osteoporosis, Osteomalacia, Rickets, Parathyroid disease, Kidney disease.

Brand Name: Esobest Injection
Generic Name: Esomeprazole
Dosage Form: Injection
Strength: 40mg
Indications: Chronic heartburn symptoms and other symptoms associated with GERD, healing of erosive esophagitis, NSAID associated gastric ulcers, Zollinger-Ellison Syndrome, Acid related Dyspepsia, Gastric & Duodenal ulcer.

Square

Brand Name: D-balance
Generic Name: Cholecalciferol
Dosage Form: Licap
Strength: 2000IU, 20000IU & 40000IU
Indications: For the prevention & Treatment of Vitamin D deficiency & associated diseases.

Brand Name: Caberol
Generic Name: Cabergoline
Dosage Form: Tablet
Strength: 0.5 mg
Indication: Hyperprolactinemia

Brand Name: Normo-K
Generic Name: Sodium Polystyrene Sulfonate
Dosage Form: Powder for Suspension
Strength: 100mg/gm
Indication: For the treatment of hyperkalemia

Brand Name: Calboral-DX
Generic Name: Coral Calcium+Vit-D
Dosage Form: Tablet
Strength: 600mg + 400IU
Indications: To prevent & treatment of low blood Calcium levels, Osteoporosis

Brand Name: Gutfix
Generic Name: Lubiprostone
Dosage Form: Licap
Strength: 8mcg
Indications: Irritable Bowel Syndrome with Constipation (IBS-C), Functional constipation of children

Brand Name: Gutlax
Generic Name: Lubiprostone
Dosage Form: Licap
Strength: 24mcg
Indication: Chronic Idiopathic Constipation (CIC), Opioid Induced Constipation (OIC)

Brand Name: Cefopen
Generic Name: Cefoperazone
Dosage Form: IM/IV
Strength: 2gm
Indications: Peritonitis & Intra-abdominal Infections, Respiratory Tract Infections, Bacterial Septicemia, Skin and Skin Structures Infection, Pelvic Inflammatory Disease, Endometritis & Female Genital Tract Infections, Urinary Tract Infections.

Brand Name: Reli Balm
Generic Name: l-Menthol, d-Camphor, Eucalyptus Oil, Mint Oil
Dosage Form: Cream
Strength: 25gm
Indication: Pain in Neck & Shoulder

Brand Name: Methigic
Generic Name: Methylprednisolone
Dosage Form: Tablet
Strength: 2, 4, 8 & 16mg
Indications: Inflammatory & allergic disorder, Rheumatoid arthritis, Bronchial Asthma

Brand Name: Vertina D
Generic Name: Doxylamine Succinate + Pyridoxine Hydrochloride
Dosage Form: Delayed Release Tablet
Strength: 10mg + 10mg
Indication: Nausea and Vomiting of Pregnancy (NVP)

Brand Name: Dubarel
Generic Name: Aushokarist
Dosage Form: Syrup
Strength: 100ml
Indications: Dysfunctional Uterine Bleeding (DUB), Menorrhagia, Secondary amenorrhea, Polycystic Ovary Syndrome (PCOS)

Brand Name: Zolibac
Generic Name: Cefazolin
Dosage Form: IM/IV Injection
Strength: 500mg & 1gm
Indications: Perioperative Prophylaxis, Respiratory Tract Infections, Urinary Tract Infections, Skin and Skin Structure Infections, Biliary Tract Infections, Bone and Joint Infections, Genital Infections, Septicemia, Endocarditis.

Team Pharma

Brand Name: Ceftem 200
Generic Name: Cefixime
Dosage Form: Capsule
Strength: 200mg
Indications: Upper and lower respiratory tract infections, Urinary tract infections, Typhoid fever, Acute otitis media etc.

Brand Name: Ceftem 400
Generic Name: Cefixime
Dosage Form: Capsule
Strength: 400mg
Indications: Upper and lower respiratory tract infections, Urinary tract infections, Typhoid fever, Acute otitis media etc.

Brand Name: Ceftem PFS
Generic Name: Cefixime
Dosage Form: PFS
Strength: 50ml
Indications: Upper and lower respiratory tract infections, Urinary tract infections, Typhoid fever, Acute otitis media etc.

Brand Name: Temtrix 1 gm IV
Generic Name: Ceftriaxone
Dosage Form: IV Injection
Strength: 1 gm IV
Indications: UTIs, LRTIs, Bone and joint infections, Bacterial meningitis, Serious bacterial infections e.g. septicemia, prophylaxis of infections associated with surgery, Typhoid fever etc.

Brand Name: Temtrix 1 gm IM
Generic Name: Ceftriaxone
Dosage Form: IM Injection
Strength: 1gm IM
Indications: UTIs, LRTIs, Bone and joint infections, Bacterial meningitis, Serious bacterial infections e.g. septicemia, prophylaxis of infections associated with surgery, Typhoid fever etc.

Brand Name: Temtrix 2 gm IV
Generic Name: Ceftriaxone
Dosage Form: IV Injection
Strength: 2gm IV
Indications: UTIs, LRTIs, Bone and joint infections, Bacterial meningitis, serious bacterial infections e.g. septicemia, prophylaxis of infections associated with surgery, Typhoid fever etc.

Ziska

Brand Name: Erdolyt
Generic Name: Erdosteine INN
Dosage Form: Capsule
Strength: 300mg
Indications: Symptomatic treatment of acute exacerbations of chronic bronchitis.

Brand Name: Expreso
Generic Name: Guaifenesin BP + Dextromethorphan hydrobromide BP + Menthol USP
Dosage Form: Syrup
Strength: 4gm +0.30gm + 0.30gm
Indications: Cough, Sore Throat, Chest Congestion.

Brand Name: Fungitac
Generic Name: Sertaconazole Nitrate
Dosage Form: 2%
Strength: Cream
Indications: Tinea pedis & Other Superficial fungal infections (SFIs)

Brand Name: Iminod
Generic Name: Imiquimod
Dosage Form: Cream
Strength: 5%
Indications: Anogenital Warts, Actinic Keratosis, Superficial Basal Cell Carcinoma.

Brand Name: Imucort
Generic Name: Deflazacort
Dosage Form: Tablet
Strength: 24mg
Indications: Asthma, COPD, rheumatoid arthritis, eczema, psoriasis, systemic lupus erythematosus, ulcerative colitis, crohns disease etc.

Brand Name: Imucort
Generic Name: Deflazacort
Dosage Form: Tablet
Strength: 6mg
Indications: Asthma, COPD, rheumatoid arthritis, eczema, psoriasis, systemic lupus erythematosus, ulcerative colitis, crohns disease etc.

Brand Name: Imucort
Generic Name: Deflazacort
Dosage Form: Suspension
Strength: 6mg/5ml
Indications: Asthma, COPD, rheumatoid arthritis, eczema, psoriasis, systemic lupus erythematosus, ulcerative colitis, crohns disease etc.

Brand Name: Z-Lidocaine Plus
Generic Name: Lidocaine HCL 2% & Epinephrine
Dosage Form: Injection (Vial)
Strength: 20mg & 0.005mg/ml
Indication: Local or Regional anesthesia.

SQUARE Pharmaceuticals Ltd. organize Samson H Chowdhury Memorial Conference 2019

The 4th Samson H Chowdhury Memorial Conference was held recently in Dhaka. Policy makers, government officials, industrialists, scientists, academicians, business professionals attended the conference that discussed various aspects of the pharmaceutical industry. Managing Director of SQUARE Pharmaceuticals Ltd. Tapan Chowdhury in his inaugural speech highlighted the role of Late Samson H Chowdhury in developing the pharmaceutical sector of Bangladesh.

The biennial conference is organized to continue the legacy of Samson H Chowdhury for development of the pharmaceutical sector of Bangladesh. This year, the conference was divided into 3 plenary sessions. The first session addressed Adverse Drug Reaction (ADR) reporting & the current state of Bangladesh Pharma industry to counter this issue. Prof. Dr. Md. Sayedur Rahman of Pharmacology Department, BSMMU was the key note speaker. In the second session prospective collaboration between industry & university/research organizations for future development of pharmaceutical industry was addressed by Key note speaker Nawabur Rahman, Director, Technical Operations, SQUARE Pharmaceuticals Ltd. Prof. Mustafizur Rahman of Center for Policy Dialogue (CPD) was the key note speaker of the third session which was about the Pharmaceutical Industry of Bangladesh- the opportunities & challenges of this industry. 3 scientists were awarded "Samson H Chowdhury Award for Young Scientist" for their outstanding research work & contribution in pharmaceutical & healthcare sector.

The awards were handed over by Major General Md. Mustafizur Rahman, Director General, DGDA; Nazmul Hassan MP, President of Bangladesh Aushud Shilpa Samity & Salman F Rahman MP, Private Industry & investment Advisor to Hon'ble Prime Minister, Advisor of Bangladesh Aushad Shilpa Samity & Vice Chairman Beximco Group of Companies.

Turkish Minister visits Incepta Pharmaceuticals Ltd.

Honourable Deputy Minister H.E. Prof. Dr. Emine ALP MEŞE of Turkish Ministry of Health visited Incepta Pharmaceuticals Ltd. Factory at Zirabo, Savar recently. During her visit to the factory she observed the manufacturing process of Vaccines & Bio-Tech Products of Incepta. She was impressed with the High-tech manufacturing facilities of Incepta in operation.

"Turkey is interested to cooperate with Bangladesh government as well as Incepta pharmaceuticals Limited, the country's most reputed pharmaceutical company. With this cooperation, Turkey will exchange Pharmaceutical information and technology to improve the healthcare facility of the people of Turkey. For this purpose, a team of experts will visit Bangladesh very soon." said Deputy Minister of Turkey Prof. Dr. Emine ALP MEŞE.

President of TMMDA told, "They are well aware about Incepta from the Pantonix injection which has the highest market share in Turkish PPI injectable market. But in this visit, they are very much interested to work on vaccines and Bio-Tech products."

Abdul Muktadir, Managing Director of Incepta Pharmaceuticals Ltd. presented the company capabilities, particularly in high-tech biotechnology and vaccine field. From the year 2000, Incepta is manufacturing quality medicines according to cGMP(Current Good Manufacturing Practice). Besides the local market, Incepta is exporting to 67 countries with good reputation. Incepta established the country's first ever Human Vaccine Plant in 2010 complying with WHO GMP standard.

This plant has the capacity to manufacture 2.4 Lacs ampoules and 3.6 Lacs Vials and has world class animal house to test." He added, "Within 4/5 years, we will be able to export our medicines to almost all the countries of the world including USA".

The Deputy Minister of Turkey H.E. Prof. Dr. Emine ALP MEŞE was accompanied by the President of TMMDA, Managing Director of Incepta, Abdul Muktadir, other Departmental Head of TMMDA and Private sector representatives from Turkish Pharma Industry.

Bapi re-elects President, Secretary General

Nazmul Hassan, a lawmaker and the Managing Director of Beximco Pharmaceuticals, and SM Shafiuzzaman, Managing Director of Hudson Pharmaceuticals, have recently been re-elected President and Secretary General respectively of the Bangladesh Association of Pharmaceuticals Industries (Bapi) for 2019-21.

The election took place at the Association's 48th Annual General Meeting, according to a statement. Abdul Muktadir, Chairman and Managing Director of Incepta Pharmaceuticals, was elected Senior Vice President while Harunur Rashid, Managing Director of Globe Pharmaceuticals, and Halimuzzaman, Deputy Managing Director of Healthcare Pharmaceuticals, were re-elected Vice President and Treasurer respectively.

Salman F Rahman of Beximco Group, Mizanur Rahman Sinha of ACME Laboratories, Tapan Chowdhury of Square Pharmaceuticals, Momenul Haq of General Pharmaceuticals and MA Hassan of Aristopharma were elected advisory committee members.

Renata to set-up subsidiary in Ireland

The Board of Directors of Renata Limited has approved the plan to establish a subsidiary company in Ireland fulfilling the regulatory requirement to export in EU countries.

Renata, a pharmaceutical and animal health products manufacturer, has also informed that earlier they committed to export in European countries and for that they established a company in UK which was disseminated in the Dhaka Stock Exchange (DSE) website recently.

However, unfortunately UK had withdrawn them from the European Union (EU) as process known as Brexit, said a disclosure posted on the DSE website recently.

Now they have decided to establish a new company in other EU countries (Ireland) to export un-interrupt in EU countries, said the disclosure.

Beximco Pharma to Acquire Eight ANDAs from Sandoz Inc. Acquisition expands Beximco Pharma's US portfolio to 14 approved ANDAs

Beximco Pharmaceuticals Limited the fast-growing manufacturer of generic pharmaceutical products and active pharmaceutical ingredients, announced the signing of a definitive agreement with Sandoz Inc., a division of Novartis, to acquire a portfolio of eight Abbreviated New Drug Applications (ANDAs) in the US for an undisclosed amount in cash.

Beximco Pharma's current US portfolio comprises six US Food and Drug Administration (FDA) approved products. Four of these products are currently being exported to the US and two products are awaiting regulatory approval. Following this transaction, Beximco Pharma's US portfolio will consist of 14 approved ANDAs.

Nazmul Hassan MP, Managing Director of Beximco Pharmaceuticals, commented: "The acquisition of these ANDAs from Sandoz, a global leader in the generics market, significantly strengthens our position in the US, expanding our portfolio to 14 approved products. The acquisition is expected to provide a major boost to our export sales in the future and we look forward to continuing to build our presence in this important strategic market for Beximco Pharma."

In August 2016, Beximco Pharma became the first Bangladeshi pharmaceutical company to export medicine to the US market following its manufacturing site approval by the US FDA in June 2015.

Beximco Pharma is a leading exporter of pharmaceuticals in Bangladesh. The Company currently has a global footprint in more than 50 countries and has been accredited by the leading global regulatory authorities including the US FDA, AGES (EU), TGA (Australia), Health Canada, GCC (Gulf) and TFDA (Taiwan).

3 pharma companies to get AEO licences soon

National Board of Revenue is set to issue authorised economic operators' licence to three local pharmaceutical companies recognising them as trusted traders in import-export procedures.

The three companies are Square Pharmaceuticals Ltd, Beximco Pharmaceuticals Ltd and Incepta Pharmaceuticals Ltd which will enjoy a set of benefits including quick release of import-export consignments from ports without physical examination by customs authorities.

AEO scheme will initially be run on a pilot basis for six months and then will become fully operational based on experiences. NBR has introduced the system to facilitate international trade and ease of doing business by trusted traders.

Customs Valuation and Internal Audit Commissionerate of NBR has already completed all procedures including evaluation of qualifications and preparedness of the companies to issue the licences.

'We want to issue licences as soon as possible so that the selected AEOs can come into operation,' CVIAC commissioner Moinul Khan told. The commissionerate sent a letter to NBR recently seeking permission to issue the licences which will initially be issued for six months, he said.

After the pilot scheme, NBR will make the scheme open also for others, he added.

According to the AEO Authorisation Rules-2018, AEO licence holders will be able to take imported goods directly to their warehouses or factory premises from port without any intervention including physical inspection of customs officials.

Customs officials, however, will be able to conduct physical inspection of imported goods on the premises of businesses.

They will also avail benefits that include completion of customs valuation procedures including submission of bill of entry and bill of export before arrival of ships at port, completion of valuation procedures with submission of important documents and prompt service from special team of customs.

Officials said that a committee headed by CVIAC commissioner had finalised the selection of the three companies after evaluation of the firms' self-assessment questionnaire containing information related to management, business, production, supply chain, compliance record, accounting and logistical system, financial solvency and safety and security requirements.

They said that officials at customs houses would, without questions, accept the declarations about consignments made by AEOs and release the goods based on documents.

CVIAC will conduct audit of activities of AEOs every three years or any time based on necessity.

The commissioner will terminate the AEO certificate of any operator if it finds false declaration in import-export, tax and duty evasion and deviation from the criteria. According to the rules, a business entity will have to fulfill a set of criteria for gaining AEO or trusted traders status.

European markets now open for ACME Lab

ACME Laboratories recently received the certificate of GMP compliance from UK MHRA (Medicines and Healthcare Products Regulatory Agency of UK).

ACME Laboratories, the country's oldest pharmaceuticals company, received the certificate following successful inspection of its solid dosage unit (SDU) at Dhulivita, Dhamrai in Dhaka, said the company press release.

"This success will open the doors for the company to enter UK and other European markets," the press release added.

The company is engaged in manufacturing and marketing of generic pharmaceuticals formulation products including human, veterinary and herbal drugs. The products of the company are sold in domestic as well as international markets.

The history of Acme Laboratories dates back to 1954, when a proprietorship firm was founded at Chashara in Narayanganj on a three-bigha land with around 33 people to manufacture drugs.

The firm relocated its plant to Dhamrai in Savar on a land of 10 acres after converting into a private limited company in 1976.

World Pharmacists Day Sept 25

"Safe and effective medicines for all" is the theme of this year's World Pharmacists Day, which falls on 25 September, the International Pharmaceutical Federation (FIP) announced. The theme for 2019 aims to promote pharmacists' crucial role in safeguarding patient safety through improving medicines use and reducing medication errors.

"Studies show that a significant number of patients are harmed during health care, resulting in permanent injury, increased length of stay in healthcare facilities, or even death. Medication errors are a contributing factor to this and pharmacists have a vital role in curtailing this global health challenge," said FIP President Dominique Jordan.

"Pharmacists use their broad knowledge and unique expertise to ensure that people get the best from their medicines. We ensure access to medicines and their appropriate use, improve adherence, coordinate care transitions and so much more. Today, more than ever, pharmacists are charged with the responsibility to ensure that when a patient uses a medicine, it will not cause harm", Mr Jordan added. FIP's member organisations and others around the globe use World Pharmacists Day to highlight the value of the pharmacy profession to stakeholders, and to celebrate pharmacy.

The official logo is freely available now, in the six official United Nations languages (Arabic, Chinese, English, French, Russian and Spanish) at www.fip.org/worldpharmacistsday. FIP is working on an app that pharmacists can use to amplify World Pharmacists Day messages.

'Breast cancer patients increasing alarmingly in Bangladesh'

The number of patients suffering from breast cancer is increasing alarmingly in Bangladesh due to lack of awareness about early detection and unwillingness in taking treatment for a number of causes like social taboos, speakers told a seminar.

They informed that about 12,764 new breast cancer patients are detected every year while the number of deaths from the deadly disease has stood annually at 6,846 across the country and the situation in getting worse day-by-day. As a result, breast cancer has become one of the top category cancers affecting Bangladeshi women and third deadly on the list of cancers for both men and women in Bangladesh, they observed.

They came up with the observations at the scientific seminar on 'Breast Cancer Imaging' held recently in the auditorium of the BIRDEM hospital in the city. Bangladesh Society of Radiology and Imaging organised the event.

Referring to the data of World Health Organization's International Agency for Research on Cancer (IARC), the speakers said, "65.5 percent of breast cancer patients delayed their diagnosis by more than six months, although 83 percent of them found lumps in their breast or had other symptoms of breast cancer."

The speakers blamed social taboos and unawareness as the main reasons for unchecked breast cancer and delay in early detection. Dhaka Medical College Hospital Professor Mizanur Rahman attended the seminar as chief guest with President of Bangladesh Society of Radiology and Imaging Professor Enayet Karim in the chair.

Secretary General of the Bangladesh Society of Radiology and Imaging Dr Shahriar Nabi delivered the welcome address while Dr Bishwajit Bhowmik and Dr Fatema Doza moderated the seminar.

The speakers talked about the importance of imaging in screening of breast cancer. Though mammogram was previously an important tool for screening of breast cancer, nowadays ultrasonography plays immense role in screening as well as diagnosis, they said.

MoU signed between TMMDA and DGDA

Turkish Deputy Minister for Health Dr Emine Alp Mese, Turkish Medicines and Medical Device Agencies (TMMDA) President Dr. Hakkı Gürsöz and 30 Turkish delegates visited Bangladesh from 06 to 09 April, 2019. They visited 5 (five) Drug and Vaccine manufacturing company, namely M/S Incepta Vaccine Ltd, M/S Beacon Pharmaceuticals Ltd, M/S Healthcare Pharmaceuticals Ltd, M/S Beximco Pharmaceuticals Ltd and M/S Square Pharmaceuticals Ltd. Turkey delegates showed interest to import medicines from Bangladesh.

Turkish Medicines and Medical Device Agencies (TMMDA) President Dr. Hakkı Gürsöz and Turkish delegates visited DGDA office on 7 April, 2019. They discussed various regulatory issues. The high level health-business delegation, led by President of Turkish Medicines & Medical Devices Agency (TMMDA) Dr. Hakki Gursoz, MD showed eagerness of the Euro Asian country to import medicine from Bangladesh. Turkey and Bangladesh can work together in manufacturing advanced lifesaving drugs, said the President of the Turkish Medicines & Medical Devices Agency. Major General Md. Mustafizur Rahman expressed his willingness to work together in regulatory system strengthening and exchange of regulatory experience to each other and signing MoU for collaboration.

They have decided that collaborations between two agencies will be made on the following issues:

a. Sharing experiences about Regulatory inspection and quality control of medicines, vaccines and medical devices; information exchange on existing national legislations, policy and particularly on scientific information.

b. Sharing the training processes and experts building Criteria and Competency of Inspector.
c. Exchanging information and experience relating to the manufacturing facilities, Technology of medicines and Medical Device,
d. Measures taken against counterfeit products.
e. Sharing of experience and knowledge on equipment and technologies required for inspection and quality control.

On 8 April, 2019 Turkey Medicines and Medical Devices Agency (TMMDA) and Bangladesh Directorate General of Drug Administration (DGDA) signed an MoU for the cooperation in drugs and medical devices. "For the long-term benefit of the people of both countries, the health sector has a big role to play," Dr. Emine Alp Mese, the Deputy Health Minister, Turkey said after the memorandum of understanding (MoU) was signed. She also praised Bangladesh's rapid economic progress from a lower to a middle-income country.

Turkish Deputy Minister for Health Dr Emine Alp Mese Monday called on Health and Family Welfare Minister Zahid Maleque, expressing her country's interest to establish state-of-the-art medical device and medicine plants in the country.

Turkish Deputy Minister said both the countries would reap benefits if they can expand their existing ties in the health sector. "Bangladesh is exporting medicines to many countries in the world. Now if Turkey can establish a state-of- the-art medical device plant here, people of Bangladesh will be benefited from it," Dr Emine Alp Mese said.

Deputy Minister Mese and Bangladesh's Health and Family Welfare Minister Zahid Maleque, MP discussed joint research and development (R&D) activities for vaccine and insulin production.

Major Activities Performed by DGDA during last three months (Jan '19- Mar '19)

No of Total Drug License (Retail & Whole sale)	130021
No of Renewal of Drug License (Retail & Whole sale)	7820
No of Sample Collected for test	402
No of sample test	784
Inaugurated Model Pharmacy (up to Feb'19)	253
Inaugurated Model Medicine shop (up to Feb'19)	235

DGDA took action against hawker at Kawran bazar, Dhaka for selling illegal medicine.

Action against MLM Company

DGDA has taken action against multi-level marketing (MLM) Company for selling food supplement with therapeutic claims. M/s Glonutra BD Ltd. Level-3, Plot-56, Gulshan, Dhaka, M/s K-Link International BD Ltd, Cumilla have been fined Tk 4 lac 40 thousand and jailed 4 persons by mobile court. One case has been filed in Drug Court against M/s K-Link International BD Ltd, Banani, Dhaka.

Case filed in Mobile Court, Magistrate Court and Drug Court

Month	Case filed in Drug Court	Case filed in Magistrate Court	Case filed in Mobile Court	Punishment in tk.	Cost of Seized unregistered medicine, food supplement, Physician sample and Government medicine
January 2019	0	1	115		around 7.5 lac tk
February 2019	1	2	216		around 10.5 Crore tk.
March 2019	0	7	182		around 54.8 lac tk.

Zahid Malik MP, Minister for Health and Family Welfare hold meeting with DGDA

During his visit to DGDA on April 2, 2019, Zahid Malik MP, Hon'ble Minister for Health and Family Welfare held a meeting at DGDA on various matters pertaining to DGDA. The meeting was presided over by Major General Md. Mustafizur Rahman, Director General, DGDA. Among others, Md. Asadul Islam, Secretary of the Ministry of Health and Family Welfare and senior Officials of the Ministry of Health and Family Welfare and DGDA were present.

The Hon'ble Minister was apprised about different activities of DGDA, especially the Price Fixation and Control of Medical Devices, Operation of Clinical Trial, countrywide drive against fake drugs and implementation of Model Pharmacy concept which were appreciated by the Minister. He congratulated DGDA for attaining Bangladesh Accreditation Board (BAB) and also ISO-17025: 2017 of American National Accreditation Board (ANAB).

The Hon'ble Minister assured to look into the problems and limitations faced by DGDA and solve them gradually. In the meeting, the Minister gave the following directives to DGDA.

- Inspect the pharma manufacturing industries and submit a list thereof to the Ministry and also take action against those companies who fail to comply with GMP.
- Prepare a revised list of Essential Medicines and submit the same to the Ministry and also collect samples of essential medicines and submit the report to the Ministry after testing at the Drug Testing Laboratories.
- Steps should be taken to obtain the WHO prequalification within next 6 months and also submit the proposed Organogram of DGDA and Drug Act 2019 for necessary approval.
- Create awareness about Anti-biotic resistance among people and for this, regular monitoring of pharmacies should be done to stop sale of Anti-biotic drugs without prescriptions. DGDA should write to all Model Pharmacies and Medicine Shops to counsel all customers to complete full-course of anti-biotic drugs and monitor the same on regular basis.
- Take action against all Pharmacies at Upazila level having no drug license.

PHARMACOVIGILANCE NEWS

Outcome of the Adverse Drug Reaction Advisory Committee (ADRAC) 9th meeting

ADRAC, which was formed by Ministry of Health & Family Welfare, 9th meeting was held on 28th November, 2018 at Directorate General of Drug Administration, which was presided by Major General Md. Mustafizur Rahman, DG, Directorate General of Drug Administration. National Pharmacovigilance Centre of Bangladesh received total 423 reports from different stakeholders. These 423 ADE reports were primarily evaluated by the ADRM cell. After primary evaluation, ADRM Cell placed 345 complete reports to the Technical Sub-committee (TSC) of the ADRAC. Out of 345 reports, 196 reports were found Certain, Probable and Possible as per WHO Causality Assessment scale and these reports were then placed to the 9th ADRAC meeting for review. After evaluation, the ADRC members commented finally 192 cases as ADRs and gave recommendation for the regulatory actions of some drug safety information based on published in the WHO Pharmaceuticals Newsletter-4 and 5, 2018 and THE PHARMA WORLD.

