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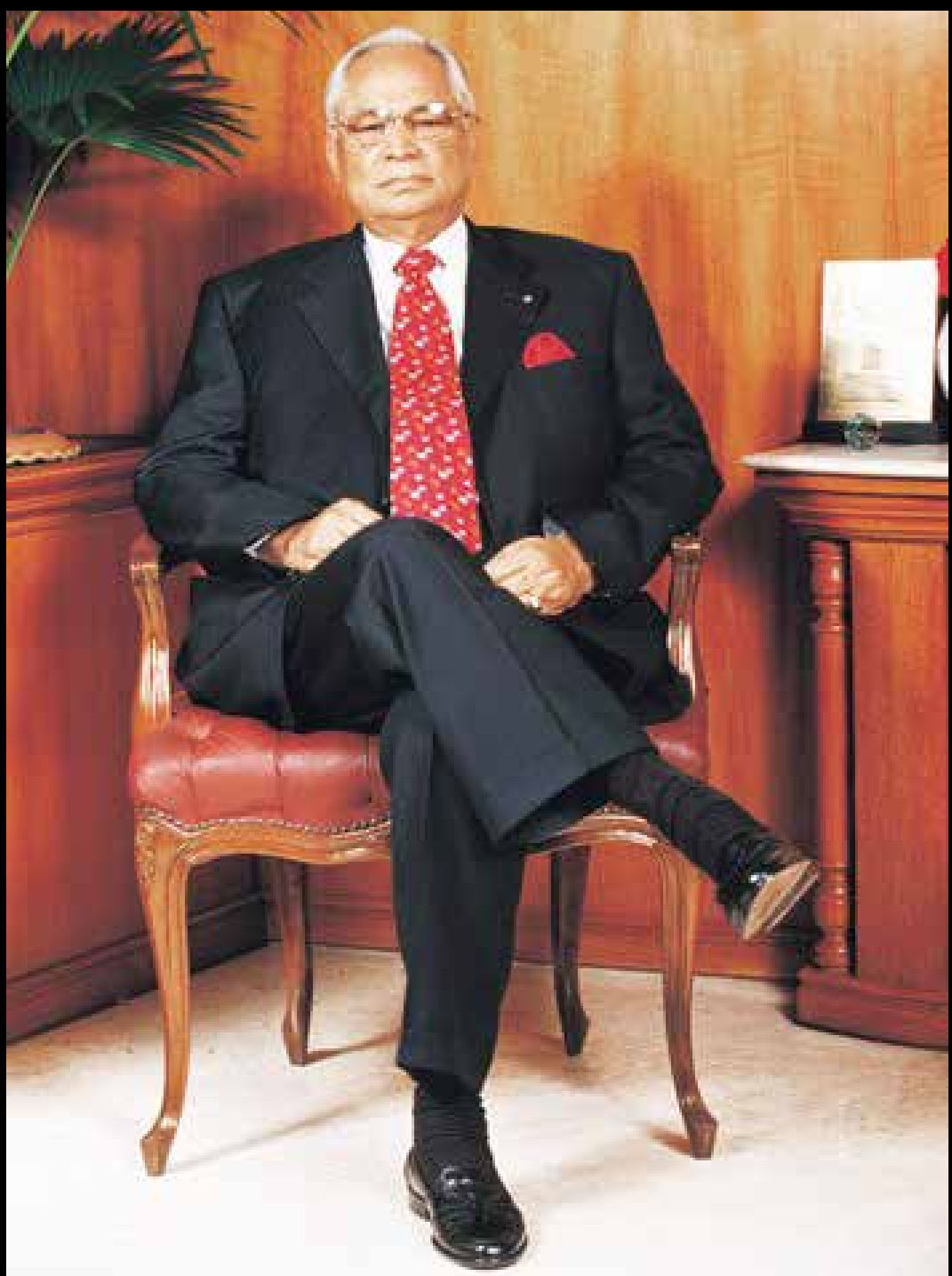
In memoriam ...

SAMSON H. CHOWDHURY



1925 – 2012

Aristopharma

Brand Name: Maxicon
Generic Name: Magaldrate + Simethicone
Dosage Form: Suspension
Strength: 480mg + 20mg/5ml
Indications: Hyperacidity, dyspepsia, gastritis, flatulence, heartburn & gas

Brand Name: Dicliz Plus
Generic Name: Doxylamine Succinate + Pyridoxine Hydrochloride
Dosage Form: Tablet
Strength: 10mg +10mg
Indication: For the treatment of Nausea & Vomiting during pregnancy

Brand Name: Linaglip Plus 500 & Linaglip Plus 850
Generic Name: Linagliptin + Metformin hydrochloride
Dosage Form: Film Coated Tablet
Strength: 2.5mg + 500mg & 2.5mg + 850mg
Indications: Indicated as an adjunct to diet and exercise to improve glycemic control in adults with type-2 diabetes mellitus.

Brand Name: Axim CV
Generic Name: Cefuroxime + Clavulanic Acid
Dosage Form: Tablet & Suspension
Strength: 250mg + 62.50mg, 500mg + 125mg Tablet & 125mg + 31.25mg/5ml Suspension
Indications: RTIs, UTIs, SSTIs, ENT infections etc.

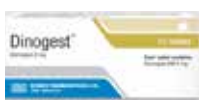
Asiatic

Brand Name: Ceftiten
Generic Name: Ceftibuten
Dosage Form: Capsule, PFS
Strength: 400mg, 60ml
Indications: Pharyngitis, Tonsillitis, Acute Bacterial Exacerbation of Chronic Bronchitis.

Brand Name: Clogfree
Generic Name: Clopidogrel
Dosage Form: Tablet
Strength: 75mg
Indications: Myocardial Infarction, Stroke, Acute Coronary Syndrome.

Brand Name: Rosunor
Generic Name: Rosuvastatin INN
Dosage Form: Tablet
Strength: 5mg, 10mg
Indications: Heterozygous & Homozygous Hypercholesterolemia, Mixed Dyslipidemia.

Beximco



Brand Name: Dinogest
Generic Name: Dienogest
Dosage Form: Tablet
Strength: 2mg
Indication: Treatment of Endometriosis

Brand Name: Vibose®
Generic Name: Voglibose
Dosage Form: Immediate release tablet
Strength: 0.2mg & 0.3mg
Indications: Improvement of postprandial hyperglycemia in diabetes mellitus, & prevention of onset of type 2 diabetes mellitus in impaired glucose tolerance.

Brand Name: D-Rise®
Generic Name: Cholecalciferol
Dosage Form: Capsule
Strength: 40000IU (cap), 20000IU (cap)
Indications: Indicated for the prevention and treatment of Vitamin D deficiency symptoms such as muscle weakness or muscle pain, fatigue, joint pain, bone pain, mood swing, depression, dizziness and eventually osteomalacia or osteoporosis.

Brand Name: Fixolin®
Generic Name: Doxofylline
Dosage Form: Tablet
Strength: Doxofylline 400mg
Indications: Maintenance therapy in

patients suffering with Asthma and Chronic Obstructive Pulmonary Disease (COPD).

Biopharma

Brand Name: Biocox 90
Generic Name: Etoricoxib
Dosage Form: Tablet
Strength: 90mg
Indications: Rheumatoid Arthritis, Osteoarthritis, and Gout & Dental Pain

Brand Name: Bestcol 5
Generic Name: Rosuvastatin
Dosage Form: Tablet
Strength: 5mg
Indications: Primary Dysbetalipoproteinemia (Type III Hyperlipopro, teinemia), Homozygous Familial Hypercholesterolemia, Slowing the Progression of Atherosclerosis and Primary Prevention of Cardiovascular Diseases.

Brand Name: Lirica 25
Generic Name: Pregabalin
Dosage Form: Capsule
Strength: 25mg
Indications: Diabetic Peripheral Neuropathic Pain, Fibromyalgia, Epilepsy and Neuropathic Pain with Spinal Cord Injury.

Brand Name: Biocort
Generic Name: Prednisolone Acetate 1%
Dosage Form: Sterile Eye Drops
Strength: 5ml
Indications: Indicated for the treatment of steroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe.

Brand Name: Mexclav 250
Generic Name: Cefuroxime + Clavulanic Acid
Dosage Form: Tablet
Strength: 250mg + 62.5mg
Indications: RTIs, UTIs, SSIs and SSTIs

Brand Name: Mexclav 500
Generic Name: Cefuroxime + Clavulanic Acid
Dosage Form: Tablet
Strength: 500mg + 125mg
Indications: RTIs, UTIs, SSIs and SSTIs

Brand Name: I-fort
Generic Name: Polyethylene Glycol 0.4% & Propylene Glycol 0.3%
Dosage Form: Sterile Eye Drops
Strength: 10ml
Indications: For the relieve of dry, irritated eyes caused by wind, sun, heating/air conditioning, computer use/ reading, and certain medications.

Brand Name: Optivir
Generic Name: Aciclovir 3%
Dosage Form: Eye Ointment
Strength: 5gm
Indications: Viral Conjuctivitis and Viral Keratitis

Brand Name: Kidsgro
Generic Name: Cod liver Oil with Multivitamin
Dosage Form: Syrup
Strength: 100ml
Indications: Ensures Physical & Mental growth of children, Improves appetite & digestion

Brand Name: Alerfast
Generic Name: Fexofenadine Hydrochloride
Dosage Form: Oral Suspension
Strength: 50ml
Indications: Allergic Rhinitis, Urticaria, Itchy Eyes and Sneezings.

Brand Name: Mexiderm-F
Generic Name: Fusidic Acid & Betamethasone
Dosage Form: Cream
Strength: 10gm
Indications: Eczema and Atopic Dermatitis

NEW ARRIVALS

Brand Name: Pimplex
Generic Name: Adapalene 0.1%
Dosage Form: Cream
Strength: 10gm
Indications: Acne Vulgaris.

Eskayef

Brand Name: Esoral
Generic Name: Esomeprazole
Dosage Form: Tablet
Strength: 20mg & 40mg
Indications: Gastric Ulcer, Symptomatic GERD

Brand Name: Hapytab
Generic Name: Desvenlafaxine
Dosage Form: Extended Release Tablet
Strength: 50mg
Indication: Major Depressive Disorder

Brand Name: Isobgul
Generic Name: Psyllium (Ispaghula) Husk
Dosage Form: Powder
Strength: 140g/Container & 3.5g/Sachet
Indications: Constipation, Constipation during pregnancy

Brand Name: Losectil
Generic Name: Omeprazole Sodium
Dosage Form: Capsule
Strength: 20mg
Indications: Peptic ulcer, Gastroesophageal Reflux Disease (GERD), NSAIDs induced gastric ulcer, acid related dyspepsia, Oesophagitis.

Brand Name: Miraten PD
Generic Name: Butamirate Citrate
Dosage Form: Pediatric Drops
Strength: 5mg/15mL
Indications: Dry cough, Productive cough, whooping cough, Pre & Post-operative cough.

Brand Name: Rivarox 2.5
Generic Name: Rivaroxaban
Dosage Form: Tablet
Strength: 2.5mg
Indication: Acute Coronary Syndrome (UA, STEMI etc.)

Brand Name: Romfen S
Generic Name: Bromfenac
Dosage Form: Ophthalmic Solution
Strength: 0.07%
Indication: Ocular pain and inflammation

Brand Name: Salomax
Generic Name: Salbutamol Sulfate
Dosage Form: Tablet
Strength: 4mg
Indication: Asthma and COPD

Brand Name: Xinc
Generic Name: Zinc Sulfate Monohydrate
Dosage Form: Syrup
Strength: Elemental Zinc 10mg/5mL
Indications: For prevention and treatment of Zinc deficiency.

General

Brand Name: Moxigen
Generic Name: Moxifloxacin Hydrochloride
Dosage Form: Tablet
Strength: 400mg
Indications: Community acquired Pneumonia, exacerbation of Chronic Bronchitis, sinusitis, mild to moderate pelvic inflammatory disease and complicated skin & soft tissue Infection.

Brand Name: Urolosin-D
Generic Name: Tamsulosin HCl+Dutasteride
Dosage Form: Capsule
Strength: 0.4 mg+0.5mg
Indications: Moderate to severe symptoms of Benign Prostatic Hyperplasia (BPH).

Globe

Brand Name: Sucosit 50
Generic Name: Sitagliptin INN
Dosage Form: Tablet
Strength: 50mg

Indications: Indicated for patients with T2DM. It can be used as mono-therapy and also be used with Metformin, Sulfonylurea or Thiazolidinediones. Sucosit can also be used as add-on to Insulin (with or without Metformin) when diet and exercise plus stable dose of Insulin do not provide adequate glycemic control.

Brand Name: Sucosit 100
Generic Name: Sitagliptin INN
Dosage Form: Tablet
Strength: 100mg
Indications: Indicated for patients with T2DM. It can be used as mono-therapy and also be used with Metformin, Sulfonylurea or Thiazolidinediones. Sucosit can also be used as add-on to Insulin (with or without Metformin) when diet and exercise plus stable dose of Insulin do not provide adequate glycemic control.

Brand Name: Polyfiz
Generic Name: Iron Polymaltose + Folic acid + zinc.
Dosage Form: Tablet
Indications: Indicated for the prevention and treatment of deficiency of iron, folic acid and zinc, before, during and after pregnancy and lactation.

Jayson

Product Name: Parcef ®
Generic Name: Ceftriaxone
Dosage Form: Injection IV
Strength: 2g
Indications: Surgical Prophylaxis, Pneumonia, Typhoid Fever, Meningitis & Septicemia.

Julphar

Brand Name: Velpacee
Generic Name: Velpatasvir + Sofosbuvir
Dosage Form: Tablet
Strength: 100mg + 400mg
Indication: Chronic Hepatitis C (Genotype 1-6) with or without cirrhosis

Brand Name: Eltrom
Generic Name: Eltrombopag
Dosage Form: Tablet
Strength: 25mg
Indication: Thrombocytopenia with chronic immune thrombocytopenic purpura, severe aplastic anemia and thrombocytopenia with Hepatitis C

Brand Name: Nexanib
Generic Name: Sorafenib
Dosage Form: Tablet
Strength: 200mg
Indication: Hepatocellular carcinoma and renal cell carcinoma

Brand Name: Enbee
Generic Name: Entecavir
Dosage Form: Tablet
Strength: 0.5mg
Indication: Chronic Hepatitis B

Brand Name: Refla
Generic Name: Deflazacort
Dosage Form: Tablet
Strength: 6mg & 24mg
Indication: Asthma, allergic reaction, anaphylaxis, rheumatoid arthritis, juvenile chronic, arthritis, ulcerative colitis, optic neuritis, dermatomyositis, nephrotic syndrome, anaemia, all kinds inflammatory Conditions

Brand Name: Maxwel
Generic Name: Multivitamin and Multimineral
Dosage Form: Tablet
Indication: For the treatment and prevention of vitamin and mineral deficiencies associated with restricted diets, improper food intake, and also indicated in patients with increased requirement for vitamin and minerals due to acute and chronic diseases, pregnancy, lactation, menopause, infections during treatment with antibiotics, convalescence.

Navana

Brand Name: Cfresh Liquigel
Generic Name: Carboxymethylcellulose Sodium 1% (CMC 1%)
Dosage Form: Sterile Eye Drops
Strength: Carboxymethylcellulose Sodium USP 10mg/10ml
Indications: As a lubricant in dry eye (keratoconjunctivitis sicca) including relief of burning, irritation and/or discomfort due to dryness of the eye

Brand Name: Stedex
Generic Name: Dexamethasone Phosphate 0.1%
Dosage Form: Sterile Eye/Ear Drops
Strength: Dexamethasone Phosphate 1mg
Indications: *Eye:* Steroid responsive Inflammatory conditions of the palpebral and bulbar conjunctiva, cornea, and anterior segment of the globe, such as allergic conjunctivitis, keratitis, iritis, scleritis, corneal injury from chemical or thermal burns or penetration of foreign bodies.

Ear: Steroid responsive inflammatory conditions of the external auditory meatus, such as allergic otitis externa, selected purulent and nonpurulent infective otitis externa when the hazard of steroid use is accepted to obtain an advisable diminution in edema and inflammation.

Brand Name: Levoquin TS
Generic Name: Levofloxacin Hemihydrate 1.5%
Dosage Form: Sterile Eye Drops
Strength: Levofloxacin Hemihydrate 15mg
Indications: Levoquin Sterile Eye Drops is indicated for the treatment of bacterial conjunctivitis caused by susceptible strains of gram-positive bacteria. It is also effective in post-operative infections.

Brand Name: Diplin 5
Generic Name: Linagliptin INN
Dosage Form: Tablet
Strength: 5mg
Indications: Indicated as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.

NIPRO JMI

Brand Name: Erdostin
Generic Name: Erdosteine
Dosage Form: Capsule
Strength: 300mg
Indication: For symptomatic relief of AECB & COPD

Brand Name: Pandura
Generic Name: Clonazepam
Dosage Form: Tablet
Strength: 0.5mg, 1mg, 2mg
Indication: Panic Disorder & Seizure Disorder

Brand Name: Losarva Plus
Generic Name: Losartan + Hydrochlorothiazide
Dosage Form: Tablet
Strength: 50mg + 12.5mg
Indication: Hypertension & left ventricular hypertrophy.

One Pharma

Brand Name: Dantron
Generic Name: Ondansetron
Dosage Form: Tablet, Syrup
Strength: 8mg, 4mg/5ml (50ml)
Indications: Post-operative nausea & vomiting, chemotherapy induced nausea & vomiting, radiotherapy induced nausea & vomiting, pregnancy induced nausea & vomiting and Gastroenteritis.

NEW ARRIVALS

Brand Name: Ponos
Generic Name: Aceclofenac
Dosage Form: Tablet
Strength: 100mg
Indications: Relief of pain and inflammation in both acute and chronic pain like OA, RA, AS, dental pain, post-traumatic pain, low back pain, gynecological pain etc.

Brand Name: Onecof
Generic Name: Ambroxol HCl
Dosage Form: Syrup
Strength: 15mg/5ml
Indications: Acute and chronic diseases of respiratory tracts associated with viscid mucus including acute and chronic bronchitis, productive cough, inflammatory diseases of rhinopharyngeal tract (e.g. Laryngitis, Pharyngitis, Sinusitis and Rhinitis), bronchial asthma with difficult departure of mucus.

Brand Name: Onefix
Generic Name: Cefixime Trihydrate
Dosage Form: Capsule, PFS
Strength: 200mg, 400mg, 100mg/5ml (30ml, 50ml)
Indications: URTI, LRTI, UTI, Typhoid fever and oral switch therapy.

Brand Name: Sharpkil
Generic Name: Cefuroxime Axetil
Dosage Form: Tablet
Strength: 250mg, 500mg
Indications: URTI, LRTI, SSTI, UTI, Gonorrhoea, early Lyme disease & subsequent prevention of late Lyme disease.

Brand Name: Onepro
Generic Name: Esomeprazole
Dosage Form: Tablet
Strength: 20mg, 40mg
Indications: Gastroesophageal Reflux Disease (GERD), Peptic ulcer, NSAIDs induced ulcer and other acid related disorders.

Brand Name: Airway
Generic Name: Montelukast
Dosage Form: Tablet
Strength: 5mg, 10mg
Indications: Prophylaxis and chronic treatment of Asthma, prevention of exercise induced Bronchoconstriction (EIB), relief of Allergic Rhinitis (AR).

Brand Name: Telfadin
Generic Name: Fexofenadine HCl
Dosage Form: Tablet, Oral Suspension
Strength: 120mg, 180mg, 30mg/5ml (50ml)
Indications: Seasonal and perennial Allergic Rhinitis (AR), Chronic Idiopathic Urticaria (CIU).

Brand Name: Onecal-D
Generic Name: Calcium Carbonate + Vitamin D3
Dosage Form: Tablet
Strength: Calcium Carbonate 500mg + Vitamin D3 200IU
Indications: Osteoporosis, osteomalacia, rickets, hypoparathyroidism, latent tetany, hypocalcaemia.

Brand Name: Azikil
Generic Name: Azithromycin
Dosage Form: Tablet, PFS
Strength: 500mg, 200mg/5ml (50ml, 35ml)
Indications: URTI, LRTI, SSTI, typhoid fever, gonoccocal & non-gonoccocal urethritis and cervicitis, genital ulcer disease(chancroid), diarrhea, Shigellosis.

Brand Name: Pileus
Generic Name: Fluconazole
Dosage Form: Capsule
Strength: 50mg & 150mg
Indications: Acute or recurrent vaginal candidiasis, mucosal candidiasis (as oropharyngeal candidiasis, oesophagitis, candiduria), systemic candidiasis and cryptococcal infections (including meningitis).

NEW ARRIVALS

Brand Name: Omelock
Generic Name: Omeprazole
Dosage Form: Capsule
Strength: 20mg, 40mg
Indications: Peptic ulcer, Gastroesophageal Reflux Disease (GERD), NSAIDs induced ulcer, Acid related dyspepsia, oesophagitis.

Opsonin

Brand Name: Cildip®
Generic Name: Cilnidipine INN
Dosage Form: Tablet
Strength: 5mg & 10mg
Indications: Hypertension, Angina & Coronary Artery Disease

Brand Name: Urilit®
Generic Name: Potassium Citrate BP
Dosage Form: Tablet
Strength: 1.08gm
Indications: Renal Tubular Acidosis with Calcium Stones, Uric Acid Lithiasis with or without stones.

Brand Name: Precodil®
Generic Name: Prednisolone BP
Dosage Form: Tablet
Strength: 2mg
Indications: Allergies, arthritis, breathing problems (eg, asthma), certain blood disorders, collagen diseases (eg, lupus), certain eye diseases (eg, keratitis), cancer (eg, leukemia), endocrine problems (eg, adrenocortical insufficiency), intestinal problems (eg, ulcerative colitis), swelling due to certain conditions, or skin conditions (eg, psoriasis).

Brand Name: Calnor®
Generic Name: Amlodipine + Olmesartan Medoxomil BP
Dosage Form: Tablet
Strength: 5mg+40mg
Indications: Hypertension with co-existing Diabetes & Uncontrolled Hypertension.

Brand Name: Linexil®
Generic Name: Linezolid INN
Dosage Form: IV infusion
Strength: 2mg/ml (300ml)
Indications: Complicated & uncomplicated SSTI, Community acquired pneumonia, Nosocomial pneumonia, Vancomycin resistant infections.

Brand Name: Larb® Plus
Generic Name: Losartan Potassium USP + Hydrochlorothiazide BP
Dosage Form: Tablet
Strength: 100mg+12.5mg
Indications: Hypertension with co-existing diabetes, Hypertension with renal impairment.

Brand Name: Ropitor ®
Generic Name: Rosuvastatin Calcium INN
Dosage Form: Tablet
Strength: 20mg
Indications: Hyperlipidemia, Hypercholesterolemia, Atherosclerosis, Primary Prevention of Cardiovascular Disease

Brand Name: Tiniril®
Generic Name: Betahistine dihydrochloride
Dosage Form: Tablet
Strength: 16mg
Indications: Vertigo, Tinnitus, Hearing loss associated with Meniere's diseases

Brand Name: Magacil® Plus
Generic Name: Magaldrate USP + Simethicone USP
Dosage Form: Chewable Tablet
Strength: 480mg+20mg
Indication: Hyperacidity related disorder

Brand Name: Eziride®
Generic Name: Hyoscine Hydrobromide
Dosage Form: Chewable Tablet
Strength: 150mcg
Indications: Motion sickness & Clozapine induced hyper salivation.

NEW ARRIVALS

Popular

Brand Name: Pelverin
Generic Name: Alverine Citrate BP
Dosages Form: Tablet
Strength: 60mg
Indication: Alverine is indicated for the treatment of Irritable Bowel syndrome, bowel movement disturbances, abdominal pain associated with menstrual periods, Relief of other conditions associated with spasm of involuntary muscle.

Brand Name: Clavurox
Generic Name: Cefuroxime + Clavulanic Acid
Dosages Form: Suspension
Strength: 5ml contains 125mg + 31.25mg
Indications: Clavurox is indicated for the treatment of common bacterial infections; e.g. ENT infections, acute bacterial exacerbations of chronic bronchitis, skin and skin structure infections, urinary tract infections, bone and joint infections, meningitis, septicemia etc.

Brand Name: Doxofyl
Generic Name: Doxofylline INN
Dosages Form: Tablet
Strength: 200mg & 400mg
Indication: Asthma, COPD & Bronchospasm.

Brand Name: Herpigel
Generic Name: Ganciclovir USP
Dosages Form: Eye Gel
Strength: 0.15%.
Indication: Herpigel is indicated for the treatment of acute herpetic keratitis.

Square

Brand Name: Utal
Generic Name: Ulipristal Acetate
Dosage Form: Tablet
Strength: 5mg
Indication: Uterine Fibroids.

Brand Name: Solider
Generic Name: Solifenacin Succinate
Dosage Form: Tablet
Strength: 5mg & 10mg
Indication: Overactive Bladder (OAB).

Brand Name: Mirakof
Generic Name: Butamirate Citrate
Dosage Form: Paediatric Drops
Strength: 15ml
Indication: Dry cough.

Brand Name: Bonizol
Generic Name: Zoledronic Acid
Dosage Form: Solution for infusion
Strength: 5mg/100ml
Indication: Osteoporosis.

Brand Name: Ulpep
Generic Name: Hingastak churna
Dosage Form: Capsule
Strength: 500mg
Indications: Gastritis, Gastric Ulcer & Duodenal Ulcer, Dyspepsia, Indigestion.

Brand Name: Jorvan
Generic Name: Jogaraj Guggulu
Dosage Form: Capsule
Strength: 500mg
Indications: Rheumatoid & Osteoarthritis pain, Neuralgias & Myalgias, Spondylitis, Backaches, Joint pain/ Arthralgia, Muscle sprain, and Joint stiffness.

Sandoz and Beximco Pharmaceuticals join the Medicines Patent Pool's growing network of generic manufacturing partners

The Medicines Patent Pool (MPP) announced the expansion of its network of generic manufacturers to include Sandoz and Beximco Pharmaceuticals Ltd. to help produce much needed hepatitis C treatments for developing countries. Both companies have signed sub-licensing agreements to manufacture Bristol-Myers Squibb's (BMS) daclatasvir (originator brand Daclinza), a new direct-acting antiviral for hepatitis C that, when used in combination with other treatments, is proven to cure multiple genotypes of the HCV virus. The MPP signed a licence and technology transfer agreement with BMS for the treatment in November, 2015.

Beximco Pharma becomes the first Bangladeshi company to achieve this unique feat following a thorough review done by the MPP. On joining the MPP's prestigious network of generic suppliers, Managing Director of Beximco Pharma, Nazmul Hassan MP said: "We are glad to be a part of this global network as the first Bangladeshi company and we believe our competitive cost of production will help improve access to this new and highly effective hepatitis C treatment for patients in many low- and middle-income countries". MPP is working to increase access to HIV, viral hepatitis C and tuberculosis treatments in low- and middle-income countries. Through its innovative business model, the MPP partners with governments, industry, civil society, international organisations, patient groups and other stakeholders to forecast, prioritise and license needed medicines. MPP is now working with fifteen generic companies on more than 100 projects to manufacture, register and deliver 13 World Health Organization-recommended HIV and hepatitis C treatments to up to 131 countries in the developing world. As of now, daclatasvir has been sub-licensed to Sandoz, Aurobindo, Cipla, Emcure, Hetero, Laurus, Natco Pharma Ltd and Zydus Cadila.

Beximco wins 3rd nod for generic drug from USFDA

Beximco Pharmaceuticals is now set to launch Metformin Hydrochloride extended-release tablets in two strengths, 500mg and 750mg, in the US market in the middle of next year, Beximco said in a statement. This is the third product from Beximco approved by the FDA. Metformin Hydrochloride tablets are generic equivalent of Bristol-Myers Squibb's Glucophage XR tablets in 500mg and 750mg strengths. Metformin is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes mellitus. Annual sales for Glucophage XR in the US were $918 million for the 12 months to October 2016, Beximco said, citing data from the Intercontinental Marketing Services.

"We are glad to receive our third product approval for the US market and this clearly demonstrates our competitive in-house capabilities, especially our strengths in extended-release formulation," said Nazmul Hassan, Managing Director of Beximco Pharma. Beximco Pharma, a unit of Beximco Group, first received the permission from the FDA to export medicines to the American market in November last year.

Beximco Pharma forms joint venture with Malaysia's BioCare

Beximco Pharmaceuticals announced the creation of a joint venture with BioCare Manufacturing based in Malaysia. Beximco Pharma will provide full technical support to BioCare to establish manufacturing facilities at Seri Iskandar Pharmaceutical Park in Malaysia to produce pharmaceutical products.

Beximco will own 30 percent of the equity shares in the company while BioCare will operate and fund the facility, Beximco Pharma said in a statement recently. "This is our first overseas manufacturing collaboration," said Nazmul Hassan, Managing Director of Beximco Pharma.

In the first phase of the project, a metered dose inhaler facility has been created and has received endorsement from Malaysia's health ministry for good manufacturing practices. Beximco Pharma expects the joint venture's first sales from the facility will be made during 2017. The company does not expect a significant contribution to its profits from the collaboration in the short term.

The Malaysian government's initiatives are aimed at increasing investment in the country's pharmaceutical industry to provide dedicated drug manufacturing facilities, improve generic drug capabilities and promote local production to qualify for government procurement.

BioCare Group, the majority shareholder of BioCare, has a strong presence in key therapeutic segments in both government and private healthcare sectors in Malaysia.

START EARLY, CHANGE DIABETES: MASHRAFE

Bangladesh one-day and T-20 cricket captain Mashrafe Bin Mortaza urged people living with diabetes to start a good innings as early as possible for changing diabetes.

"If anyone wants to live well with diabetes, the best option is to be diagnosed and treat early to avoid long term complications," Mashrafe said at press meet on 'Start Early, Change Diabetes'. The press meet was organized by Danish pharma giant Novo Nordisk, who is working for changing diabetes over 50 years in Bangladesh. The captain recently joined with Novo Nordisk and Diabetic Association of Bangladesh (DAB).

The captain will work to create awareness on the primary prevention, early diagnosis, better treatment and good control of diabetes. He will also focus on the benefit of healthy lifestyle and diet to prevent diabetes.

Mashrafe said: people living with diabetes should maintain 678 numbers to live well. He explained six as blood glucose level before breakfast, seven as HBA1C (three-month average blood glucose level) and eight as blood glucose level two hours after breakfast.

Peter Ulvskjold, Corporate Vice President, Business Area South East Asia, said, unfortunately, diagnosis in itself is not enough to reverse the global diabetes burden. Out of the people who are diagnosed with diabetes, it is estimated that around 50 percent receive care –however, less than half of those who receive care achieve their treatment targets, Peter said.

Therefore, our focus area is to ensure that people with diabetes receive the right care and support to live a good life with diabetes, Peter added. A Rajan Kumar, Managing Director of Novo Nordisk, said: "Our ultimate aim is to ensure that more people can live a life with diabetes free of complications."

Dr. Mohammad Saiful, Head of Marketing of Novo Nordisk said: "Our changing diabetes activities will help patients to achieve their control and also help the country to achieve sustainable development goals."

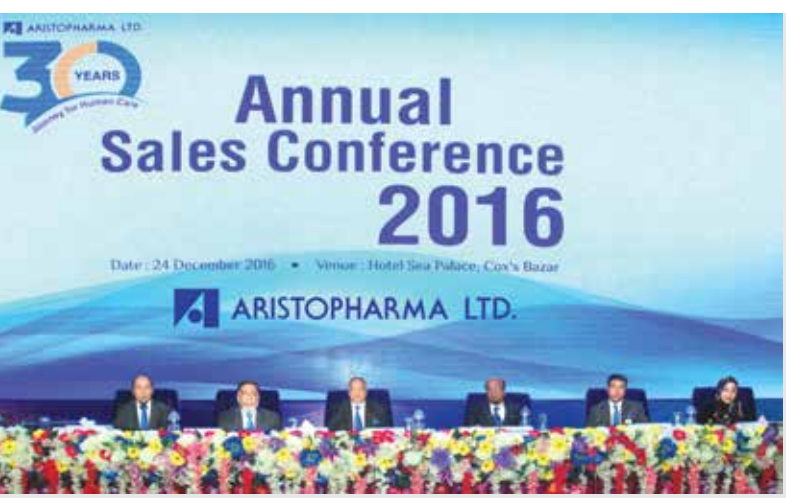
Incepta holds Annual Sales Conference 2017

Incepta Pharmaceuticals Limited organised its Annual Sales Conference-2017 at the International Convention City, Bashundhara in the city recently.

Hasneen Muktadir, the Vice-chairman of Incepta Pharmaceuticals Limited inaugurated the conference, while Chairman and Managing Director Abdul Muktadir discussed about the various success stories of Incepta in 2016 in the local and international markets. He also focused on the objectives for 2017. He mentioned that Incepta continues its journey towards its inherent vision to become a global company with strong footstep all over the world by maintaining a constant commitment to research, developing innovative products and quality management.

As recognition of export business, Incepta has earned the Silver Export Trophy for the fiscal 2013-14.

Hasneen Muktadir said that Incepta is continuously trying to launch electrifying & market winning products with an objective to provide these products at an affordable price along with maintaining its high quality. Best performers and achievers were awarded for their excellent performance in 2016. The daylong program ended with a colorful cultural program.



Aristopharma celebrates its 30 Years Journey and Annual Sales Conference-2016

Aristopharma, one of the leading pharmaceutical companies of Bangladesh, celebrated its 30 Years Journey and Annual Sales Conference recently at Cox's Bazar. The company started its operation in 1986 and in 2016 it has completed its 30th year of glorious journey. Currently Aristopharma ranks no. 7 among all local and multinational companies in Bangladesh Pharma market & no.1 position in the Ophthalmic market of Bangladesh. Moreover, it also exports medicines to around 33 countries of the world.

The Chairman & Managing Director of Aristopharma, M. A. Hassan, thanked all of his employees for their devotion towards the company & also informed about its new factory located at Gachha, Gazipur which will open export opportunities to regulated markets like Europe & America. Other directors and senior officials also shared strategies for future development of the company. Around two thousand and five hundred employees working in different parts of the country attended the conference. At the end, awards were given to the achievers in different categories.

Opsonin Pharma holds Annual Sales Conference 2017

The "Annual Sales Conference 2017" of Opsonin Pharma Limited was held at the International Convention City Bashundhara ICCB in the city recently. A large number of field level officials of the company attended the conference, says a press release.

Opsonin Pharma Ltd. has achieved significant growth in 2016 among top pharmaceutical companies of Bangladesh. Currently the company is holding 4th position in terms of sales volume in the pharma market of Bangladesh, the press release claimed.

Chairman Captain Abdus Sabur Khan (Retd.), Managing Director Abdur Rouf Khan, Deputy Managing Director Abdur Rakib Khan, Director Marketing and Sales Syed Golam Rahman, General Manager Sales Abdul Momen Talukder, Manager Product Management Department, Sudip Kumar Saha and other high officials were also present in the conference.

Director Marketing and Sales Syed Golam Rahman discussed different aspects of sales and prescription of the year 2016 and focused on the marketing and sales planning for the year 2017.

NIPRO JMI Pharma Annual Sales Conference held

NIPRO JMI Pharma, a Japan Bangladesh joint venture company, arranged Annual Sales Conference 2016 at the International Convention Center, Bashundhara, Dhaka recently. Md. Abdur Razzaq, the Managing Director, inaugurated the program and expressed his gratitude to all employees for the incredible growth of the company. He also expressed his profound gratefulness to the physicians and other stakeholders for their sincere support. Considering the huge demand, he addressed to launch high-tech products like Biotech, Sterile, Steroids and Hormones in the near future to uphold the company position in Pharma Industry.

Md. Mizanur Rahman, Chief Executive Officer (CEO) of the company highlighted the achievements of 2016 and placed the objectives and action plan for 2017. He also thanked all participants for making the conference successful.

Chairman of the organization, Jabed Iqbal Pathan revealed that NIPRO JMI Pharma has started exporting medicine in different countries of the world and it is growing day by day. Other Directors, foreign delegates and Managers along with around 1000 sales personnel coming from different regions of the country were also present at the conference.

JAYSON PHARMA HOLDS ANNUAL SALES AND MARKETING CONFERENCE 2016

The Annual Sales and Marketing Conference 2016 of Jayson Pharmaceuticals Ltd. was held recently in Dhaka. All Managers and officials of the company participated in the program enthusiastically and with great inspiration. Md. Salimullah, honorable Chairman of the JAYSON Group, inaugurated the program. All Directors of JAYSON group, General Manager (Sales & Marketing) and Sales Manager graced the occasion with their presence.

Apollo Hospitals Dhaka saves the life of 1.3 pound New born for the first time in Bangladesh

Apollo Hospitals Dhaka has successfully managed and treated a newborn with a weight of 1.3 pounds. It is the first case in Bangladesh, in which a newborn of 1.3 pound has survived in Bangladesh. The mother of the baby had chronic hypertension which led to a superimposed pre-eclampsia in spite of taking anti-hypertensive medication. Due to less fetal movement and growth and the condition of the mother and decrease in blood circulation of the baby, a caesarian surgery was performed on the mother by Dr. Gulshan Ara, Senior Consultant and Coordinator, Gynaecology & Obstetrics, Apollo Hospitals Dhaka. The baby was born during 28 weeks of the pregnancy period of the mother. The early delivery of the child deprived her of complete immunity making her infection prone.