Recommendation made by 9th ADRAC based on regulatory decision of different NRAs published in WHO Pharmaceuticals Newsletter-4 & 2018 and THE PHARMA WORLD

ADRAC recommended for following regularly actions regarding the following 10 generic medicines for changing the Product Information Leaflet (PIL) based on the regulatory decisions of the International Agencies/Authorities published in WHO Pharmaceuticals Newsletter (Issue 4 & 5, 2018) and THE PHARMA WORLD:

Recommendation by ADRAC 9th meeting for Regulatory Action

Name of Medicine	Adverse Drug Reaction	Recommendation By ADRAC
Benzocaine	Risk of blood disorder in infants and children	**Warning:** Methemoglobinemia **Contraindication:** Infant & Children younger than two years
Fluroquinilone antibiotics	Risk of hypoglycemia and mental health adverse effect	**Box Warning:** Increased risk of tendinitis and tendon rupture
Granulocyte-colony stimulating factor (G-CSF) drugs	Risk of large vessel vasculitis	**Adverse Effects:** large vessel vasculitis **Warning:** Allergic reactions, Splenic rupture, Alveolar hemorrhage, hemoptysis and Sickle cell disorders.
Metronidazole	• Risk of hepatic impairment • Severe Hepatotoxicity or acute hepatic failure	**Adverse Effects:** Chance of severe hepatotoxicity or acute hepatic failure with Cockayne's syndrome. Risk of hepatic impairment.
Erythropoietins	Risk of severe cutaneous adverse reactions(SCAR)	**Adverse Effects:** severe cutaneous adverse reactions (SCAR) & Stevens Johnsons Syndrome.
Desogestrel	Severe psychiatric disorders: panic attack, suicidal intention and self-included injurious behavior.	**Adverse Effects:** panic attack, suicidal intention and self-included injurious behavior.
Ceftriaxone	Risk of convulsions and involuntary movement	Risk of convulsions and involuntary movement.
Neuromuscular blocking agents (e.g suxamethonium, pancuronium & vecuronium)	Prevention of unintended paralysis through medication errors	To **UPDATE** label to include a warning indicating that the product is a **PARALYSING AGENT.**
Ulipristal	New measures to minimize risk of liver injury	**Contraindication:** Ulipristal is not recommended for use in patients with liver disease.
Amlodepine	Alopecia	**Adverse Effect:** Alopecia

Top 10cos dominate Pharma Market

The top 10 local pharmaceutical companies continue holding more than 67 per cent share of the Bangladesh medicine market while 194 others hold only 32 per cent, according to the IQVIA data.

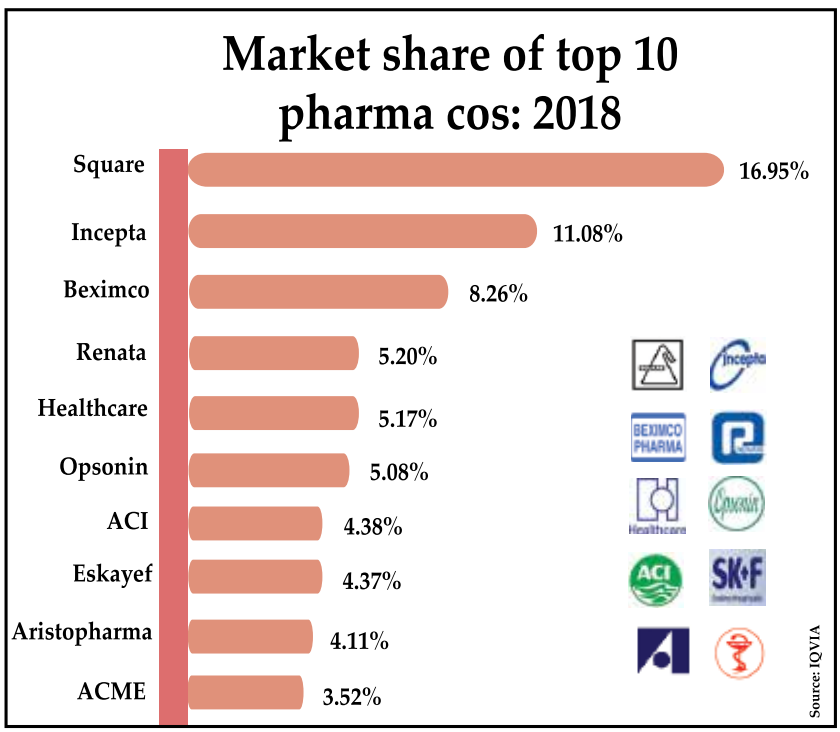
The data of IQVIA, an American multinational product-based company serving the combined industries of health information technologies and clinical research, showed that market share of the top 10 companies in 2018 decreased by 0.3 percentage points to 67.82 per cent from 68.12 per cent in 2017.

'It's a matter of fact the companies who are trying to be aligned with global quality standards, are attaining manufacturing and marketing excellence day by day. Moreover, the financial strength of these companies also gives them the space to adopt modern technologies,' Tapan Chowdhury, Managing Director of Square Pharmaceuticals said.

"Such trend is being observed elsewhere, like in the Philippines, Malaysia and Thailand," Incepta Pharmaceuticals Managing Director Abdul Muktadir said.

Centre for Policy Dialogue distinguished fellow Mustafizur Rahman said that the market share of the top 10 companies decreased in 2018 but the fall was insignificant. He said that holding around 67 per cent market share by the top 10 companies was a bit high in terms of market concentration but it was not a matter of major concern.

He suggested that the authorities should check whether small companies were facing any problems in improving their business. The IQVIA data also showed that among the top 20 therapeutic medicines, anti-ulcerants class (acidity) accounted for the highest sales (Tk 3,013.48 crore) in 2018 followed by cephalosporin class (antibiotic) with sales worth Tk 1,687.61 crore.



Annual sales of human insulin accounted for Tk 702.19 crore, calcium Tk 700.95 crore, antirheumatic drugs (non-steroid painkiller) Tk 659.41 crore, antiepileptics (nervous system drug) Tk 650.87 crore and non-narcotic analgesics (painkiller) Tk 643.47 crore.

The size of local pharmaceutical market stood at Tk 205.12 billion in 2018. The industry recorded a 16.51 per cent growth between 2014 and 2018.

Square accounted for the highest 16.95 per cent market share with annual sales worth Tk 34.76 billion in 2018. It is followed by Incepta Pharma with 11.08 per cent market share, Beximco with 8.26 per cent, Renata with 5.20 per cent, and Healthcare Pharma 5.17 per cent.

Of the other top companies, Opsonin Pharma holds 5.08 per cent market share, ACI 4.38 per cent, Eskayef 4.37 per cent, Aristopharma 4.11 per cent, and Acme holds 3.52 per cent share, according to IQVIA data.

The market situation will be better with healthy growth, if more companies enjoy larger market share, he observed, adding the industry is gradually moving towards that end.

The industry leaders identified absence of sufficient knowledge, training and exposure to global regulatory standards as the major challenges for local pharmaceutical sector.

The government should provide flexible provisions for importing active pharmaceutical ingredients (APIs), equipment and machinery for the sector. Besides, industry-friendly policies should be taken after proper evaluation to facilitate its investment outside the country, they added.

Source: New Age & The Financial Express

'Hepatitis B and C can be treated by antiviral drugs'

Dr. Faroque Ahmed
Head
Dept. of Hepatology
Dhaka Medical College & Hospital

Q&A

As an eminent Hepatologist of the country, how do you evaluate the current status of liver diseases in the country?

Bangladesh is one of the most densely populated countries of the world, having more than 160 million population in 1,44,000 square kilometer area. Recently, it has been listed as one of the topmost countries with emerging economy. Gradual urbanization with changing socio-economic condition and life style changes in rural people is also observed in the past decades. These factors have shown various impacts on communicable and non-communicable diseases, especially in harboring non-communicable diseases and in the modes of transmission of communicable diseases.

This picture is reflected in incidence and severity incidence and severity in various liver diseases also. Though, we have more or less homogenous population, the pattern of liver diseases has regional variation which is observed in different parts of our country.

Several population based studies revealed that, about 8 million people of Bangladesh are suffering from chronic Hepatitis B and C infection. Acute Hepatitis occurs mostly due to Hepatitis E virus though less commonly but Hepatitis A and B are also encountered for acute hepatitis, apart from these Drugs Induced Liver Disease (DILI) is not uncommon. Among the non-communicable diseases, Non Alcoholic Fatty Liver Disease (NAFLD) incidence and prevalence is on the rise.

A nationwide retrospective study in 2013, data regarding patients of liver diseases presenting in different Medical College Hospitals in seven administrative divisions of Bangladesh during the period between January 2012 to December 2012 were analyzed and found that, majority of liver disease patients were of chronic liver disease and its complications like ascites, esophageal varix, hepatic encephalopathy etc. Acute viral Hepatitis, Non-Alcoholic fatty liver disease, and chronic Hepatitis B patients are also predominant. While, liver abscess, biliary ascariasis is, obstructive jaundice, chronic pancreatitis was less common.

As Bangladesh possessing fast growing economy in recent decade, management of patients of liver diseases is also focused and need government priorities, special medicines and logistics along with building up centers where the expertise can provide medical and surgical care for patients with liver diseases.

Please tell us in brief about viral Hepatitis?

Viral Hepatitis is liver inflammation due to a viral infection. It may be acute due to recent infection, or may be chronic.

Most cases of viral hepatitis are caused by five hepatotropic viruses (Hepatitis A, B, C, D, E). Other viruses which can cause acute hepatitis are Cytomegalovirus, Epstein-Barr Virus, Herpes Simplex Virus, Yellow Fever.

Among the 5 hepatotoxic viruses, Hepatitis A and E causes acute and Hepatitis B and C causes chronic hepatitis. Though Hepatitis B can cause both acute and chronic Hepatitis.

Hepatitis A and B can be prevented by vaccination. Hepatitis B and C are the major cause of chronic liver disease, liver cirrhosis and its complications like liver cancer. Early detection and treatment with antiviral drugs can prevent these diseases. All the drugs are available in our country. Hepatitis B vaccination has been incorporate National immunization schedule since 2004.

Transmission of Hepatitis A & E is feco-oral and Hepatitis B, C, D is parenteral, that is through blood and blood products, saliva, body fluids, infected syringe, needle razors, sexual contacts etc.

Safe drinking water, proper sanitation, waste management, sterilization of instruments used in operation theatre and in other massive procedures, prevent needle sharing among drug abuses all are needed to prevent viral Hepatitis.

Patients affected of Hepatitis A and E virus usually develop anorexia, nausea, vomiting, body ache, malaise, fever which occurs between 2-4 weeks after virus inoculation and lasts for 2-3 days, followed by Jaundice manifested by yellow coloration of eyes, skin, mucus membrane and dark urine. Patient usually suffers for 2-4 weeks and recover completely. Some patient may require specialist consultation and hospital admission when acute viral Hepatitis is in severe form.

What is the treatment of Hepatitis B & C? How can we prevent these?

Hepatitis B and C can be treated by antiviral drugs. In case of Hepatitis B infection, the aim is to suppress viral replication, prevent inflammation of the liver and thus prevent developing chronic liver diseases. In chronic Hepatitis C, oral drugs named Directly Acting Anti-viral (DAA) has largely replaced previously recommended interferons and has been available in our country for the last several years. Even the patient already developed liver cirrhosis should be treated by antiviral drugs with an aim to prevent further disease progression and liver cancer.

Hepatitis B can be prevented by vaccination Hepatitis C vaccines are not available yet. Both the infection can be prevented by taking various measurers like safe blood transfusion, proper sterilization of instruments used in operation or invasive procedures ensuring disposable syringes, safe sex etc. public awareness development is the key to success in preventing Hepatitis B and C infection.

What are your suggestions to create awareness among the common people about viral Hepatitis?

Public awareness development is essential to prevent and treat this communicable disease. Print and electronic media should be the chief way to communication and aware mass people regarding the transmission and management of the diseases. Doctors of these specialties can be involved here. Along with this, small groups can be targeted as local government Leaders, Teachers, Immams, other socially acceptable persons should be motivated first, then local populations can be further reached by them, through seminar, meeting, banner, and rally, these are the other ways to give message to common people.

Do we have all the state-of-art facilities for the treatment of all kinds of liver diseases?

We have all kinds of treatment against Hepatitis B, C, viral infections, chronic liver disease, liver cancer, but some specialized treatments like liver transplantation is yet to be ensured.

Please tell us in brief about Hepatocellular Carcinoma and its treatment?

Hepatocellular Carcinoma (HCC) is a primary malignancy of the liver occurs mainly in patients with underlying chronic liver disease and cirrhosis. HCC is third leading cause of death due to cancer, worldwide, in Asia and Africa with high incidence.

In the past, ACC usually presented in advanced stage with right upper quadrant prim, jaundice, and weight loss. Now-a-days, due to increasing awareness and screening of Hepatitis B & C infected and cirrhosis patients by imaging studies and alpha-fetoprotein (AFP) in regular intervals. It has been observed that, incidence of ace in developed countries is more than twice the incidence in developed countries. The causative factors for ACC are Hepatitis B virus (HBA) and cirrhosis due to HBA, Hepatitis C Virus (HCV), non-alcoholic fatty liver disease (NAFLD), alcohol etc. In developing countries like Bangladesh, viral Hepatitis (predominantly Hepatitis B) represents the major risk for HCC.

Patients with HCC may present as single mass lesion or diffuse lesions in imaging studies. Laboratory tests includes tests, which evaluate the severity of underlying liver disease, etiology of liver disease that includes Complete Blood Count (CBC) liver function tests, coagulation studies like ultrasonography, Magnetic Resonance Imaging (MRI), triphasic computed tomography (CT) scan etc.

It can be mentioned that, intriphasic CT scan, HCC may appear as a focal lesion, with early enhancement on the arterial phase with rapid washout of contrast on the portal venous phase.

Management of HCC patients should be in a multi-disciplinary setting, including Hepatologists transplant and hepatobiliary Surgeons Medical Oncologists, Intervention radiologists. Liver transplantation is the best choice of management, where available. Facilities of liver

transplantation are yet not available in our country.

However, in developing countries like Bangladesh, other treatment like resection, trans arterial chemo-embolization (TACE), Radio Frequency Ablation (RFA) systemic therapy with soraferib etc. can be offered.

Do you think that drugs produced locally are adequate for the management of liver diseases?

Bangladesh is a country of emerging economy large population. Numerous pharmaceutical companies are manufacturing drugs which are needed for the people and also exporting to significant number of countries. The drugs used in liver disease, through import until past decades, are now mostly manufactured locally. Some essential drugs used in various liver disease are still not manufactured, namely penicillamine, Zinc acetate, used in treatment of Wilson disease.

What we need now, is the production of raw materials locally, so that we can serve people with all the medicines needed for liver disease in an affordable price and also strengthen our present support based pharma industries.

What is your message or guidelines for the patients of liver disease?

Bangladesh is a densely populated country having 160 million people, large numbers of them reside in rural areas; liver disease prevalence varies in nature and patters in urban and rural areas. Gradually increasing awareness regarding common liver diseases and availabilities of various drugs help us treating lots of patients with acute and chronic liver disease for communicable liver diseases, prevention is the main stay of management, hence testing and detection of viral infections and vaccination of Hepatitis A, B and effective treatment with antivirals for whom are detected, will help a lot.

Treatment with indigenous drugs, totka, ojha, etc. for any kind of liver disease should be strictly prohibited. Life style change like moderate exercise, taking fresh fruits and vegetables, and avoiding fatty and junk foods, cold drinks, alcohol, smoking etc. Reducing amounts of carbo-hydrates, red meat, salt foods will help to prevent the metabolic diseases namely non-alcholic fatty liver disease.

Reducing obesity, proper treatment of diabetes, dyo-dislipidemia, hypertension and thus maintaining healthy lifestyle is necessary to prevent metabolic liver diseases.

As the "Vice-President of Association for the study of liver diseases of Bangladesh", would you please tell us about the role of your organization regarding Hepatic disorders in Bangladesh?

As a Vice-president of Association for the study of liver disease Bangladesh, I can state that this is the nationwide Hepatologists Association, and along with arranging Livercon (International Liver Related Conference) each year, the members of the association take part in CME, seminar, in country and abroad regularly, which help, in quality improvement in management of patients with liver disease. Public awareness creation by participating in programs in Print and Electronic Media, various institution based, mass screening and vaccination programs, free health camps. Rally, etc. are regular activities of the organization.

To eliminate Hepatitis B by 2030, as declared by World Health Organization, we the members of the Association for the study of liver disease in Bangladesh, are committed to ensure this, work along with government and non-government organization, help people to create mass awareness to prevent Hepatitis, treat the affected patients and to step forward in a healthy nation.

DID YOU KNOW?

Drugs typically contain the actual drug, or active pharmaceutical ingredient (API), and inactive ingredients (excipients). Inactive ingredients "are not intended or expected to have a direct biological or therapeutic effect but instead are added to alter the physical properties of an oral solid dosage form (tablet or capsule) to facilitate absorption; to improve stability, taste, and appearance; or to render the therapeutic tamper resistant. Increasing numbers of clinical reports describe allergic reactions to excipients such as lactose and chemical dyes, write Reker and colleagues in Science Translational Medicine.

Doctors have developed an algorithm using machine learning and smartphone-based photoplethysmography (PPG) to detect diabetes. They used contact PPG to obtain waveforms of color changes in blood vessels with heart beat — which is also used by apps to measure heart rate — to develop the screening test for diabetes.

People who suffer from heart disease are advised to move around seven minutes for every 20 minutes they spend sitting to prolong life, according to Canadian Cardiovascular Congress.

Women who eat processed meats such as sausage and bacon regularly have a 9 percent higher risk of breast cancer compared to those who don't, according to International Journal of Cancer.

The American Heart Association recommends eating non-fried fish like salmon, herring, lake trout, tuna-which are all high in Omega-3 fatty acids- at least twice a week, to help reduce the risk of heart failure, coronary heart disease, cardiac arrest and ischemic stroke.

'Treatment of Hepatitis C virus has undergone a revolution over last decade'

Prof. Dr. Mobin Khan
Ex-Professor & Founder Chairman
Department of Hepatology
BSMMU & Director,
The Liver Centre, Dhaka

Q&A

As an eminent Hepatologist of the country, how do you evaluate the current status of liver disease in the country?

Current status of liver disease has good news and bad news for the country. The good news is Hepatitis virus related to chronic liver diseases have been on decline over recent years in Bangladesh. Over last two to three decades, prevalence of Hepatitis B in children reduced from 15.8% to 4.2% and in adults from 27.2% to 5.1%. Also, the prevalence of Hepatitis C has declined from 1% to 0.2%. This has been possible with growing awareness of people regarding Hepatitis B and C, death of already affected cirrhotic Hepatitis B and C patients, and prevention of Hepatitis B transmission through national immunization program which was instituted in the EPI in 2003. The bad news is, non-alcoholic fatty liver disease (NAFLD) is increasing with an alarming pace. Prevalence of NAFLD is 32 to 35 percent in the country and it is high among children, women and middle age people.

Please tell us in brief about Viral Hepatitis?

Viral Hepatitis is infection and inflammation of hepatic parenchyma due to hepatotropic virus. Five common hepatotropic virus that we encounter in practice are – Hepatitis A virus, Hepatitis B virus, Hepatitis C virus, Hepatitis D virus and Hepatitis E virus. Hepatitis A and E is transmitted through feco-oral route and causes acute infection of liver. While Hepatitis B and Hepatitis C is responsible mainly for chronic hepatic infection. Hepatitis B is transmitted through saliva, blood and sexual intercourse. While Hepatitis C is mainly transmitted through blood. Chronic liver disease due to Hepatitis B and C virus if untreated may lead to cirrhosis and hepatic cancer.

What is the treatment of Hepatitis B & C? How can we prevent these?

Treatment of Hepatitis C virus has undergone a revolution over last decade. Now-a-days, around 90% cure can be achieved through use of oral antiviral agents (OAA) in case of chronic Hepatitis C and early cirrhosis. Use of injectable pegylated interferon in the treatment of Hepatitis C has virtually fallen out of practice. Oral antiviral agents are also known as direct acting antiviral agents (DAA). Latest guidelines recommend use of DAA as a single agent or fixed dose combinations based on genotype of Hepatitis c virus, progression of liver disease, presence of HIV co-infection and presence other comorbid diseases. Currently recommended DAA for Hepatitis C are sofosbuvir, dasabuvir, daclatasvir, velpatasvir, ledipasvir, obmitasvir, elbasvir, pibrenatasvir, ribavirin, ritonavir, grazoprevir, glecaprevir, paritaprevir, and voxilaprevir.

While massive advancement has been made in the treatment of Hepatitis C, a few developments has taken place in the treatment of Hepatitis B during this time. Pegylated interferon is still used in selective cases of Hepatitis B induced chronic Hepatitis. But among approved oral antiviral agents, Tenofovir and Ente-

cavir are commonly used. Lamivudine and Adefovir are falling out of choice because of high relapse rate. Telbivudine is costly and treatment response is not satisfactory. Only a modified formulation of Tenofovir-Tenofovir alafenamide fumerate has recently been approved for practice as a new agent. The main hurdle of Hepatitis B treatment is the cccDNA of the virus which remain within hepatocyte nucleus and the failure of immune system to resolve chronic Hepatitis B. Currently no drug is available which can eradicate the cccDNA. Therefore, complete cure of Hepatitis B remains elusive.

On the other hand, Hepatitis B can be prevented with vaccine. Three doses of Hepatitis B vaccine given at 0, 1 and 6 months is usually enough to achieve optimum immunity against Hepatitis B virus. But, there is no vaccine available for Hepatitis C. Avoidance and protection from transmission remains the only way of prevention in Hepatitis C.

Do we have all the state-of-art facilities for the treatment of all kinds of liver disease?

Yes, we have all the state-of-art facilities for the treatment of all kinds of liver disease but there is a caveat. Although, we have been successfully using all modalities of non-invasive and invasive treatment in different liver diseases, successful liver transplantation is yet to be achieved. Oral antiviral agents as well as pegylated interferon and other chemotherapeutic agents are now produced locally. Endoscopic, transabdominal, trans-jugular and trans-arterial procedures for various hepatic problems are now being performed on a regular basis.

Please tell us in brief about Hepatocellular Carcinoma and its treatment?

Hepatocullular Carcinoma (HCC) is a malignant tumor of hepatic origin. Hepatits B virus remains the leading cause of HCC in Bangladesh. A study done in 2014 showed that HBV is responsible for 41% cases of HCC while HCV accounts for 5% and approximately 20.5% likely to be associated with fatty liver diseases. HCC mainly develops on the top of cirrhosis. Therefore, one of the treatment recommendations of HCC is to follow up patients with cirrhosis of liver for surveillance. Patients with suspected HCC are evaluated through multiphasic CT or MRI and selective patients with indeterminate nodule may need biopsy for confirmation. Depending on the stage of HCC and underlying, cirrhosis treatment may vary. Radiofrequency ablation, adjuvant chemotherapy, bridging therapy for those awaiting liver transplantation, transarterial chemoembolization, and systemic therapy are the treatment modalities currently recommended by international bodies.

Do you think that drugs produced locally are adequate for the management of liver disease?

We have been treating liver diseases in the liver center using locally available drugs for years. From our experience, locally producing drugs are as effective as the international originator brands. This is a great sign of relief that these drugs are being produced in the country and their quality is being maintained. Local production has made the treatment cost-effective and accessible for the underprivileged.

What are your suggestions to create awareness among the common people about Viral Hepatitis?

All forms of communication tools should be used to decipher information regarding viral Hepatitis to common people in an accessible way and comprehensive language. Awareness can be raised through article writing for newspapers and online news portals, writing notes or blogs for social media, producing short videos for television and YouTube, arranging regular seminars and symposiums. Both physicians and interested non-medical persons can engage actively in the above-mentioned activity to create and increase awareness regarding viral Hepatitis among common people.

What is your message or guidelines for the patients of liver disease?

My message for patients with chronic liver disease is that they should not worry about their disease as modern modalities of treatment are available in the country. What they should do is; follow-up regularly with their Hepatologists and stick to their advice.

As the Founder President of "Hepatology Society of Bangladesh", would you please tell us about the role of your organization regarding hepatic disorders of Bangladesh?

'Hepatology Society of Bangladesh' is working relentlessly for increasing awareness about liver diseases among common population through press conference, article writing and book publishing. Every year on 28th July a press conference is arranged on the occasion of World Hepatitis Day to raise awareness about viral Hepatitis. On the advent of increasing NAFLD Hepatology Society observed the first international NASH day last year by disseminating updated information on NAFLD and its complications by arranging a press conference. Besides, we are arranging biannual international Hepatology Conference to update knowledge of specialist physicians and surgeons of Bangladesh on the latest development in the field of hepatology.

'We have all the facilities for the management of all kinds of liver diseases except liver transplantation'

Prof. (Dr.) Salimur Rahman
Dept. of Hepatology
BSMMU, Dhaka

Q&A

As an eminent Hepatologist of the country, how do you evaluate the current status of liver diseases in the country?

As a senior Hepatologist of the country, I would like to say that the most common Liver disease of the country is viral Hepatitis. Among the viral Hepatitis, Hepatitis B is one of the well-known and is very much common in this part of the world. Hepatitis B may lead to chronicity and this chronic liver disease may also lead to liver fibrosis and ultimately to liver cirrhosis, liver failure and liver cancer which may even cause death of the patient.

Hepatitis C is also found in our country. Hepatitis C is as serious as Hepatitis B but the process is little slower than Hepatitis B.

However, the Jaundice which we see in our day-to-day life is virus Hepatitis A and E. Hepatitis E is most common in adult population and Hepatitis A is common in children. These two viruses are water and food borne and when we take contaminated water or food, the virus enter in our body through oral route. Food and water is contaminated from stool of the infected person. Those two diseases do not develop chronicity.

Another disease is fatty liver. Usually, it is found not only in obese people but also found in thin people. Other liver diseases are Liver Cancer, Auto-immune Liver diseases and drug induced liver diseases.

Please tell us in brief about viral Hepatitis?

I have already said about the prevalence of viral Hepatitis. Hepatitis A & E is water and food borne disease.