Among many complications, the newborn suffered from congenital heart defect, retinal problems, urinary tract infection, anemia and milk protein allergy- disabling the child from breastfeeding. After treatment of the newborn for 95 days by Dr. Abu Sayeed Mohammad Iqbal - Coordinator & Senior Consultant – Paediatrics, the child is now of 3 months, currently leads a healthy life similar to any other infant of similar age. This is the first case in Bangladesh in which a newborn of this weight has survived. To discuss this case in details a press conference was organized in the auditorium of Apollo Hospitals Dhaka recently in which Dr. Ratnadeep Chaskar, Chief Operating Officer, Enayet Ullah Khan, Director, Business Development, Dr. Arif Mahmud, Senior General Manager, Medical Services and consultants of the hospital were present.

Eskayef pledges to conquer with courage

Eskayef Bangladesh Limited renamed as Eskayef Pharmaceuticals Limited

Eskayef, one of the leading pharmaceutical companies in Bangladesh organized its Annual Conference 2016 in the International Convention City Bashundhara (ICCB), Dhaka recently.

The theme of the conference took inspiration from the unshakable courage of Faraaz Ayaaz Hossain, who sacrificed his life for humanity & friendship through displaying outstanding courage during the horrific incident at the Holey Artisan Bakery in Dhaka.

With the theme- 'Conquer with Courage', Eskayef's team from across the country pledged to display the spirit of Faraaz Hossain throughout their professional & personal lives.

The conference started with a minute of silence in memory of Faraaz & others who were martyred in the terror attack of July 1st. Zaraif Hossain, elder brother of Faraaz delivered an emotional yet motivational speech to around 3500 professionals of Eskayef.

Anisul Hoque, the eminent writer & Associate Editor of the Prothom Alo said, 'Faraaz got his learning of self-sacrifice from his mother. We are so proud to have a mother like Faraaz's mother in Bangladesh.'

'Faraaz showed determination, he showed courage of conviction, he demonstrated the highest value of doing what is right', said Latifur Rahman, the Chairman of Transcom Group & Eskayef Bangladesh Limited. During the speech, he urged everyone to work with courage, sincerity & ethics.

Simeen Hossain, Faraaz's mother, the Managing Director and CEO of Eskayef says, 'We must work hard together and convert our courage into driving force to take ourselves to newer heights & create history.' She also formally announced the renaming of Eskayef Bangladesh Limited to Eskayef Pharmaceuticals Limited, as Eskayef aims to continue expanding its reach even further in the global pharmaceutical arena. Simeen also placed an update on the noble humanitarian projects taken up by the Latifur & Shahnaz Rahman Foundation, an Eskayef initiative.

The company's directors including Shahnaz Rahman, Saifur Rahman, Atiqur Rahman, Arshad Waliur Rahman, Shahzreh Huq & Ahmed Shafi Chowdhury were present in the conference. Distinguished guests from other Transcom companies and Eskayef's business partners from Myanmar, Sri Lanka, Afghanistan & Ethiopia were also present in the event.

Director Marketing, Dr. Mohammad Mujahidul Islam presented the business overview of the company, Director Sales, Mir Mostafizur Rahman presented the sales review & Director Technical Services, Ikhtiar Hossain highlighted the technical aspects of the company.

The best performing professionals from both Eskayef & Transcom Distribution Company Limited received crest of honor from the chairman of Eskayef, Latifur Rahman.

Inauguration of Model Pharmacy

To improve access to affordable quality medicine and pharmaceutical services in retail drug outlets such as- model pharmacy and Model Medicine shop till Jan'17 a total no of 7 (seven) Model pharmacy in Dhaka and 5 (five) Model pharmacy and 3 (three) Model Medicine shop in Sylhet have been inaugurated by Honorable Health Minister Mohammad Nasim, MP, State Ministers for Health Zahid Maleque, MP and Director General of DGDA Major General Md. Mustafizur Rahman. This is a noble initiative taken by the present govt. which will improve consumers' access to an appropriate use of quality medicine and pharmaceutical services, greater consumer awareness of the importance of using medicine appropriately and the need for vigilance against fake and substandard medicine. This will also create employment opportunity for the pharmacists.

Development Fair-2017 held

A Development Fair–2017 was held recently in Dhaka and other districts of the country in honor of the celebration of the return day of Bangabandhu Sheikh Mujibur Rahman, the father of the nation . The head office of Directorate General of Drug Administration and the different district level offices under its control took part in this Development Fair. In this fair all offices of DGDA showed video clips and presentation on different issues like-

1. Different development activities of DGDA
2. Awareness about antibiotic resistance
3. Rational use of drugs
4. Pharmacovigilance
5. Presentation on DGDA daily activities monitoring dash board, website and face book of DGDA.

From this Development Fair the people of Bangladesh have been informed about different activities of DGDA which will have a positive impact on the use of medicines and medical devices.

DGDA Logo

A logo of the Directorate General of Drug Administration has recently been launched. This logo has red and green color similar to the color of National Flag of Bangladesh. In the middle, there is picture of capsule, syringe and leaf which is the symbolic presentation of allopathic, traditional medicine and medical devices. The magnifying glass symbolizes that DGDA regulate and monitor activities related to control of drug (allopathic, traditional) and medical devices.

Major Activities Performed by DGDA during Oct '16-Dec '16

1.	No of Total Drug License (Retail & Whole sale)	123680
2.	No of Renewal of Drug License (Retail & Whole sale)	9430
3.	No of Sample Collected for test	1405
4.	No of sample test	1932
5.	Issue of GMP Certificate	11
6.	Issue of CPP	848
7.	Issue of FSC	135
8.	Issue Form-10	327

Cases 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	Jail/ Sealed	Cost of Seized unregistered medicine, food supplement, Physician sample and Govt. medicine
October '16	3	0	255	4534900	Jail: 10 person sealed: 5 pharmacy	2582116
November '16	5	13	245	16357000	Jail: 5 person sealed: 3 pharmacy	56168092
December '16	1	25	116	2881500	Jail: 6 person sealed: 1 pharmacy	4260170
Total	**9**	**38**	**616**	**23773400**	**Jail:21person sealed: 9 pharmacy**	**63010378**

Recommendations guiding physicians in biomedical research involving human subjects

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> IT IS ESSENTIAL THAT THE RESULTS OF LABORATORY EXPERIMENTS BE APPLIED TO HUMAN BEINGS TO FURTHER SCIENTIFIC KNOWLEDGE AND TO HELP THE SUFFERING HUMANITY

Introduction

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient".

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part of experimentation involving human subjects.

In the field of biomedical research, a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because, it is essential that the results of laboratory experiments be applied to human beings to further scientific knowledge and to help the suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide for the physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries.

I. Basic Principles

1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation, and on a thorough knowledge and scientific literature.
2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor, provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.

3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interest of the subject must always prevail over the interest of science and society.
6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
7. Physician should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefit.
8. In publication of the results of his or her research, the physicians are obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
10. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case, the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with the national legislation.

Whenever the minor child is in fact able to give consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

1. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. Medical Research Combined with Professional Care (Clinical Research)

1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, reestablishing health or alleviating suffering.
2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic method.
3. In any medical study, every patient—including those of a control group, if any—should be assured of the best proven diagnostic and therapeutic methods.
4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee.
6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. Non-Therapeutic Biomedical Research Involving Human Subjects (Non-Clinical Biomedical Research)

1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of life and health of that person on whom biomedical research is being carried out.
2. The subjects should be volunteers—either healthy persons or patients for whom the experimental design are not related to the patient's illness.
3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.
4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject. ●

FDA Expectations on Data Integrity

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Introduction

Currently the world is data driven. The integrity of data is very crucial from FDA point of view. As per many regulatory bodies data integrity is the degree to which re-coded data is complete, consistent and accurate throughout its lifecycle. As per FDA, EMA TGA and MHRA, data manipulations, misrepresentation, tampering, unwarranted deletions/extensions and concealing are serious offence. In the last few years, FDA has issued warning letters and import alert to hundreds of companies in India and abroad. FDA expects that all data generated at the site must pass data integrity criteria as laid down in the official guidelines. It further requires that the data shall be recorded as the job is performed and original/certified copy of the same shall be maintained over its life cycle. FDA has turned very strict about meta-data i.e. date, time; author, subject associated with principle data sets. As per FDA Data Integrity is applicable to both paper and electronic data concerning with QC/QA/Production/R&D/Storage/ Distribution/Clinical Trials. In general it is applicable to all type of products including human drugs, veterinary products, cosmetics, medical devices, biotech products. The successful compliance to data integrity requires good documentation practices involving data entry/ maintenance/archiving/access control/ training and governance.

Current FDA Expectations

Current FDA Expectations for integrity of data are unlimited. FDA is seeking control over all types of static and experimental date generated/ applied to the site. The major FDA expectations with respect to data integrity are as per below:

1. Backup data shall be exact and complete in terms of configuration, values and style
2. Original and backup data shall be secured from alteration, inadvertent erasing, corruption, deletion, modifications and loss
3. Data Integrity System must ensure integrity of data as per ALCOA principles.
4. The Meta data i.e. file name, bytes, configuration, ownership time/date stamp shall be considered as an integral part of all data sets. The same shall be recorded along with the main data.
5. Hand written records shall be protected from weathering and damage
6. All types of data e.g. hand written, electronic and automatically generated shall be recorded as it is generated.
7. Each data shall be categorized as "Original" or True Copy or Controlled copy or uncontrolled copy"
8. The data sets shall be complete i.e. it shall represent all tests/ protocol/ observations/ comments/ signature/ data and time/product name
9. The automated and electronic data recording systems shall be validated through competent IT engineers from time to time.
10. Recorded data such as BMR, MFFR, SOP, Manuals, Certificates, HPLC Graphs, Spectrum data, Reports, APR, OOS reports, C&P plans and Training records shall be specifically checked for metadata/unwarranted additions/ deletions/ modifications/ corruption by the data owners or third parties.
11. The integrity of electronic submissions to regulatory authorities shall be verified using MD5 Checksum which can check/ compare configuration and bytes of original data with the transmitted data.
12. All data on electronic media must be protected from unwarranted modification through access control and audit trail.
13. Electronic data capturing system shall be validated initially and revalidated when upgraded/ downgraded or when shifted to new environment
14. Antivirus system shall be used for all electronic data and shall be validated/verified for its intended function
15. New electronic data handling systems/ devices shall be verified for functions such as creation/ modification/ transfer/ archiving/ migration/ transmission/ deletion of wide range of date-sets. The special checks shall be performed to verify images/ figures/ tabulated data in files
16. The radio buttons on all electronic data handling devices

shall be marked legibly and represent fixed set of values
17. All data handling systems shall be verified for acceptance/ saving/ transmission and functionality
18. Whenever electronic data is migrated/ transmitted to a new system, the intra-system compatibility shall be verified/validated
19. SOPs for corrective and preventive actions, OOS, training, internal audits, annual review, deviation control, change control, data capturing/ recording/ storage shall be in place for guidance of staff
20. There shall be pass-word and audit trail on all software and data recording systems
21. The management should ensure that the staff is not loaded with too much of data handling task so as to make them reluctant to data-integrity functions. Further the staff shall be equipped with suitable resources to practice/implement data integrity as required by FDA
22. The management and QA should ensure that the staff is aware of the importance of data integrity and its disastrous effect for non-compliance
23. QA must ensure that QC/ production staff do not have direct access to time and date stamping devices to automated date/time marking devices
24. Ensure that the batch records are filled parallel to the operation performed at the site of operation to prevent data errors arising from forgetfulness
25. Ensure that the blank batch records are distinctly numbered for accountability. Further ensure that discarded forms are stamped as discarded and maintained appropriately for traceability.
26. Monitor access rights and audit trail of automated systems in order to prevent falsification or unintentional changes
27. Ensure that automated data capturing and printing systems are installed in close proximity to the corresponding instrument such as weigh balances/pH meters
28. Ensure that in process sampling points are easily accessible so as to nullify temptation for falsification of records
29. Prevent direct access of unauthorized personnel to original data (This will restrict intentional falsification)
30. Review the audit trails regularly to detect unwarranted changes in electronic data
31. Regularly evaluate the efficacy of data handling system. Perform challenge tests
32. Regularly conduct training programs for data integrity
33. Be vigilant about time/date/ operator code as applied to manual/electronic data
34. Make sure that site has ample resources to improve data handling/ governing system
35. Ensure that all electronic data systems are validated, controlled and revalidated from time to time. Further conduct risk analysis for each system on regular basis
36. Monitor the suitability of EDP contractors. In case he is not up-to-date, employ additional resources
37. Ensure that subcontractors/ Contractors/ Loan Licensers/ Contract Laboratories comply to data integrity regulations as per FDA norms
38. Ensure IT service providers are well aware about data integrity requirements
39. Ensure that all personnel employed at the site are afraid to deliberate falsification of data
40. Ensure that all key personnel are trained in data integrity seriously and wholesomely
41. Ensure that there is clear undertaking from all key personnel for compliance to data integrity SOPs
42. Ensure that the paper records are legible, traceable and permanent
43. Ensure that paper documents are authored using permanent/ indelible ink. The lead pencils/ faint inks/loose papers shall be prohibited
44. Ensure that any error in manually recorded data is cancelled by using single-line cross-outs with name, date and reason
45. Ensure that opaque correction fluid are never used for obscuring the recorded data
46. Check that pages in bound notebooks/ registers/ forms are properly numbered/ coded as applicable
47. Check that issuance of reports/ Forms/ Notes/ Instruction memo is suitably controlled
48. Ensure that in eBMR, data is saved along with metadata after each entry
49. Ensure that electronic systems are configured to disable and prohibits to over writing
50. Strictly control configuration of data annotation tools so as to obscure data display
51. Ensure that each data file is annotated with metadata indicating the author, time and date of creation and place. Further, see that the metadata is readily available for review over retention period
52. All data shall be preserved in a secure and traceable manner
53. Ensure that HPLC Meta data holds username, date/time, integration parameters, and change justification if any
54. All static records (written records) shall be maintained in a safe and secure manner in chronological order
55. All 'dynamic' records such as soft copies shall be stored with access control and audit trail to detect any changes
56. All backup records (a true copy of the original data) shall be maintained securely and shall bear a marking (certified true copy)
57. The back electronic file should contain the data in a style matching with original data. The replicate data shall be comparable with original data
58. Ensure that the data recovered from crashed systems is not used as original data
59. Ensure that user manuals and standard operating procedures are available for handling hardware, software, peripheral devices, networking and cloud infrastructures
60. Ensure that data integrity is applied equally both to

cGMP data and GMP data

61. Ensure that whenever any data is modified/deleted/reformatted/recovered a scientific justification is provided
62. Note that data integrity is equally applicable to both manual and electronic data records
63. Be sure that data flow to electronic and manual systems is valuated
64. Ensure that the data integrity team is well trained to mitigate the risk associated with data creation, maintenance, replication and migration
65. Ensure that all elements concerning with data handling system e.g. man, methods, machines, hardware, software and materials are suitably controlled
66. Ensure that all automated and electronic data handling systems are validated for software, access control, audit trail, integrity against virus
67. Check that data handling systems are only configured by authorized personnel. Once configured the access shall be restricted
68. FDA suggests that Data Integrity System administrator role shall be assigned to a person who has both regulatory and system administration skills
69. Ensure that a list of authorized individuals and their access privileges for each data system is maintained
70. Ensure that only authorized individuals are permitted to enter, amend, stored and discard the recorded data
71. Ensure that blank forms issued for data entry are properly numbered and reconciled against the filled forms received back after data entry.
72. Ensure that incomplete or erroneous forms are kept as part of the permanent record along with written justification for their replacement
73. Ensure that any gap in manual/electronic records are properly explained
74. Ensure that unofficial records are neither created nor maintained
75. Ensure that all data sets are marked as "For official use" and are securely stored
76. FDA recommends that all blank forms such as BMR shall be controlled by serializing them
77. Electronic copies used as true copies of paper or electronic records shall preserve the original data and associated metadata
78. Ensure that electronic records are compatible with the assigned storage systems so as to maintain the entire content, style and meaning of the original records. Further, if the original data is readable by machine the duplicate record shall also have the same property
79. FDA considers audit trails as a part of actual electronic records. The audit trails shall be reviewed by QA personnel on regular basis to identify the unwarranted changes
80. FDA expects that a paper printout or static record as derived from operation of weighing balances, pH mater, and FTIR instruments shall satisfy all data integrity requirements. The record shall be complete and shall have clear time and date stamp. The record shall be achievable without deterioration of next and images
81. FDA permits electronic signature provided it can be clearly linked to the signatory
82. FDA expects that data integrity controls shall be applied to all critical data generated and archive at the site
83. FDA requires graphs/Charts/spectra and text matter generated during analysis shall be retained in original. The record shall be complete, true and factual. The doctoring of such record is strictly prohibited
84. FDA requires that the data shall be recorded and saved parallel to each completed action. The delayed entry is not acceptable
85. FDA expects that data recording system shall be designed in a way to prevent modification/falsification/corruption/deletion over required period.
86. Data integrity strongly prohibits data recording on loose papers
87. FDA requires that data shall not be stored in temporary files as data therein can be manipulated
88. FDA strongly prohibits testing multiple samples or multiple analysis of a single sample until the desired passing results are derived
89. FDA recommends that BMR shall be recorded using LIMS (Laboratory Information Management System) or EBRS (Electronic Batch Record System) which saves each entry individually
90. Ensure that suspected falsification or alteration of records are fully investigated to determine the effect of the event on product quality and safety
91. Ensure that all people at the site know that FDA is very strict about data integrity
92. Ensure that documents are very cautiously handled to avoid errors/ damage
93. FDA recommends audits/training/ CAPA/OOS investigations to maintain data integrity
94. FDA warrants that data has no value without metadata such as date, time, and authors' name, type of file, bytes and subject associated with it

SOPs for Data Integrity

FDA advocates that Data Integrity shall be managed through well designed standard procedures. The procedures shall be specific to organizational need and shall be maintained up-to-date.