Hepatitis B and C is transmitted through needle/syringe, blood and blood products and also through sexual contact.

What is the treatment of Hepatitis B & C? How can we prevent these?

There is very good treatment for Hepatitis B & C. We can very easily prevent Hepatitis B. You can take vaccine for Hepatitis B which will give lifelong immunity.

Unfortunately, there is no preventive vaccine for Hepatitis C but curative oral treatment is available. All the drugs are available in our country in a reasonable price.

I have already mentioned about the prevention, you should take care of the mother who has Hepatitis B while delivering baby and you should give immediate vaccination to the baby within twelve hours of delivery.

For both hepatitis B & C, we should use disposable syringe and needle and take virus free blood and blood product when nesessary. For both the disease, you should have safe sex. You have to be committed to the religion and be faithful to your partner.

What are your suggestions to create awareness among the common people about viral Hepatitis?

We must create the awareness about the disease in common people. It should be done through education which should start from the text book. It can also be done through Bill Board, Leaflets, Newspapers, Radio and TV.

Our government is taking active role to create awareness. Government is very serious about the program. We have short films. Now-a-

> YOU CAN EASILY SCREEN HEPATITIS B BY SCREENING TEST. IT IS CHEAP AND CAN EASILY BE DONE WITHIN MINUTES.

days, people are very interested in short film and they learn about the disease without much effort.

What are the steps to early screening for Hepatitis B? Is 'Hepatitis Virus Panel' available throughout Bangladesh?

You can easily screen Hepatitis B by screening test. It is cheap and can easily be done within minutes.

Yes, these tests are available all over the country and are available even at village level.

Do we have all the state-of-art facilities for the treatment of all kinds of liver diseases?

Yes, we have all the state-of-art facilities for the treatment of all kinds of liver diseases except liver transplantation. I must say, we have started liver transplantation but due to some problem we had stop it temporarily. Probably, very soon we are going to start liver transplantation.

Is any specialized organization in our country doing research work in this field?

All the professional organizations do research in this field. All the post graduate students do research during their course. Government gives fund for research. Bangabandhu Sheikh Mujib Medical University also gives fund for research.

Please tell us in brief about Hepatocellular carcinoma and its treatment?

Hepatocellular carcinoma is a very grave disease. It usually occurs when the patient having Hepatitis B and C and especially with cirrhosis of liver.

First step is to prevent the disease and if the disease is already present, then early treatment is very important. If it is diagnosed at a very early stage, patient may get cured.

Sometimes, you can treat Hepatocellular carcinoma by liver transplantation. There are some good oral drugs which is very costly but available in the country. We can also do resection, RFA and TACE.

What is the mortality rate of patients having liver disease in Bangladesh?

In acute Hepatitis A and E, mortality rate is very low. It's about less than 1%. If a pregnant mother has Hepatitis E, the mortality rate is high and is 25%–30%.

In adults, Hepatitis B virus infection, 95% patients are clear from the virus. Only (5%) become chronically infected. These people are at higher risk of death from cirrhosis and liver cancer.

Treatment of Liver diseases is quite expensive. How can we make it affordable for the common people?

I have already mentioned that for Hepatitis A & E mortality is very less. If you give them rest, normal diet and symptomatic treatment, most of them will recover.

But, for Hepatitis B about 5% & for Hepatitis C about 85% patients develop chronicity. All the drugs needed for treatment of Hepatitis B & C are available in this country. In developed countries, these types of drugs are very expensive but we have generated a generic version which is very cheap in comparison to the western countries. Few companies are producing this drug which is very effective.

High antibiotic resistance in Bangladesh

A high prevalence of antibiotic resistance was detected among most tested bacterial pathogens in Bangladesh, according to a review of 46 studies published between 2004 and 2018. Resistance data were available from only 6 of the country's 64 districts, and over 80 percent of the studies were conducted in the capital, Dhaka. Escherichia coli was the most common cause of urinary tract infection; a median of 94.6 percent of isolates were resistant to ampicillin, 67.1 percent to amoxicillin/clavulanic acid, 65.2 percent to ciprofloxacin, and 72 percent to cotrimoxazole. For Klebsiella species, the median number of isolates resistant to ampicillin, amoxicillin/clavulanic acid, ciprofloxacin, and cotrimoxazole was 100 percent, 58 percent, 67.4 percent, and 72.7 percent, respectively. Similarly, high resistance rates were reported in Pseudomonas spp, Enterococcus spp, and Streptococcus pneumoniae.

WHO issues warning about counterfeit leukemia drug

An alert to consumers in the Americas and Europe from the World Health Organization warns that fake versions of leukemia drug Iclusig, or ponatinib, are being sold in certain countries and online. The genuine drug is manufactured by Takeda Pharmaceutical subsidiary Ariad, and the fake contains acetaminophen, not ponatinib.

'Bangladesh has a laudable achievement for curing Hepatitis B'

Prof. Dr. Mamun Al Mahtab (Shwapnil)
Chairman
Department of Hepatology
Bangabandhu Sheikh Mujib Medical University

Q&A

As an eminent Hepatologist of the country, how do you evaluate the current status of liver diseases in the country?

The main burden of liver disease in Bangladesh is due to Hepatitis B virus infection. However, non-alcoholic fatty liver disease is fast picking up. It is now the second commonest cause of chronic Hepatitis in Bangladeshi women. According to published literature, every year approx.. 20,000 people die in this country from chronic liver diseases. In fact, liver diseases are the third commonest cause of deaths among patients dying in Medicine wards of the different public medical colleges and hospitals of Bangladesh. Primary liver cancer also ranks third in the list of cancer related deaths in Bangladesh. One alarming fact remains that Bangladeshi people develop primary liver cancers 18 years earlier than the world average. The average age of developing primary liver cancer is between 45-55 years of age, meaning that people in this country develop primary liver cancers at the peak of their productive life.

The economic burden of liver disease is also huge in Bangladesh. Recent scientific literature shows that cost of investigations in 1 million Bangladeshi Hepatitis B virus infected is USD 1 billion, cost of hospital attendance and surveillance is USD 1 billion, minimum cost of treatment for 50% Bangladeshi Hepatitis B virus infected for 6 years is USD 3 billion, cost of investigation and follow up for Hepatitis B virus related chronic liver disease is USD 3000-10000 and cost of investigation and follow up for Hepatitis B virus related primary liver cancer is USD 10000-50000.

Please tell us in brief about viral Hepatitis

Hepatitis A virus is the commonest cause of acute Hepatitis among Bangladeshi children, whereas Hepatitis E virus causes most of the acute Hepatitis in adults. However, with our economic prosperity and resultant improve hygienic conditions, we are now seeing increasing numbers of Hepatitis A virus related acute Hepatitis in young adults. This is because once someone gets infected with Hepatitis A virus, it confers immunity for life, which is not the case with Hepatitis E virus. As our living and hygienic conditions are improving, we are less frequently exposed to Hepatitis A virus in our early years of life. It may be noted that both Hepatitis A and E viruses are water and food borne.

However, when we think of chronic live diseases, Hepatitis B virus remains the champion. Despite the fact that Bangladesh was the first country in the region to introduce mass vaccination against Hepatitis B virus in the EPI schedule more than 16 years back, Hepatitis B still remains the leading cause of chronic Hepatitis, liver cirrhosis and primary liver cancer in Bangladesh. More than 60 percent of each of these diseases in Bangladesh are due to Hepatitis B virus with Hepatitis C virus trailing behind as the second commonest cause of such diseases in Bangladesh by wide margin. Hepatitis B is also the second commonest cause of acute Hepatitis in Bangladesh next to Hepatitis A and E viruses in children and adults respectively.

> MOST MAINSTREAM ELECTRONIC AND PRINT MEDIA HAVE PUBLISHED NEWS HIGHLIGHTING THIS ACHIEVEMENT BY TWO BANGLADESHIS

What is the treatment of Hepatitis B & C? How can we prevent these?

Good drugs are now available for both Hepatitis B and C virus infections for Hepatitis B the most widely used oral preparations are entecavir and tenofovir. We have generic versions of both these drugs produced in Bangladesh and since they are produced in Bangladesh, we also get them at a cheaper rate compared to most countries of the world.

Bangladesh has a prestigious achievement for curing Hepatitis B. Me and my Bangladeshi born co-investigator Dr. Sheikh Mohammad Fazle Akbar, now working as a full time faculty in Ehime University, Japan lead the research for development of a new drug that is highly effective against Hepatitis B. I conducted the phase-I/II and phase-III clinical trials of this new drug called NASVAC in Bangladesh. Our research was published in two leading Hepatology journals of the world, namely Hepatology International and Plos One. We have received significant international recognition for this research including awards from American Association for Study of Liver Diseases, Euroasian Gastroenterological Association and Turkish Hepato-Biliary and Pancreatology Association to name a few. I was also interviewed by VoA for this research. Most mainstream electronic and print media have published news highlighting this achievement by two Bangladeshis.

However, the most important recognition for NASVAC for us was the inclusion of this discovery in a joint publication by South-South Office of UN and A2i project of PMO of Bangladesh. Our Hon'ble Prime Minister Sheikh Hasina inaugurated this publication at the UN General Assembly in 2017, where 14 such innovations from Bangladesh including NASVAC have been included, that were developed through South-South collaboration and is expected to the benefit mankind.

NASVAC has been registered in Cuba in 2015. The Drug Administration of Bangladesh has already approved the recipe of NASVAC after long evaluation and the drug is expected to be commercialized in Bangladesh in 2019. It will be the first drug to be developed and commercialized in the country, a unique feat to the scientific glory of the nation.

For Hepatitis C, we also have very good oral drugs. The most widely used one is a combination of sofosbuvir and velpatasvir. We have generic version of this drug in Bangladesh. Our government is distributing the drug free of cost to Bangladeshi patients suffering from Hepatitis C. The cost of each course of this treatment varies from Tk. 84,000 to 1,68,000 compared to USD 100,000 to 200,000 in the US market. This is yet another example of the visionary and welfare oriented leadership of Hon'ble Prime Minister Sheikh Hasina's government. It is worth mentioning here that antivirals for Hepatitis B and C produced in Bangladesh are now exported to more than 100 countries of the world.

Both Hepatitis B and C are transmitted through blood and blood products. We have very effective vaccine against Hepatitis B which is produced in Bangladesh. Unfortunately, there is no vaccine against Hepatitis C. We have to be vigilant for screening for Hepatitis B and C before receiving blood transfusion and before going for any surgery, dental procedure etc. If we want to be safe from these two deadly viruses.

What is your message or guidelines for the Hepatitis B and C patients?

Both Hepatitis B and C are treatable and preventable. We don't need to panic if we have any of these viral infections. We should also not isolate Hepatitis B and C infected patients from family, work place and society. They are not threat to us. We should always keep in mind that these viruses do not spread by hugging, shaking hands, sharing wash room, utensils or clothing's or through breast milk.

Do we have all the state-of-art facilities for the treatment of all kinds of liver diseases?

Bangladesh now has state-of-the-art facilities for treating advanced and end stage liver diseases, although such facilities are limited. Me and my team now offer trans-arterial chemoembolization (TACE) for liver cancers. This is the most advanced treatment modality for treating liver cancers anywhere in the world. This is a cath lab based procedure and me and my fellow team member Hepatologists are performing TACE independently for more than two years now. We have performed almost 150 cases of TACE and our outcome is at per with developed centres.

Me and my team performing autologus hemopoetic stem cell transplantation for liver failure patients. With almost 100 cases successfully completed in little more than a year, we can proudly claim to have the highest experience of performing this state-of-the-art procedure in our region. Our research has been published in top Hepatology Journals including Hepatology International and Euroasian Journal of Hepato-gastroenterology.

Recently, we have introduced liver dialysis in Bangladesh which will be beneficial for patients suffering from

acute and chronic liver failures. This is a innovative technique that lowers serum bilirubin level and reduces Hepatic inflammation. I was interviewed by BBC Bangla for introducing this new modality in Bangladesh.

Besides interventions like radiofrequency ablation for liver cancers, therapeutic ERCP for bile duct diseases etc. are also being regularly performed by me and my fellow Hepatologists.

The only thing that frustrates me that we are still not doing liver transplantation in Bangladesh whereas Pakistan has completed more than 100 cases, not to mention that India is global leader in liver transplantation. Even countries like Myanmar and Nepal now have their own liver transplantations programme. I am, however, hopeful that our able Hepatobiliary Surgery colleagues will introduce this time demanding operation in Bangladesh soon.

Do you think that drugs produced locally are adequate for the management of liver diseases?

I take much satisfaction in saying that we are highly satisfied with the quality and range of drugs that our local pharma industry is giving us for treating our liver disease patients. We also get these drugs at a cheaper rate than most countries of the world. That drugs for liver diseases produced in Bangladesh are being exported more than 100 countries of the world is a testimony to what I have just mentioned. I just, in particular, thank Beacon Pharmaceuticals, Incepta Pharmaceuticals and Everest Pharmaceuticals for taking the lead in this particular field and making nation's proud.

Besides alcohol use disorder what are the other causes for fatty liver? How is fatty liver diagnosed?

Other than alcohol, common causes of fatty liver in Bangladesh include obesity, diabetes, dyslipidemia, hypothyroidism, polycystic ovary syndrome and Hepatitis C virus infection

Fatty liver is usually diagnosed at ultrasonography of liver. Another new and very useful modality diagnosis of fatty liver is fibroscan.

What is your advice for the patients of liver disease?

I will advise people to drink boiled water and freshly cooked food. We should avoid fatty food and late night heavy dinner. Fast food should also be avoided and regular physical exercise is mandatory. All should get vaccinated for Hepatitis B virus and the legislation for screening of blood and blood products should be strictly implemented. These simple measures can keep live diseases a thousand miles away.

Liver disease patients should seek medical advice from Hepatologists or at least Internists where Hepatologists are not available and must never refer to taboos and traditional medical practitioners.

We know that the treatment of Liver diseases is very expensive. How can we make it affordable for the common people?

The government is taking measures to make treatment of liver diseases accessible and affordable to the common people. Hepatologists are now serving in many governments medical college hospitals across the country. It is now the demand of time that a National Institute of Hepatology is established. Hon'ble Prime Minister Sheikh Hasina has taken this point into consideration and has very kindly issued a directive to establish this institute few years back. I am confident that the new leadership of the Ministry of Health and Family Welfare in the able hands of Hon'ble Minister Zahid Malek and Hon'ble State Minister Dr. Murad Hasan will take appropriate measures to fulfill this dream of the nation.

Be prepared to take FAST action if you suspect a Stroke

Would you be able to recognize if you or someone close to you were having a stroke? A stroke is a 911 medical emergency and every second counts for survival. To help you recognize the signs of stroke, the National Stroke Association wants you to remember F-A-S-T, or fast.

F stands for «face.» Signs of stroke include drooping or numbness on just one side of the face. An uneven smile is another clue that something›s wrong.

A stands for «arm.» Is just one arm weak or numb? If the person tries to lift both arms, does one drift downward? In general, stroke signs appear on just one side of the body.

S stands for "speech." When a stroke happens, the person can't speak or their speech is slurred or hard to understand. He or she won't be able to accurately repeat a simple sentence.

T stands for "time." It's time to call 911 if you see any of these symptoms. Even if the symptoms go away, the person needs to get to the hospital fast. There's a finite window of opportunity for care, particularly the administration of a specialized clot-busting medication, needed when the stroke is due to a blood clot.

Calcitriol injection

The MHLW and the PMDA have announced that the package insert for the injectable form of calcitriol (Rocaltrol Injection®) should be revised to include shock and anaphylaxis as adverse drug reactions. Calcitriol is indicated for secondary hyperparathyroidism in patients undergoing maintenance renal dialysis. A total of four cases involving shock or anaphylaxis have been reported in patients treated with injectable calcitriol in Japan during the previous three fiscal years. A causal relationship with the product could not be ruled out in one of the cases. MHLW/PMDA concluded that the revision of the package insert was necessary based on the results of the investigation of the currently available evidence.

Azithromycin

The HSA has announced that a clinical trial, investigating effectiveness of long-term azithromycin to prevent bronchiolitis obliterans syndrome (BOS) in certain haematological patients, was terminated prematurely because of an increase in the rate of haematological malignancy relapses and mortality in patients that had a haematopoietic stem cell transplantation (HSCT). Azithromycin is a macrolide antibiotic. It is not approved for the prophylaxis of BOS in HSCT patients. There are 15 generic azithromycincontaining products registered in Singapore. The aim of the clinical trial was to investigate if early administration of azithromycin could improve airflow declinefree survival two years after allogeneic HSCT. The trial investigators concluded that early administration of azithromycin for prophylaxis of BOS in HSCT patients resulted in worse airflow decline-free-survival than did placebo. However, the findings were limited by the early termination of the trial and further investigation was required.

Fluoroquinolone antibiotics tied to deadly Heart Vessel Tears

Patients should avoid a class of antibiotics called fluoroquinolone due to an increased risk of heart vessel tears associated with their use, the U.S. Food and Drug Administration warned. "These tears, called aortic dissections or ruptures of an aortic aneurysm can lead to dangerous bleeding or even death," the agency said in a statement. The risk for these ruptures rises with the use of fluoroquinolone antibiotics delivered by injection or as a pill, and the drugs "should not be used in patients at increased risk unless there are no other treatment options available," the FDA added. Fluoroquinolones have been a mainstay of antibiotic therapy, particularly for upper respiratory conditions, and have been around for more than three decades. They include ciprofloxacin, Levofloxacin, Gemifloxacin and Moxifloxacin.

Hydrochlorothiazide

The EPVC has announced that the Summary of Product Characteristics and Package Leaflet for hydrochlorothiazide will be updated to include the risk of non-melanoma skin cancer (basal cell carcinoma and squamous cell carcinoma) as an adverse reaction. Hydrochlorothiazide is widely used to treat hypertension, cardiac, hepatic and nephrogenic oedema or chronic heart insufficiency. Pharmacoepidemiological studies have shown an increased risk of nonmelanoma skin cancer with exposure to increasing cumulative doses of hydrochlorothiazide. Patients taking hydrochlorothiazide should be informed of the risk and advised to regularly check their skin. Also, patients should be advised to limit exposure to sunlight and UV rays, and suspicious skin lesions should be examined, potentially by performing histological examinations of biopsies.

Secukinumab

MHLW and PMDA have announced that the package insert for secukinumab (Cosentyx®) should be revised to include risk of inflammatory bowel disease as an adverse reaction. Secukinumab is indicated for psoriasis vulgaris, psoriatic arthritis and pustular psoriasis in patients who were not sufficiently responsive to conventional therapies. Cases of inflammatory bowel disease have been reported in patients treated with secukinumb in Japan. MHLW/PMDA concluded that revision of the package insert was necessary based on the results of their investigation of currently available information.

Febuxostat for Uric Acid

The US FDA has mandated that the gout drug febuxostat carry a boxed warning to alert doctors and patients to the increased risk for cardiovascular death with the drug. The warning also states that the drug use should be limited to patients who do not respond to or cannot tolerate allopurinol. The warning follows results from a post-marketing randomized trial comparing febuxostat with allopurinol in some 6000 patients with gout and CV disease: there were 15 CV deaths for every 1000 patients treated with febuxostat for 1 year, versus 11 for every 1000 treated with allopurinol. For all-cause mortality, the numbers were 26 deaths per 1000 treated with febuxostat, versus 22 per 1000 with allopurinol. Clinicians should advise patients to seek medical attention right away if they experience symptoms like chest pain, shortness of breath, and irregular heartbeat while taking the drug.

Marketing and Promotional Challenges of the Pharmaceutical Industry of Bangladesh

Mohammad Rafiqul Islam
Managing Director
Cure Care Plus Ltd., HR &
Pharmaceutical Consultant
and Trainer

The Bangladesh pharmaceutical industry is one of the thrust sectors contributing to the health care system and carrying the flag of the country in many other countries for which the country can be proud of.

Although, business in this sector is very challenging, but the need for medicines in a densely populated country like Bangladesh, is growing day by day and it will continue to grow even in the near future.

This need for medicines has attracted investors to invest in this sector, but in most of the cases of new entrants as businessmen in this sector, have not done their homework properly before investing in the pharmaceutical sector.

Unlike other businesses, the ROI from this sector is comparatively slow and sometimes their patience to continue the business fade out and the entrepreneurs either give up to continue the business and sell off their company or keeps trying to gain profit.

These companies are struggling with their balance sheet due to lack of proper policy and high attrition rate. Some of the companies even do not have any budget for HR development and thus bank on sales forces completely.

There is a real need for these companies to pay attention to the development of HR and change their marketing and sales function in order to sustain future growth and performance.

For these companies the sales force are the main and only communication channel and all the focus is on the target given to these sales people and following up on the figures of sales in almost all the monthly or quarterly meetings is almost the only agenda.

But the factors that influences the pharmaceutical selling is; perceived product differentiation , great heterogeneity in the prescribing habits of the physicians ,restricted access to the physicians, the company branding and the product branding .

With the exception of a few, most of the players of this industry are struggling to sustain with just the "ME TOO" products with literally no proper planning or policies.

These companies are of different sizes and they have so many products in their basket that it has become difficult for a single representative to visit a physician with all the products.

There are different representatives from the same company to visit the physicians in an area .This makes it more difficult to obtain a holistic understanding of physician needs and respond to them although it allows a sharp promotional focus on individual products. However, in many practicing doctors, competing brands are perceived to be only weakly differentiated, and the promotional focus on products has become less effective.

This type of sales force structure can be called product-based sales force structure. The larger companies have no other alternative other than product –based sales force structure.

In a market segment-based structure, the medical representatives are responsible for the promotion of all their products in their designated segment, within a geo-

graphic area. This allows the representatives to better understand their customers, tailor the offerings to their needs and, thereby, compensate for the loss of product differentiation.

In my opinion a market segment-based sales force structure can still be working better in the small and medium sized companies.

Communication challenges

Although, face- to- face communication is considered the best in the hierarchy of communication, but considering the high cost of a medical representative's call, do all physicians have a similar need for the extensive information that can be provided in a face-to-face visit?

Time has come to address this issue and to think of better alternatives or parallel promotional activity along with the face- to- face promotion.

I would not suggest to ignore or to discontinue the visits of the representatives because these visits operate as a multi-function communication channel, which can carry many types of communications from the company to physicians and other types of customers (e.g. information about diseases, products, patients, other physicians), and from customers back to the firm (e.g. customer needs, perceptions, preferences and behaviors; competitor activities).

But I would say that some of the functions performed by such visits might be carried out with equal or greater effectiveness at lower costs by some other channels such as e-mails, telephones, text messages in festivals and birthdays, CMEs, etc.

It has been observed that physicians' usage of the Internet has increased significantly. The Internet was being used for accessing personal e-mails; searching information about medical advances in specific diseases, and gathering information about personal and healthcare products; and for the purpose of professional communication.

Over the years, various traditional means of pharmaceutical marketing techniques have been used by the pharmaceutical companies. These various pharmaceutical marketing strategies are targeted towards various customers like physicians and retailers.

> "EXTENDED MARKETING MIX TO INCLUDE PRODUCTS THAT ARE SERVICES AND NOT JUST PHYSICAL THINGS

Increased market competition and drastic reduction of time and restriction on MR for access to Doctor's chamber and Hospitals is now a great challenge for successful marketing.

Not all physicians receive visits by pharmaceutical representatives. Some markets refuse to see pharmaceutical representatives. Others are not visited by pharmaceutical representatives for a variety of reasons: they may not show up on the list of physicians, live in remote areas, or may not prescribe enough to be worth for a visit.

The new challenges may be tackled by finding new ways of communication and by developing new media mix for managing physicians. It has become essential for companies to shift from a marketing and sales-focused model to an access driven customer need model.

The enhanced competition can be tackled through adopting Internet as an emerging marketing communication medium for pharmaceutical promotions. The participation in the CMEs is another good means of communication with the physicians.

In other words there has to be a channel mix for each segment of clients (physicians).

All these areas can well be addressed if the companies now switch their marketing activities using all the 7 "Ps" of the marketing mix instead of the conventional 4 "Ps" which are Product, Price, Promotion and Place.

These extended 3"Ps", that is People, Process and Physical Evidence are the creation of Booms and Bitner in 1981 which now allowed the extended Marketing Mix to include products that are services and not just physical things.

The "P" of the extended marketing mix that represents People, is what is seriously missing in many of the pharmaceutical companies.

With the change in the "marketing mix" from 4"Ps" to "7Ps" the addition of the "P" representing the People is now the key to success.

Right from the Sales Person to Managing Director, all have a pivotal role to play to serve the customers and create customer satisfaction. The people are responsible to take the company forward and also to maintain personal relationship with the customers (physicians) and this personal relationship with the customers or potential customers has become a vital component for the pharmaceutical business which can well be maintained by the senior management personnel.

Besides, the face- to-face interviews by medical representative, such relation can be maintained through interaction by mobile phones or other contact medias like face book, messenger, viber, whats App e-mails etc. Such communications are useful as well as cost-effective saving time spent on the busy roads as well as the waiting time at the physicians chamber.

In other words, there has to be a channel mix for each segment of clients (physicians) involves the senior marketing management for building up a good business relationship with the clients (physicians) as and when applicable.

(The writer is a Managing Director, Cure Care Plus Limited and a HR & Pharmaceutical Consultant and Trainer. He may be reached at e-mail: r154islam@gmail.com)

Five different ways the GDPR will change medicinal services

Ankit Kankar

The General Data Protection Regulation (GDPR) which introduced in May, 2018 has had critical ramifications on all organizations. In any case, because of the dimension of privacy of patient data, the GDPR has spread out explicit data for human services associations meaning huge scale changes should be made. Prominently, medicinal services information (individual, hereditary, biometric) under the GDPR will be liable to a higher standard of security than individual information when all is said to be done.

Be that as it may, what does this all mean in all actuality? Here are five different ways the GDPR will influence the medicinal services industry over the coming years.

More secure individual information

Under the GDPR, human services associations should better see how their patient data is gathered and where it is put away. Advanced information is obviously influenced, yet this change, additionally influences paper records.

The GDPR orders that information ruptures must be accounted for within 72 hours. Normally, this will drive medicinal services experts and associations to care more for the information they hold and, obviously, the higher fines in play will go about as another motivation to significantly enhance information security.

Itemized persistent profiles

With information gathered at focuses running from specialist's medical procedures to specific human services associations, the information impression of an individual is typically exceptionally divided. One of the center parts of the GDPR is guaranteeing that there's increasingly accessible data about the reason and area of any information that is gathered. This implies human services suppliers will have an increasingly point by point perspective of their patients, which could prompt better and progressively precise finding, just as more focused on medications at lower cost.

The contrast, however is that the GDPR reveres directly to be overlooked, which could develop as an obstruction to enhanced analysis.

"It is a lawful necessity for all human services suppliers to hold records for an endorsed period if there should be an occurrence of question. This should be followed near both guarantee the record isn't discarded rashly or the subject is denied a transfer when it is legitimate to do as such."

Commanding that tolerant information has more structure could be gigantically useful to HCPs. The GDPR places a structure around how this information can be gathered, utilized and in which situations it must be erased, yet singular patient consideration should profit by decreased discontinuity.

Placing patients in charge

Social insurance is the one part of our lives that has remained profoundly touchy and private. Be that as it may, test results are frequently shared generally to achieve a finding, with the patient having

little knowledge into how this data is gathered, who approaches it and how it is put away. GDPR places people immovably accountable for their information.

"A portion of the new information subject rights additionally enable clients to feel in charge – for instance, they have more grounded rights to stop how their information is to be utilized on the off chance that they alter their opinion about assent. Exhibiting that you have pondered how you use information and have set up suitable insurance can help, even where the client must choose between limited options."

Utilizing new information sources

As per Future Health Index information, 57% of patients possess or utilize an associated consideration gadget to screen different wellbeing pointers, yet just a single third of these people (33%) have ever imparted this data to their specialist. Besides, FHI found that social insurance is the business on the overall population most trust with its own information. There is, in this manner, a solid establishment from which to make wellbeing information accumulation part of more people groups' lives.

On the HCP side, advances from interpersonal interaction are progressively being utilized to convey understanding consideration and support. Human services experts routinely use systems, for example, Whatsapp to send tolerant information to one another. As this data moves over the system, this could mean delicate information is held outside the EU, breaking GDPR directions.

From information bits of knowledge to better anticipation

Talking at the 'Enormous information: Connected answers for better human services' gathering held in Brussels before the year, EU wellbeing magistrate Vytenis Andriukaitis alluded to the European Reference Networks (ERNs) that expect to advance cross-outskirt medicinal services: "The accomplishment of ERNs additionally relies upon huge information: they will incorporate divided wellbeing informational collections, produce new clinical, hereditary, social and ecological information, and make utilization of these information."

The majority of information that medicinal services associations have been gathering for quite a long time is still regularly unstructured and difficult to reach. The thoughts behind enormous information and how it can open the bits of knowledge contained with social insurance data is a noteworthy motivation behind, why GDPR could offer the human services industry a tremendous chance. The bits of knowledge that originate from the drive to structure and coordinate information could quicken new treatments and support moves to enhance counteractive action.

Generally speaking, the GDPR is an explanation behind the wellbeing division to be energized – it could help open the potential in tremendous stores of information that have stayed lethargic for quite a long time.

(The Author is Manager Product & Digital Communication, BioSpectrum Asia, BioSpectrum India, NuFFooDS and may reached at email: ankit.kankar@mmactiv.com)

Drug-Induced Liver Injury

Khandaker Sagir Ahmed, PhD.
Director (CC)
Directorate General of Drug Administration
Mohakhali, Dhaka

Introduction

Liver is the principle organ for maintaining the body's internal environment. It plays an astonishing array of vital functions in the maintenance, performance and regulating homeostasis of the body. It is involved with almost all the biochemical pathways to growth, fight against disease, nutrient supply, energy provision and reproduction (Sharma et al., 1991). The major functions of the liver are carbohydrate, protein and fat metabolism, detoxification, secretion of bile and storage of vitamin. Thus, to maintain a healthy liver is a crucial factor for the overall health and well being (Subramaniam and Pushpangadan, 1999). Drug-Induced Liver Injury (DILI) also known as Hepatotoxicity implies chemical-driven liver damage. Certain medicinal agents, when taken in overdoses and sometimes even when introduced within therapeutic ranges, may injure the organ. Other chemical agents, such as those used in laboratories and industries, natural chemicals (e.g., microcystins) and herbal remedies can also induce hepatotoxicity. Chemicals that cause liver injury are called hepatotoxins. More than 900 drugs have been implicated in causing liver injury and it is the most common reason for a drug to be withdrawn from the market. Chemicals often cause subclinical injury to liver which manifests only as abnormal liver enzyme tests. Drug induced liver injury is responsible for 5% of all hospital admissions and 50% of all acute liver failures. More than 75 percent of cases of idiosyncratic drug reactions result in liver transplantation or death (Ostapowicz et al., 2002).

Why should we care about Drug-Induced Liver Injury (DILI)

1. Drugs used for the therapeutic intent may be caused serious or fatal liver injury patient- unpredictable, scary
2. Although rare, DILI may result in disapproval of a new drug or its removal from the market-very costly
3. It is a troublesome problem for drug development, regulatory agencies and patient care-difficult problem
4. It's not necessarily a dangerous drug, but may be an especially susceptible patient or subject.

Mechanisms of Drug-induced Liver Injury

Drugs are metabolized by the liver p450 system in a series of phase I and phase II reactions. Toxic intermediates can illicit hepatocyte damage and death by inducing apoptosis or necrosis. Drugs that bind to cellular membranes can elicit an immunologic reaction upon presentation to major histocompatibility complex (MHC) particles, resulting in inflammation.

The vast majority of drugs is lipid soluble and metabolized in the liver and excreted in bile or urine. The first step of drug metabolism is known as a phase I reaction and is mediated by enzymes of the hepatic cytochrome p450 system. Intermediate bioactive products generated in this step may interact with various cellular organelles (e.g. mitochondria) leading to hepatocyte dysfunction and cellular demise. These potentially toxic

intermediate products are then inactivated through glucurono-, glutathione- or sulfa-conjugation in subsequent phase II reactions. In order to limit Hepato-toxicity, the generation rate for phase I products should not exceed the liver's capacity to inactivate them. Depletion or deficiency of the compounds responsible for the phase II conjugation reactions may result in accumulation of toxic metabolites. One of the earliest events in DILI is the inhibition of the mitochondrial respiratory chain, resulting in increased reactive oxygen species (ROS) and depletion of adenosine triphosphate (ATP). There are several mechanisms contributing to mitochondrial dysfunction: the mitochondrial respiratory chain may be inhibited, diminishing ATP production and resulting in increased ROS levels. Furthermore, certain drugs, such as amiodarone, may inhibit-oxidation of fatty acids, resulting in steatosis or steatohepatitis. Dideoxynucleotide analogs, often used in the treatment of HIV, may impair mitochondrial DNA replication. Drug toxicity may also result from the opening of the mitochondrial permeability transition pore (MPTP), which is strongly associated with cell death.

ROS generation, ATP depletion, and the aforementioned mitochondrial insults may combine to induce intracellular damage. Ultimately, hepatocytes commit to apoptosis, but this process requires energy (ATP), which may not be available due to mitochondrial dysfunction and depleted ATP stores. In this instance, hepatocyte death occurs through the necrotic pathway, which may enhance hepatic inflammation.

Immune-mediated injury is also an important mechanism of DILI and may be characterized by a prolonged interval between administrations of the drug and recognized liver toxicity. The liver contains components of both the innate and adaptive immune system. Bioactive drug metabolites bind to cellular proteins and are exposed to major histocompatibility complex (MHC) molecules on antigen presenting cells. This interaction triggers an immune response directed against the hepatocyte. Halothane, for example, triggers the generation of antibodies directed against cytochrome p450 CYP2E1. Thus, identifying drug-induced antibodies in patients' blood may help in the diagnosis. Apart from antibody-mediated cell death, locally released cytokines and ROS also enhance hepatic injury

Patterns of drug-induced liver injury

Drugs may have a characteristic pattern or signature of hepato-toxicity. Although not exclusive, this is based less on the symptoms and signs but more importantly on the ratio of elevation of trans-aminase and alkaline phosphatase. Based on the level of elevation of trans-aminase or alkaline phosphatase and the ratio (R) of elevation of baseline ALT to baseline alkaline phosphatase (ALT/ULN)/(ALP/ULN), drug-induced liver injury is classified as either hepatocellular, cholestatic or mixed types. Hepatocellular DILI: ALT ≥ 3 ULN and $R \geq 5$; Cholestatic DILI: ALP ≥ 2 ULN and $R \leq 2$; Mixed DILI: ALT > 3 ULN and ALP > 2 ULN and $R > 2 < 5$. The degree of elevation in liver enzymes has poor correlation with severity of liver disease. Instead, the pattern of liver disease indicates near term and long-term consequences.

In Dr. Hyman Zimmerman's original observation the fatality rate was dependent on individual drugs; 10% for iso niazid, 10% for methyldopa, 40% for phenytoin and 50% for halothane hepatitis. Hy's law has been corroborated in several studies including a recent single center study from India, which found a mortality of 21.5% in a setting where transplantation was not available.

Patterns of liver disease caused by drugs

Acute hepatitis:	Isoniazid, pyrazinamide, rifampicin, ibuprofen, nimesulide, cotrimoxazole, phenytoin, dapsone
Cholestatic:	Chlorpromazine, amoxicillin–clavulanic acid, flucloxacillin, carbamazepine, phenytoin
Autoimmune:	Minocycline, nitrofurantoin, alpha methyldopa
Steatohepatitis:	Tamoxifen, amiodarone, tetracycline, valproic acid
Granulomatous hepatitis:	Dapsone, sulphonamides
Cirrhosis:	Methotrexate, amiodarone
Bland cholestasis:	Anabolic steroids, danazol
Nodular regenerative hyperplasia:	Didanosine, stavudine
Vanishing bile duct syndrome:	Carbamazepine, cotrimoxazole
Peliosis hepatis:	Anabolic steroids, azathioprine
Hepatic adenoma:	Oral contraceptive, anabolic steroids

Drug-induced Liver Injury Severity Index

Elevated trans-aminase or alkaline phosphatase alone without jaundice or hyperbilirubinemia qualifies as mild disease. Elevated liver enzymes without symptoms may be part of an adaptation process especially when transaminases are less than 5 × ULN (upper limit of nor-

mal). Presence of hyperbilirubinemia with a bilirubin of >2 mg/dl qualifies as moderately severe disease. Presence of prolonged international normalized ratio (>1.5), encephalopathy or ascites with or without hospitalization accompanied by hyperbilirubinemia or jaundice connotes severe disease. Mortality in the latter category varies depending on the exposed drug, being 21% for ant tuberculosis drug-induced liver injury and 9–17% in non-tuberculosis drug-induced liver injury.

Risk factors:

The risk of developing hepato-toxicity involves a complex interplay between the chemical properties of the drug, environmental factors (e.g., the use of concomitant drugs or alcohol), age, sex, underlying diseases (e.g., HIV or diabetes), and genetic factors. The most extensively documented risk factors are concomitant drug use and diseases. There is recent evidence for an increase in drug-induced liver disease among patients with HIV, Hepatitis B virus, and Hepatitis C virus infections, which suggests a role for cytokine balance in these patients. Genetic factors include genes that control the handling of the drug (metabolism, detoxification, and transport), as well as those that influence cell injury and repair. Additionally, genetic polymorphisms with functional effects occur with many of the genes that encode drug-metabolizing enzymes and drug transporters. However, whether a genetic polymorphism of a drug-metabolizing enzyme has clinical relevance depends on its functional role in them metabolism of a drug. Familial sensitivity to the toxic effects of metabolites has also been shown, which indicates that these may be inherited defects in the defense against specific drug-related injuries.

Prevention of drug-induced liver injury:

Given the idiosyncratic nature of most drugs, it is difficult to predict who and when during the course of treatment will develop hepato-toxicity. Rational drug prescribing is central to minimizing DILI particularly in patients with risk factors such as old age, co morbid diseases, HIV status, daily dose of drug >50 mg, or poly pharmacy. Caution should be exercised in the empirical treatment for tuberculosis given the high incidence of severe DILI including acute liver failure. Knowledge of drug–drug interaction and drug–disease interaction is also important. Except for few drugs such as methotrexate, clinically significant DILI is usually accompanied by symptoms, such that vigilance for symptoms is the key in the detection of early onset DILI. Patients and caregivers should be educated about the development of new symptoms such as nausea, vomiting, anorexia, dark urine or jaundice. The suspected drug or drugs should be stopped at the slightest suspicion of DILI, in order to prevent progressive liver damage. Debate continues about the need and the timing of liver function tests particularly in those who need to be on medications for a long duration. There is no clear evidence that such a practise influences much in the detection or prevention of clinically significant liver injury. Additional constraints include the costs and inconvenience of the tests, physician ambiguity and varying guidelines with regard to timing of the tests. Studies by Lammert et al have clearly shown the importance of dose dependent hepato-toxicity.

Patients receiving methotrexate for psoriasis are reported to be at increased risk for fibrosis and/or cirrhosis, such that serial liver biopsies have been recommended. Subsequent studies have questioned the effectiveness of liver biopsies in detecting advanced liver fibrosis and its impact on patient management. Increasing evidence attests to the role of host and environmental factors such as obesity, diabetes mellitus, alcohol or concomitant medications as playing an important role in the hepatic fibrosis process. As liver injury particularly fibrosis is reflected poorly in liver tests, the decision to perform liver biopsies in the presence of risk factors must be made on a case by case basis.

Regulatory Actions due to Drug-induced Liver Injury DILI:

(Marketed Drugs: 1995-2009)

It is the responsibility of every National Regulatory Authority to ensure quality- assured, safe and effective medicines at an affordable cost to the people. If any serious liver injury occurs during pre-clinical, clinical and after marketing of drugs, regulatory action should be taken as per National Rules and Regulation. Below is the example of Regulatory action taken by US-FDA, the most, stringent regulatory authority in the world, on the Marketed Drugs, during the period 1995-2009.

Withdrawals

- bromfenac
- troglitazone
- pemoline

Special Use

- trovofloxacin
- felbamate

Warnings

- acetaminophen
- nefazodone
- pyrazinamide/rifampin
- valproic acid
- ximelegatran*non-US
- lumaricoxib*non-US
- tolcapone
- nevirapine
- terbinafine
- zifirlukast
- interferon 1b/1a

- atomoxetine
- leflunomide
- saquinavir
- bosentan
- erlotinib
- telithromycin
- telithromycin
- natalizumab
- lipokinetix
- kava

Conclusion:

Hepato-toxicity is a potential complication of nearly all classes of medication. Most cases of DILI are benign, and improve after drug withdrawal. It is important to recognize and remove the offending agent as quickly as possible to prevent the progression to chronic liver disease and/or fulminant hepatic failure. There are no definite risk factors for DILI, but pre-existing liver disease and genetic susceptibility may predispose certain individuals. Although most patients have clinical symptoms that are identical to other liver diseases, some patients may present with symptoms of systemic hypersensitivity. Treatment of drug-and herbal-induced liver injury consists of rapid drug discontinuation and supportive care targeted to alleviate unwanted symptoms.

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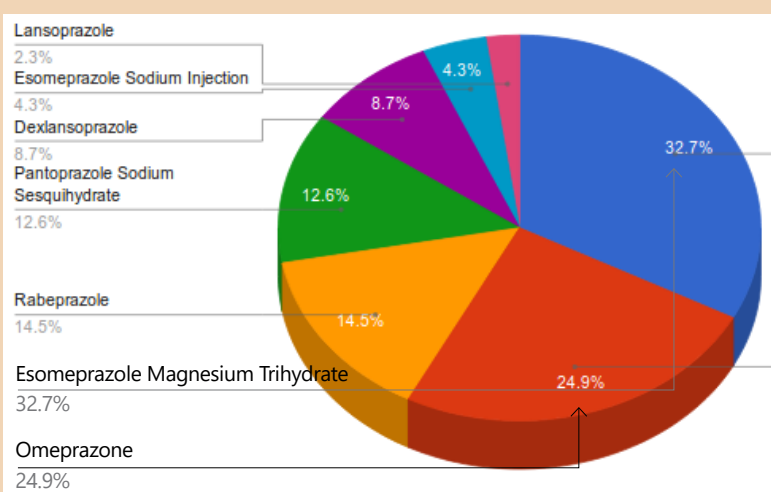
Bangladesh Esomeprazole Magnesium Trihydrate Market 2018

Current Therapeutic market position

Esomeprazole Magnesium Trihydrate is under the therapeutic class of Proton Pump Inhibitor. The main line of drugs of this therapeutics includes; Esomeprazole Magnesium Trihydrate, Omeprazole, Rabeprazole, Pantoprazole Sodium Sesquihydrate, Dexlansoprazole, Esomeprazole Sodium Injection and Lansoprazole. In recent year 2018, Esomeprazole Magnesium Trihydrateremained in first place for market size of Proton Pump Inhibitor. Esomeprazole Magnesium Trihydrate meets 30.3% demands of an ever-changing market of Proton Pump Inhibitor. The other Proton Pump Inhibitor meet market demand 25.5% for Omeprazole, 14.5% for Rabeprazole, 13.8% for Pantoprazole Sodium Sesquihydrate, 8.4% for Dexlansoprazole, 5% for Esomeprazole Sodium Injection and 2.5% for Lansoprazole.



Source: MedAnalytics News

'The principal risk factors of peptic ulcer disease are H. pylori infection and NSAID use'

Prof. Dr. Md. Abdur Rahim Miah
Chairman of Gastroenterology
Bangabandhu Sheikh Mujib
Medical University

Q&A

What is the prevalence of gastrointestinal disease in Bangladesh? Do you have any survey report in this regard?

Bangladesh is a developing country with high prevalence of different digestive diseases. Overall 20-25% of the patients attending the out & inpatient departments of different medical institution in Bangladesh presented with different gastrointestinal disorders. This prevalence of different gastrointestinal diseases varies. Several population survey on different diseases have been done in Bangladesh such as prevalence of dyspepsia, peptic ulcer disease (PUD), diarrhoeal diseases including intestinal TB, Hepatitis–B and HCV infection. A population survey in 1975, showed that 41.4 % of the general population have some form of ulcer like dyspepsia and the point prevalence of peptic ulcers is 15% (DU -11.98% and GU- 3.58%). Whereas the incidence of peptic ulcer in western countries is 1.5% possibly because of very high prevalence of H. Pylori infection in Bangladesh which is now a recognized cause of PUD worldwide. Endoscopic studies have shown that up to 15-30% of patients using NSAIDs may develop gastric and duodenal ulcers. The prevalence of gastric and duodenal ulcers among the long-term NSAID users is reported to be 10–20% and 2–5% respectively. The prevalence of IBS in different studies is found to be 20-28%.The overall diarrhea prevalence among children <5 years old was found to be 5.71%. The prevalence of Hepatitis–B virus infection in Bangladesh in different population ranges from 2-10%. The prevalence of Hepatitis-C virus infection in rural adult population in Bangladesh is reported to be 0.6%.

What are the common gastrointestinal diseases in Bangladesh?

Common Gastrointestinal Diseases in Bangladesh are- Non-Ulcer Dyspepsia (NUD), PUD, IBS, Diarrheal Diseases, Malabsorption Syndrome, Acute And Chronic Pancreatitis, Jaundice, Chronic Liver Diseases, Cholelithiasis, Hepatocelluar Carcinoma (HCC), Malignancies (Ca-Esophagus, Ca- Stomach, Colonic Carcinoma, Ca-Pancreas)

What is Irritable Bowel Syndrome (IBS)? What are the symptoms and how it can be prevented?

Irritable bowel syndrome (IBS) is a functional gastrointestinal (GI) disorder characterized by abdominal pain and altered bowel habits in the absence of a specific and unique organic pathology.

IBS is being diagnosed by Rome IV criteria:

Recurrent abdominal pain on an average at least 1 day per week during the previous 3 months that is associated with 2 or more of the following:

a. Related to defecation (may be increased or unchanged by defecation) b. Associated with a change in stool frequency c. Associated with a change in stool form or appearance d. Types of IBS- made on the basis bowel habit and stool pattern e. IBS-D(Diarrhea Predominant) f. IBS-C(Constipation Predominant) g. IBS-M(Diarrhea/Constipation)

Symptoms:
Manifestations of IBS are as follows:

- Abdominal pain
  - Pain frequently is diffuse without radiation
  - Common sites of pain include the lower abdomen, specifically the left lower quadrant
  - Acute episodes of sharp pain are often superimposed on a more constant dull ache
  - Meals may precipitate pain
- Altered bowel habits
  - Constipation: variably results in complaints of hard stools of narrow caliber, painful or infrequent defecation, and intractability to laxatives
  - Diarrhea: usually is described as small volumes of loose stool, with evacuation preceded by urgency or frequent defecation
  - Postprandial urgency is common
  - alternation between constipation and diarrhea, characteristically, one feature generally predominates in a single patient, but significant variability exists among patients
- Abdominal bloating/distention
- Additional symptoms consistent with irritable bowel syndrome are as follows:
  - Clear or white mucorrhea of a noninflammatory etiology
  - Dyspepsia, heartburn
  - Nausea, vomiting
  - Sexual dysfunction (including dyspareunia and poor libido)
  - Urinary frequency and urgency have been noted
  - Worsening of symptoms in the peri-menstrual period
  - Comorbid fibromyalgia
  - Stressor-related symptoms

IBS is not a preventable disease but some alteration in dietary habit and life style may become very helpful to prevent the flare up of symptoms.

Please tell us in brief about peptic ulcers? What are the causes of peptic ulcer and how to treat it?

Peptic ulcers are defects or breaks in the GI mucosa having appreciable depth at endoscopy that extend through the muscularis mucosa into the sub-mucosa due to the acid–peptic activity of gastric juice. The arbitrary criterion is that an ulcer has a diameter of 5 mm or larger, and lesions smaller than 5 mm are called erosions. Peptic ulcer disease (PUD) generally encompasses both gastric (GUs); and duodenal ulcers (DUs) but practically peptic ulcers cover all ulceration that occurs at any level of the GI tract due to acid- peptic injury. Peptic ulcers are localized defects of the GI mucosa extending to at least the depth of the muscularis mucosa. Arteries are located deep to the muscularis so superficial lesions are less likely to result in complications. Through the endoscope, an ulcer is identified as a mucosal break with depth.

Causes of Peptic Ulcer: The principal risk factors of peptic ulcer disease are H. pylori infection and NSAID use. However, some patients with peptic ulcer disease have neither of these risk factors. So there are three types peptic ulcer-

1) Helicobacter pylori associated PUD - H. Pylori infection is now recognized as the major (80%) causal factor for peptic ulcerogenesis. Over 95% of DU and 60-80% of gastric ulcers are reported to be associated with H. pylori infection. In the Western countries, the prevalence of H. pylori infections roughly matches the age (i.e. 20% at age 20, 30% at age 30, 80% at age 80 etc.). Prevalence is higher in third world countries where it is estimated to be about 70% of the population, whereas least in the developed countries (maximum of 40%).The mechanisms by which H. pylori is involved in the pathogenesis of peptic conditions are unclear.

In Bangladesh, sero-prevalence of H. pylori in apparently healthy young adult population is 92% but only 15% of the population suffer from PUD (point prevalence 12% for DU and 3.58% for GU), whereas in Africa the prevalence of H. pylori infection is over 90% but prevalence of PUD is only 1-2% confirming that all H. pylori strains are not pathogenic for PUD. Recently, it has been discovered that only CAG-A (Cytotoxin Associated Gene Protein-A) positive H.pylori is related to the causation of PUD particularly DU. Recently some authorities claimed that in fact, DU is an infectious disease caused by H.pylori infection and possibly a curable disease if this organism can be successfully eradicated by therapy as evident by a marked reduction in the ulcer recurrence rate to <5% after eradication of the bacteria instead of 60-80% with anti-secretory drugs alone. At present, overall prevalence of H. pylori infection is decreased worldwide, more so in developed countries with a declining prevalence of PUDs.

2) NSAIDs-induced Peptic Ulcers: NSAIDs (e.g. Aspirin, Ibuprofen, Naproxen, Indomethacin, Diclofenac etc represent the second most common cause of PUD. The prevalence of gastric and duodenal ulcers among the long-term NSAID users is reported to be 10–20% and 2–5% respectively. Endoscopic studies have shown that up to 15-30% of patients using NSAIDs may develop gastric and duodenal ulcers. Approximately 2–5% per year of long-term NSAID users will have an ulcer that causes clinically significant dyspepsia or a serious complication.

3) Idiopathic peptic ulcer-Peptic ulcers not related to H.Pylori or NSAIDs include - PUD associated with Zollinger Ellison's Syndrome, antral G-cell hyperplasia, idiopathic gastric acid hypersecretion, systemic mastocytosis or Basophilic leukemia with hyperhistaminemia, stress ulcer, MEN type-1, hyperthyroidism, uremia, primary polycythemia, Carcinoid syndrome, infections other than H. pylori(e.g. Cytomegalovirus /Herpes

simplex viral infection) and radiotherapy /chemotherapy .

How to treat PUD?

Steps in the management of PUD: In the first step of the management of PUD, the doctors must explain the natural history of the disease to the patients with particular emphasis to it's relapsing state, it's tendency towards natural resolution in time and the relatively low incidence of major complications. Secondly, they should also be explained the fact that in majority of cases ''peptic ulcer is, in fact, a curable infectious disease caused by H. pylori'' and cure of PUD is possible by successful eradication of this organism. After H.pylori eradication, the ulcer recurrence rate is reported to be < 2% in western countries instead of 60-80% when treated with H2-blockers or PPI only.

A) Medical Treatment:

General measures-

- Rest to the patient is not needed for uncomplicated PUD.
- Diet should be normal. There is no evidence that dietary modification plays any important role in the treatment of PUs and any particular food item delays ulcer healing or cause ulcer recurrences. Some authorities claimed that red chili may be cytoprotective to upper GI mucosa rather than interference with ulcer healing. Bland diets (spice free, soft rice) have no advantages over a normal diet. Frequent small meal should be avoided as it increases gastric acid secretion that may interfere with ulcer healing.
- Milk should be avoided or should not be used frequently. Peptone is a very good stimulator for gastric acid secretion (7.8 ± 0.9). Milk is an equally strong stimulant like peptone (8.9 ± 2.1) although it has a buffer action in neutralizing the gastric acid.
- Alcohol, excessive tea and coffee should be avoided.
- Stopping of smoking because it interferes with ulcer healing .It is reported that smoking of ≥ 30 cigarettes/ day have an ulcer healing rate of only 40% at end of 4 weeks of therapy and smoking of < 9 cigarettes/ day have an ulcer healing rate of 80% after end of 4 weeks of therapy.
- Avoidance of NSAIDs if at all possible. If not possible then higher doses (double dose) of H2-blocker/PPI should be given along with NSAIDs therapy.