In general at least following SOP shall be in place:

ID	SOP Title
1.	Data integrity: Training
2.	Data integrity: Preventing and Correcting Data Errors
3.	Data integrity: Management Role
4.	Data integrity: Duties And Responsibilities of Data Integrity Team

5.	Data integrity: Archiving electronic data
6.	Data integrity: Auditing data integrity systems
7.	Data integrity: Checking Deficiencies in Electronic Records
8.	Data integrity: Checking the integrity of Raw Data
9.	Data integrity: Validation of Data recording system on HPLC/GC
10.	Data integrity: Verification of calculation systems
11.	Data integrity: Verification of Batch Formula for transcription errors
12.	Data integrity: Verification of automated calculation systems
13.	Data integrity: internal audit
14.	Data integrity: HPLC /GC Systems
15.	Data integrity: Common errors
16.	Data integrity: Oath
17.	Data integrity: Scanned Documents
18.	Data integrity: Migrated data
19.	Data integrity: Prohibited acts in data handling and Management
20.	Data integrity: Entry in BMR
21.	Data integrity: Visual inspection records
22.	Data integrity: Checking integrity of Hand written and electronic records
23.	Data integrity: Self Audit Procedures
24.	Data integrity: Truncation and Rounding of Numbers
25.	Data integrity: Detecting fraudulently generated data
26.	Data integrity: Making entries in laboratory notebooks
27.	Data integrity: Duties and responsibilities
28.	Data integrity: Printed documents
29.	Data integrity: Controlling unwarranted changes
30.	Data integrity: Data migration
31.	Data integrity: Data Storage and archiving
32.	Data integrity: Planning
33.	Data integrity: Handling Electronic data
34.	Data integrity: Evaluation of Training procedures
35.	Data integrity: Manual
36.	Data integrity: Online Checks
37.	Data integrity: Handling HPLC Data (Negative List)
38.	Data integrity: Verification
39.	Data integrity: Error investigation plan
40.	Data integrity: Data archiving plan
41.	Data integrity: Verification of Calculation Systems

Please note that the above SOPs are just for the purpose of illustration. The type and content of SOPs will vary from site to site.

Conclusion

Pharma industry shall not take data integrity casually. It shall be adopted whole heartedly .There shall be standard procedures for designing, training and implementing. The risks, errors, omissions and falsification of the data shall be strictly prohibited.

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18. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm495891.pdf
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Source: The Pharma Review

Anti-Ulcerants: Are We in Right Track

S.M. YASIR ARAFAT[1] | MD. JAHID HASAN[2]

Proton pump inhibitors (PPIs) is a time tested drug for effective suppression of gastric acid and is indicated in several upper gastrointestinal disorders [1]. These drugs irreversibly inhibit the gastric H^+, K^+ ATPase pump and reduce both basal and stimulated gastric acid output [2]. They are shown to be effective in the treatment of gastro-esophageal reflux disease (GERD), peptic ulcers, and dyspepsia [3-6]. Along with antibacterials, they are used for the eradication of *Helicobacter pylori* [7]. PPIs are also prescribed as a concomitant medication to prevent non-steroidal anti-inflammatory drug (NSAID) associated ulcers in high-risk patients and also patients who receive Glucocorticoid for prolonged duration [8]. Two main indications for long-term use of PPIs are, reflux disease and use of maintenance non-steroidal anti-inflammatory drugs (NSAIDs), which puts patients at risk for non-steroidal gastropathy. Except for hyper secretory states, which are very rare disorders, most other indications for acid suppression do not require years and years of PPI exposure [9].

The National Institute for Health and Clinical Excellence (NICE) published its guidelines on proton pump inhibitors in 2000 [10]. Its recommendations for using these drugs—particularly in the long term—are relatively selective. Inspite of limited prescribing recommendation, rise of PPI usage is far beyond a change in morbidity [11]. These are frequently prescribed without a clear indication and for a longer period than recommended [12]. Although it might be assumed that overprescribing occurs mainly in primary care but inappropriate use of PPI in secondary care is also abundant [10]. In hospital inpatients taking proton pump inhibitors in Australia [13], Ireland [14], and the UK [12], respectively 63%, 33%, and 67% of patients did not meet their country's criteria for taking the drug. In a series of hospital inpatients in Michigan, USA, 20% of patients were taking a proton pump inhibitor on admission and another 40% were prescribed the drug during their hospital stay (mostly for prophylaxis). On discharge, half of the patients were taking a proton pump inhibitor—more than double the number who were taking the drug when admitted [15]. Another study from New Zealand found that 40% of hospital inpatients were taking proton pump inhibitors inappropriately [16].Two thirds of these patients were still taking the drugs on discharge and most were still taking them six months later. In a Swedish cohort of patients who had been taking proton pump inhibitors for four years, 27% were able to discontinue the drug altogether [17]. A prospective audit of a series of patients admitted as a medical emergency to a hospital in Wales found that a quarter of patients were taking a proton pump inhibitor. In only half of the patients was the indication for the drug deemed appropriate [18]. Though fewer data is available to our country it can be assumed that situation is almost same in Bangladesh.

PPI are relatively safe and less toxic in comparison to other drugs but it is not free from side-effects and cannot be overlooked. The long-term use of PPIs is associated with a higher risk of community acquired pneumonia, osteoporosis and hip fractures.[19-20] Another important recognized consequences of prolonged use is acute interstitial nephritis and pseudomembranous colitis.[19] An increase in the prevalence of pneumonia and *Campylobacter* enteritis is reported, as well as a doubling of the risk of infection with *Clostridium difficile*.[21] Investigators around the world have published many studies looking at longer-term exposure among patients may increase the risk of hepatotoxicity, nephrotoxicity, or other unusual side effects but fortunately incidence is not so common. More common potential adverse effects relating to the two known class effects of PPIs: Hypochlorhydria and Hypergastrinemia.[22] Rebound secretion of Hydrochloric acid after discontinuation of drug may potentiate increase sensation of burning and lead to further consumption of PPI.[22] Moreover several investigation had shown the strong association of iron deficiency anemia with prolonged use of PPI which may be fatal if untreated.[23]

Besides, side-effect profile, it causes enormous burden of health expenditure throughout the world. In the United Kingdom, they constitute the largest expenses for any single drug group [24]. In 2006, expenditure on these drugs was £425m (€595m; $872m) in England [25]. Germany has resulted in an annual spend of € 927 million (i.e. $ 1.2 billion) in 2010 and £7bn globally [26]. Bangladesh is a densely populated country with significant health related Millennium Development Goals (MDGs) with progressive pharmaceuticals sector mostly driven by anti-ulcerants [27-33]. The current market size is about 14 billion with having almost persistently double-digit growth. There are 267 licensed pharmaceutical companies and the market is almost self-sufficient in meeting local demand as 97% of the drugs are manufactured locally [27-33]. Anti-Ulcerants are significantly dominating the huge volume sale with marked impact on company revenue. Recent tradition shows, anti-ulcerants as a therapeutic class tops the whole market with having about 15% of the total market share. Moreover, brand wise ranking based on sales volume shows among the top 25 brands, there

are 11 anti-ulcerant brands with the top 4 anti-ulcerant brands [33]. Yet studies consistently show that proton pump inhibitors are being overprescribed worldwide, in both primary and secondary care. Between 25% and 70% of patients taking these drugs have no appropriate indication. This means that, at least, £100m from the National Health Service (NHS) budget and almost £2 bn worldwide is being spent unnecessarily on proton pump inhibitors each year and it could be saved if proper utilization can be maintained [10]. But what is the evidence that well established guidelines are not followed?

Table: Top Anti-Ulcerant brands with their rank in pharmaceutical sells in Bangladesh.

SN	Brand	Generic	Rank
1	SECLO	Omeprazole	1
2	MAXPRO	Esomeprazole	2
3	SERGEL	Esomeprazole	3
4	PANTONIX	Pantoprazole	4
5	LOSECTIL	Omeprazole	6
6	NEOTACK	Ranitidine	9
7	FINIX	Rabeprazole	11
8	EXIUM	Esomeprazole	13
9	NEOCEPTIN R	Ranitidine	20
10	XELDRIN	Omeprazole	23
11	ENTACYD PLUS	Antacid	25

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Liver Cancer: Overview & Management Strategy

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> HEPATO CELLULAR CARCINOMA COMPRISES OF 80% OF ALL PRIMARY LIVER CANCERS. HCC IS THE SIXTH MOST COMMON CANCER WORLDWIDE, BEING THE FIFTH IN MEN AND THE EIGHTH IN WOMEN. THIS CANCER IS THE THIRD LEADING CAUSE OF CANCER DEATHS WORLDWIDE. THE INCIDENCE OF HCC IS HIGHEST IN ASIA AND AFRICA

Liver is the largest internal organ of our body. This organ is affected by various types of malignant tumour like other organs. The malignant tumours are of two types. The one originated from the component of the liver tissue is primary tumour and the other spread from other organ of the body is metastatic tumour. Malignant metastatic tumours are much more common than the primary tumours.

Primary liver tumours

Hepato cellular carcinoma (HCC) is the most common and comprises of 80% of all primary liver cancers. HCC is the sixth most common cancer worldwide, being the fifth in men and the eighth in women. This cancer is the third leading cause of cancer deaths worldwide. The incidence of HCC is highest in Asia and Africa.

Outcomes for patients with HCC have been historically poor, regardless of treatment, with overall 5-year survival rates of 20% to 40%. For patients with HCC and end-stage cirrhosis, survival without liver transplantation is often less than 1 year.

Other types of liver cancers, including intrahepatic cholangiocarcinoma, hepatoblastoma and angiosarcoma, Cyst adenocarcinoma are relatively rare. HCC is a complex disease entity with multiple possible etiologies, and associated with many risk factors and cofactors. Cirrhosis is present in about 80% to 90% of HCC and has a prominent role in the development of HCC.

Major risk factors including chronic infection with hepatitis B virus (HBV), hepatitis C virus (HCV), alcoholic liver disease, nonalcoholic steatohepatitis (NASH) and cirrhosis due to any cause. Additional risk factors for developing HCC include intake of aflatoxin-contaminated food, diabetes, obesity, certain hereditary conditions such as hemochromatosis, and various metabolic disorders. Chronic HBV infection has 200 fold and HCV have 25 fold increased chance of developing HCC than normal population. It is estimated that HBV alone is responsible for 50% to 80% of HCC worldwide. Co-infections with HBV and HCV produce a cumulative effect on the development of HCC. Sometimes HCC is also noted in normal liver.

Diagnosis

Most of the time HCC remains asymptomatic and grows silently, diagnosed incidentally during investigations, mostly in advanced and complicated stage. Some common symptoms are mild abdominal pain, dragging sensation, mass effect, Hemorrhage, jaundice and sometimes with manifestation of rupture of the tumour. Diagnostic accuracy of ultrasound, Computerized tomography (CT), Magnetic resonance imaging (MRI) and angiography is dependent on a number of variables. Alpha-Fetoprotein (AFP) is elevated in 60%–70% of patients. Viral markers HBsAg & Anti HCV and Anti-HBc total (for occult HBV infection) to be done in every patient. Diagnostic laparoscopy is helpful for evaluation in doubtful cases. Percutaneous FNAC or biopsy should not be done routinely as there is chance of dissemination of cancer cells. Results of surgery (Hepatic resection or Transplantation) is compromised after such procedure. Clinical findings, Viral markers, tumour markers and imaging characteristics should be considered collectively, it is reasonable to assume a diagnosis of hepatocellular carcinoma. Most of the liver cancers are in association with cirrhosis, it is important to consider the severity of liver disease before a treatment strategy is planned. Child-Pugh Scoring (A, B &C) determines the severity of liver disease on the basis of serum albumin, bilirubin, prothrombin time, ascites and encephalopathy.

Therapy

The optimal management of HCC depends on a variety of factors including the size, number, and distribution (unilobar vs. bilobar), the relationship to hepatic vasculature, the status of distant metastases, the severity of liver disease (Child-Pugh score) and the general status of the patient.

Three basic treatment options are available: Hepatic Resection, Liver transplantation & Ablation.

Hepatic Resection

This should be the prime consideration. Tumour location, extent of hepatic involvement and hepatic functional reserve is the prime issue. Resections may be in the form of Right hepatectomy, Left hepatectomy or Segmentectomy. It is untoward to note that only about 18% to 20% 0f HCC can undergo curative resection. Following successful resection, long-term survival is possible, with 5-year survival rates as high as 74% in patients without significant decompensation. It is unfortunate that after liver resection, as many as 75% of patients will develop intrahepatic recurrence within 5 years. In complicated situation palliative resection (cytoreductive) is helpful than other non resectional procedures.

Transplantation: Total hepatectomy and replacement with part or whole liver is going to be the standard therapeutic option. It not only removes the HCC but also eliminates the existing tumour generating environment in the cirrhotic liver. Liver transplantation (OLT) also eliminates concerns about the capacity of the post resection remnant liver volume.

In general, liver allograft is allocated to patients according to their Model for End Stage Liver Disease (MELD) score, an equation, including creatinine, bilirubin, and international normalized ratio (INR), which accurately predicts mortality from complications of cirrhosis. Under the MELD system, the patient with the highest MELD score and, therefore, the highest risk of dying without a liver transplant, is transplanted first.

> “ANY MALIGNANT TUMOUR IN THE BODY HAVE THE POTENTIALITY OF METASTAZING TO LIVER. COMMONLY THE CELLS FROM THE MALIGNANT TUMOUR OF COLON, RECTUM, STOMACH, PANCREAS, BREAST, LUNG, NEURO ENDOCRINE ORGANS, KIDNEY, ESOPHAGUS, OVARIES, UTERUS & SKIN ETC METASTASIZE TO THE LIVER

Patients undergoing OLT for HCC also evaluated by Milan criteria (single tumour ≤5 cm, maximum of 3 total tumours with none >3 cm) or University of California, San Francisco (UCSF) criteria (single tumour <6.5 cm). Patients meeting Milan criteria had similar 5-year post-transplant survival to patients meeting UCSF criteria. Overall survival at 1, 3, and 5 years after transplantation are 82%, 65%, and 52% respectively.

Ablation of liver tumours: This is the destruction of tumour by various means.

Radiofrequency ablation (RFA)

RFA involves percutaneous or intraoperative insertion of an electrode into the lesion under image guidance (US/CT). Radiofrequency energy is emitted through the electrode and generates heat leading to coagulative necrosis. RFA is feasible for tumours of less than 3 cm and some strategies can increase the treatment area up to 5 cm (multiprobe arrays, internal cooling of the electrode & vascular clamping).

Noncurative treatment is used for patients with unresectable cancer. The goal of this type of treatment is to make symptoms better and slow the growth of the cancer.

Transarterial chemoembolization (TACE) - a procedure in which chemotherapy drugs are injected into the blood vessels that feed the tumours. This delivers a high dose of chemotherapy into the tumour while lowering the blood supply that feeds the tumour without systemic effect.

RFA & TACE also needed for down staging of the tumour for subsequent resection and bridge for transplantation & multimodal management.

Percutaneous ethanol injection (PEI) - destroys tumours by injecting tumour with alcohol (ethanol)

Radiotherapy, which uses high-energy radiation to kill cancer cells and shrink tumours.

There are 2 types of radiotherapy: External beam radiation therapy (EBRT) - used by a machine outside the body to deliver the radiation and Internal radiation therapy - used by a radioactive substance, such as yttrium-90, that is injected to a liver cancer.

Medication

Sorafenib is a noncurative oral medication only to be used in liver cancers that cannot be treated with surgery. Median survival is about 10.7 months and side effects occurred in 52% of patients treated with Sorafenib.

Multi modal management strategy should be of choice during advanced stage of HCC.

Secondary Liver Tumour (metastatic):

Spread of malignant tumour cells from other parts of the body (Metastasis), this is the most of common liver cancer.

Commonly the cells from the malignant tumour of Colon, Rectum, Stomach, Pancreas, breast. Lung, Neuro endocrine organs, kidney, esophagus, ovaries, uterus & skin etc metastasize to the liver. Any malignant tumour in the body have the potentiality of metastazing to liver. It might happen during the presence of primary tumour (synchronous) or any time later (metachronous) after removal of tumour. One quarter of

patients with primary colorectal cancer have synchronous and nearly half of all colorectal cancer eventually develop metachronous metastasis to liver.

Diagnosis of liver metastasis:

Most of the tumours spread asymptomatically. Clinically it is difficult to detect the hepatic metastasis in early stage. Enlarged liver or hepatic mass may be detected in certain cases. Strong suspicion and evaluation by tumour maker(s), imaging by Ultrasound, Contrast enhanced CT, MRI & Angiogram are the standard strategy. Laparoscopy is a reliable minimally invasive method of diagnosing.

Treatment:

Management strategy of Hepatic metastasis is planned with the management of primary tumour.

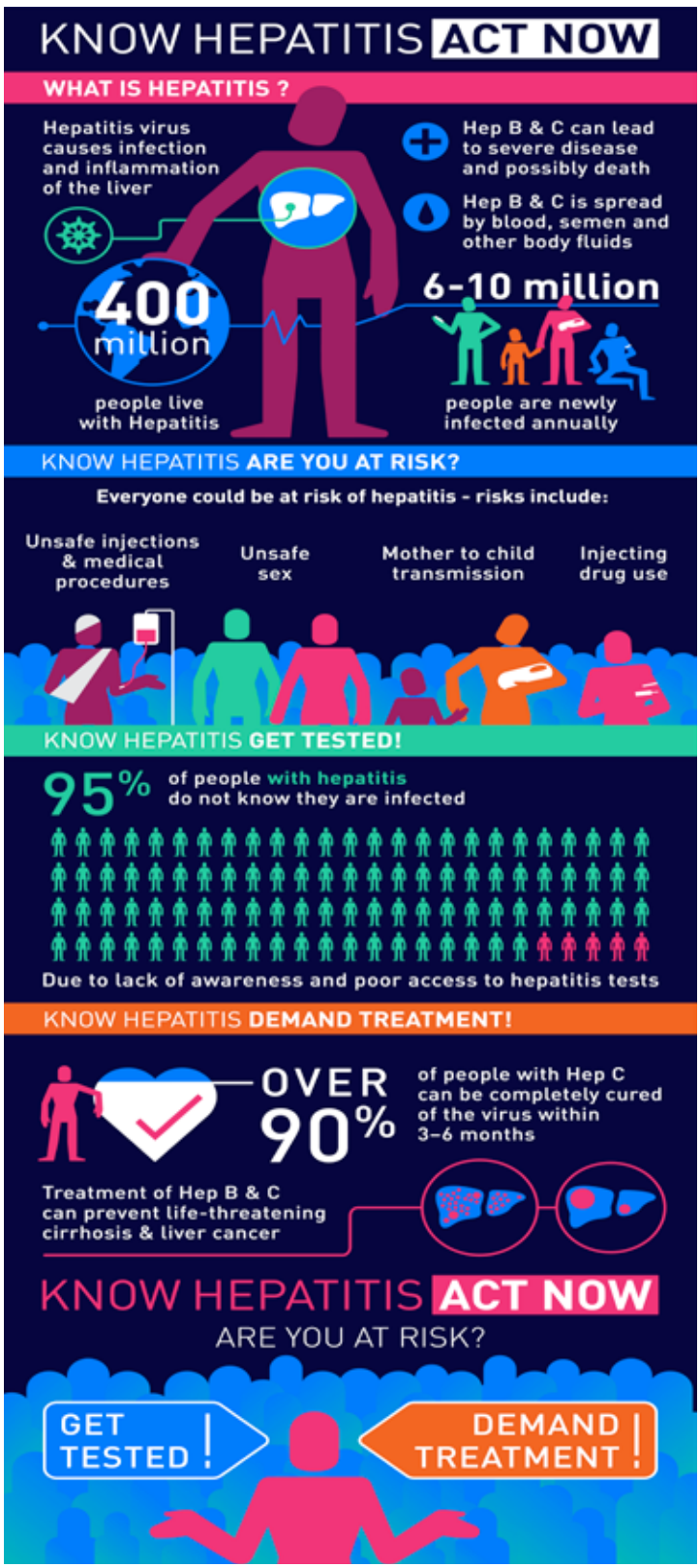
Meastatatic tumour is treated with various types of hepatic Resections, Ablations. Portal vein embolization to get Ipsilateral atrophy and contralateral compensatory hypertrophy of the remnant liver for safe subsequent resection of the metastasis. Chemotherapeutic agents, according to the specificity for the tumour is used for cytoreduction and down staging the tumour.