Treatment with ulcer healing drugs should be given for 8-12 weeks. Ulcer healing rate of all these drugs is virtually the same and have equal efficacy in pain relief (70-80%) at the end of 6-8 weeks of therapy. About 70 to 95% of DU will heal within 6 to 8 weeks of therapy but complete healing of GU needs 8-12 weeks. The response to the more effective antisecretory regimens is more rapid in the first four weeks, but the result at the end of 6 -8 weeks is similar with all therapies. In cases of GUS but not DU, there is a need to monitor ulcer healing by X-Ray or endoscopy at the end of treatment.

As the efficacy of all these drugs in ulcer healing is almost the same, the choice of a particular drug depends on the cost-benefits, ease of administration with good patient compliance and minimal side effects. Antacids are mostly used for symptom relief in the early days of therapy. The healing efficacy of conventional anticholinergics is not comparable with the agents mentioned above. In the past, anti-cholinergic agents and tricycle antidepressants were used for treating acid peptic disorders but because of their toxicity and the discovery of potent antisecretory agents, these are rarely used now a days. New antimuscarinic agents such as pirenzipine, are effective but not available in Bangladesh.

Anticholinergic drugs have weak antisecretory ability and no antibacterial activity against H. pylori and should be considered obsolete for treatment of ulcer disease. These agents may have some place in Hp-negative, NSAID-negative PUD.

B) MUCOSA-PROTECTIVE AGENTS (Citoprotectors):

- Sucralfate: 1 gm three times daily one hour before meals and 1 gm at bed time daily is the standard dose.
- Colloidal bismuth subcitrate: 120 mg 4 times daily or 240 mg twice daily one hour before meal.
- Prostaglandin analogues: Misoprostol 200 µg qid.

C) Measures to prevent ulcer recurrence

i. H. Pylori eradication therapy for positive patients should be given as successful eradication reduces ulcer recurrences to < 20% after 1–2 years of therapy. The most common cause of recurrence after antibiotic therapy is failure to achieve successful eradication of H.pylori. If eradication is not possible, 40% ulcer recurrence occurs within 6 months and almost 100% at the end of one year.

ii. Prophylactic anti-ulcer therapy for NSAID users with high-risks (prior peptic ulcer disease or ulcer complications, use of corticosteroids or anticoagulants, age > 60 years, serious comorbid illnesses).

Treatment options: For patients with NSAIDs associated PUD, it is recommended that NSAIDs should be discontinued if possible. Current evidence indicates that PPIs are more effective than H2 receptor antagonists, sucralfate, and misoprostol in healing NSAID-associated ulcers when continuous NSAID treatment is required. When NSAIDs can be dis-

continued, an H2 receptor antagonist is an effective alternative.

- Proton pump inhibitor 20mg b.i.d daily
- Misoprostol 200 mcg orally 4 times daily

Treatment with COX-2 inhibitors in patients with active ulcers who continue to require anti-inflammatory therapy is not recommended. In the Maastricht III Consensus Report, eradication of H. pylori is advisable in patients who plan to start long-term NSAID therapy.

In all patients with recurrent ulcers, NSAID usage (unintentional or surreptitious) and hypersecretory states (including gastrinoma) should be excluded.

D) Measures to prevent development of complications

i) Avoidance of Alcohol ii) stoppage of smoking iii)Successful eradication of H. Pylori if positive iv)Avoidance of judicious use NSAIDS with PPI therapy v) Long term maintenance therapy with PPI/H2-Blockers when indicated

Recommendations

Treatment decisions are based on the situation (e.g. presentation, complicating issues, sense of urgency) and etiology of the ulcer disease. For an uncomplicated, small, H. pylori-related DU, both treatment of the infection and the ulcer can be carried out in the same time frame (e.g. two weeks).Treatment of large and complicated ulcers will need to be individualized. Clearly, in the presence of a large or complicated ulcer (e.g. major upper GI bleeding), diagnosis of the cause can wait until the crisis is over and is convenient both for the patient and the physician. For routine symptomatic ulcers, diagnosis and treatment can be done concomitantly. Symptomatic ulcers, regardless of cause, typically respond well to antisecretory drug therapy and most physicians would consider the least expensive PPI as the treatment of choice. The only instance in which antiulcer therapy is required beyond the antibiotic treatment period is larger or complicated ulcers (e.g. bleeding ulcers) or in the setting of sustained NSAID use. There is no place for the routine use of antacids, sucralfate, or prostaglandins for DU, and certainly not for GU. There is no urgency to diagnose H.pylori and confirmation of the diagnosis can certainly be delayed until it is convenient for the patient and physician. However, if the ulcer is diagnosed by endoscopy, endoscopist should take biopsy samples to diagnose or exclude H. pylori infection.

Surgical Treatment : Because of much more advancement regarding the early diagnosis, and discovery of the potent anti-ulcer drugs and widespread use of PPI's for treatment of PUD since the 1990s,along with endoscopic approaches for the treatment of peptic disease and its complications has led to a substantial decrease in the number of operations (like "highly selective vagotomy") is rarely needed for uncomplicated peptic ulcers. Refractory ulcers are an exceedingly rare occurrence. Surgery needed in case of perforation, haemorrhage, gastric outflow obstruction,etc.

- Elective surgery is recommended for refractory PUD, non-healing giant ulcers and frequent symptomatic relapses despite continuous maintenance therapy and complications like gastric outlet obstruction and carcinoma stomach. For DU, surgical treatment is designed to decrease gastric acid secretion and when needed, operations most commonly done are (1) vagotomy with drainage (e.g. pyloroplasty, gastroduodenostomy, or gastrojejunostomy), (2) highly selective vagotomy (which does not require a drainage procedure), and (3) vagotomy with antrectomy. The specific procedure required depends on the underlying circumstances: elective vs emergency, the degree and extent of duodenal ulceration, and the expertise of the surgeon.

In conclusion, because of much advances during the last 4 decades regarding the aetiopathogenesis with discovery of H. Pylori as the major causal factor worldwide and specific treatment for H. Pylori eradication , discovery of highly potent ulcer healing drugs, "PUD is not a curable disease and once a peptic ulcer patient, always a peptic ulcer patient" the another dictum of Schwartz may not be true in near future.

Patients now-a-days are self-prescribing and overusing anti-ulcerant drugs i.e. PPIs as these are availabel as OTC drugs. What are the consequences of such irrational use of drugs?

Consequences of Irrational Use of Anti-Ulcerant Drugs are:

Antacids Therapy: i) very poor patient ii) to be used as effective ulcer healing agents, the dose of antacids needed usually produce significant side effects-

- diarrhea (magnesium-containing agents)
- constipation (Aluminum and Calcium-containing Calcium carbonate and sodium bicarbonate antacids)
- In patients with chronic kidney disease magnesium-containing agents can cause hypermagnesemia (milk alkali syndrome), rebound acidity etc.
- Nausea, Anorexia

PPI Therapy: In general, proton pump inhibitors are remarkably safe and well-tolerated group of agents and adverse effects are relatively low.

Common adverse effect include: headache, nausea, diarrhea, abdominal pain, fatigue, dizziness

Infrequent adverse effects in-

clude: rash, itch, flatulence, constipation, anxiety, depression, myopathy, loss of libido, Gynaecomastia, Galactorrhea.

Do you think that the medicines locally produced are of quality and good enough to treat gastrointestinal disease?

Regarding quality, efficacy and safety of drugs that are locally produced in Bangladesh I like to say that in instances same drug different pharmaceuticals shows some variation in efficacy and we have to choice an imported drug for proper treatment of the patients. So the quality of some locally made drug of some pharmaceuticals appears not be good enough to treat different gastrointestinal diseases.

What suggestions you have to improve the quality of life for our gastrointestinal patients and how to avoid this disease?

Suggestions to improve the quality of life and prevention of gastrointestinal disease:

- Caesation of Smoking
- Avoidance of Alchohol
- Avoidance of or Judicious use of NSAIDs to treat NSAID induced PUD.
- Improvement of sanitary status and safe disposal feces ,waste water and waste garbage
- Improvement of general hygienic status by ensuring supply of safe purified water and other drinks, maintaining proper food & water hygiene from environmental contamination etc
- Practicing some healthy habit
  - drinking less water during eating
  - don't eat full stomach
  - completing dinner at least 2-3 hrs before sleep
- Reduction of weight in obese patients
- Less intake of red meat
- Eating of high fibre food
- Eating fresh fruits & vegetable
- Safe blood transfusion practice
- Safer sex practice
- Vaccination against Hepatitis-B, A and E Virus Infection

QUICK HIT

Stethoscopes are potential sources of hospital-acquired infections: A stethoscope is an essential diagnostic tool in a physician's armamentarium. It is also the most recognizable sign of the medical profession. But, now they are gaining another new identity, as potential routes of infection transmission. Failure of stethoscope hygiene is becoming a common cause of transmission of infection.

New and effective way to avoid infection after surgeries involving implantable electronic devices, including pacemakers: As per Cleveland Clinic major infections were reduced by 40 percent with the use of dissolvable envelopes that wrap around devices and automatically release antibiotics [American College of Cardiology Annual Scientific Session, and simultaneously published in the New England Journal of Medicine]

Calcium supplements linked to dementia risk in women with stroke Calcium supplements may be associated with an increased risk of dementia in older women who have had a stroke or other signs of cerebrovascular disease.

Bronchitis and a number of other infections up the risk of mental illnesses in children and adolescents, possibly by influencing the youngsters' immune systems, according to JAMA Psychiatry research.

Bacteria that trigger gum disease may also spur Alzheimer's, according to startup-funded research that found the microbe in the brains of people with the disease.

Female brains stay younger longer than men's; according to a new PNAS study that found women's brains maintained a higher metabolism throughout life.

Almost 99 percent of bacteria are beneficial and even essential for our existence: We wouldn't survive in this world without bacteria in our body, particularly in our skin, mouth and gut, and the environment. But the question is about how we manage them. If we create adverse situations by taking antibiotics, they will devise defensive strategies to protect themselves and gradually multiply.

'UK, MHRA approval is a global recognition of ACME for its quality management system'

Short Profile of
Mizanur Rahman Sinha

Mizanur Rahman Sinha is the Managing Director of the ACME Laboratories Ltd., a reputed pharmaceutical company having consolidated its position among top 10 companies of Bangladesh.

Besides this, Mizanur Rahman Sinha is also the Chairman of MARS Aviation Limited, SINHA Fabrics Limited and SINHA Wool Wears Limited. Moreover, he is the Managing Director of ACME Overseas Trading Limited, SINHA Printers Limited, KALYAR Packaging Limited, ACME IT Limited and ACME Distribution Limited.

He has been twice declared as a Commercially Important Person (CIP) for his life-long contribution in various business sectors of the country namely Pharmaceuticals, Garments, Trading, Printing & Packaging and Aviation.

In addition to his business endeavors, Mizanur Rahman Sinha is relentlessly striving to serve the people of the country. He was twice elected Member of Parliament (MP) and held offices of the Government of the People's Republic of Bangladesh as State Minister of Health & Family Affairs and State Minister of Ministry of Textile. He was also a Member of Parliamentary Sub-Committee for Ministry of Civil Aviation & Tourism.

Q&A ***As the Managing Director of ACME Laboratories Ltd., would you please tell us about the journey of your company since its inception?***

In 1954, our father, Late Hamidur Rahman Sinha, founded ACME as a modest Proprietorship Firm at Narayangonj with a very noble motto to ensure health, vigour and happiness for all.

At that time, the prevailing business environment for establishing any industry in East Pakistan by a Bengali entrepreneur was quiet challenging. But driven by his great vision, ardent desires and courage, Mr. Hamidur Rahman Sinha successfully led the journey of ACME through this tough time with undeterred zeal and enthusiasm. In this noble journey, the continued support and cooperation of our mother, Late Nurjahan Sinha, was undoubtedly a vital source of inspiration.

During pre-liberation period, ACME's journey was more crucial as the multinational companies were becoming more and more dominant in the pharmaceutical market. With a proven business track record during pre-partition period coupled with rich business legacy from his father, Mr. Hamidur Rahman Sinha came up with sound strategic plans for laying down a strong foundation of ACME.

After independence of Bangladesh in 1971, ACME relocated its factory to Dhaka for an interim period with a view to permanently transfer it in a larger suitable location outside Dhaka City. In a newly independent country, ACME continued to strive more to serve the people with stronger com-

mitment in line with its original vision.

In 1976, ACME was converted into a Private Limited Company for giving it a permanent shape.

In 1983, ACME's plant was shifted to Dhamrai, about forty kilometers away from Dhaka City. At that time we, the sons of Hamidur Rahman Sinha, took office in ACME in different capacities. I became Managing Director and CEO of the company and two of my brothers, Dr. Jabilur Rahman Sinha and Mr. Afzalur Rahman Sinha became Deputy Managing Directors of the Company.

After the sad demise of our father, Hamidur Rahman Sinha, in 1994, our eldest brother, Nasir-Ur Rahman Sinha became Chairman of the company. At that crucial time, we had to work very hard in building a highly motivated team of Directors, shareholders and working professionals to complete the unfinished tasks of the late Founder. With the wholehearted efforts of the key Directors and dedicated professionals, we concentrated in re-building the plant of ACME and huge expansions with completely new sets of state-of-the-art production facilities with a view to meet the global challenges of the medicinal world of 21st century. We also had to turn the nationwide Marketing, Sales & Distribution network into one of the strongest teams making ACME one of the top players in the Pharmaceutical Industry of Bangladesh.

In 1995, ACME started its first International Operation by exporting medicine to Bhutan.

In 1999, ACME achieved ISO 9001:1994 certificate for developing and practicing Quality Management System to run its day-to-day operations. In the same year, ACME launched Veterinary Division to provide quality and affordable medicines for the livestock, poultry and aquaculture farmers.

In 2009, ACME achieved the then latest version of ISO standard, ISO 9001:2008 certificate.

In 2011, The ACME Laboratories Limited converted into a Public Limited Company to increase its capacity and accelerate its speed to strengthen its foothold on both domestic and international markets.

In 2014 Nasir Ur Rahman Sinha, voluntarily retired from the post of the Chairman and Afzalur Rahman Sinha was appointed as Chairman of the company.

In 2017 ACME Achieved the latest version of ISO Standard, ISO 9001:2015 certificate.

In 2019, ACME achieved UK MHRA GMP Certificate, proving yet once again that ACME believes as well as practices quality in every step of its operations. The business frontier of United Kingdom and Europe is now open to ACME where, we believe, it will become a force to reckon in near future.

In brief, ACME's starting in 1954 was a humble but noble initiative. In 1976, converting the sole Proprietorship Firm into a Private Limited Company was a successful step for sustainable growth. Finally, transforming ACME into a Public Limited Company in 2011 has turned it into a great company. Now with 7,500 professional work force and nationwide network, ACME is regarded as a leading company in the domestic market and exports to 22 countries across the globe to ensure health, vigour and happiness for countless patients both at home and abroad.

Recently, ACME has got another feather in its cap. You have got prestigious UK, MHRA approval. How does it help ACME to develop further?

UK, MHRA approval is not just a certification or an approval!

In broader sense, it is a global recognition of ACME for its quality management system that meets global standards. It took strong commitment and huge efforts for us to achieve this approval that recognizes our capability to develop products at our facilities for stringent regulated markets.

Obviously, this phenomenal achievement will enhance our confidence to go bigger and beyond the ordinary. For me, this is just the beginning of yet another successful journey in the global market.

What plans your company has to expand your footprints in the global market?

As you know, ACME is one of the leading companies in Bangladesh that promotes quality medicine at affordable price. In recent years, we have made huge investment in establishing new world class facilities, latest technologies, enhancing industry-focused

This is the story of ACME's dynamic journey of successful transformation from good to better and better to a great company – a glaring example of passionate, consistent and excellent business practice.

Development of ACME at a glance

1954	Late Hamidur Rahman Sinha founded ACME as a proprietorship firm
1976	The firm converted into a private limited company
1983	Commercial operation with modern facilities began at the factory in Dhamrai
1995	ACME started its first International Operation by exporting medicine to Bhutan
1999	ACME achieved ISO 9001:1994 certificate. In the same year, launched Veterinary Division
2001	Achieved upgraded version of ISO standard ISO 9001:2000
2006	ACME completed 18-storied corporate office
2009	Achieved latest version of ISO standard, ISO 9001:2008 certificate
2011	ACME converted into a public limited company
2017	Achieved latest version of ISO Standard, ISO 9001:2015 certificate
2019	ACME achieved UK MHRA GMP Certificate

human resources, establishing API park etc. not only to cater the domestic market but also to create a strong presence in the global pharmaceutical market. Apart from our current strong footprint in ROW markets, we are now stepping into stringent regulated markets like UK, US, Canada and some other European countries. After having a glimpse of our latest facilities, plenty of foreign companies are now truly interested for contract manufacturing at our facilities. I firmly believe ACME has a bright future for global expansion.

Although, declared as a thrust sector, lack of clinical trial laboratory are standing on the way of BE study, which in turn, hampering exports. How do you address this issue?

I see this issue in a different light.

Due to the lack of laboratory for clinical trial and BE study, export of medicine does get hampered i.e. the process of registration takes longer time and becomes expensive, particularly in those countries where BE study is a mandatory requirement. This is because we are now conducting BE study in foreign countries that incur high cost and take longer time.

However, this lack of laboratory will affect domestic market more as BE study will be required soon by our national regulatory authority for the medicines we are supplying to the domestic market.

Thus, we do need adequate BE test facilities that would save a lot of time and foreign currency and it will be useful for both locally marketed products and exported products. I assume that no individual company can do it alone, it will require combined effort of many companies and I think, the Government can play a much greater role in developing such facilities in the country.

Another burning issue is Adverse Drug Reaction (ADR) monitoring. How your company plans to create awareness among all the stakeholders about ADR to make it successful?

I would like to thank the DGDA for incorporating Pharmacovigilance (PV) in the Drug Policy in 2013. From the very beginning of the introduction of PV, ACME took the matter of ADR & AE reporting seriously.

We have developed a dedicated team to deal with ADR monitoring and reporting as part of PV. This team is formed by representatives from different departments including some from the plant. The team is headed by qualified person for pharmacovigilance (QPPV).

There are SOPs to handle the total procedure of Pharmacovigilance including ADR and AE reporting.

Experts from abroad have trained the QPPV team. Subsequently, the QPPV team has trained all the staff of the company as well as continue to train every new recruit on how to handle ADR and AE reporting from any stakeholder according to SOP.

Clear instructions on how to manage ADR and AE reporting are displayed on banners and posters in our corporate office, plant premises and all of our sales centers across the country.

We have developed ADR and AE reporting forms according to the guideline of DGDA. Our nationwide sales team have made these forms available to all our prescribers and users of our medicines. They are clearly communicated to fill in a form and send it to us whenever they experience an incident of ADR or AE.

We are holding awareness programs on ADR and AE reporting periodically with our prescribers. We have also prepared awareness communication materials to be put on display for public viewing in medicine shops, hospital notice boards & doctors' chambers.

ACME maintains a dedicated cell phone number where all our stakeholders can report ADR any time as this number is open for 24 hours.

In brief, ACME is working systematically to create an efficient process and adequate awareness on ADR reporting with the prescribers and users of medicines. But to create mass awareness on ADR and AE, I feel the Health Ministry still have a lot more to do.

Perhaps you remember that ACME was the first pharmaceutical company and most probably the only company who has participated in the mass publicity and awareness program on **"Apnar Shishuke Tika Din"** and incorporated the logo of **"Apnar Shishuke Tika Din"** in every product carton.

I would suggest the Health Ministry can think of creating and running similar mass public awareness programs on ADR and AE. ACME will always be there to assist and support such initiatives.

As a leading company, how do you emphasize the importance of R&D in your company?

R&D is one of the core and vital departments of a pharmaceutical manufacturing company that is directly involved in developing new products & new formulations as well as to improve existing products. R&D is quite crucial for developing new drug delivery systems and various dosage forms including packaging.

Along with regular dosage forms like tablets, capsules and syrups, we have been producing products like HFA inhalers, suppositories, nasal sprays, injectable, IV infusions, hormones, steroids etc. These products have been well accepted by medical practitioners, chemists and patients both in the domestic market as well as in importing countries.

We have built up a sophisticated R&D facility equipped with state-of-the-art equipment and facilities with

a highly experienced team. We will continue to invest more to ensure that our R&D achieves global standard to work on continuous innovation for excellence.

After graduation from LDC, what challenges Bangladesh is going to face in the global market due to withdrawal of some facilities?

As we know, On 6 November 2015, the World Trade Organization (WTO) Council decided to extend the exemption for LDC WTO members to implement provisions of the TRIPS agreement related to pharmaceutical products, which will last until 2033, when the waiver will be discussed again. Least Developed Countries (LDCs) requested a permanent waiver exempting them from the obligation to implement the provisions until a country would graduate from the LDC category.

When Bangladesh graduates from LDC category, it is expected in 2024, we will no longer enjoy this waiver. Of course, it will be great to be economically graduated. But the withdrawal of the waiver will have some obvious impacts on our pharmaceutical industry, if we do not become ready then.

The challenges will be in the areas of raw material sources, R&D, BE study, clinical study etc. Therefore, we need to establish adequate backward linkage for quality raw materials e.g. by having own API Industry, develop skilled manpower especially in R&D, the companies will need to set up well equipped R&D laboratories, Government needs support to set up BE laboratories and clinical study facilities etc.

I am hopeful, by the time Bangladesh graduates from LDC category, the pharmaceutical industry with the support from Government will be ready to handle the challenges we may have to face from the withdrawal of the waiver.

FAST FACTS

- *According to WHO, due to Antibiotic resistance in people, there is an estimation over 7.5 lakh people die every year and number will raise to 10 lakh by 2050 as common infections and minor injuries are claiming lives, raising a concern in the post-antibiotic era.*
- *The pharmaceutical industry in Bangladesh has done remarkably well, growing at more than 15 percent a year, with sales of approximately $2.4 billion in 2017. The growth rate in India, Pakistan and China are 15 percent, 11 percent and 9.5 percent respectively.*
- *According to an estimate of World Bank, about 64 lakh people in Bangladesh are getting poor to meet medical expenses every year. Because, patients bear 77% of total treatment expenditure from their own pockets, while 23% spent by the government. According to WHO, patients'own expenditure should not exceed 32%.*
- *Average financial allocation in Bangladesh's health sector from 1990 to 2014 is 6.53%. In the budget for fiscal year (2017-18), Tk. 20652 crore has been allocated for the health sector, which is 5.2% of the total budget. According to WHO, at least 15% of total budget should be allocated for the health sector.*
- *There are only three doctors per 10,000 people in the country.*
- *About 1 out of 4 diabetic adults worldwide suffers from some kind of a kidney disease, says study published in the Journal of the American Medical Association.*
- *Vitamin A supplementation lowers overall child mortality by 23 percent. Hepatitis B vaccine reduces radiologically confirmed pneumonia by 18 percent, while PCV decreases incidents of radiological pneumonia by 23-35%.*
- *About 12,764 new breast cancer patients are detected every year while the number of deaths from the deadly disease has stood annually at 6,846 across the country and the situation in getting worse day-by-day.*

Heart-Breaking news for egg lovers

Eggs may not be all they've been cracked up to be. A new study says eggs are a major source of dietary cholesterol and that cholesterol in the diet ups the risk of heart disease and premature death. The researchers followed nearly 30,000 adults over three decades and found that eating three or four eggs a week was tied to a 6 percent higher risk of heart disease and an 8 percent risk of dying from any cause. "The more cholesterol you consume, the higher your risk of heart disease and dying," said study senior author Norrina Allen, an associate professor of preventive medicine from Northwestern University Feinberg School of Medicine in USA. When the researchers looked at what foods contained a lot of dietary cholesterol, eggs, red meat and processed meats stood out. "We found dietary cholesterol, particularly eggs, had a strong association with cardiovascular disease, especially stroke," Allen said.

Why your heart needs a good night's sleep

Six hours: That's the minimum amount of sleep per night you need to help your heart stay healthy, new research suggests. The study found that chronic lack of sleep and poor sleep quality raise the odds of fatty plaque accumulation in arteries – a condition known as atherosclerosis, which increases the odds of heart attack and stroke. There are many ways to fight heart disease, including "pharmaceuticals, physical activity and diet," said lead researcher Jose Ordovas. "But this study emphasizes we have to include sleep as one of the weapons we use to fight heart disease – a factor we are compromising every day." Ordovas is an investigator at the National Center for Cardiovascular Research in Madrid, Spain.

Are beets good for diabetes?

Research suggests that eating beets or drinking beet juice might benefit people with high blood pressure. High blood pressure is common among people with diabetes, particularly those with type 2 diabetes. The presence of nitrates in beet juice is reportedly responsible for the pressure-reducing effect of beets. These nitrates improve the ability of blood vessels to widen, promoting blood flow. A recent study, published in the journal Hypertension, found that drinking a cup of beet juice each day seemed to cause a significant drop in blood pressure among people with hypertension.

Eating fried foods could increase death risk, study warns

A new study featuring in The BMJ cautions that women over 50 who regularly eat fried foods may be increasing their own death risk. Many studies have shown that eating fried foods on a frequent basis can lead to unwanted health consequences. Research has provided evidence that eating fried foods can affect cardiovascular health and heighten the risk of type 2 diabetes. In a new study on women over the age of 50 years from the United States, investigators from the University of Iowa in Iowa City, IA have found that overindulging in fried foods can increase a person's risk of death from multiple causes. The researchers also looked at which fried foods are likely to be the most dangerous for health. A study paper reporting the findings now appears in The BMJ.

How fasting can improve overall health

In a University of California, researchers found evidence that fasting affects circadian clocks in the liver and skeletal muscle, causing them to rewire their metabolism, which can ultimately lead to improved health and protection against aging-associated diseases. The study was published recently in Cell Reports. The circadian clock operates within the body and its organs as intrinsic time-keeping machinery to preserve homeostasis in response to the changing environment. And, while food is known to influence clocks in peripheral tissues, it was unclear, until now, how the lack of food influences clock function and ultimately affects the body. This study opens new avenues of investigation that could ultimately lead to the development of nutritional strategies to improve health in humans.

High-fiber diet cuts risk of death from cancer, stroke and heart disease by up to a third, major study finds

Most people around the world do not eat the amount of fiber needed to prevent key life-threatening illnesses, new research suggests. A nutritional review, which includes 185 studies and 58 clinical trials conducted over nearly 40 years, found that eating at least 25g to 29g of fiber per day was linked to a 15 to 30 per cent reduction in rates of life-threatening cancers, strokes and heart disease. For every 1,000 participants, researchers found that eating more fiber translated into 13 fewer deaths and six fewer cases of coronary heart disease. Researchers did not find any risks associated with eating fiber but the nutritional review's authors noted that consuming lots of it could have ill-effects for people with low iron or mineral levels.

Result is the culmination of activities

Srinivasan V

We all know **result is the culmination of many identified activities**. A student scores good marks and comes out with flying colours, only after years of hard work and preparation in studies. Likewise, in ethical Pharma selling/marketing, **achievement of objectives – targets – is the result of implementation of identified activities, i.e. strategies, consistently**. The identified activities may be:

- Understanding the products well
- Identification of right doctors for right products
- Effective detailing for each product
- Doctor and Chemist call averages more than norm with good quality calls every day
- Hard work – morning and evening work
- Conduct Market survey/Retail Chemist Prescription Audit (RCPA) to arrive at the correct potential of each and every Doctor, record it, and then decide how much we want to get from each Doctor for our products
- Correct implementation of promotional, gift, and sampling strategy for each product
- Visit to Retailers before meeting each Doctor to find out the extent of support by the nearby Doctors, check availability of products, then book (order) POB where necessary, and ensure prompt supply by concerned Stockist/Distributor.
- Updation of Doctors list as per strategy depending upon extent of response to our promotion of products over a period of time.

If these are done properly in all sincerity and consistently, result will come automatically, barring exceptions.

However when Line Managers visit their team members, generally the discussion centers around Sales Vs Target productwise, then go for joint work to meet some important Doctors, before they leave. Unfortunately, many of the first line managers still feel and behave like Senior Medical Representatives. **If the Line Managers really want to develop their team members and make them stand on their own feet, the focus during joint work and in any meeting should be mainly about whether the team member ensures 100% implementation of each and every identified activities, i.e. strategies**, afterwards only the other topics should come up for discussion. **Such Line Managers and their team members may be more successful than their counterparts. They may go for field work happily every day**. In the light of this, Pharma Companies must ensure that whenever they induct newly promoted/selected Line Managers, this must be explained to them well for total adherence.

(The author Mr.Srinivasan V has over 35 years of rich experience in Pharma Industry, having headed Sales Administration, HR, Personnel, and Training functions in reputed Companies. He has over 500 published articles in India and abroad to his credit. His book "Reach for the Stars" is considered as the Bible for Medical Representatives in Pharma Industry. He can be reached at shridhar1956@rediffmail.com, Mobile 9972390513)

What's new in Gastroenterology and Hepatology?

Impact of molecular subtype on colorectal cancer risk reduction with aspirin and NSAIDs

Aspirin and other NSAIDs inhibit colorectal carcinogenesis (CRC), but there are limited data on their CRC risk reduction by molecular subtype. In a population-based case control study, regular use of aspirin or NSAIDs was associated with an approximately 30 percent reduction in CRC risk. Specifically, aspirin or NSAID use was associated with a lower risk of microsatellite stable, BRAF wildtype, and KRAS wildtype CRCs but was not associated with risk reduction for high microsatellite instability, BRAF-mutated, or KRAS-mutated CRCs. Additional studies are needed to validate these results and understand the mechanism through which these agents reduce CRC risk.

Hemostatic nanopowder approved for use in gastrointestinal bleeding

Hemostatic nanopowder can be used to treat bleeding in the gastrointestinal tract due to lesions such as ulcers and tumors. It is sprayed onto a bleeding site under endoscopic guidance and forms a stable mechanical barrier at the site of bleeding. In prior reports, success rates for achieving initial hemostasis in patients with nonvariceal upper gastrointestinal bleeding are 75 to 100 percent, with rebleeding rates of 10 to 49 percent. Recently, Hemospray, a hemostatic nanopowder, was approved as a device by the US Food and Drug Administration.

Magnetic sphincter augmentation versus proton pump inhibitor for moderate-to-severe regurgitation

Regurgitation refractory to proton pump inhibitors (PPI) is traditionally treated with an anti-reflux procedure, such as Nissen fundoplication. In a randomized trial of patients with moderate-to-severe regurgitation refractory to single-daily-dose PPI, laparoscopic magnetic sphincter augmentation (MSA, ie, magnetic beads placed around the lower esophagus) was superior to twice-daily-dose PPI in normalizing the total number of reflux episodes and acid exposure, leading to better relief of regurgitation and higher reflux-related quality of life scores.

Global H. pylori antibiotic resistance rates

The choice of initial Helicobacter pylori treatment regimen is guided by the risk for antibiotic resistance. In a meta-analysis that included 178 studies from 65 countries, primary and secondary resistance to clarithromycin, metronidazole, and levofloxacin were high (≥15 percent) in the majority of World Health Organization regions. Primary resistance to clarithromycin was lower in the Americas and the Southeast Asia region. However, the study was limited by heterogeneity and a disproportionate amount of data for the Americas region reflecting studies from South America. These findings highlight the importance of local surveillance data to guide the choice of eradication regimens.

Aspirin combined with proton pump inhibitor for patients with Barrett's esophagus

Epidemiologic data suggest that drugs that inhibit cyclooxygenase, such as aspirin, might prevent high-grade dysplasia and esophageal cancer in patients with Barrett's esophagus. In a recent trial, over 2500 patients with Barrett's esophagus were randomly assigned to low or high-dose esomeprazole, with or without full-dose aspirin, and were followed for a median of nine years. Compared with low-dose proton pump inhibitor (PPI) alone, aspirin combined with high-dose PPI resulted in the longest time interval to a composite endpoint (all-cause mortality, esophageal carcinoma, or high-grade dysplasia). However, the difference in event rate between aspirin and no aspirin was relatively modest and not statistically significant, and it is uncertain whether low-dose aspirin (which many patients with Barrett's esophagus use for other indications) would have a similar effect.

Aspirin intake and hepatocellular cancer risk

The use of aspirin and other nonsteroidal antiinflammatory drugs (NSAIDs) reduces the risk of several malignancies; the evidence base is most robust for colorectal neoplasia. The possibility that regular long-term aspirin use might reduce the risk of hepatocellular carcinoma (HCC) was addressed in a combined cohort study. Among the 133,371 participants who were followed for over 26 years, there were 108 cases of HCC. Regular use of aspirin (but not other NSAIDs) was associated with a 50 percent reduced risk of HCC. The association was dose- and duration-dependent; a decreased risk was apparent with use of 1.5 or more standard-dose (325 mg) tablets per week for five or more years.

Atorvastatin and antivirals: interaction

The Egyptian Pharmaceutical Vigilance Center (EPVC) has announced that the product information for atorvastatin will be updated to include a warning about the potential increase in atorvastatin levels when coadministered with elbasvir/grazoprevir and glecaprevir/pibrentasvir. The combined use of glecaprevir/pibrentasvir with atorvastatin is now contraindicated. Atorvastatin is a synthetic lipid lowering agent indicated for the prevention of cardiovascular diseases and hypercholesterolaemia. Elbasvir/grazoprevir and glecaprevir/pibrentasvir preparations are indicated for the treatment of hepatitis C (HCV). Risk of myopathy may be increased with the concomitant use of atorvastatin and antivirals for treatment of HCV.

Zoster and Influenza vaccines

Medsafe has placed zoster and influenza vaccines on the medicines monitoring scheme to obtain further information on the risk of lichen planus or lichenoid drug eruption. Zoster vaccine (Zostavax®) is a live attenuated virus vaccine used to prevent herpes zoster (shingles). Annual influenza vaccination (Afluria Quad®, Fluarix Tetra®, FluQuadri® and Influvac Tetra®) is an important measure for preventing influenza infection and mortality. Patients can receive both vaccines at the same time using separate syringes and injection sites. The potential safety signal was triggered by a report received by the Centre for Adverse Reaction Monitoring (CARM). The report describes a 67-yearold female patient who experienced a lichen planus rash after receiving both zoster and influenza vaccines. The overall benefit-harm balance of zoster and influenza vaccines remains positive.

Fluoroquinolones

The MHRA has announced that fluoroquinolones should only be used after careful assessment of benefits and risks, and after consideration of other therapeutic options in patients at risk for aortic aneurysm and dissection. Fluoroquinolones are antibiotics authorized for serious, lifethreatening bacterial infections and four of them are (ciprofloxacin, levofloxacin, moxifloxacin and ofloxacin). Data from epidemiologic and non-clinical studies indicate an increased risk of aortic aneurysm and dissection after intake of fluoroquinolones. Health-care professionals are advised to inform patients, particularly those at risk (e.g. elderly), about rare events of aortic aneurysm and dissection. It is important that patients seek immediate medical attention in case of sudden onset severe abdominal, chest or back pain.

Proton pump inhibitors: increased mortality

Proton pump inhibitors (PPIs) such as omeprazole are used in oesophagitis, gastroesophageal reflux disease and peptic ulcer disease. PPIs have few severe adverse effects in the short term. But this is not the case in the long term.

- Proton pump inhibitors (PPIs) are widely used in oesophagitis, gastroesophageal reflux disease and peptic ulcer disease. They provoke few severe adverse effects in the short term, but this is not the case in the long term (infections, fractures, hyponatraemia, etc.).
- A cohort study in about 350 000 patients in the United States, followed for 5.7 years, showed that patients receiving a PPI had a 25% increased risk of death compared with those receiving H2-receptor antagonists. In patients treated for more than one month, the risk appeared to increase with the duration of exposure. Other epidemiological studies have produced similar results.
- These findings cast doubt on the harm-benefit balance of long-term and prophylactic PPI therapy. To address these risks, PPI withdrawal must be managed carefully and the use of alternative acid-suppressing agents should be considered.

Nonsteroidal anti-inflammatory drugs in pharyngitis: risk of peritonsillar abscess

To relieve fever or sore throat, it is better not to use nonsteroidal anti-inflammatory drugs (NSAIDs), but to use paracetamol instead. In 2017, an epidemiological study was carried out on the risks of peritonsillar abscess after pharyngitis. From the database of the Observatory of General Medicine based on input from more than 120 doctors in France, the analysis covered 105 802 pharyngitis in approximately 68 000 patients who consulted for pharyngitis between 1995 and 2010. NSAIDs expose patients to aggravated infections, probably by damaging the immune response. In practice, the risk of NSAIDs and corticosteroids aggravating infections is known. To relieve fever or pain associated with an infection, non-drug measures should be considered as the first choice, and paracetamol as the drug of choice.

MYTH VS REALITY

Myth: Colonoscopies are unpleasant and uncomfortable
Reality: The actual screening is neither painful nor unpleasant. During the test, patients are sedated to eliminate or minimize any discomfort, and the actual procedure only lasts 15-30 minutes. For most, normal activities can be resumed the next day.

Myth: There are several ways to screen for colon cancer without undergoing a colonoscopy.
Reality: There are several screening options for colorectal cancer, including flexible sigmoidoscopy, fecal occult blood test and double-contrast barium enema and virtual colonoscopy; however, a colonoscopy is considered the most accurate. It detects more cancers, examines the entire colon and can screen, diagnose and remove polyps in the same procedure.

Myth: A polyp means I have cancer.
Reality: Polyps are benign growths that have the potential to develop into cancerous tissue if left unchecked. They can be removed easily during a colonoscopy, eliminating the possibility that they could become cancerous.

Myth: IBS is similar to (or the same thing as) IBD/ Crohn's/colitis
Reality: Crohn's disease and ulcerative colitis are types of inflammatory bowel disease (IBD). While IBD sounds similar to IBS, they are very different from each other. IBD is an organic disease characterized by the presence of inflammation in the intestine. In IBS, there is no visible disease and the symptoms are a result of an improperly functioning digestive tract. IBS does not turn into IBD, and people with IBS aren't at an increased risk for any of the complications associated with IBD, such as surgery, requiring an ostomy, or developing colorectal cancer. However, it is possible to have both conditions. Go to www.badgut.org/information-centre/symptom-chart/ to view a table that demonstrates the differences between IBS and IBD.

Myth: Leaky gut syndrome causes IBS.
Reality: Many individuals believe that a proposed disorder called 'leaky gut syndrome' causes many ailments, often including IBS. The claim is that toxins and bacteria leak through damaged sections throughout the digestive tract, and then enter the blood stream where they proceed to wreak havoc on the body. However, there is no evidence that this disease even exists, let alone causes IBS, which is a functional disorder, not an organic disease.

Myth: IBS isn't a big deal.
Reality: Some individuals might have mild symptoms, but for others, IBS can change their entire life. The impact of the ABCD symptoms that constitute IBS can lead to a huge decrease in quality of life. Persistent diarrhea can make those affected afraid to leave home unless they are positive that they will have continuous access to a toilet. Chronic constipation can cause such intense pain and bloating that those affected are unable to get out of bed, as any type of physical movement, including sexual activity, causes intense pain. Symptoms like these can lead to social isolation and missed work or school that, in turn, can increase depression and other mental health symptoms.

Myth: Fatty liver isn't anything to worry about
Reality: Fatty liver, as the name suggests, refers to a build-up of fat in the liver (anything over 5% of the total organ size). Many people with fatty liver don't even know they have the condition. Sometimes, it causes no problems at all. But that doesn't mean you should ignore it. Fatty liver can increase your risk of more serious conditions including cirrhosis (scarring of the liver), liver disease or liver cancer. Why? This is because a build-up of fat damages your liver cells and causes inflammation. Your liver is the only organ in your body that can regenerate itself by replacing old, damaged cells with new ones. As your liver struggles to get rid of the fat, scar tissue builds up, making it difficult for your liver to transport nutrients around the body and increasing pressure in the surrounding veins. Potential complications from a scarred liver include bruising, bleeding, kidney failure, liver cancer, diabetes and eventually, liver failure.

Myth: Fatty liver disease is irreversible
Reality: Currently, there is no medication that can reliably treat fatty liver. However, you can make certain lifestyle changes to reduce your risks or even reverse the condition.

- Avoid alcohol
- Reduce your sugar intake
- Cut out fatty foods
- Exercise regularly
- Maintain a healthy weight
- Control your blood sugar levels

"Eating a healthy diet with plenty of fresh fruits, vegetables, whole grains and lean meats like chicken and fish can make a big difference in managing the condition," says Dr Lui.

IBD may be an independent risk factor for heart disease

Patients with inflammatory bowel disease (IBD) are at a significantly higher risk of myocardial infarction (MI), says a study reported in the journal Inflammatory Bowel Diseases. The relative risk of MI was highest in younger patients and decreased with age. The researchers examined a database of medical records for more than 29 million people, of which, 131,680 had ulcerative colitis.

Check B12 deficiency in all patients on metformin

Diabetes patients taking metformin should have their vitamin B12 levels assessed regularly to avoid peripheral nerve damage. Vast majority of patients are not tested and almost 1 in 10 have vitamin B12 deficiency. In a study of more than 150 women with diabetes presented at the Society for Endocrinology BES 2018 conference in Glasgow, the researchers showed that 64% had not been tested for vitamin B12 deficiency. Moreover, almost 10% of patients were found to have vitamin B12 deficiency. Currently, there are no official guidelines on the screening for vitamin B12 levels in patients treated with metformin, although the British Society of Haematology recommends that levels are checked if there is a strong clinical suspicion of deficiency.

Scaling up prevention and treatment towards the elimination of Hepatitis C

Researchers assessed the global impact of scaling up interventions to reduce hepatitis C virus (HCV) transmission and to improve access to screening and treatment using a global, dynamic transmission model for hepatitis C virus (HCV). The model included demographic and epidemiological data including HCV prevalence and mortality, number of people who inject drugs (PWID), and current coverage of treatment and prevention programs for 190 countries. Interventions that reduce HCV transmission risk among non-PWID by 80 percent and increase harm reduction services to 40 percent of PWID could avert 14.1 million new HCV infections by 2030, according to the model. A comprehensive package of prevention, screening, and treatment interventions could avert 15.1 million new infections and 1.5 million deaths from cirrhosis and liver cancer.

UK NICE publishes guidance on antibiotic prescribing for acute cough

The UK National Institute for Health and Care Excellence (NICE) released an antimicrobial prescribing strategy for acute cough associated with upper respiratory tract infection or acute bronchitis in adult and pediatric patients. The guidelines aim to limit antibiotic use and reduce antibiotic resistance. According to the guidelines; health care providers should only consider an antibiotic when patients have a higher risk of complications and should immediately prescribe an antibiotic if the patient is systemically very unwell during a face-to-face examination. They also provide recommendations for first- and alternative antibiotic choices and dosage and treatment length.

Could pomegranates offer the key to new IBD treatments?

Studies of pomegranates, "the fruit of the gods," are increasingly revealing why they are so beneficial. Urolithin A, derived from pomegranates, and its synthetic equivalent could help treat inflammatory bowel disease, according to a new study. In a new study, researchers from the University of Louisville in Kentucky identified a natural compound that could help improve IBD treatments. The researchers also explain the mechanisms through which it most likely fights IBD symptoms. The compound, called urolithin A (UroA), is a metabolite produced

as a result of the interaction of gut bacteria and certain polyphhenols present in pomegranates and some other fruits — particularly berries.

Statins help the Heart, No matter your age

Cholesterol-lowering statins are already known to help cut heart risks for seniors and the middle-aged. Now, research confirms the meds can also help people aged 75 and older. "Statin therapy has been shown to prevent cardiovascular disease in a wide range of people, but there has been uncertainty about its efficacy and safety among older people," said lead investigator Anthony Keech, a professor of medicine, cardiology and epidemiology at the University of Sydney in Australia.

IBS vs Diarrhea

Let's start with what diarrhea is. Diarrhea is often caused by your immune system's response to an unwanted or unfamiliar microorganism in the gut. It's your body's way of protecting itself from a potentially harmful intruder. During an episode of diarrhea, your body is attempting to rid itself of the unwanted microorganism. So, while annoying and inconvenient, diarrhea is often your body's normal response to an abnormal intruder.

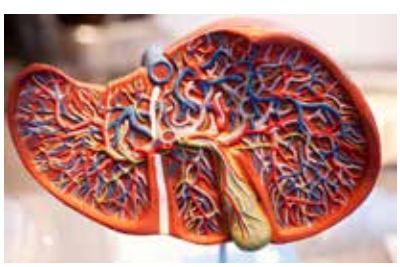
- Diarrhea is defined as having at least three loose or liquid bowel movements in a day.
- It may be accompanied by abdominal cramping or pain, fever, nausea or bloating.
- If left to resolve on its own, diarrhea often lasts for a few days.

IBS, on the other hand, is a chronic condition, which means those who suffer from IBS will experience consistently recurring symptoms that last for prolonged periods of time. While the symptoms of IBS vary, the most common include:

- Severe abdominal pain or cramping
- Excess gas
- Diarrhea and/or constipation
- Clear or white mucus in the stool

Given the similarities in symptoms, many people worry that their diarrhea is a sign of IBS or something more serious.

New therapeutic avenue in the fight against chronic liver disease



An international team of researchers, affiliated with UNIST, has identified a novel route that regulates the signaling pathways induced by extracellular matrix (ECM). A new diagnostic marker and therapeutic target in the fight against chronic liver diseases. The research team has discovered that endotrophin (ETP) plays a crucial role in producing a pathological microenvironment in liver tissues of chronic liver disease. ETP is a marker of collagen type VI (COL6) formation, known as the link between obesity and cancer. "ETP levels in adipose tissues are elevated in obesity or diabetes and are associated with adipose tissue fibrosis, inflammation, and angiogenesis, leading to metabolic dysfunction in adipose tissues and systemic insulin resistance," says researcher. "Through the identification of the correlation between ETP and chronic liver disease, this study opened new doors in the fight against liver diseases.

Hypertension drug shows promise in liver disease

While there are therapies to treat some forms of liver diseases, including hepatitis C and autoimmune hepatitis, options have been limited for treating portal hypertension. A drug used to lower blood pressure within a system of veins and inflammation could effectively treat a potentially life-threatening condition of the liver, say, researchers, including one of the Indian origin. The study on mice showed that the drug sivelestat may lower portal hypertension - associated with cirrhosis and other chronic liver diseases - thereby improving symptoms and its outcomes. Portal hypertension is a condition where there is an increase in pressure within the portal vein that carries blood from abdominal organs to the liver. While there are therapies to treat some forms of liver diseases, including hepatitis C and autoimmune hepatitis, options have been limited for treating portal hypertension. "Sivelestat has been safely used in humans with acute lung injury and bronchopulmonary dysplasia. This suggests sivelestat and similar drugs constitute a potential means to decrease portal hypertension in patients with chronic liver disease," said Vijay Shah, the gastroenterologist at Mayo Clinic in the US.

AMR genes are abundant and diverse in global sewage samples

Metagenomic analysis of bacteria in untreated sewage from 79 sites across 60 countries revealed that countries in Africa, Asia, and South America had higher concentrations and more diverse types of antimicrobial resistance (AMR) genes compared to countries in Europe, North America, and Oceania. Across all sample sites, a total of 1,625 different AMR genes belonging to 408 gene groups were identified; genes encoding resistance to macrolides, tetracyclines, aminoglycosides, beta-lactams, and sulfonamides were the most abundant. There was a significant increase in the abundance of AMR genes belonging to a specific antimicrobial class with increasing usage of that antimicrobial class, but total antimicrobial usage did not correlate to overall AMR gene abundance. Between countries variability was better explained by Human Development Index scores, sanitation, and general health.

Global reduction in pneumonia cases and deaths

The global incidence of pneumonia in children under the age of 5 dropped 22 percent from 178 million in 2000 to 138 million in 2015. During that time period, pneumonia-related deaths dropped 47 percent, and the burden of clinical pneumonia attributable to HIV decreased by 45 percent. Lung infection remains a leading cause of preventable illness and death in the under-five age group. In 2015, over half of all pneumonia cases occurred in India, Pakistan, Nigeria, Indonesia, and China, and 49 percent of pneumonia deaths occurred in India, Nigeria, Pakistan, Democratic Republic of the Congo, and Ethiopia.

Global antibiotic use among children

Researchers analyzed wholesale antibiotic sales data for 2015 from 70 middle- and high-income countries and identified child-appropriate formulations to serve as a proxy for antibiotic use among children. The World Health Organization's Essential Medicines List divides antibiotics into three categories: access (first choice for common infections, should be available in all facilities), watch (for specific indications, high risk of resistance), and reserve (should be held back as a last resort). As a measure for appropriate use, researchers compared the quantity of antibiotics consumed from the 'access' category with those from the 'watch' category. Access antibiotic use relative to watch antibiotic use varied widely from 94 percent in Slovenia to 27 percent in China, with the median being more than 76 percent.

Global resurgence of measles due to gaps in vaccination coverage

Between 2000 and 2017, the total number of reported measles cases and estimated measles deaths worldwide decreased 80 percent, according to the World Health Organization (WHO) and the US Centers for Disease Control and Prevention (CDC). However, between 2016 and 2017, there was a 31 percent increase in measles cases due, in part, to increased surveillance efforts but largely as a result of gaps in vaccination coverage. The Americas, the Eastern Mediterranean Region, and Europe experienced the largest spike in measles cases.

Critical gaps in post-abortion care

The quality of post-abortion care remains low worldwide as critical gaps in care persist, according to an analysis of survey data collected between 2007 and 2017 in ten countries: Bangladesh, Haiti, Kenya, Malawi, Namibia, Nepal, Rwanda, Senegal, Tanzania, and Uganda. In seven of the ten surveyed countries, less than 10 percent of primary-level facilities could provide basic post-abortion care which includes the capacity to remove products of conception, administer antibiotics and uterotonics, and transport patients to referral hospitals. In eight of the ten surveyed countries, less than 40% of referral-level facilities could provide comprehensive post-abortion care which includes the capacity to administer blood transfusions and perform major abdominal surgery.

EU approves Shionogi's chronic liver disease therapy

Shionogi's lusutrombopag has been approved by the European Commission as a treatment of severe thrombocytopenia in adult patients with chronic liver disease undergoing invasive procedures. In two late-stage trials, up to 75.5% of patients who were treated with lusutrombopag did not need platelet transfusion prior to the primary invasive procedure or rescue therapy for bleeding in the seven days after their procedure versus 12.5% who received the placebo. (DIA)

100 mg of thalidomide in myeloma delays disease progression

A midstage Japanese study involving 34 patients with multiple myeloma, who were administered 100 mg maintenance doses of thalidomide daily, found that the dosage was safe and effective in hindering disease progression for longer than 36 months. The study's findings were reported in the International Journal of Hematology. (DIA)

Plazomicin for complicated UTI

Once-daily plazomicin was noninferior to meropenem for the treatment of complicated urinary tract infections (UTIs) caused by multidrug-resistant Enterobacteriaceae, according to the results of a phase 3 clinical trial involving 609 patients. On day 5 of treatment, the composite cure rate was 88 percent for those treated with plazomicin and 91 percent for those treated with meropenem. Compared to those in the meropenem group, a higher proportion of patients in the plazomicin group had microbiologic eradication of Enterobacteriaceae that were not susceptible to aminoglycosides (78.8 versus 68.6 percent) and Enterobacteriaceae that produce extended-spectrum β-lactamases (82.4 versus 75.0 percent).

Some Diabetes Drugs linked to higher heart risks

Two common classes of type 2 diabetes drugs may lower blood sugar levels, but new research suggests those same drugs might boost the risk of heart attack, stroke and heart failure. The drug classes in question are sulfonylureas and basal insulin. Sulfonylureas cause the body to release more insulin. They're taken orally and have been used since the 1950s. Basal insulin is given as an injection, and it's engineered to be released slowly throughout the day. Meanwhile, the study found that newer – and typically more expensive – drugs appear to lower the risk of heart disease and stroke. Currently, people with type 2 diabetes are given metformin, and if they need a second treatment, they're often given sulfonylureas or basal insulin. But these findings call that practice into question.

Bempedoic acid could help those with tough-to-treat Cholesterol

People whose high cholesterol is resistant to treatment with statin drugs may soon have a new treatment option. This new class of drugs helps block synthesis of artery-clogging cholesterol, researchers explained. The drugs target an enzyme called ATP citrate lyase (ACL), part of the production pathway for "bad" LDL cholesterol in the body. In the new trial, bempedoic acid, a pill that blocks ACL, reduced LDL cholesterol levels significantly when added to standard statin therapy. The addition of bempedoic acid on top of a statin drug showed "a much greater reduction in LDL-C than what would be expected simply by increasing the dose of statin therapy".