Hepatic Metastasis from colorectal cancer and Neuro endocrine tumours has better prognosis then that of other primary tumours.

Conclusion:

Every efforts to be taken for prevention of hepatitis B & C (Silent Killers) among the people in a nation to minimize the overall incidence of HCC. Those suffering from hepatitis B and C should have regular follow up for development of HCC, so that it could be singled out in early stage where the result of treatment is highly encouraging. Hepatic resections (Curative/palliative) should get top priority in the management strategy of all types of liver cancers.

Individuals with any cancer in the body should have evaluation for the presence of synchronous hepatic metastasis. After removal of any primary tumour, regular follow up protocol should include the assessment for metachronous hepatic metastasis. Multimodal management strategy should be offered in complicated conditions. Early detection and adequate therapeutic measures can definitely offer high survival benefit for all kinds of liver tumours.



SOURCE: WHO

Bangladesh Pharmaceuticals Marketing Scenario 2017 Ahead!

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Former CEO of a Pharma company

> "THE INDUSTRY NEEDS TO FOCUS ON STRENGTHENING BACKWARD LINKAGES. THE GOVERNMENT ALSO NEEDS TO CREATE AN EXPORT-FRIENDLY ENVIRONMENT WITH ACTIVITY FROM BOTH PUBLIC AND PRIVATE SECTOR STAKEHOLDERS

BMI View

Replicating India's success in the generic drugs sector will remain a challenge for Bangladesh. The country's strategy of leveraging upon an extension of the patent waiver for least developed countries presents limited opportunities, as many of these markets have low levels of healthcare access and per pharmaceutical spending. Moreover, the key growth opportunities for generic medicines lie in the emerging countries and selected developed markets where Bangladesh firms will have to work within the intellectual property framework. Pharmaceuticals: BDT171.6bn (USD2.2bn) in 2015 to BDT 190.8bn (USD2.4bn) in 2016; +11.2% in local currency terms and +9.1% in US dollar terms.

The pharmaceutical sector in Bangladesh is one of the thrust sectors and plays a vital role for the country's economy. The sector utilizes highly skilled manpower along with advanced machinery for manufacturing high quality generic medicines and vaccines for local and international markets at competitive prices. With a current market size of $1.2 billion, the market is poised to cross $2 billion by 2018. In fact, provided the political situation remains as stable as it has been for the last year, the growth may be even higher than projected.

The Balancing Act between Global and Domestic Markets

According to IMS projections, the global pharmaceutical market will grow to USD 1.135 trillion from USD 953 billion at a compound annual growth rate (CAGR) of 3-6% during 2013-2017.

Led by China, the BRIC countries (Brazil, Russia, India, and China) accounts for almost 70% of all pharmaceutical market sales. Parallel to the global picture, the emerging countries show a positive growth trend, where Bangladesh is one of the Tier 3 pharmerging countries that is forecasted to contribute to this industry growth by 6–9% between 2013–2017.

In the global market, the lion's share of export is contributed by patented drugs. In the domestic market, however, the inverse is true: 85% of the drugs sold are generics and 15% are patented drugs. The local market comprises of 83 active pharmaceutical companies, out of which top 20 companies control 85% of the market share. The local market size currently rests at USD 1.53 billion, with local manufacturers meeting 97% of the demand.

As a member of WTO and being enlisted as one of the LDCs, Bangladesh currently enjoys the benefits of intellectual property rights that allows producing generic drugs and exports until 2032 without compulsory licenses or paying the patent holders and thus providing an advantage to the local manufacturers and exporters. This has allowed pharma companies to exports to 107 countries in Europe, Asia, Africa and Latin America with export standing at USD 72 million in 2015.

Growth Incentives

Healthy growth trajectory is boosting the pharmaceutical manufacturers towards R&D for newer generics with global standards in place. The DGDRA Bangladesh is playing the key role in inspecting the WHO, GMP and SOP of the pharmaceuti-

cal manufactures and enrolling the certification for subsequent two years' validity from the date of inspection.

Furthermore, to meet the staggering local and international demand, the government has extensively imposed lower or zero import duty and VAT for certain raw materials/items and certain capital machineries, and also allowed tax holidays of four to six years to investors in this sector.

Rapid Growth Poised to Stay

The Bangladeshi pharmaceutical market is growing at a fast pace and has a promising future. According to Business Monitor International's latest report, Bangladesh has moved one step upward to occupy the 14th position amongst 17 regional markets.

This sector offers an enormous investment opportunity and has the potential to export alongside the RMG sector in terms of value, catering to increasing consumption worldwide.

Under WTO's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), 48 LDCs, including Bangladesh, were granted exemption from drug patent fees in producing generic drugs until 2016. Recently, this was extended to 2032.

Although the advantage that can be gained from TRIPS has been much lauded in Bangladesh, in reality not much benefit has been gained due to lack of infrastructure required for producing quality generic drugs cost effectively.

To rectify this, the industry needs to focus on strengthening backward linkages. The government also needs to create an export-friendly environment with activity from both public and private sector stakeholders.

Localize Pharmaceutical Value Chain to Reduce Costs: One of the highest cost components in medicine production is APIs, which can contribute as much as 40% of the total cost. At the moment, 80% of these APIs are imported from India and China.

Although 15 Bangladesh companies (such as Beximco, Square and Opsonin) are manufacturing active pharmaceutical ingredients (API), this is a very small percentage of the 85 active companies in the market.

> "A CENTRAL BIOEQUIVALENCE AND DRUG TESTING LABORATORY WOULD HELP THE INDUSTRY BY NOT ONLY REDUCING THIS COST, BUT ALSO ALLOWING FOR ROUTINE QUALITY CHECKS ON LOCALLY PRODUCED DRUGS, FURTHER STRENGTHENING THE CASE FOR ENTRY INTO DEVELOPED MARKETS.

Backward integration in APIs is a key issue for the pharma industry's growth. Currently India, the top generic drug player, has 3500 Drug Master File (DMFs) approval for APIs whereas we have none.

To mitigate this, the government has taken the significant step of constructing an API Industries Park at Munshiganj, 40 km from the capital. About 40 companies are planned to be established at the park, which will include a central effluent treatment plant incinerator.

However, the project, originally scheduled to be completed by 2012, has been repeatedly delayed, with costs rising by 55%. As a result, progress in backward integration regarding APIs has stalled.

Bioequivalence testing, which determines if the generic version is identical to original brand, is another crucial part of the value chain. This is mandatory for product registration in any developed market and is very expensive when conducted abroad such as in USA or Europe.

A central bioequivalence and drug testing laboratory would help the industry by not only reducing this cost, but also allowing for routine quality checks on locally produced drugs, further strengthening the case for entry into developed markets.

Greater collaboration between industry and academia: A potent and mature medical academic community is instrumental to fostering a healthy R & D culture in the industry. The government can take cues from its Indian counterpart, which has taken steps to establish specialized pharmaceutical institutes such as the National Institute of Pharmaceutical Education and Research (NIPER).

More long-term commitment to creating export-friendly environment: In addition to the existing tax holidays and import duty exemptions, the government can also explore other options such as creating Special Economic Zones (SEZs) for the pharma industry to create localized, internationally competitive export environments. SEZs already have a proven track record as SEZs in India and China have significantly boosted pharma exports.

Engage in Contract Manufacturing with MNCs: Bangladesh's considerable cost advantages makes it a good candidate for contract manufacturing as MNCs are looking to shift outsourcing operations from previously cost effective regions such as India and China. Already a 60 billion USD business, contract manufacturing has huge potential for Bangladesh.

‘With progressive modernization of lifestyle, Non-alcoholic fatty liver disease is on the rise in Bangladesh’

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Q&A

As an eminent Hepatologist of the country, would you please enlighten us about the burden of liver disease in our country?

Liver is an important organ of the human body. Like all other organs, it is also afflicted by different diseases. Therefore, it is important to know the overall burden of liver diseases in our country. According to one study involving patients admitted in department of gastro-enterology and hepatology in medical college hospitals of seven different administrative divisions of Bangladesh, among all the patients admitted in 2012 and 2013 in those hospitals, 13.2% were diagnosed with different liver diseases.

Bangladesh is a densely populated country. A large proportion of total population live in cities. Many of them stay in highly congested places. As a result, there is increased risk of contamination of water resources. Also, road side food vendors selling drinks and/or foods made from contaminated water in open sky are easily available. So, viral hepatitis is the highest prevalent disease in our country. In the previously mentioned study, it was found that 20 percent of the admitted patients were of acute viral hepatitis. If we consider the non-admitted cases of acute viral hepatitis the number would be a lot higher. Among hepatitis caused by different viruses hepatitis E has an incidence of 22.5 percent according to one study. Hepatitis B and Hepatitis C have an incidence of 5 to 7 percent and 0.2 to 1 percent, respectively. Among the patients of chronically infected Hepatitis B, 60% and 64% develop cirrhosis and hepatocellular carcinoma, respectively. In case of hepatitis C the number is 30% and 17%, respectively. Other important causes of cirrhosis in Bangladesh are Non-alcoholic fatty liver disease, Wilson’s disease and Alcoholic cirrhosis.

With progressive modernization of living style in Bangladesh Non-alcoholic fatty liver disease (NAFLD) is on the rise. In one study, incidence of NAFLD was found to be ranging from 1.1 to 7.6 percent distributed over different divisions. This is high in comparison to previous studies. Liver abscess and biliary ascariasis occurs with significant incidence. Irritable Bowel Syndrome (IBS) and dyspepsia were found to be the major causes of abdominal discomfort who sought treatment in hepatology and gastroenterology departments in different hospitals.

Although, alcohol consumption was previously low due to religious and cultural prohibition in our country. But with increasing modernization we are seeing a rise in alcoholic liver diseases, too.

Now, Please tell us in brief about the types of Hepatitis, especially Hepatitis B & C? What are the treatments?

‘Hepatitis’ literally means inflammation of Liver. Liver can be inflamed by various agents. Among them most common is Hepatitis Viruses. Other important causes of hepatic inflammation include alcohol, fat that is deposited in liver and various drugs. Also, infection by bacteria and amoeba are important causes of inflammation

but they usually produce localized destruction of liver cells leading to abscess. Viral Hepatitis most commonly occurs by five important viruses. These are named by first five capital letters of English alphabet: Hepatitis A, B, C, D and E viruses.

Hepatitis A and E cause acute hepatitis. These are self-limiting diseases and may require one to two weeks for recovery. Simple bed rest is enough in these cases. Whereas, hepatitis B and C usually lead to chronic hepatic inflammation termed chronic hepatitis. Chronic viral hepatitis, if untreated, can lead to hepatic cirrhosis and hepatocellular carcinoma. Antiviral drugs for the treatment of chronic Hepatitis B and Hepatitis C are being produced in Bangladesh and are available at a reasonable cost. For chronic hepatitis B, there are two treatment options: Pegylated Interferon in injectable forms and Oral Antiviral Agents (OAA). OAAs include: lamivudine, infovir, entecavir, telbivudine and tenofovir in order of discovery. Pegylated interferon is costly. But, it has a good seroconversion rate in chronic hepatitis B. OAAs are well tolerated and are affordable. In treatment of chronic hepatitis C previously only pegylated interferons were used. Now, OAAs like sofosbuvir, daclatasvir, ledipasvir, velpatasvir etc. are available in our country. Good news is that chronic hepatitis C cure rate is 90% when regimens developed using these drugs are taken properly.

Do we have all the state-of-the-art facilities and treatment options for the treatment of liver disease, including Hepatitis?

Currently many of the state-of-the-art facilities are available in our country. Well-trained hepatologists are providing treatments of various liver diseases countrywide. Still one problem remains: all the diagnostic facilities and invasive treatment procedures for different liver diseases are mainly Capital-centric. Ensuring availability of all facilities in divisional districts is an ongoing process. We hope these facilities will be de-centralized soon.

> “CHRONIC HEPATITIS BY HEPATITIS B AND C VIRUSES CAN BE TREATED AND CIRRHOSIS CAN BE PREVENTED WITH EARLY DETECTION AND INITIATION OF TREATMENT

Attempt to start liver transplantation has not been successful yet. We hope this will be started in one or two years time.

What are you suggestions to create awareness among the common people about Hepatitis B & C?

We know that Hepatitis B and C poses a major threat in our health. These viruses spread through blood route. Using un-screened blood, recurrent use of unsterilized injection, accidental prick by medical personnel, using same blade by barber, unprotected sex and vertical transmission from mother to fetus are important causes of transmission of hepatitis B and C virus. So, awareness should be raised about the mode of transmission of hepatitis B and C virus along with the threat it poses on health. All the available methods to reach common people should be used to raise awareness. Writing articles in newspapers, magazines, social media (like facebook) and blogs could be one of the means to inform people. Scientific seminar, symposium, press-conferences could be arranged on a regular basis. Television programs should be arranged to reach general people, especially those living in village. Short you tube videos could be produced to reach young generation.

Hepatitis B is considered a ‘Silent Infection’. What are the steps to early screening for Hepatitis B? Is “Hepatitis Virus Panel” available throughout Bangladesh?

Hepatitis B is an uncanny virus. It silently enters the liver cells and moves to nucleus of liver cells to utilize its machinery. Thus, it uses cell’s resources to multiply itself. Our immune system is activated against the virus. This causes inflammation against infected liver cells. As a result hepatitis ensues. In many of the cases the virus is eradicated from the infected person by his/her immune system. But, in majority it remains silent or decreases its expression slowly destroying the cells of the liver. Since its entry into the liver hepatitis B virus produces different molecules which are designated as antigens (Ag). In response to the antigens specific molecules are produced by the immune system of body. These are named antibodies (Ab). Actually these are the molecules that are detected in an infected person and that comprise ‘hepatitis B panel’. When the virus enters a host it expresses its surface antigen first. This is known as HBs Ag. After acute infection, HBs Ag is cleared from the body within 6 months. If it persists after 6 months the person is said be a chronic carrier of hepatitis B. Other ‘Hepatitis B Panel’ tests include: Anti HBs Ab, Anti HBc IgM & IgG, HBe Ag, Anti HBe Ab and HBV DNA. These test are done to categorize various phase of the disease.

HBs Ag is detected in serum for screening purposes. It can be done by both ICT and ELISA method. ELISA method is more specific and confirms presence of Hepatitis B in body. ICT method is available in Upazilla level and ELISA method is available in all districts levels. But, the later test is more costly. So, for screening purpose primarily ICT method can be used.

Not all the Hepatitis B Panel tests are available countrywide. Especially, Hepatitis B virus DNA is a costly test and is only available in Dhaka. But,

when these tests become more available, the cost will be lowered. So, what we need first is an aware generation who knows the impact of hepatitis B in health and, therefore, seeks advice in appropriate place.

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

Hepatology Society of Bangladesh is doing research on liver diseases for a decade. But, because of lack of funding, number of researches done are not up to the mark. Most of the researches are mainly being done by individual or group effort. So, I would request funding agencies to come forward to sponsor larger studies in this field.

What are your messages or guidelines for the patients of liver disease?

Different liver diseases require different guidelines for management. Therefore, my message for the patient of liver diseases is to consult a hepatologist and follow his/her advice accordingly. I would also request them to inform their acquaintances who are suspected of liver disease about the importance of early diagnosis and availability of treatment in our country. Most of the liver diseases can be treated. Especially, chronic hepatitis by hepatitis B and C viruses can be treated and cirrhosis can be prevented with early detection and initiation of treatment. These treatments are available in our country. So, you don't need to fly abroad for treatment of liver diseases.

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

Besides doing research in the field of liver disease, our organization regularly arranges awareness programs on liver diseases. We arrange yearly press-conferences in World Hepatitis Day. We invite distinguished hepatologists and scientists from reputed institutions worldwide bi-annually to arrange 'International Hepatology Conference' and keep our physicians and specialist from different field informed about the latest development in the management of liver diseases. Training programs for young doctors are also arranged. Television Interviews are given to increase awareness about liver diseases. ●

‘Our Gastroenterologists have high level of clinical knowledge but lack logistic supports’

PROF. DR. A.S.M.A. RAIHAN
Department of Gastroenterology
BSMMU, Shahbagh, Dhaka

Q&A

As an eminent gastroenterologist of the country, would you please tell us in brief, prevalence of gastrointestinal diseases in the country?

True prevalence of gastrointestinal disease is not known. However, in a population-based survey conducted in Ghior Upazilla under the district of Manikganj from January 2007 to April 2008, among 9037 adults, 61.9% were found to have dyspepsia, Reflux like dyspepsia was the commonest subtype of dyspepsia comprising 44% of total population and 71% of the dyspeptics. Prevalence of irritable bowel syndrome (IBS) was found to be around 9.5% in the community.

Many GI diseases, such as Irritable Bowel Syndrome, GERD are becoming increasingly common. What factors do you think are playing role for such incidence?

Irritable Bowel Syndrome is related with many factors including life style, rapidly developing urbanization leading to change in dietary habits, mental stress and more dependency on food outside home may have some role in increasing frequency of IBS. IBS has been increasing because of introduction of new, unaccustomed food in the menu like oats, corn flakes with milk, over eating, change in diet for dieting or weight reduction protocol including diet rich in vegetables and fibers, oats, excess of butter and other oily foods. GERD is increasing because of frequent intake of fast food rich in fat and oil, rich in cheese and cream. Grills and Kebab also are responsible. All of the categories of food cause gastric stasis and relaxation of lower oesophageal sphincter (LES). More health care purchasing capacity and health awareness may lead to more medical consultation.