Non-antibiotic drugs contribute to the spread of antibiotic resistance

High levels of the non-antibiotic epilepsy drug, carbamazepine, in the environment contribute to antimicrobial resistance by promoting the transfer of resistance genes between bacteria, researchers at The University of Queensland found. Carbamazepine triggered bacterial cells to increase cell membrane permeability and produce pili which are used during the gene transfer process to connect cells and pass genes between different bacteria. This is the first study to explore the role of non-antibiotic pharmaceuticals in facilitating the transfer of resistance between bacteria in this way.

New therapy prevents malaria recurrence

Tafenoquine, a single-dose therapy for Plasmodium vivax malaria, significantly reduced the risk of infection recurrence compared to treatment with placebo or primaquine, according to the results of a double-blind, randomized control trial conducted in Ethiopia, Peru, Brazil, Cambodia, Thailand, and the Philippines. At six months, the percentage of patients free from recurrence was 62.4 among those who received tafenoquine, 27.7 percent in the placebo group, and 69.6 percent among those who received primaquine.

High levels of antibiotic resistance found worldwide, WHO report

The most commonly reported resistant bacteria were Escherichia coli, Klebsiella pneumoniae, Staphylococcus aureus, and Streptococcus pneumoniae, followed by Salmonella spp.

WHO's first release of surveillance data on antibiotic resistance reveals high levels of resistance to a number of serious bacterial infections in both high- and low-income countries. WHO's new Global Antimicrobial Surveillance System (GLASS) reveals widespread occurrence of antibiotic resistance among 500 000 people with suspected bacterial infections across 22 countries.

The most commonly reported resistant bacteria were Escherichia coli, Klebsiella pneumoniae, Staphylococcus aureus, and Streptococcus pneumoniae, followed by Salmonella spp. The system does not include data on resistance of Mycobacterium tuberculosis, which causes tuberculosis (TB), as WHO has been tracking it since 1994 and providing annual updates in the Global tuberculosis report.

Among patients with suspected bloodstream infection, the proportion that had bacteria resistant to at least one of the most commonly used antibiotics ranged tremendously between different countries – from zero to 82%. Resistance to penicillin – the medicine used for decades worldwide to treat pneumonia – ranged from zero to 51% among reporting countries. And between 8% to 65% of E. coli associated with urinary tract infections presented resistance to ciprofloxacin, an antibiotic commonly used to treat this condition. "The report confirms the serious situation of antibiotic resistance worldwide," says Dr Marc Sprenger, director of WHO's Antimicrobial Resistance Secretariat.

"Some of the world's most common – and potentially most dangerous – infections are proving drug-resistant," adds Sprenger. "And most worrying of all, pathogens don't respect national borders. That's why WHO is encouraging all countries to set up good surveillance systems for detecting drug resistance that can provide data to this global system." To date, 52 countries (25 high-income, 20 middle-income and 7 low-income countries) are enrolled in WHO's Global Antimicrobial Surveillance System. For the first report, 40 countries provided information about their national surveillance systems and 22 countries also provided data on levels of antibiotic resistance.

Data presented in this first GLASS report vary widely in quality and completeness. Some countries face major challenges in building their national surveillance systems, including a lack of personnel, funds and infrastructure.

However, WHO is supporting more countries to set up national antimicrobial resistance surveillance systems that can produce reliable, meaningful data. GLASS is helping to standardize the way that countries collect data and enable a more complete picture about antimicrobial resistance patterns and trends.

In October 2015, WHO launched the Global Antimicrobial Surveillance System (GLASS) working closely with WHO Collaborating Centres and existing antimicrobial resistance surveillance networks and based on the experience of other WHO surveillance programmes.

For example, TB drug resistance surveillance has been implemented in 188 countries over the past 24 years. HIV drug resistance surveillance started in 2005 and by 2017, over 50 countries had reported data on pretreatment and acquired resistance using standardized survey methods.

Any country, at any stage of the development of its national antimicrobial resistance surveillance system, can enroll in GLASS.

Source: WHO

icddr,b develops law cost rapid Diagnostic Test Kit for Cholera

Scientists at the icddr,b, in partnership with Incepta Pharmaceuticals, have developed a locally-made low-cost dipstick device – Cholkit – for rapid and effective diagnosis of cholera, generating new hopes of better management the disease.

If commercially produced, the development of the dipstick will reduce the dependence on imported cholera testing kits and will open the avenue of export as well, scientist said. The device is dipped into a tube with stool specimen and provides qualitative result (coloured band) readable by the naked eye within a maximum of 15 minutes' time.

"Presently, in addition to the laboratory culture of stool samples, imported rapid diagnostic test (RDT) kits are being used for cholera detection," said Dr Firdausi Qadri, a scientist in the Infectious Diseases Division at icddr,b, who led the development of Cholkit.

Its implication is high for the fact that globally, an estimated 1.3 billion people are at risk of cholera among which South Asians constituting the largest share. In Bangladesh, at least 66 million people are at risk of cholera, with nearly 110,000 cases reported annually, according to a statement of icddr,b. Scientists said following a rigorous three-year research and development process, the rapid diagnostic test (RDT) has successfully met requirements and guidelines for such tests, which are capable of detecting *Vibrio cholerae* from stools.

A field evaluation of Cholkit has recently been published in the scientific journal PLOS Neglected Tropical Diseases that showed the sensitivity and specificity of the dipstick is similar to the commercially available rapid diagnostic test (RDTs) when used in

field settings for *Vibrio cholerae* from stool specimens. A total of 7,720 stool samples were tested during the evaluation where Cholkit has shown sensitivity of 76 percent and specificity of over 90 percent while other RDTs showed around 72 percent and 86.8 percent respectively.

The gold standard for detecting cholera is laboratory confirmation by stool culture, which is sensitive to several factors, including the quality of sampling, delays in shipment, laboratory equipment, and skilled human resources. It also needs longer period of time (24 to 72 hours) and costs $6 to $8 per sample, icddr,b says.

From the public health perspective, the management of cholera outbreaks needs immediate detection as the pathogen has immense potential to spread and cause epidemics in a short period of time, it said. Dr Firdausi Qadri said studies have found management of cholera outbreaks depend on early detection of cholera cases.

Now that Bangladesh has a locally-made device, it would help early detection of cholera, while the country has the potentials to create new avenues for export to other endemic countries in the future, she said. "Thus, Bangladesh will have completed locally-produced cholera preventions tools - a vaccine and a rapid diagnostic test to combat this ancient disease," she added.

The Incepta-produced Cholkit is now being used in 22 cholera sentinel surveillance sites across Bangladesh. The sites are managed jointly by icddr,b and Institute of Epidemiology Disease Control And Research.

Top Blockbuster Drugs for 2019

Major blockbuster drugs slated for launch in 2019 are expected to have a significant impact on treating certain cancers, diabetes, peanut allergies, and other conditions. Many medication launches will treat a variety of cancers, says Christopher Peterson, PharmD, director of Emerging Therapeutics for Express Scripts. "Cancer therapies represent about one-third of all specialty drugs in the pipeline, so a significant number of cancer drug approvals is expected into the future," he says.

Cancer drugs

Sacituzumab govitecan (Immunomedics), a novel, first-in-class antibody-drug conjugate (ADC) for treating breast cancer, was granted priority review by the FDA in July 2018. It is one of the top cancer medications expected to receive FDA approval in 2019, according to Aimee Tharaldson, PharmD, senior pharmacist with Emerging Therapeutics at Express Scripts. Tagraxofusp (Elzonris, Stemline Therapeutics), for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) cancer, is also expected to receive final approval in 2019.

Other expected major cancer drug launches include oral selinexor (Karyopharm Therapeutics) to treat multiple myeloma and oral erdafitinib (Janssen), which received breakthrough therapy designation in March 2018, for urothelial cancer.

LOXO-292 (Loxo Oncology), received breakthrough designation from the FDA for patients with metastatic RET-fusion-positive non-small cell lung cancer (NSCLC) as well as a last-line treatment of RET-positive thyroid cancer, is another cancer therapy to watch, says John Santilli, president of Market Access Intelligence.

Diabetes Drugs

In the lucrative diabetes drug market, semaglutide (Ozempic, Novo Nordisk), a GLP-1 agonist for type 2 diabetes approved in 2018, may achieve blockbuster status in 2019, Santilli said. "Ozempic has been gaining market share during this year in Canada and Denmark, in addition to the United States." Another potentially big diabetes drug, sotagliflozin (Zynquista, Lexicon), has a PDUFA date of March 22, 2019. The oral dual inhibitor of SGLT-1 and SGLT-2 is used in combination with insulin to improve blood sugar control in patients with type 1 diabetes, Peterson says.

Inflammatory conditions

The projected big new drugs for inflammatory conditions in 2019 include upadacitinib (AbbVie) for rheumatoid arthritis and risankizumab (Boehringer Ingelheim and AbbVie) for psoriatic arthritis, Crohn's disease, and other inflammatory conditions, according to Tharaldson.

Viaskin Peanut (DBV Technologies), which has a PDUFA date of June 22, 2019, is a novel allergy immunotherapy, administered daily via transdermal patch for desensitizing pediatric patients with peanut allergies.

Another potential blockbuster drug is esketamine (Ketanest, Janssen) nasal spray, which received breakthrough designation and is expected to be approved by FDA in early May 2019. Esketamine treats major depressive disorder, with imminent risk for suicide.

HIV

In the HIV market, bictegravir/ emtricitabine/ tenofovir alafenamide (Biktarvy, Gilead Sciences), launched in 2018, will "continue to provide strong growth for the company in 2019 on its way to becoming a blockbuster drug," Santilli says.

(Source: FIERCE PHARMA)

FDA approves atezolizumab plus

The US Food and Drug Administration granted accelerated approval to atezolizumab plus the chemotherapy nab-paclitaxelfor the first-line treatment of unresectable locally advanced or metastatic, PD-L1-positive triple-negative breast cancer (TNBC).

FDA approves vaccine effective against six childhood diseases

The US Food and Drug Administration (FDA) approved the three-dose hexavalent combination vaccine VAXELIS for use in children aged six weeks to four years. The vaccine was developed jointly by Sanofi and Merck and provides active immunization against diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B, and invasive disease caused by influenza type B.

FDA Approves Ontruzant a Biosimilar to Herceptin

The US Food and Drug Administration (FDA) has approved Ontruzant (trastuzumab-dttb), a biosimilar referencing Herceptin® i (trastuzumab), across all eligible indications, namely adjuvant treatment of HER2-overexpressing breast cancer, metastatic breast cancer and metastatic gastric cancer or gastroesophageal junction adenocarcinoma in patients who have not received prior treatment for metastatic disease.

USFDA has approved a new depression drug

The US Food and Drug Administration have approved a new depression drug, esketamine, for patients who have not responded to other antidepressants. The treatment, a nasal spray related to the party drug ketamine, will be the first fast-acting depression drug on the market.

FDA approves Adhansia XR for the treatment of ADHD

The US Food and Drug Administration (FDA) approved Adhansia XR (methylphenidate hydrochloride) extended-release capsules CII, a central nervous system (CNS) stimulant, for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in patients six years and older. In a simulated Adult Workplace Environment (AWE) study, Adhansia XR demonstrated statistically significant improvement over placebo at 1, 2, 5, 8, 11, and 16 hours post-dose, but not at hour 14 post-dose.

FDA Approves First Drug for Postpartum Depression

Postpartum depression is a common and often devastating condition for new mothers, but the U.S. Food and Drug Administration recently approved the first drug to help combat it.The drug, Zulresso (brexanolone), is delivered via intravenous infusion. “Postpartum depression is a serious condition that, when severe, can be life-threatening,» noted the FDA›s Dr. Tiffany Farchione. “Women may experience thoughts about harming themselves or harming their child.” The condition “can also interfere with the maternal-infant bond,” added Farchione, who is acting director of the Division of Psychiatry Products in the agency’s Center for Drug Evaluation and Research. The FDA decision “marks the first time a drug has been specifically approved to treat postpartum depression, providing an important new treatment option,” she said in an agency statement.

Hello DOCTOR

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GLOSSARY OF TERMS
GASTROENTEROLOGY

Abdominal Wall Hernia: A painful condition that happens when part of your digestive system pokes through an opening in your abdominal muscles.

Achalasia of the Oesophagus: A condition affecting swallowing when the waves of peristalsis or contraction in your throat are absent or disordered.

Alimentary Canal: Another name for the entire digestive tract.

Barrett's Oesophagus: A condition that can occur after long term acid reflux when the cells lining your oesophagus change.

Bloating: An uncomfortably full or swollen feeling in your abdomen.

Colonoscopy: An investigation using a camera on a flexible tube to examine your large intestine.

Constipation: Infrequent or difficult to pass bowel movements.

Dysphagia: A medical term for difficulty swallowing.

Endoscopy: An investigation using a camera on a flexible tube to examine your digestive tract.

Electrogastrography (EGG): A diagnostic test that measures electrical activity in the stomach using electrodes placed on the skin.

Epiglottis: The flap that covers your windpipe when you are swallowing to prevent food getting into your lungs.

Gastroscopy: An investigation using a camera on a flexible tube to examine your throat, stomach or small intestine.

GORD or Gastro-oesophageal Reflux Disease: A condition that occurs when stomach acid frequently rises into your throat, causing pain and discomfort.

Indigestion, Heartburn or Acid Reflux: A common symptom caused by stomach acid rising into your throat, often after overeating. Can be a sign of a more serious condition such as a peptic ulcer or GORD.

IBS or Irritable Bowel Syndrome: A long term condition that can make you sensitive to certain foods. Symptoms include constipation, diarrhoea, and abdominal cramps.

Liver Function Test: Blood tests that can help identify problems with your liver or gallbladder by measuring the levels of certain enzymes and proteins.

Laparoscopic surgery: "Minimally invasive" surgery in which small (usually 5- to 10-millimeter) incisions are made. The laparoscope and surgical instruments are inserted through these incisions. The surgeon is guided by the laparoscope, which transmits a picture of the internal organs on a monitor.

Lipase: Enzyme produced in the pancreas and secreted into the small intestine that aids in the digestion of certain fats from food.

Oesophageal Laser or Photodynamic Therapy: Laser treatment to remove abnormal cells for conditions like oesophageal cancer and Barrett's dysplasia.

Oesophageal Manometry: A test to check the strength of the valve that prevents acid escaping from your stomach into your oesophagus.

Oesophageal Stent: An implant that can open up narrowed sections of the oesophagus.

Oesophagus: A medical term for the part of your throat leading from your mouth to the stomach. Not to be confused with the trachea or windpipe, which goes to your lungs?

Proton pump inhibitors: Drugs that suppress acid production in the stomach.

Zollinger-Ellison syndrome: A rare disorder of the gastrointestinal system caused by a tumor called a gastrinoma. Gastrinomas most often occur in the pancreas. The tumor secretes the hormone gastrin, which increases acid levels in the stomach, leading to severe, recurrent ulcers of the esophagus, stomach, and intestines.

Secretin stimulation test: Test that measures the ability of the pancreas to respond to the hormone secretin.

Ultrasound: The use of high-frequency sound waves to produce images of the organs and structures inside the body.

FACTS ON **FINGER TIPS**
LIVER DISEASES

Overview

The liver is an organ about the size of a football that sits just under your rib cage on the right side of your abdomen. The liver is essential for digesting food and ridding your body of toxic substances.

Liver problems

The liver is an organ about the size of a football that sits just under your rib cage on the right side of your abdomen. The liver is essential for digesting food and ridding your body of toxic substances.

Symptoms

Signs and symptoms of liver disease include:

- Skin and eyes that appear yellowish (jaundice)
- Abdominal pain and swelling
- Swelling in the legs and ankles
- Itchy skin
- Dark urine color
- Pale stool color, or bloody or tar-colored stool
- Chronic fatigue
- Nausea or vomiting
- Loss of appetite
- Tendency to bruise easily

Causes

Liver disease has many causes.

Infection

Parasites and viruses can infect the liver, causing inflammation that reduces liver function. The viruses that cause liver damage can be spread through blood or semen, contaminated food or water, or close contact with a person who is infected. The most common types of liver infection are hepatitis viruses, including:

- Hepatitis A
- Hepatitis B
- Hepatitis C

Immune system abnormality

Diseases in which your immune system attacks certain parts of your body (autoimmune) can affect your liver. Examples of autoimmune liver diseases include:

- Autoimmune hepatitis
- Primary biliary cirrhosis
- Primary sclerosing cholangitis

Cancer and other growths

Examples include:

- Liver cancer
- Bile duct cancer
- Liver adenoma

Other

Additional, common causes of liver disease include:

- Chronic alcohol abuse
- Fat accumulating in the liver (nonalcoholic fatty liver disease)

Prevention

To prevent liver disease:

- Drink alcohol in moderation.
- Avoid risky behavior.
- Get vaccinated.
- Use medications wisely.
- Avoid contact with other people's blood and body fluids.
- Take care with aerosol sprays.
- Protect your skin.
- Maintain a healthy weight.

Brand Name	Generic Name	Manufacturer	Date of Approval	Treatment
Mavenclad Tablets	Cladribine	EMD Serono, Inc.	Mar 29, 2019	Multiple Sclerosis
Jatenzo Capsules	Testosterone Undecanoate	Clarus Therapeutics, Inc.	Mar 27, 2019	Hypogonadism – Male
Mayzent	Siponimod	Novartis Pharmaceuticals Corporation	Mar 26, 2019	Multiple Sclerosis
Sunosi	Solriamfetol	Jazz Pharmaceuticals plc	Mar 20, 2019	Narcolepsy, Obstructive Sleep Apnea/ Hypopnea
Zulresso Injection	Brexanolone	Sage Therapeutics	Mar 19, 2019	Postpartum Depression
Rocklatan Ophthalmic Solution	Netarsudil and Latanoprost	Aerie Pharmaceuticals, Inc.	Mar 12, 2019	Glaucoma (Open Angle), Intraocular Hypertension
Trazimera Injection	Trastuzumab-qyyp	Pfizer Inc.	Mar 11, 2019	Breast Cancer, Gastric Cancer
Spravato Nasal Spray	Esketamine	Janssen Pharmaceuticals, Inc	Mar 05, 2019	Treatment-Resistant Depression
Herceptin Hylecta for Subcutaneous Injection	Trastuzumab & Hyaluroni-dase-oysk	Genentech, Inc.	Feb 28, 2019	Breast Cancer
Adhansia XR extended release Capsules	Methylphenidate Hydro-chloride	Adlon Therapeutics L.P.	Feb 27, 2019	Attention Deficit Hyperactivity Disorder
Esperoct	Turoctocog alfa pegol	Novo Nordisk	Feb 19, 2019	Hemophilia A
Egaten	Triclabendazole	Novartis Pharmaceuticals Corporation	Feb 13, 2019	Fascioliasis
Cablivi Injection	Caplacizumab-yhdp	Ablynx NV	Feb 06, 2019	Acquired Thrombotic Thrombocytope-nic Purpura
Jeuveau	PrabotulinumtoxinA-xvfs	Evolus, Inc.	Feb 01, 2019	Glabellar Lines
Tosymra Nasal Spray	Sumatriptan	Dr. Reddy's Laboratories, Inc.	Jan 25, 2019	Migraine
Ontruzant Injection	Trastuzumab-dttb	Samsung Bioepis Co., Ltd.	Jan 18, 2019	Breast Cancer, Gastric Cancer
Ultomiris Injection	Ravulizumab-cwvz	Alexion Pharmaceuticals Inc.	Dec 21, 2018	Paroxysmal Nocturnal Hemoglobinuria
Elzonris Injection	Tagraxofusp-erzs	Stemline Therapeutics, Inc.	Dec 21, 2018	Blastic Plasmacytoid Dendritic Cell Neoplasm
ProAir Digihaler Inhalation Powder	Albuterol Sulfate	Teva Pharmaceuticals USA, Inc.	Dec 21, 2018	Bronchospasm Prophylaxis, Asthma, Chronic Obstructive Pulmonary Disease
Vaxelis Suspension for Intra-muscular Injection	Diphtheria & tetanus toxoids & acellular	Merck and Sanofi	Dec 21, 2018	Diphtheria Prophylaxis, Tetanus Prophylaxis, Pertussis Prophylaxis, Poliomyelitis Prophylaxis, Hepatitis B Prophylaxis, Haemophilus influenzae Prophyla
Inbrija Inhalation Powder	Levodopa	Acorda Therapeutics, Inc.	Dec 21, 2018	Parkinson's Diseases
Asparlas Injection	Calaspargase pegol-mknl	Servier Pharmaceuticals LLC	Dec 20, 2018	Acute Lymphoblastic Leukem
Motegrity Tablets	Prucalopride	Shire plc	Dec 14, 2018	Chronic Idiopathic Constipation
Herzuma Injection	Trastuzumab-pkrb	Celltrion, Inc. and Teva Phar-maceutical Industries Ltd.	Dec 14, 2018	Breast Cancer
Tolsura Capsules	Itraconazole	Mayne Pharma US	Dec 14, 2018	Blastomycosis; Histoplasmosis; Aspergil-losis
Dextenza Ophthalmic Insert	Dexamethasone	Ocular Therapeutix, Inc.	Dec 03, 2018	Postoperative Ocular Inflammation

Wish to Export to **Nigeria**

General:

1. These Guidelines are for the interest of the general public and in particular Importers of Pharmaceutical and Veterinary Drugs in Nigeria.
2. It is necessary to emphasize that, no drug shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of NAFDAC Act CAP N1 (LFN) 2004, other related Legislations and the accompanying Guidelines.

Applications:

1. A written application for registration of imported drug should be made on the company's letter head paper to the Director-General (NAFDAC), ATTENTION: The Director, Registration & Regulatory Affairs (R & R) Directorate, Ground Floor, NAFDAC Office Complex, Isolo Industrial Estate, Oshodi-Apapa Express Way, Isolo, and Lagos State.
2. The application letter should include the generic name of product and brand name (where applicable).
3. An online application form for Product Registration should be purchased at; http://registration.nafdac.gov.ng and completed.
4. A separate application form should be submitted for each product.

Documentation:

1. The following documents (all originals) and two (2) sets of photocopies (including print-out of the completed online Registration form) are to be submitted at the Liaison Office of the Director (LOD), R & R Directorate, Ground Floor, NAFDAC Office Complex, Oshodi-Apapa Express Way, Isolo, Lagos State or any NAFDAC Office (outside Lagos).
2. Notarized Declaration (Appendix I), to be completed (typed), signed by Declarant and notarized by a Notary Public in Nigeria.
3. Power of Attorney or Contract Manufacturing Agreement. An applicant on behalf of a manufacturer outside Nigeria must file an evidence of Power of Attorney from the manufacturer which authorizes him to speak for his Principal; on all matters relating to the latter's specialties.
4. Contract Manufacturer Agreement. An applicant filing an ap-

plication on behalf of his company, and being the owner of the product, shall provide a Contract Manufacturing Agreement.

5. Evidence of Business Incorporation of the importing Company with Corporate Affairs Commission in Nigeria.
6. Manufacturing License/Certificate of Free Sale.
7. Evidence that they are licensed to manufacture drugs for sale in the country of origin (Manufacturer's Certificate). The license shall be issued by a relevant Health/Regulatory Body in the country of manufacture.
8. Certificate of Pharmaceutical Product (COPP-WHO Format)
9. There must be evidence by the competent Health Authority, that the sale of the product does not constitute a contravention of the drug laws of that country.
10. Current Good Manufacturing Practice (cGMP) of the manufacturing facility.
11. Dossiers: The applicant shall submit two (2) copies of the Dossiers.
12. Evidence of Registration of Brand Name with Trademark Registry in the Ministry of Industry, Trade and Investment. This should be registered in the name of the owner of the Trademark/Brand name as the case may be (Trademark Class 5 for Drugs).
13. Copy of valid Annual License to practice for the Superintendent Pharmacist issued by Pharmacists Council of Nigeria.
14. Evidence of valid Premises Retention License for the facility.
15. Comprehensive Certificate of Analysis for product(s)
16. The Certificate of Analysis must be presented on a letter-head paper of the quality control laboratory where the sample was tested/evaluated
17. Label or artwork of the product
18. Letter of Invitation for Good Manufacturing Practice (GMP) Inspection: A letter of invitation to inspect the factory abroad shall be written by the manufacturer

Labeling Guidelines for Imported Drugs:

1. Labeling should be informative and accurate.
2. Minimum requirements on the package label in accordance with the Drug Labeling Regulations include:
   a. Name of product (brand name) where applicable and generic name.
   b. Name and full location address of the manufacturer.
   c. Provision for NAFDAC Registration Number on product label
   d. Batch No., Manufacturing date and Expiry date.
   e. Dosage form & strength
   f. Indications, frequency, route, conditions of administration (Over the counter; OTC drugs).
   g. Dosage regimen on the package (Over-the-Counter; OTC drugs).
   h. Patient Information Leaflet (PIL)
   i. Prescribing information (for POM).
   j. Net content of product
   k. Quantitative listing of all the active ingredients per unit dose
3. Adequate warnings where necessary.
4. Where a brand name is used, there MUST be the generic name which should be conspicuous in character, written directly under the brand name.
5. Any drug product whose name or package label bears close resemblance to an already registered product or is likely to be mistaken for such registered product, shall not be considered for registration.
6. See the Agency's Drug Labeling Regulations and other relevant Regulations for specific details.

Note:

1. For New Chemical Entities (NCE), there must be evidence that Clinical Trials have been undertaken in the relevant population. Such clinical trial reports must be submitted and reviewed
2. No combination drug product shall be registered or considered for registration unless there is scientific documented evidence to prove that such a product has clinical advantage over the single drug available for the same indication(s).
3. Failure to comply with these requirements may result in the disqualification of the application or lead to considerable delay in the processing of registration.
4. A successful application will be issued a Certificate of Registration with a validity period of five (5) years.
5. NAFDAC reserves the right to revoke, suspend or vary a certificate during its validity period.
6. Filing an application form or paying an application fee does not confer registration status.
7. Failure to respond promptly to queries or enquiries raised by NAFDAC on the application (within 90 working days) will automatically lead to the closure of the Application.
8. The time line for product registration from acceptance of submissions to issuance of Registration number is one hundred and twenty (120) working days.