What are your guidelines for the patients with GI disorders to improve their quality of life?

Healthy diet practice including avoidance of excessive intake will improve quality of life. I would request to take medicine regularly and to consult with physician for any difficulty including side effects of drugs.

Compared to developed countries, where do we stand in management of gastrointestinal diseases in Bangladesh?

Our country is small but population is vast. Although in last two decades number of gastroenterologist has increased significantly over the country, it is still inadequate to meet the necessity of the country. Our gastroenterologists have got high level of clinical knowledge but lack of logistic supports like instruments, inpatient hospital facilities, lack of adequate laboratories facilities, lack of imaging specialist especially trained for gastrointestinal diseases and lastly not to be unmentioned, cost of investigations, negatively influences the management outcome.

What is your suggestion to the young GI specialists of the country?

My suggestion to my young colleagues to be sincere in profession, to be careful in history taking, physical examination and judicious use of investigation, critical reading of contrast X-ray and imaging like CT scan and MRI to get maximum information. Finally, I would advise them to share the difficult cases with senior colleagues.

Being available over the counter, patients now-a-days are self-prescribing and overusing anti-ulcerent drugs i.e. PPIs. What are the consequences of such irrational use of drugs?

Long term use of PPI may cause iron deficiency, anaemia and osteoporosis. Use of PPI is a risk factor for frequent infective diarrhea.

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

Drugs produced locally are almost adequate for management of GI diseases except the necessity of some less frequently needed drugs for some difficult diseases like IBD. ●

‘Biggest challenge in managing GI problems is disproportionate Patient-Doctor ratio’

PROF. DR. PROJESH KUMAR ROY
Professor & Head
Dept. of Gastroenterology
Bangabandhu Sheikh Mujib Medical University
Dhaka

Q&A

As an eminent Gastroenterologist of the country, would you please tell us in brief, prevalence of gastrointestinal diseases in the country?

Gastrointestinal diseases are the leading cause of outpatient consultation both in hospitals and private practice. But till date accurate country wise data regarding prevalence of gastrointestinal disease is not available. Among the GI diseases, Peptic Ulcer Disease, GERD and IBS are the most common. Other common diseases like Dyspepsia, Fatty Liver Disease, Abdominal Tuberculosis, Acute Viral Hepatitis, Hepatitis B and Hepatitis C virus infection, Cirrhosis of Liver, IBD. GI and Liver Malignancy are also a major concern now a days.

Many GI diseases, such as Irritable Bowel Syndrome, GERD are becoming increasingly common. What factors do you think are playing role for such incidence?

As mentioned above IBS and GERD are becoming common in Bangladesh. For this several factors are playing major role. These are change in the dietary habit, change in life style, urbanization, less physical activity, obesity, stress, alcohol, food adulteration etc.

What are your guidelines for the patients with GI disorders to improve their quality of life? What role does diet play in this regard?

Different diseases require different approaches for improving quality of life. But in general the following measures can be taken: Eating more fibers, taking less refined carbohydrate (especially sugar containing food) and excess fatty meal, regular exercise, controlling obesity, avoidance of smoking and alcohol, reducing stress etc. Finally, one should consult a gastroenterologist before taking any medication.

Compared to developed countries, where do we stand in the management of GI diseases in Bangladesh?

In terms of management, compared to developed countries, we have most of the medications needed for the treatment. Thanks to the pharmaceutical industry that they are bringing new molecules to our country even before it is available in our neighboring countries. The only problem we are facing at the moment is excess burden of patients, which we hope to minimize in the near future as more gastroenterologists will emerge to serve the nation.

Being available over-the-counter, patients now-a-days are self-prescribing and overusing anti-ulcerant drugs i.e. PPIs. What are the consequences of such irrational use of drugs?

Self prescription of anti ulcerants are causing various problems. As the symptoms subsides partially, various diseases like existing gall stone disease and malignancies are diagnosed late. As a result disease becomes more complicated and ultimately increases the suffering of the patients and their relatives. Moreover, long term use of anti ulcerants has its own side effects. Recent studies also suggest that chronic kidney disease and diarrheal diseases are emerging due to continuous long term PPI use. I think it’s time for the Pharmaceutical industry, Physicians and Government to take necessary steps to stop this harmful practice.

From your perspective, what do you think is the biggest challenge in managing GI problems today?

Biggest challenge in managing GI problems today is disproportionate patient- doctor ratio. Other factors are self-prescription of drugs and indiscriminate use of over the-counter (OTC) drugs. Lack of awareness also leads to delayed presentation of the patients to the doctors, especially in case of female patients. Sometimes follow up of patients and compliance to treatment become a major concern. Diagnostic facilities are also sometimes inadequate in rural areas.

What advice do you have for students interested in pursuing gastroenterology as a career?

For the students pursuing Gastroenterology as a career, I would suggest them to be passionate and sincere to their profession. In the modern world, science, especially medical science is evolving every day. A drug that is used today, may not be used at all after a few years for treating the same disease. So, it is very important to be academic and keep themselves up to date regarding latest developments of drugs and various therapeutic procedures. They should also engage themselves in various research activities for the development of the specialty because many diseases have its unique character depending on the country/region. Overall, they should be good clinicians, academicians, researchers and on the top of all, good human beings.

Where do you see the gastroenterology field in Bangladesh in the next 10 years?

Our country is growing economically which is causing improvement in sanitation and awareness of food hygiene. So food and water borne diseases will be reduced in coming future but will not be eliminated. Dietary changes will also lead to increase in diseases common to developed countries. Rapid urbanization and change in life style will cause rise in metabolic disorders. Various new therapy and new modalities of treatment will be available globally and in the current world of globalization we shall not lag behind from the rest of the world.

‘In the treatment of Hepatitis C, Bangladesh has made a revolution’

PROF. (DR.) SALIMUR RAHMAN
Professor
Department of Hepatology
Bangabandhu Sheikh Mujib Medical University
Shahbag, Dhaka

Q&A

As an eminent Liver Specialist of the country, would you please tell us in brief about the prevalence of Hepatic diseases in the country?

The major hepatic diseases in our country are viral hepatitis like Hepatitis B, Hepatitis C and related complications like liver cirrhosis, liver cancer etc. In our country, prevalence of Hepatitis B is quite high as a major liver disease. However, it is declining gradually. Even a few years back the prevalence of Hep B was 8-10% in Bangladesh. According to the survey we have conducted, the prevalence of Hepatitis B today has come down to 5-6%. Other surveys in the country also showed the same prevalence rate. In all surveys, prevalence of Hep C is shown to be around 1% in Bangladesh, whereas in all our neighboring countries i.e. India, Nepal, Pakistan, prevalence of Hep C is very high.

Please tell us in brief about the types of viral hepatitis, especially Hepatitis B & C. What are the survival rates of these diseases in Bangladesh?

Viral hepatitis can be caused by 5 different types of viruses – A, B, C, D and E. Hepatitis A, E, B, C are common in our country. Due to repeated use of needles, sharing contaminated needles, contact with infected blood, Hepatitis B and C are spread. On the other hand, Hepatitis A and E spread through contaminated water and food.

In adults, Hep B virus clears off 90-95% cases, while the rest 5% become chronically infected. These people are at higher risk of death from cirrhosis of liver and liver cancer. On the other hand, 95% of children are vulnerable to developing chronic liver diseases due to Hep B infection.

Characteristics of Hepatitis C are reverse. 85% Hepatitis C positive patients remain as chronic carrier for rest of their life, that means, the virus clears off from the rest 15%. Around 20% of the remaining 85% develop Chronic liver diseases including cirrhosis and cancer and are at risk of death.

Do we have all the state-of-the-art facilities for the treatment of all kinds of liver diseases? Compared to developed countries, where do we stand in management of liver diseases in Bangladesh?

Diagnostic facilities for Hep B and C are available in our country and the standard of the same is at par with the developed countries. As for diagnosis, most types of screening e.g. blood/ serological tests including Hepatitis B antibody, Hepatitis C antibody, HBSAg, anti-HCV, anti-HAV etc. are done here. We are also capable of tests which are of molecular level, i.e. DNA, RNA tests etc. to find out the genotypes or subtypes. Regarding treatment, all kind of facilities for Hepatitis B and C are available in Bangladesh except liver transplantation. Especially, in the treatment of Hepatitis C, I would say, Bangladesh has made a revolution. Whereas a tablet costs around $1000 in the developed country, we get the same here at Tk. 500-700 only. Apart from this, all kinds of Hepatitis B drugs including vaccine are available in our country.

> IN ADULTS, HEP B VIRUS CLEARS OFF 90-95% CASES, WHILE THE REST 5% BECOME CHRONICALLY INFECTED. THESE PEOPLE ARE AT HIGHER RISK OF DEATH FROM CIRRHOSIS OF LIVER AND LIVER CANCER. ON THE OTHER HAND, 95% OF CHILDREN ARE VULNERABLE TO DEVELOPING CHRONIC LIVER DISEASES DUE TO HEP B INFECTION

What are your suggestions to create awareness among the common people about the liver diseases?

Awareness building regarding Hepatitis is of paramount importance for prevention of Hepatitis. Vaccination is an important element in prevention of such liver diseases. We must not neglect this aspect. Even, there are liver diseases like Hepatitis A and E which are water borne. So, we should be very careful about drinking water. We should also avoid contaminated food and also take boiled water. Vaccination is the key to prevent Hepatitis B. So, everyone should vaccinate against Hepatitis B.

Awareness program should be conducted in different ways. What we do to create mass awareness about hepatitis are: we run different programs on Radio and Television, write in the newspapers, give interviews in print and electronic media, organize rally etc. on regular basis. Then, we organize seminars, workshops etc. in the schools and colleges, district level hospitals, medical college hospitals as a part of awareness building campaign. Apart from the above, we conduct different programs on the World Hepatitis Day every year.

Access to Hepatitis C treatment still remains beyond the reach of the poor people. What measures do you think can be taken on national level to increase access to screening and treatment services throughout Bangladesh?

You'll be happy to know that there has been a revolutionary change in the treatment of Hepatitis C. Prices of medicine are within the reach of the common people and much less compared to the developed countries. Hepatitis C medications can be purchased in Bangladesh at only 1% of the price that is offered by the developed countries. We don't need injections anymore, oral medications are there, which are more effective. You'll be surprised to know that medicines from Bangladesh are being taken to America, Europe and other parts of the world because of the lower price and high efficacy. In the near future, the scenario will change and patients would be benefited even more.

Is there any specialized private or public organization in our country doing research work in this field?

Bangabandhu Sheikh Mujib Medical University, Dhaka Medical College Hospital and other Medical Colleges of the country, and some other big hospitals having Hepatology Department where different types of research work are being conducted. MD students do their thesis work on liver diseases in these departments. Sometimes, we the doctors do research work at personal level. Through this, many new things come out. Then, we have an association – "Association for the Study of Liver" where we have different types of activities like seminar, symposium, workshop, training programs etc. to orient and train the young doctors of this discipline.

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

Drugs produced locally are excellent and in some cases, much better than that of developed countries as far as the efficacy and price are concerned. We have studied the local drugs and published our results also, which bears testimony to the above observation.

What is your advice for the patients of liver diseases?

All Hepatitis A, E, B, C have different treatment regimen. Actually, hepatitis is a disease which happens through oral-fecal route. So, we have to ensure pure drinking water and hygienic food, improve the public sanitation system, improve refusal disposal system etc. Only then, it would be possible to curtail the prevalence of this disease. In Taiwan, Hep B has been drastically reduced through vaccination alone. So, vaccination against Hepatitis B is very important. Liver diseases originating from consumption of excess alcohol (AFLS) is very common for the western world. Fortunately, this is almost nil in our country due to religious values.

A YEAR IN **REVIEW**

Most innovative Medical Researches of 2016

The Microbiome to Prevent, Diagnose, and Treat Disease

When it comes to life-saving potential and market opportunities, it turns out the gut is a gold mine. The FDA has begun reviewing targeted prevention products, including protective microbial colonies for oral disease. Meanwhile, therapeutics and diagnostics companies are targeting diseases ranging from C. difficile gastroenteritis, inflammatory bowel disease, and irritable bowel syndrome to acne, and diabetes, and cancer. The cancer efforts are centering around the ability to use bacteria to starve out tumors by competing for the same nutrients, as well as the ability for bacteria to activate the immune system to fight off tumor cells on their own.

Diabetes Drugs that Reduce Cardiovascular Disease and Death

In 2016, companies reemerged to reveal how a couple of new medications were dropping the rates in the double digits. The first drug, empagliflozin, was approved in 2014 as a prescription medication to improve glycemic control. A study of the drug's benefits in 2015 yielded significant results: patients showed reduction in non-fatal heart attack or non-fatal stroke by 14 percent when added to standard of care. This showed to reduce CV death by 38% and all mortality by 32%. This past June, the FDA Advisory Committee recommended the approval of the cardiovascular indication of empagliflozin. In the same month, liraglutide, an injected medicine approved in 2010, also showed a marked reduction in major CV events by 13% in CV death by 22%, and all mortality by 15%.

Cell-free Fetal DNA Testing

potential for genetic diseases, like Down's Syndrome, Edwards Syndrome, and Patau Syndrome can cause a great deal of stress, especially due to the vague and uncertain results of present tests. Now a novel diagnostic has been developed that will measure the fetal DNA in the mother's blood at 10 weeks, when 10% of the DNA in the blood belongs to the fetus. Studies show that the DNA testing dramatically decreased the false positives for Down and Edwards syndromes, while increasing the rate of a correct prediction by 10 and 5 times respectively. All cases of aneuploidy were detected.

Cellular Immunotherapy to Treat Leukemia & Lymphomas

Chimeric antigen receptor (CAR) T-cell therapies represent a type of immunotherapy where patient's immune system T-cells are removed and genetically reprogrammed to seek and destroy tumor cells. These CAR T-cells are grown in a laboratory and sent back to the patient to be infused into the patient following chemotherapy. The cells then behave as immune system cells should. They seek out antigens, multiply, attack and kill the foreign cancer cells. The new cells often also stay in the body to minimize any chances of relapse. Some studies focusing on acute lymphoblastic leukemia (ALL) have reported a remission rate of 90%.The groundbreaking treatment is expected to be presented to the FDA in 2017 for treatment of ALL, which is expected to trigger a wave of approvals for other blood cancers and lymphomas.

Cancer Screening via Protein Biomarker Analysis

In 2016, a new biomarker platform is hitting the market that focuses on changes in the structure of certain proteins circulating in blood or other biological fluids to indicate the presence or absence of cancer. The new tests can give you real-time information on the presence of cancer by evaluating the structural isoforms of protein biomarkers to differentiate those produced by cancer as compared to those produced by benign cells. When compared with standard PSA testing for prostate cancer, preliminary results of the new structural isoform test showed 100 percent sensitivity with no false negatives and approximately 80 percent specificity.

Gene Editing using CRISPR

CRISPR stands for clustered regularly interspaced short palindromic repeats. The method, which is being touted as a way to completely eliminate genetic diseases- employs a nuclease enzyme called Cas9 repairs the target DNA, to disrupt an unwanted gene or edited to change or repair a gene. The total cost to do this in a laboratory has been as little as $30. In April of 2015 news broke that embryos in China had been modified. The pharmaceutical industry has begun to look into CRISPR-based gene therapy, with first trials likely beginning in 2016. For example, host cells can be retrieved and engineered in the lab to "correct" conditions like sickle-cell disease. From there, the hope is that a wider variety of genetic disorders can be tackled, as well as other genome engineering to induce resistance to pathogens such as HIV.

3-D Visualization and Augmented Reality for Surgery

This past year, two of the most intricate surgical practices, ophthalmology and neurology, have been experimenting with new technology that not only keeps surgeons' heads up, but also immerses the surgeon into a high resolution, 3D visual representation of their subject. These stereoscopic systems also use data to generate visual templates for surgeons to execute certain tasks within a surgery. Experts and surgeons that have piloted the new systems believe the added comfort and visual information will allow surgeries to operate more efficiently and effectively. Additionally, medical residents will now have a clearer picture of exactly what the surgeon is seeing and doing, thereby gaining a better anatomical and technical understanding of surgery than ever before. Along the same lines, some of the world's biggest software companies are building augmented reality lenses that are capturing the imagination of both the surgeon and medical educator.

Naturally Controlled Artificial Limbs

Within the last few years, researchers announced the discovery that neural signals associated with limb movement can be de-coded by computers. These codes can be used to operate external devices, like an artificial limb. Sensors can be implanted into muscles to identify these neural signals and relay them to a computer that can move and control a limb. Various research groups have demonstrated that sensors implanted into the brain itself can similarly be used to control prosthetic arms, wheelchairs, and even a full body exoskeleton.

Bioabsorbable Stents

The stent, which is made of a naturally dissolving polymer, widens the clogged artery for two years before it is absorbed into the body in a manner similar to dissolvable sutures. The disappearing stent leaves nothing behind, thus eliminating risk of inflammation that can lead to late-stent thrombosis and restenosis. The patient is then free to go off platelet inhibiting or blood thinning medication, thereby qualifying them for a larger range of medical interventions when needed.

Could Common Heartburn Drugs Up Your Stroke Risk?

Sometimes, solving one problem only creates another. PPIs or proton pump inhibitors are increasingly popular choice for treating acid reflux and heartburn. But according to a research presented at American Heart Association conference, these medications may also increase the risk of ischemic stroke. "PPIs have been associated with unhealthy vascular function, including heart attacks, kidney disease and dementia," said the study's lead author. Ischemic stroke, the most common type of stroke, is caused by clots blocking blood flow to or in the brain. However, the risk appears to be driven by people who take high doses. People treated with a low dose of PPIs did not have a high risk of stroke. Those treated with the highest doses of PPIs had the highest risk of stroke. The extent of risk also depends on the specific PPI taken.

The research was conducted in Denmark among a quarter-million patients who suffered from stomach pain and indigestion, and were taking one of four PPIs: omeprazole (Prilosec), pantoprazole (Protonix), lansoprazole (Prevacid) and esomeprazole (Nexium). Overall stroke risk increased 21% among patients who were taking a PPI, according to the study. At the lowest doses, the authors found either no or minimal increased risk of stroke. At the highest doses, they found that stroke risk increased 33% for Prilosec and Prevacid patients, 50% for Nexium patients and 79% for Protonix patients. In comparison with non-users, PPI users were older and had more health conditions, including atrial fibrillation at baseline (3.4 vs. 3.8 percent). The study accounted for age, gender and medical factors, including high blood pressure, atrial fibrillation (irregular heart beat), heart failure and the use of certain pain relievers that have been linked to heart attack and stroke.

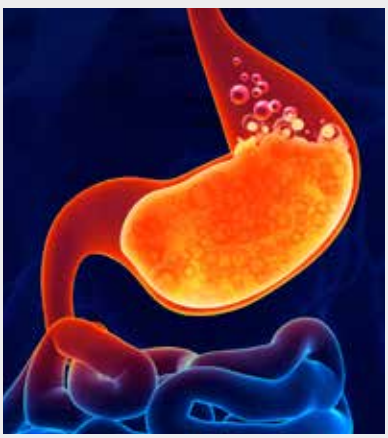
For ischemic stroke, researchers found:

- Overall stroke risk increased by 21 percent when patients were taking a PPI.
- At the lowest doses of the PPIs, there was slight or no increased stroke risk.
- At the highest dose for these 4 PPI's, stroke risk increased from 30 percent for lansoprazole (Prevacid) to 94 percent for pantoprazole (Protonix).
- There was no increased risk of stroke associated with another group of acid-reducing medications known as H2 blockers, which include famotidine (Pepcid) and ranitidine (Zantac).

Doctors prescribing PPIs, should carefully consider whether their use is warranted and for how long: "We know that from prior studies that a lot of individuals are using PPIs for a much longer time than indicated, which is especially true for elderly patients."

Authors believe that their findings, along with previous studies, should encourage more cautious use of PPIs. "A lot of people are using these drugs without a clear indication, such as a clear diagnosis showing they should use these drugs every day," said the study co-author. "They should think about quitting those drugs."

DID YOU KNOW?



Acid reflux not caused by acid

GERD may not be due to acid reflux as its name implies, but may actually be caused by a cytokine-mediated inflammatory response that damages the esophagus, according to a new study. Gastric reflux doesn't damage esophageal epithelial cells directly, but stimulates them to secrete cytokines that attract immune cells, which is what ultimately damages the esophageal mucosa. In this small study, the investigators aimed to test the idea in 12 patients whose GERD was successfully controlled by proton pump inhibitors (PPIs). Two weeks after stopping PPIs, all patients had evidence of esophagitis. However, the changes that re-occurred were not consistent with chemical burns due to stomach acid. The esophageal epithelium was not eroded in these patients but was infiltrated by T lymphocytes, along with findings of basal cell hyperplasia and papillary elongation. This matched the new concept that acute GERD is primarily a cytokine-mediated process of inflammation. "Someday we might treat GERD with medications that target the cytokines or inflammatory cells that really cause the damage to the esophagus," said co-senior author.

Smartphones, tablets and weight gain in teens

Teens glued to their tablet, smartphone or computer for hours on end may be more likely to become obese. The researchers at Harvard T.H. Chan School of Public Health found that those who used screen devices for five or more hours daily were twice as likely to drink more sugary beverages and engage in too little physical activity. As a result, these teens showed a 43 percent increased risk of obesity compared with kids who don't use smartphones or tablets at allFive or more hours of screen device time every day was linked to a doubled risk of drinking sugary beverages and getting too little exercise every day, and a 74 percent increased risk of poor sleep.

Avoiding over-the-counter heartburn medications could save cancer patients' lives

Something as seemingly harmless as a heartburn pill could lead cancer patients to take a turn for the worse. They could lower possibility of survival and recovery for cancer patient. Something as seemingly harmless as a heartburn pill could lead cancer patients to take a turn for the worse. Researchers from University of Alberta discovered that proton pump inhibitors (PPIs), which are very common medications for heartburn and gastrointestinal bleeding, decrease effects of capecitabine, a type of chemotherapy usually prescribed to gastric cancer patients. According to the researchers, PPIs affected progression-free survival by more than a month; the overall survival in cancer patients was reduced by more than two months, and the disease control rate decreased by 11 per cent. Although this research was focused on gastric cancer patients, the team has followed up with another study in early stage colorectal cancer and discovered that those who took PPIs and capecitabine were also at risk for decreased cancer treatment efficacy. In that study, patients who took PPIs while on capecitabine had a decreased chance of being cured of their colorectal cancer.

Warfarin and azole antifungal drugs

The MHLW and the PMDA have announced that the package inserts for warfarin and miconazole (Florid®) have been updated to include a contraindication of administering warfarin and miconazole concomitantly due to increased risk of bleeding. The package inserts for other antifungal drugs (voriconazole, itraconazole, fluconazole and fosfluconazole) have also been updated to include precautions about concomitant administration with warfarin. A total of 41 cases associated with serious bleeding during concomitant administration or, after discontinuation of concomitant administration of miconazole and warfarin have been reported in Japan. Due to the contraindication of concomitant administration of miconazole and warfarin, the use of other azole drugs, including those recommended as first-line treatments is expected. Thus, MHLW/PMDA considered that caution is also required for concomitant administration of warfarin and other azole antifungal drugs.

Direct-acting antiviralsfor hepatitis C

The HPRA has issued advice to health-care professionals on monitoring the international normalised ratio (INR) more closely in patients concurrently treated with vitamin K antagonists. A signal of a potential drug interaction leading to a reduced INR has recently been identified with co-administration of direct-acting antivirals and vitamin K antagonists. The case reports on which the signal was based were reviewed by the EMA's PRAC. The PRAC has recommended that the product information of direct-acting antivirals should be updated to include a recommendation for close monitoring of INR in patients treated with vitamin K antagonists, as liver function may change during treatment with direct-acting antivirals. While no change in the pharmacokinetics of warfarin is expected, close monitoring of INR is recommended with all vitamin K antagonists.

Incretin-based therapies

Health Canada has concluded in a review that there is not enough evidence to confirm a link between incretin-based therapies and pancreatic cancer. During the last few years, a small number of studies have found a possible link between the use of incretin-based therapies and an increased risk of pancreatic cancer. This led Health Canada to conduct a review. At the time of the review, 15 cases of pancreatic cancer that may have been linked to the use of incretin-based therapies had been reported to Health Canada. Although some non-clinical studies using animal or human models have suggested that the use of incretin-based therapies may be linked to an increased risk of pancreatic cancer, results from clinical trials and many studies looking at the patterns, causes, and effects of health and disease conditions in people, do not support this link.

Ondansetron

Health Canada is working with the Drug Safety and Effectiveness Network to further investigate the extent of ondansetron (Zofran®) use during pregnancy and the risk to the foetus. Health Canada has requested that manufacturers submit information they may have regarding birth defects and use of ondansetron during pregnancy. At the time of the review, Health Canada had received 14 reports of birth defects in the newborn babies of mothers treated with ondansetron. Findings from published scientific studies were inconsistent and inconclusive. There were concerns with study design, and the majority had a number of limitations such as use of concomitant medications. Available information were not sufficient to establish a link between the use of ondansetron during pregnancy and the risk of birth defects. Health Canada will continue to monitor safety information involving the use.

Diclofenac

The MHLW and the PMDA have announced that the package inserts for diclofenac preparations (Voltaren® and Rectos®) have been updated to include the risk of gastrointestinal stenosis and obstruction as clinically significant adverse reactions. A total of five cases of gastrointestinal stenosis or obstruction associated with the use of diclofenac have been reported in Japan. In addition, the company core datasheet (CCDS) has been updated.

Afatinib maleate

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for afatinib maleate (Giotrif®) has been updated to include the risk of acute pancreatitis as a clinically significant adverse reaction. Following an investigation of available evidence and advice from experts, the MHLW/PMDA concluded that revision of the package insert was necessary. Precautions to the package insert have been revised to include: Acute pancreatitis: Acute pancreatitis may occur.

FDA APPROVALS

DRUG NAME	GENERIC	MANUFACTURER	DATE OF APPROVAL	TREATMENT
Soliqua - formerly iGlarLixi	Insulin Glargine and Lixisenatide	Sanofi-Aventis U.S. LLC	November 21, 2016	Diabetes Type 2
Xultophy Injection - formerly IDegLira	Insulin Degludec and Liraglutide	Novo Nordisk	November 21, 2016	Diabetes Type 2
Intrarosa	Prasterone	Endoceutics Inc.	November 17, 2016	Dyspareunia
Vemlidy	Tenofovir Alafenamide	Gilead Sciences, Inc.	November 10, 2016	Chronic Hepatitis B
Lartruvo Injection	Olaratumab	Eli Lilly and Company	October 19, 2016	Soft Tissue Sarcoma
Carnexiv Injection	Carbamazepine	Lundbeck Inc.	October 7, 2016	Seizures
Amjevita Injection - formerly ABP 501	Adalimumab-Atto	Amgen Inc.	September 23, 2016	Plaque Psoriasis, Rheumatoid Arthritis, Ankylosing Spondylitis, Ulcerative Colitis, Crohn's Disease Maintenance, Psoriatic Arthritis
Exondys 51 Injection	Eteplirsen	Sarepta Therapeutics	September 19, 2016	Duchenne Muscular Dystrophy
Kyleena Releasing Intrauterine System	Levonorgestrel	Bayer HealthCare Pharmaceuticals Inc.	September 16, 2016	Contraception
Yosprala Delayed-Release Tablets	Aspirin and Omeprazole	Aralez Pharmaceuticals Inc.	September 14, 2016	Ischemic Stroke – Prophylaxis, Gastric Ulcer Prophylaxis
Cuvitru Injection	Immune Globulin Subcutaneous	Shire US, Inc.	September 13, 2016	Primary Immunodeficiency Syndrome
Lomaira Tablets	Phentermine Hydrochloride	KVK-Tech, Inc.	September 13, 2016	Weight Loss, Obesity
Erelzi Injection	Etanercept-szzs	Sandoz Inc.	August 30, 2016	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis
Troxyca ER Extended-Release Capsules - formerly ALO-02	Naltrexone and Oxycodone	Pfizer Inc.	August 19, 2016	Pain
Sustol Extended-Release Injection - formerly APF530	Granisetron	Heron Therapeutics, Inc.	August 9, 2016	Nausea/Vomiting – Chemotherapy Induced
Flonase Sensimist Nasal Spray	Fluticasone Furoate	GlaxoSmithKline Consumer Healthcare LP	August 2, 2016	Allergic Rhinitis
Qbrelis Oral Solution	Lisinopril	Silvergate Pharmaceuticals, Inc.	July 29, 2016	Hypertension, Congestive Heart Failure, Myocardial Infarction
Adlyxin	Lixisenatide	Sanofi	July 27, 2016	Diabetes Type 2
Viekira XR Tablets	Dasabuvir, Ombitasvir, Paritaprevir & Ritonavir	Abbvie, Inc.	July 22, 2016	Chronic Hepatitis C
Xiidra Ophthalmic SolutiongbZ	Lifitegrast	Shire US Inc	July 11, 2016	Dry Eye Disease
Syndros Oral Solution	Dronabinol	Insys Therapeutics, Inc.	July 1, 2016	Anorexia – AIDS Patients; Nausea/Vomiting – Chemotherapy Induced
Epclusa Tablets	Sofosbuvir & Velpatasvir	Gilead Sciences, Inc.	June 28, 2016	Chronic Hepatitis C
Rayaldee Capsules	Calcifediol	OPKO Health, Inc.	June 17, 2016	Secondary Hyperparathyroidism
Vaxchora Suspension	Cholera Vaccine, Live, Oral	PaxVax Bermuda Ltd.	June 10, 2016	Cholera Prophylaxis

Novel Tenofovir Drug OK'd for Hepatitis B

The USFDA has approved Gilead Sciences' tenofovir alafenamide (TAF), to be sold as Vemlidy, for adults with chronic hepatitis B infection with compensated liver. TAF is a prodrug for tenofovir, an antiviral agent previously approved under the name Viread for HIV and HBV infection. The new version will come with a boxed warning about risk of lactic acidosis and severe hepatomegaly with steatosis, as well as post-treatment severe acute exacerbation of hepatitis B. Two phase III trials reported earlier this year supported the approval. Those studies found the drug was as effective as Viread but with less toxicity. The company did not indicate what it would charge for the new drug, but promised that its patient assistance programs would help eligible patients with out-of-pocket costs.

Novel Diabetes Drug Approved by USFDA

Eli Lilly and Company announced the USFDA approved Synjardy XR (empagliflozin and metformin hydrochloride extended-release) for the treatment of patients with type 2 diabetes. When used with diet and exercise, Synjardy XR can improve blood sugar control in these patients, according to a press release from Lilly. The drug is co-marketed by Lilly and Boehringer Ingelheim. Synjardy XR is a combination of empagliflozin and metformin, which have complementary mechanisms of action. Empagliflozin is a sodium-glucose co-transporter 2 inhibitor that removes surplus glucose through the urine by inhibiting re-absorption in the kidney, according to Lilly. Metformin is a commonly used diabetes treatment that lowers glucose production and absorption. The recent approval is based on positive findings from multiple clinical trials that analyzed the co-administration of empagliflozin and metformin. These clinical trials also studied the drugs as a monotherapy, or plus sulfonylurea in patients with type 2 diabetes. While the drug is effective in patients with type 2 diabetes, Lilly warns that it is not indicated in patients with type 1 diabetes or diabetic ketoacidosis, and these patients should not use Synjardy XR. Synjardy XR can potentially cause serious side effects, such as lactic acidosis, where lactic acid accumulates in the blood.

FDA accepts BLA for subcutaneous formulation of rituximab

The FDA has accepted the biologics license application from Genentech for a subcutaneous formulation of rituximab for multiple blood cancer indications. The co–formulation, created with Halozyme's proprietary recombinant human hyaluronidase enzyme, has been approved and marketed as MabThera SC outside the United States. Rituximab is a cancer medication that can be used in combination with methotrexate to treat symptoms of adult rheumatoid arthritis. The most common side effects of the drug are headache, fever, chills, stomach pain, nausea, and diarrhea.

FDA approves Biogen drug for leading genetic cause of infant death

USFDA has approved Biogen Inc's drug to treat spinal muscular atrophy, the leading genetic cause of death in infants. It is the first FDA-approved medicine for spinal muscular atrophy, a devastating disease that affects about one in 10,000 live births. The drug, nusinersen, which was discovered by Ionis Pharmaceuticals and licensed to Biogen, will be sold under the brand name Spinraza. The FDA approved it for use across the full range and severity of the disease. In the most severe form of spinal muscular atrophy, known as type 1, or infantile SMA, babies rarely make it to their second birthday. SMA is caused by deficiency of a protein called smn in the spinal motor neurons. It leads to severe and progressive muscular atrophy and weakness, including in muscles needed for breathing and swallowing. Spinraza, which is injected into the spinal fluid, increases levels of the deficient protein. In clinical trials, nusinersen led to dramatic improvement in motor milestones and extended survival. It has been tested with successful results in all severities of the disease, including in infants with the genetic deficiency who have yet to show symptoms of the disease.

Clovis's ovarian cancer drug wins accelerated FDA approval

The USFDA granted accelerated approval to Clovis Oncology Inc's ovarian cancer drug in patients with a specific gene mutation whose disease had advanced despite two or more rounds of chemotherapy. The drug, rubraca, which secured approval about two months earlier than scheduled, targets patients whose tumors have a mutation called BRCA, identifiable using an FDA-approved companion diagnostic test. About 15-20 percent of ovarian cancer patients have the BRCA mutation, the FDA said. Rubraca is expected to compete against Tesaro Inc's niraparib and AstraZeneca Plc's lynparza. All three drugs belong to a closely watched class of new medicines called PARP inhibitors, which block enzymes involved in repairing damaged DNA, thereby helping to kill cancer cells. Maintenance therapy immediately follows initial treatment to keep patients cancer-free if they go into remission. Rubraca is expected to generate sales of $267 million in 2018, according to brokerage Janney Montgomery Scott. Other drugmakers, including AbbVie and Medivation, which was recently bought by Pfizer Inc for $14 billion, also have PARP inhibitors in development.

Gastroenterology Courses & Conferences 2017

TITLE	VENUE	SCHEDULE
24th Annual Convention and Scientific Seminar of Bangladesh Gastroenterology Society	BICC, Dhaka	Feb 10–12, 2017
Hot Tropics: Updates for the Practicing Gastroenterologist 2017	Florida , USA	Feb 11–11, 2017
Saudi Gastroenterology Association15th Conference 2017	Jeddah , Saudi Arabia	Feb 11–12, 2017
12th European Crohn's And Colitis Organisation Congress 2017	Barcelona , Spain	Feby 15–18, 2017
World Endoscopy Organization Congress 2017	Hyderabad , India	Feb 16–19, 2017
Belgian Week of Gastroenterology 29th Annual Meeting 2017	Antwerpen , Belgium	Feb 17–20, 2017
Dysphagia Research Society 25th Annual Meeting & Post-Graduate Course 2017	Portland, USA	Mar 02–04, 2017
33rd PSG Annual Congress 2017	Karachi, Pakistan	Marh 02–04, 2017
Canadian Digestive Diseases Week 2017	Banff , Canada	Mar 03–06, 2017
17th Annual Gastroenterology And Hepatology: Viva La Vida 2017	Carolina , USA	Mar 07–10, 2017
89th Japan Gastric Cancer Association Annual Meeting 2017	Hiroshima , Japan	Mar 08–10, 2017
Asociación Española de Gastroenterología (AEG) 2017	Madrid, Spain	Mar 08–10, 2017
Sydney International Endoscopy Symposium 2017	Sydney , Australia	Mar 15–17, 2017
Journées Francophones Hepato-Gastroenterology & Digestive Oncology'17	Paris , France	Mar 23–26, 2017
Italian Society Of Digestive Diseases 23rd Congress 2017	Bologna , Italy	Mar 29–Apr. 01, 2017
German Society Of Endoscopy And Imaging 47th Congress 2017	Berlin, Germany	Apr 06–08, 2017
European Gastro Update 2017	Vienna , Austria	Apr 06–08, 2017
European Association for the Study of the Liver 52nd Annual Meeting 2017	Amsterdam, Netherland	Apr 19–26, 2017
Japanese Society Of Gastroenterology 103rd Annual Meeting 2017	Tokyo, Japan	Apr 20–22, 2017
5th Canadian Obesity Summit 2017	Banff Springs, Canada	Apr 25–29, 2017
Hiv And Hepatitis Management: The New York Course 2017	New York, USA	May 11–12, 2017
Swedish Society For Gastroenterology 2017	Gothenburg, Sweden	May 17–19, 2017
6th Con. of Gastroenterologists & Hepatologists in Bosnia & Herzegovina	Sarajevo, Bosnia	May 17–20, 2017
European Meeting on Hiv & Hepatitis Treatment Strategies & Antiviral Drug Resistance 2017	Rome, Italy	June 07–09, 2017
50th ÖGGH Annual Meeting & 28th Postgraduate Course 2017	Linz, Austria	June 08–10, 2017
35th Gastroenterology And Endotherapy European Workshop 2017	Brussels, Belgium	June 19–21, 2017
British Society of Gastroenterology Annual Meeting 2017	Manchester , UK	June 19–22, 2017
8th Congress of the Africa M-E Association of Gastroenterology'17	Addis Ababa, Ethiopia	July 05-09, 2017
ASSA SAGES Congress 2017	P. Elizabeth, S. Africa	Aug 05–08, 2017
Congreso Argentino de Gastroenterología y Endoscopia Digestiva 2017	Rosario, Argentina	Sept 07–09, 2017
12th Euro-Global Gastroenterology Conference	Paris, France	Sept 11-12, 2017
Japan Digestive Disease Week 2017	Fukuoka, Japan	Oct 12–15, 2017
World Congress of Gastroenterology (WCOG) at ACG 2017	Florida, USA	Oct 13–18, 2017
25th United European Gastroenterology (UEG Week) 2017	Barcelona, Spain	Oct 28–Nov. 01, 2017
5th Int'l Symposium on Complications in GI Endoscopy 2017	Hamburg, Germany	Nov 02–02, 2017
Congreso de las Asociaciones Colombianas del Aparato Digestivo 2017	Bogotá, Colombia	Nov 02–05, 2017
13th Int'l Conference on Clinical Gastroenterology & Hepatology 2017	Las Vegas, USA	Nov 13-15, 2017

GLOSSARY OF TERMS
GASTROENTEROLOGY

Abdominoperineal resection: Surgical removal of the anus, rectum and sigmoid colon, resulting in the need for a permanent colostomy.
Ascites: Fluid in the abdomen.