AHMED KAMRUL ALAM has been promoted recently as Director, Marketing of Square Pharmaceuticals Ltd. He completed his B. Pharm and M. Pharm from University of Dhaka. He has also completed his MBA from IBA of the same University. Earlier, he passed SSC and HSC from Sylhet Cadet College. He started his career with Square on 1st January 1995 with high career aspiration and reached leadership position as Group Product Manager within six years of his service. During his career, he worked in various functional areas like Sales and Distribution, Medical Services, Regulatory Affairs, Market Research and Creative Services Department. He is closely involved with the marketing activities of Square Herbal and Nutraceuticals Ltd. As a special assignment, he worked with International Marketing Department and was posted in Pakistan as Business Development Manager. He is a certified Internal Quality Management System (QMS) auditor. He has also completed Postgraduate Diploma Program in World Trade. Alam was a part-time faculty member of two leading Private Universities. He is a member of Pharmaceutical Executive Club (PEC), Pharmacy Graduates' Association (PGA), Bangladesh Pharmaceutical Society (BPS) and IBA Alumni Association.

MD. MAMAUNUR RAHMAN joined as DGM, Marketing at Pharmasia Ltd. recently with the major portfolios of marketing divisions. Prior to this, he was the Head of Marketing & Sales in Asiatic Laboratories Ltd.

Rahman also worked as Sr. Manager, Corporate Product Management Department of Pharma & Healthcare SBU of Orion Group. Formulating strategies, making decision, manage, promote, direct, plan, and coordinate activities for smooth execution of total product portfolios of existing and new product lines is his core areas of expertise. He is also one of the few marketing professionals having vast expertise in healthcare related business activities with the strong expertise in total branding related activities.

Rahman has a successful marketing track record with over 18 years of professional experience in Pharma Marketing including Export, Veterinary & Herbal-Ayurveda & Nutraceuticals. Rahman did his graduation and post-graduation in Pharmacy from Jahangirnagar University & did MBA from the University of Dhaka. Rahman is also a highly-acclaimed Silva graduate with the course of SILVA METHOD. He is extensively trained in his professional area from many world-renowned marketing experts of Asia, Europe & America and Mr. Rahman travelled many countries across the world. He is also a freelance writer on his professional arena.

MD. IBRAHIM RASHED has recently been promoted as Manager, Sales & Marketing of Sharif Pharmaceuticals Ltd. Prior to this, he worked as Deputy Sales Manager from 2016 in the same company. He obtained his Master Degree in Business Management. He is an enthusiastic and ambitious sales professional with mentionable leadership skill.

Worth knowing about...

Is it okay to switch from brand to generic?

While many patients can switch between brand and generic versions of drugs without any problems, there are certain conditions and situations where switching between brand and generics is not a good idea. Some people may be very sensitive to the different inactive ingredients, or they may have a health condition that requires a very specific dose to remain stable. Also, several companies may manufacture the same generic product, but the inactive ingredients they use may vary. Finally, not all generic versions of a brand medication are the same (since they are made by different manufacturers and may have different inactive ingredients), so some patients may respond differently to one generic version of a medication than another. Ultimately, the question is not whether brand or generic drugs are better, but which drug is the best choice for *you*. Because everyone is different, the solution can vary from person to person. Luckily, your doctor or pharmacist can help you find what works best for you.

Are generic versions as strong as brand?

Many people believe that the often-cheaper price of generic drugs means that are not getting the same drug dose as you would. The FDA requires manufacturers of generic drugs to prove that the active ingredient in the generic version will produce the same result as the brand-name drug. Though generic drugs have the same active ingredient, the inactive ingredients often vary (e.g., binders, fillers, dyes, etc.). Changing even one of these components can have a major effect on how the drug behaves. Different inactive ingredients can alter how quickly the drug dissolves, is absorbed, cleared, and eliminated from the body. When you put all of this together in the form of a pill or capsule, the generic drug may have a similar effect as the brand version, but recreating the identical effect is nearly impossible. Equate this to baking a cake. Duncan Hines has a distinct flavor, and while "off-brand" competitors may still taste good, the flavor isn't quite the same.

Generic Drugs vs. Brand: What you need to know

One of the most common questions I get as a pharmacist is, "Are generics really as good as brand medications?" Unfortunately, there is no cut-and-dried answer. It's not really a question of whether a brand drug is better than a generic drug, but whether the specific version of the drug you are taking is giving your body what it needs. Two of the most common concerns patients tend to have about generic medications:

Coming Soon: Battery-Free Pacemakers Powered by the Heart?

Scientists say they've taken a first step toward creating a pacemaker that runs on the heart's own energy rather than batteries. Pacemakers are electronic devices implanted to regulate your heartbeat -- usually because of a condition that slows your heart's normal rate. Traditional pacemakers have two parts: a battery-powered pulse generator implanted under the collarbone, and insulated wires that connect it to your heart. Because those batteries eventually wear down, pacemakers have to be replaced every five to 12 years. So, some scientists have been working an alternative: battery-free pacemakers that in theory would never have to be replaced. The "most promising" approach right now is to harness the energy of the heartbeat to power the pacemaker, said researcher and study author Bin Yang. One problem with the experimental devices developed so far has been their rigid structure, which limits their power.

TITLE	VENUE	SCHEDULE
Radiology & Oncology Congress 2019	Abu Dhabi, UAE	Apr 08–10, 2019
Human Genetics Meet 2019	Abu Dhabi, UAE	Apr 08–10, 2019
APASL Single Topic Conference on Liver Immunology and Genetics 2019	Kanto, Tokyo	Apr 18–20, 2019
International Conference on Liver and Hepatitis	Budapest, Hungary	Apr 24–25, 2019
Internal Medicine and Hospital Medicine	Paris, France	May 08–09, 2019
Global Congress on Endocrinology and Gynecology 2019	Osaka, Japan	May 13–14, 2019
6th Asia Pacific Oncologists Annual Meeting	Atrium, Singapore	May 13–14, 2019
7th World Congress on Hepatitis & Liver Diseases	Osaka, Japan	May 15–16, 2019
Int'l Liver Transplantation Society (ILTS) Annual Congress 2019	Toronto, Ontario	May 15–18, 2019
Diabetes Meet 2019	Singapore	May 17–18, 2019
APASL Single Topic Conference on Hepatitis Delta 2019	Baku, Baku	May 30–31, 2019
10th Int'l DIP Symposium on Diabetes, Hypertension, Metabolic Syndrome and Pregnancy	Florence, Italy	May 29–Jun 01, 2019
13th Biennial Congress of The European-African Hepato-PancreatoBiliary Association (E-AHPBA) 2019	Amsterdam, Holland	June 02–09, 2019
Singapore Hepatology Conference (SHC) 2019	Singapore	June 07–08, 2019
International Conference on Hepatology and Liver Diseases	Dubai, Abu Dhabi	June 10–11, 2019
15th Euro Obesity and Endocrinology Congress	London, UK	June 17–18, 2019
DIA 2019 Global Annual Meeting	San Diego	June 23-27, 2019
2nd International Conference on Fatty Liver (ICFL 2019)	Berlin, Germany	June 27–29, 2019
International Women Health Conference and Expo	London, UK	July 03–05, 2019
14th Euro-Global Gastroenterology Conference	Zurich, Switzerland	July 08–09, 2019
7th International Conference on Hepatology	Sydney, Australia	July 15–16, 2019
16th World Congress on Gastroenterology & Therapeutics	Osaka, Japan	July 22–23, 2019
21st Asia Pacific Diabetes Conference	Sydney, Australia	July 29–30, 2019
Gastroenterology and Digestive Disorders Conference	Auckland, Zealand	Aug 14–15, 2019
6th World Congress on Midwifery & Women's Health 2019	Baltimore, USA	Sept 09–10, 2019
Liver Cirrhosis and Hepatitis	Tokyo, Japan	Sept 23–24, 2019
18th Int'l Conf. on Gastroenterology & Digestive Disorders	Dubai, UAE	Sept 23-24, 2019
3rd Edition of International Cancer Conference (ICC 2019)	London, UK	Sept 23-24, 2019
15th Annual Congress on Gastroenterology & Hepatology	Hong Kong	Sept 27–28, 2019
6th Asia-Pacific Congress of Int'l Oncology (APCIO) 2019	Malaysia	Oct 02–05, 2019
19th World Gastroenterologists Summit 2019	Sydney, Australia	Oct 14–15, 2019
4th Int'l Conference on Digestive and Metabolic Diseases	Rome, Italy	Oct 21-22, 2019
4th World Congress on Frontiers in Cancer Research & Therapy	Melbourne, Australia	Oct 21–22, 2019
World Congress on Pancreatic Cancer and Liver Diseases	Tokyo, Japan	Oct 23–24, 2019
4th Int'l Conference on Internal Medicine & Hospital Medicine	Vancouver, Canada	Oct 25–26, 2019
19th Int'l Conference on Gastroenterology and Hepatology	Abu Dhabi, UAE	Nov 18–19, 2019
World Congress on Complementary and Alternative Medicine	Dubai, UAE	Dec 02–03, 2019
6th International Conference on Diabetes and Endocrinology	Texas, USA	Dec 07–09, 2019
7th Global Experts Meeting on Nursing and Nursing Practice	Barcelona, Spain	Dec 09–10, 2019
Int'l Conference on Metabolic Diseases and Liver Cancer	Dubai, UAE	Dec 16–17, 2019

N.B. *Dates/Venues of forthcoming conferences are subject to change/cancellation etc. with or without notice. So, intending participants are advised to check all details relating to VISA and other relevant matters before departure.*

11th ASIA PHARMA EXPO 2019 offered business networking for 12,800 trade professionals

Largest international pharma exhibition displayed latest pharma manufacturing technologies ever in Bangladesh pharmaceutical industry

The 3-day 11th Asia Pharma Expo 2019 (APE 2019) & Asia Lab Expo 2019 was held during January 31 to February 2, 2019 at ICCB, Dhaka, Bangladesh. Zahid Maleque, MP, Honb'le Minister, Ministry of Health & Family Welfare was the at the Opening Ceremony along with Salman F Rahman, MP, Private Industry & Investment Advisor to the Honb'le Prime Minister; Dr. Md Murad Hasan, MP, State Minister, Ministry of Health & Family Welfare; Md Asadul Islam, Secretary, Ministry of Health & Family Welfare; and Major General Md Mustafizur Rahman, Director General, Directorate General of Drug Administration were the Special Guests.

The President of Bangladesh Association of Pharmaceutical Industries (BAPI) Nazmul Hasan delivered the address of welcome. He said that apart from exporting medicines to different countries, the main objective of BAPI is to provide medicines to the people at affordable prices. The Exhibition was organized by GPE EXPO PVT. LTD. jointly with the Bangladesh Association of Pharmaceutical industries since year 2003 at Dhaka.

The EEPC INDIA (formally known as Engineering Export Promotion Council, set up by Ministry of Commerce, Govt. of India) and FICCI put up the INDIA Pavilions at the Exhibition. The Exhibition was also supported by EEPC INDIA and FICCI.

A Technology Seminar was organized on Data Integrity & Data Reliability from Pharma Industry. Presentation was made by Dr. Govind S. Pandey, USFDA & other Regulatory Audit Expert. The local pharma market of Bangladesh with more than 300 pharmaceutical companies of Bangladesh with current exports worth USD 72+ million are anticipated to reach country's pharma formulation exports to USD 60 billion by 2021.

With APE 2019 – Asia Pharma Expo completes 17 years presence in Bangladesh pharmaceutical industry, and offering an unparalleled business platform for the entire spectrum of the pharmaceutical manufacturing technologies & solution providers networking with the comprehensively all the fraternity of pharma manufacturing plant professionals along with the Regulatory, Research, Academics, and local Indenting Partners. The focused industry segments were; Pharmaceuticals, Healthcare, Biotech, API, Neutraceuticals, Cosmetics, Beverages, Distilleries.

At APE 2019, more than 650 exhibiting companies from 31 countries across the world exhibited their latest technologies to upgrade the pharma manufacturing standard of Bangladesh to a newer height. The 3-days Exhibition was attended by 12,800+ trade visitors to explore the complete spectrum of latest pharma manufacturing technologies & products on display, which include:

● PROCESSING Machineries for formulation & API manufacturing ● PACKAGING Machineries & Materials ● CLEANROOM & Utility Eqpts& Services ● WATER TREATMENT & Management Systems ● ANALYTICAL & BIOTECH Lab Instruments● PROJECT Consultants & Turnkey Contractors ● API, Pharma Bulk Actives, Excipients, Additives& many more

An overwhelming exhibition participation response by the local Business Associates as well as technology solution providers from outside Bangladesh was noticed. The next edition of ASIA PHARMA EXPO 2020 & ASIA LAB EXPO 2020 will be held in February 2020 at Dhaka, Bangladesh. For more information, please visit www.AsiaPharma.org or email to mail@AsiaPharma.org for more information.

Eminence Business Media's "2nd Annual Pharma Project & Portfolio Management Summit 2019"

Eminence Business Media's "2nd Annual Pharma Project & Portfolio Management Summit 2019" concluded on February 21st & 22nd, 2019 at Hotel Orchid, Mumbai. The theme of the summit was Bringing 'Vision' to your projects: Strategizing Innovation from Lab to Launch. The summit was an outstanding success with 90+ delegates attending the conference with Labindia Analytical Instruments Pvt. Ltd., Pharma Mantra & Global Awards and Rewards partnering the event, says a Company Press Release.

The two-day summit ensured the continuous engagement of the audience, speakers and exhibitors through networking activities and discussions with regards to the ever–evolving challenges of the pharmaceutical project & portfolio management teams and how to overcome those challenges.

The summit saw as many as 14 sessions & a panel discussion over the two days, attended by the CEO's, MD's, Project Management Heads, Portfolio Management Heads, Product/Project/ Portfolio Managers, Quality Assurance / Quality Control managers, Supply Chain Managers of the pharmaceutical & biopharmaceutical manufacturing companies.

The day started with Ms. Guneet Kaur Hayer, Managing Director, Eminence Business Media speaking about Eminence Business Media's Vision on Pharma Project & Portfolio Management.

The event was inaugurated with the opening remarks by the chairperson John Robert – Sun Pharmaceuticals Ltd. in the presence of various eminent personalities from the Pharma Industry. He spoke about building a project strategy which embarks a new dawn for Pharma Project & Portfolio Management. The opening remarks were followed by the presentation on Project Management Strategies revolutionizing the construction space by eminent industry leaders of the industry.

Day one also witnessed a panel discussion on "The science & art of developing a MASTERPLAN" with very learned panel members. A special Campfire Discussion which included the audience discussion on 'Evolving Role of Project Managers in successful Project Implementation' was also arranged with Ms. Jamila Joseph, SVP & Head, Innovative Technologies & Clinical Research, Reliance Life-Sciences & Dr. Laila Fatima, Associate Director, Dr. Reddy's as the session leaders.

Day two of the summit also witnessed the official launch of John Robert's book "Leadership Journey of a Project Manager" by Sandeep Gupta, Vice Chairman Nutraceuticals, IDMA followed by John Robert signing the book and handing over a copy of the same to all the delegates. The summit was concluded with the closing remarks by the Chairperson, John Robert followed by a group photo of the delegates attending the summit.

Second edition of PHARMACONNECT surpassed all expectations, hailed huge success

Surecom Media's annual flagship event PHARMACONNECT 2019 – Pharma Suppy Chain Conference was convened at The Westin Mumbai Garden City on January 2019. This second edition was endowed with participation by more than 310 pharma and logistics industry professionals from around the country and abroad. Five intriguing panel discussions were held in the conference which touched each and every aspect of India's pharmaceutical supply chain.

Ajeet Kumar, Surecom Media's Director, provided the opening remarks and noted the organisation's commitment to delivering first-rate logistics conferences to the entire industry. The 1st panel discussion of the conference on 'Mastering Import/Export Compliance for Global, Multi-Layered Supply Chain' elucidated the elements of export compliance, import compliance and trade agreements.

In the 2nd panel discussion, Surendra Deodhar, VP- Materials Management, Reliance Life Sciences; Rajesh J Rao, Head- Supply Chain Management, Cadila Pharmaceuticals Limited; Raja Sundaramurthy, DGM – FDF Logistics, Mylan Labs; Balaji S, Sr Director – Industrial & Logistics Services, Advisory & Transactions, CBRE; Rajeshh Rao, Former Head – SCM, Emcure Pharma; Sanjay Kulkarni, Sr General Manager – Corporate Demand Planning, Glenmark Pharmaceuticals; and Rajesh Pednekar, Head – Logistics and Distribution, Cipla, brainstormed on the issues pertaining to 'End-to-End Optimisation - Seamlessly transitioning operations from Product Development to Launch'. The wide canvas of questions that were debated ranged from basic issues like storage and packaging, personnel management, due diligence, regulatory audits, to complex ones, such as greater standardisation and visibility, network design and planning, etc.

The post lunch session kicked off with the 3rd panel discussion on 'Bridging Clinical and Commercial Operations.' Addressing a dozen of questions of relevance on development and commercialisation of drugs and devices, accelerating regulatory and marketplace acceptance, and inter-company cooperation between teams- clinical researchers to product marketers so as to achieve accelerated clinical and commercial development, industry leaders, addressed the various factors that aims at crafting a balance between science and commercial strategies.

The 4th panel discussion of the conference 'Why efficiency & efficacy matters and how can we get it delivered' brought on stage industry leaders, who briefed on integrated and collaborative approaches to develop sustainable supply and value chains that will enable Indian pharmaceutical companies to steadily reduce costs, increase their flexibility and delivery reliability, and maintain high standards of quality, safety and environmental protection on a global basis.

The 5th and last panel discussion witnessed professionals and specialists from the respective fields sharing their knowledge and expertise on the topic 'How do we bring about change in pharma delivery in the country' and mapping out logistics strategies that need to be closely aligned with a company's manufacturing and commercial strategies.

Event	Venue	Date
Vietnam Medi-Pharm 2019	Hanoi, Vietnam	May 08–11, 2019
China Int'l Medical Equip. Fair	Shanghai, China	May 14 – 17, 2019
KIHE 2019	Almaty City, Kazakstan	May 15–17, 2019
Oral Health 2019	Dubai, UAE	May 20–21, 2019
Hospitalar Fair & Congress 2019	Sao Paulo, Brazil	May 21–24, 2019
Africa Health 2019	Johannesburg, S.Africa	May 28 – 30, 2019
Global Pharma Regulatory Summit 2019	Mumbai, India	May 29–30, 2019
Madex Expo 2019	Johannesburg, S.A	Jun 05–06, 2019
Pharmatech Asia 2019	Bangkok, Thailand	Jun 12–15, 2019
CPhI & P-MEC China 2019	Shanghai, China	Jun 18 –20, 2019
Medical Taiwan 2019	Taipei,Taiwan	June 27–30, 2019
Interphex Japan 2019	Tokyo, Japan	Jul 03 – 05, 2019
Indian Pharma Expo 2019	New Delhi, India	Jul 09 –11, 2019
MDA 2019	Bangkok, Thailand	Jul 10–12, 2019
C-Medical Fair 2019	Shanghai, China	Jul 11–13, 2019
World Healthcare Exhibition	Kuala Lumpur, Malaysia	July 25–27, 2019
Medicall Chennai 2019	Chennai, India	Jul 26 – 28, 2019
Vietnam Medi-Pharm Expo 2019	Ho Chi Minh, Vietnam	Aug 01–03, 2019
Pharma Tech Expo 2019	Ahmedabad, India	Aug 20 –22, 2019
K-Hospital Fair 2019	Seoul, Korea	Aug 21–23, 2019
Medical Phillipines 2019	Pasay, Philippines	Sept 03–05, 2019
Medical Fair Thailand 2019	Bangkok, Thailand	Sept 11 – 13, 2019
Egy Health Exhibition 2019	Cairo Egypt	Sept 12–14, 2019
Cambodia Phar-Med Expo 2019	Phnom Penh, Cambodia	Sept 17–18, 2019
Oman Health Exhibition 2019	Muscat, Oman	Sept 23–25, 2019
Thailand Lab 2019	Bangkok, Thailand	Sept 25–27, 2019
Maghreb Health & Maghreb Lab 2019	Algiers, Algeria	Sept 25–27
Medic West African 2019	Lagos, Nigeria	Oct 09–11, 2019
Algeria Health Exhibition 2019	Algiers, Algeria	Dec 05–08, 2019
Saudia Int'l Pharma & Medlab Expo 2019	Riyadh, KSA	Dec. 09–11, 2019

N.B. Dates/Venues of forthcoming events are subject to change/cancellation etc. with or without notice. So, intending participants are advised to check all details relating to VISA and other relevant matters before departure.

FAST FACTS

- *In Bangladesh, at least 66 million people are at risk of cholera, with nearly 1,10,000 cases reported annually.*
- *As per Export Promotion Bureau latest data in July-January of the running 2018-19 (FY19) financial year, its generic products export performance was US$79.27 million which is $14.81million higher than target and is 36.6 per cent higher over the corresponding period of the last fiscal of $60.24 million.*
- *Medicines worth US$ 103.46 million were exported from the country during the last fiscal, from US$ 89.17 million the country shipped during FY 2016-17, according to EPB.*
- *Pneumonia in Bangladesh took the lives of over 16,960 under-five children in 2016, which is close to two deaths every hour.*
- *Children's Emergency Fund (Unicef) data shows that only 42 percent of children under 5 with pneumonia symptoms receive care in Bangladesh.*
- *Pneumonia claimed the lives of an estimated 880,000 children – more than for malaria and diarrhea combined, approximately 16 percent of the 5.6 million under-five deaths in 2016 in the world.*

Medicine export increases by 30.35 pc in 9 months

Pharmaceutical sector needs modern drug testing lab for further development

Export earnings from pharmaceutical sector increased significantly during the first nine months (July to March) of the ongoing fiscal 2018-19 due to higher demand in the international market, according to the industry insiders.

The government has set the export target amounting US$112.19 million for the current fiscal year and the export target for the first nine months was $82.93 million. The lifesaving medicine export earnings was $99.74 million during the nine months. The medicine export increased by 20.27 percent from the target of the government.

On the other hand, medicine export was $76.52 million during the corresponding period of the last fiscal 2017-18. In this calculation, the export increased by 33.55 million.

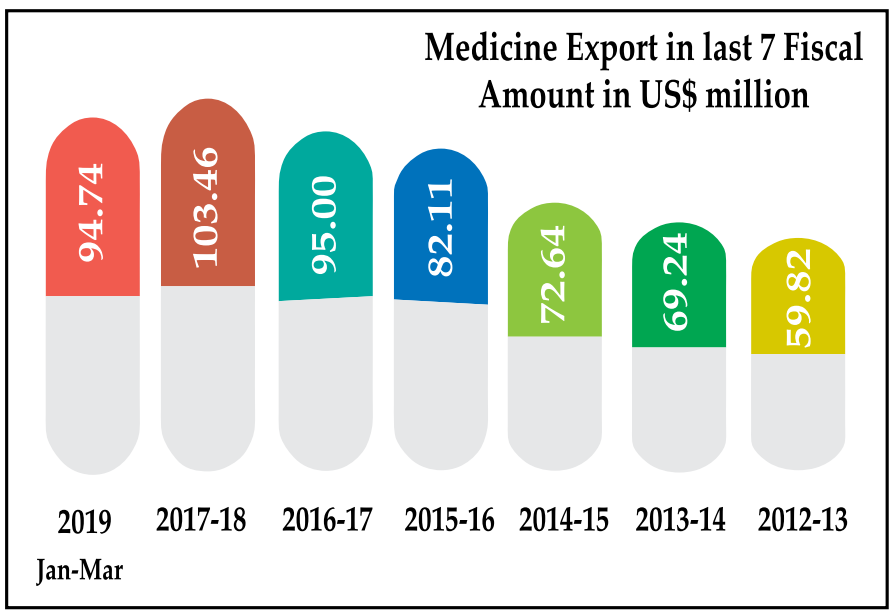
The medicine export earnings was $103.46 million in 2017-18, followed by $95 million in 2016-17, $82.11 million in 2015-16, $72.64 million in 2014-15, $69.24 in 2013-14 and $59.82 million in 2012-13 million, according to the data of the Export Promotion Bureau (EPB).

Experts opined that the pharmaceutical companies have the potential to earn more through exports in the next five years, but the sector needs fiscal benefits and policy support.

A couple of local companies have also gained access to the highly regulated markets of the US and the UK which is the major reason behind earning more from the sector, they said.

Talking to the Daily Industry, Nazmul Hassan, President of Bangladesh Association of Pharmaceutical Industries (BAPI) said cash incentive can encourage the stakeholders to increase export earnings as well as to supply low cost medicine for the people.

Cash incentive is must to consider the potentiality of the pharmaceutical sector, he pointed out. Drug testing is expensive which is mandatory for exports, he said adding a modern drug testing lab can ensure lower costs of the drugs.



The size of domestic market was worth $2 billion last year and the sector meets 97 percent of the local demand and the international medicine market size is more than Tk 120 billion. Over 100,000 people are directly involved in the pharmaceutical sector, said the sources.

There are some 257 registered pharmaceutical companies in Bangladesh, 194 of which are in operation. The industry manufactures about 5,600 brands of medicines in different dosage forms. Square, Incepta, Beximco, Eskayef, Opsonin, Renata, ACI, Acme, Aristopharma and Drug International are the top pharmaceutical companies by market share, sources said.

Minister for Health Zahid Malek said the government will provide the necessary support to the sector to help it become a top exporter. Industry insiders said if the pharmaceutical sector gets proper incentives and policy support for the next five years, exports will increase. The diversification of export products is needed to increase export in non-traditional market, experts said.

Lack of improvement in export diversification was due to four reasons including infrastructure deficit, present global economy and trade policy, lack of exportable industrial products, and withdrawal of generalized system of preferences (GSP). According to former Health Minister Mohammed Nasim, Bangladesh is currently exporting medicines to more than 151 countries across the world. India, Sri Lanka, Germany, USA, France, Italy, UK, Canada, The Netherlands and Denmark are the biggest importers of Bangladeshi medicines, Minister said.

The pharmaceutical sector of Bangladesh is one of the most prospective sectors which can grow close to 15 per cent for the next five years riding on the expanded domestic market as well as new foreign markets. Globally, healthcare provides are increasingly endorsing generic drugs and Bangladesh can capitalise the trend to penetrate the markets in the US, France, Germany, Japan and the UK, according to the experts.

Source: Daily Industry