Celiac disease: Digestive disease that damages the small intestine and prevents the proper absorption of nutrients from food. Celiac disease occurs when the body reacts abnormally to gluten, a protein found in wheat, rye, barley and oats.

Cirrhosis: A slowly progressing disease in which healthy liver tissue is replaced with scar tissue, eventually preventing the liver from functioning properly. The scar tissue blocks the flow of blood through the liver and slows the processing of nutrients, hormones, drugs and naturally produced toxins.

Crohn's disease: A chronic inflammatory disease that involves all layers of the intestinal wall. Crohn's disease can disrupt the normal function of the bowel in a number of ways.

Diverticulitis: An inflammation or infection of small sacs or outpouchings (diverticula) of the inner lining of the intestine which protrude through the intestinal wall.

Elastase: An enzyme found in fluids produced by the pancreas which aids in the digestion of several proteins.

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

Esophageal manometry: A test used to measure the strength and coordination of the esophagus during swallowing to identify the source of problems in the upper digestive system.

Fecal occult blood test (FOBT): Stool testing for blood, which is recommended every year starting at age 50, in addition to the flexible sigmoidoscopy test every five years, to screen for colon cancer and polyps.

Helicobacter pylori (H. pylori): A bacterium believed to be a major cause of peptic ulcers.

Hemorrhoids: Swollen blood vessels which line the anal opening, caused by excess pressure from the straining during a bowel movement, persistent diarrhea or pregnancy.

Hiatal hernia: Abnormal bulge or protrusion of a portion of the stomach through a hole in the diaphragm where the esophagus and the stomach join.

HIDA scan: Also called cholescintigraphy, during this test a radioactive material, called hydroxy iminodiacetic acid (HIDA), is injected into the patient. The test is used to diagnose certain conditions of the liver and gallbladder.

Inflammatory bowel disease (IBD): Diseases which cause inflammation of the bowel. IBD includes Crohn's disease and ulcerative colitis.

Inguinal hernia: An inguinal hernia develops when a portion of an internal organ, such as the intestine, along with fluid, bulges through a weakened area in the muscular wall of the abdomen.

Intravenous pyelogram (IVP): A technique to evaluate the function of the urinary tract by injecting dye into the tract and then viewing its flow by X-ray.

Irritable bowel syndrome: A condition in which the colon muscle contracts more readily and causes abdominal pain and cramps, excess gas, bloating and a change in bowel habits that alternate between diarrhea and constipation.

Paracentesis: The removal of the accumulation of fluid in the abdomen.

Portal hypertension (colon): An increase in the pressure within the portal vein (the vein that carries blood from the digestive organs to the liver.)

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

FACTS ON FINGER TIPS
GASTROPARESIS

Definition
Gastroparesis, also called "paralyzed stomach" is a serious condition manifested by delayed emptying of stomach contents into the small intestine after a meal. Young and middle-aged women are at the highest risk for developing idiopathic gastroparesis.

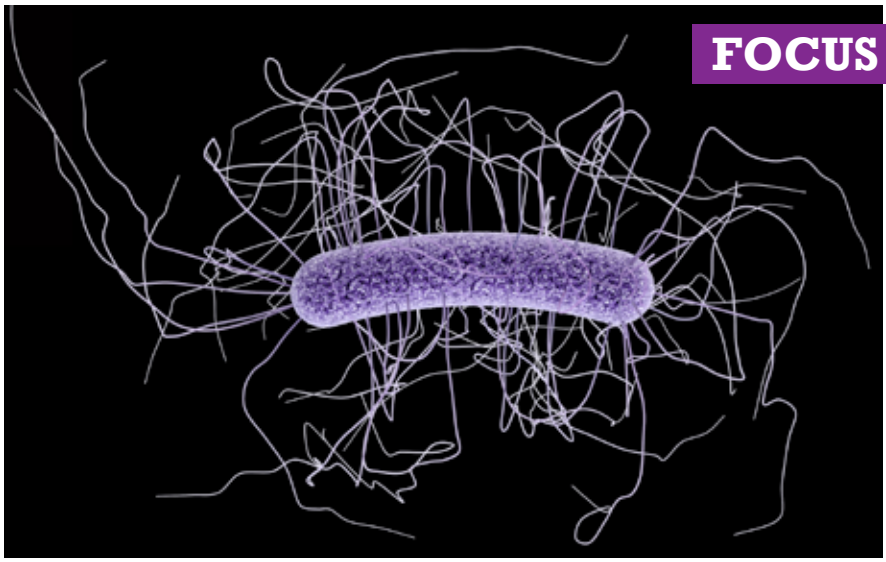
Symptoms
The common symptoms are-
- Chronic nausea
- Vomiting (especially of undigested food)
- Abdominal pain
- Feeling of fullness after just a few bites
- Lack of appetite
- Gastroesophageal reflux
- Spasms of the stomach wall
- Weight loss and malnutrition

Causes & Risk Factors
Most people diagnosed with gastroparesis have idiopathic gastroparesis. The primary cause of gastroparesis is damage to or dysfunction of peripheral nerves and muscles. Other factors include:
· Vagus nerve damage · Uncontrolled diabetes · Certain medications i.e. tricyclic antidepressants, calcium channel blockers, clonidine, dopamine agonists, lithium, nicotine, and progesterone · Conditions such as Parkinson's disease, multiple sclerosis, amyloidosis, and scleroderma · Viral infection · Radiation therapy or chemotherapy · Hypothyroidism · Abdominal or esophageal surgery · Scleroderma (a connective tissue disease)

Diagnosis
- Upper gastrointestinal endoscopy
- CT scan, MRI, and ultrasound
- Upper GI series or barium X-ray
- Gastric emptying study
- Electrogastrography
- Wireless capsule test
- Scintigraphic gastric accommodation
- Small intestine X-ray

Treatment
- **Dietary changes**
  Eat smaller meals more frequently · Chew food thoroughly · Avoid fibrous fruits & vegetables, fatty foods and carbonated drinks · Drink water throughout each meal
- **Medications**
  To stimulate the stomach muscles- Metoclopramide, erythromycin, Domperidone.
  To control nausea and vomiting- Prochlorperazine, thiethylperazine, ondansetron and diphenhydramine.
- **Surgery**

HEARTBURN DRUGS MAY RAISE RISK OF STOMACH INFECTIONS



People who take heartburn drugs such as Prilosec and Nexium may be at increased risk of two potentially serious gut infections, a new study suggests. Both bugs cause abdominal pain and diarrhea, but can become more serious — especially C. diff. According to the U.S. Centers for Disease Control and Prevention, almost half a million Americans were sickened by the infection in 2011, and 29,000 of them died within a month. The heartburn drugs in question included both proton pump inhibitors (PPIs) — brands like Prilosec, Prevacid and Nexium — and H2 blockers, such as Zantac, Pepcid and Tagamet, the study authors said. All suppress stomach acid production, and the researcher's suspect that may make some people more vulnerable to gastrointestinal infections. The U.S. Food and Drug Administration has already warned about a risk of C. diff infection linked to proton pump inhibitors. Buckley, who was not involved in the study, said it's also important to see the results in a bigger context. Long-term use of PPIs, in particular, has been tied to a number of health risks, including nutrient deficiencies, bone loss and heart attack, he said. Because PPIs are so common and available over-the-counter, people may assume they're "100 percent safe," Buckley pointed out. The new findings don't actually prove that either PPIs or H2 blockers raised the risk of gut infections. But it is plausible, according to the researchers, led by Dr. Thomas MacDonald, a professor of pharmacology at the University of Dundee in Scotland. They suspect that drugs that suppress stomach acids can change the balance of "good" and "bad" bacteria in the gut, which may make people more susceptible to infections. Patients and doctors should be aware that the drugs might contribute to the risk of certain infections. ●

Source: Medlineplus.gov

YOU NEVER KNEW!

- Sitting for more than three hours a day can cut two years off a person's life expectancy.
- Sleeping less than 7 hours each night reduces your life expectancy.
- You are about 1 centimeter taller in the morning than in the evening.
- The adult human heart weighs about ten ounces.
- It takes an interaction of 72 different muscles to produce human speech.
- Of the 206 bones in the average human adult's body, 106 are in the hands and feet (54 in the hands and 52 in the feet).
- The human brain has about 100 billion neurons. From the age of 35 years about 7,000 neurons are lost daily.
- The amount of carbon in the human body is enough to fill about 9,000 'lead' pencils.
- The brain itself is incapable of feeling pain. Once the skull is opened it is possible to operate on the brain with the patient awake.
- Nerve impulses travel at over 400 Km/hr speed.
- We give birth to over 200 billion red cells every day.
- In one square inch of our hand, we have nine feet of blood vessels, 600 pain sensors, 9000 nerve endings, 36 heat sensors and 75 pressure sensors.
- The life span of a taste bud is ten days.
- 1 Can of Soda a day increases your chances of getting type 2 diabetes by 22%
- Exercise, like walking, can reduce breast cancer risk by 25%.
- 8.5% of adults worldwide currently have diabetes. That's almost twice as much as it was in 1980.
- Your body produces enough heat in only thirty minutes to boil a half-gallon of water.
- Human bone is as strong as granite, relative to supporting resistance.
- By the age of eighteen your brain stops growing.
- Humans share about 50% of DNAs with banana

ANTI-MICROBIAL RESISTANCE

-An Overlooked Adverse Event

Antimicrobial resistance (AMR) – one of the greatest threats to achieving UN's Sustainable Development Goals – is increasingly being recognized as an issue of global concern that requires global collective action.

If AMR remains unchecked

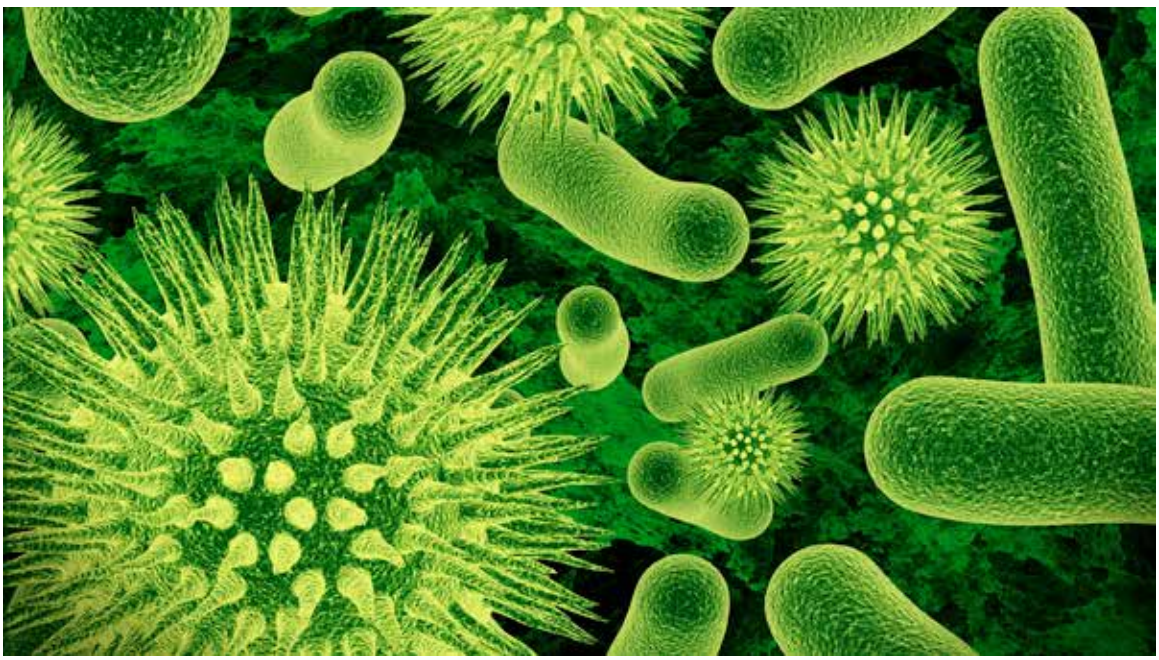
The progress achieved by modern medicine in the past 70 years is at serious risk of coming undone. Already today more than half a million deaths annually are attributable to antimicrobial resistance – a number projected to rise to 10 million in 2050 if no action is taken. Solutions to contain this issue need to reflect the broad ecological nature of AMR, which require a multi-sectorial response, including management of the medicines' pathway from the manufacturing facility to the patient's bedside. Assuring quality, safety, and effectiveness of antibiotics need to go hand-in-hand with data generation on antibiotic use, resistance levels, and patients' access to effective antibiotics. As more data is generated to reveal the magnitude of the problem, it shows that the post-antibiotic era may already have begun. Every year, 214,000 newborn sepsis deaths are estimated to be directly attributable to bacteria that are resistant to available antibiotics. That is roughly one third of all neonatal sepsis deaths. In the last years, antibiotic resistance has started to compromise the effectiveness of carbapenems – a last-line class of antibiotics used against serious bacterial infections. According to a study from the Southeast Asian region, more than 75% of Acinetobacter isolates, 30% of Klebsiella isolates, and 10% of E. coli isolates displayed resistance to carbapenems. Of particular concern is the increasing prevalence of carbapenem-resistant Enterobacteriaceae (CRE), as mortality rates in patients with CRE infections are high. Another study done in health facilities in the African region detected 100% resistance to ampicillin in Klebsiella sepsis isolates.

Cross-cutting nature of AMR needs broader set of actors

This crosscutting nature of the issue means that it has direct consequences for our social and economic development. In 2015, countries adopted the Global Action Plan on Antimicrobial Resistance at the World Health Assembly, as a blueprint and guideline for the development and implementation of National Action Plans on Antimicrobial Resistance. Recognition of the threat AMR poses to the successful fulfilment of the Sustainable Development Goals propelled the topic to the level of Heads of States at the United Nations General Assembly in September 2016. Following HIV/AIDS, non-communicable diseases, and Ebola, AMR is only the fourth health issue to ever be brought up at the General Assembly as a matter of urgent consideration. The combination of the cross-cutting nature of AMR and recent political developments underline the need to involve actors that previously haven't been directly engaged with the topic. The increasing political and technical attractiveness of AMR can be helpful for this broader engagement, but that may not be enough. Means of implementation to turn words into action are essential.

Ensuring sustainable access to effective antibiotics

Since 1987, no new class of antibiotics has been discovered. Lack of profitability and major scientific bottlenecks has meant that pharmaceutical companies have withdrawn in big numbers from the anti-infectives research and development (R&D) field. Moving away from the current patent based innovation model and designing incentives and investment strategies that can help overcome the scientific and financial bottlenecks is urgently needed, but is currently subject of intense debate by key stakeholders. New approaches are needed not only in R&D, but also in the way we manage antibiotics. Environmental pollution from antibiotic production sites, substandard quality of antibiotics, and unnecessary use in human medicine and livestock production are just some of the drivers of AMR, which needs to be addressed. Antibiotic stewardship measures need to be considered and developed at every step of the antibiotic lifecycle – from development, to production, to use. Such measures need however to be balanced carefully against the need to ensure universal access to effective antibiotics for all in need. Some populations still haven't even entered the antibiotic era. It is estimated that



half of the one million deaths in children under 5 years of age from pneumonia every year could have been averted had they had access to the necessary antibiotics. Within health systems, antimicrobial stewardship programmes aiming to minimise unnecessary use of antibiotics and limit the spread of resistant bacteria need to be anchored within an integrated strategy for drug safety monitoring. Such programmes include training of doctors, pharmacists, and others handling antibiotics to do the necessary benefit–risk assessment, as well as to use standard treatment guidelines to decrease irrational use of antibiotics. Likewise, data generation on AMR on resistance levels and antibiotic use, but also the availability of antibiotics, will require context-specific new ways of thinking to fill existing significant knowledge gaps. In addition, increasing in-country technical expertise is crucial – particularly in resource-poor settings – to conduct pilot studies to inform countries' situation analyses.

The role of pharmacovigilance in AMR management

Disproportionally greater reporting on antimicrobial treatment failure can be an indication of two major public health issues: presence of antimicrobial resistance and/or medicines of poor quality. The complexity emerges with the latter being a direct driver of the former. Detection of observed-to expected ratios of reported clusters of adverse events can be an enabling factor in identification of resistance spread patterns in the respective area. Use of poor quality medicines containing sub-therapeutic doses of the active pharmaceutical ingredient can express itself clinically with expected antipyretic effect while prolonging the illness period. Such medicines often fly under the radar of the pharmacovigilance reporting system while driving bacterial resistance. Pattern interpreting algorithm analysis therefore needs to carefully account for antimicrobials of poor quality that can contribute to statistical bias. This and other approaches in data generation can help bridge the knowledge gap in antimicrobial surveillance. Pharmacovigilance tools can support the WHO's efforts to strengthen the evidence base through enhanced global surveillance and research coordinated via the recently established Global AMR Surveillance System. Pharmacovigilance systems in all high-income countries and in many low- and middle income countries can directly assist and inform both policies and medicines regulatory processes when developing a National Action Plan on AMR. Pharmacovigilance data collection and regulatory strengthening therefore has a crucial role to play to catalyse the urgently needed systemic and cultural change in how we can manage and use antibiotics to ensure their effectiveness and longevity for generations to come.

Source: Uppsala Monitoring Center

Direct-acting antivirals for hepatitis C

The US Food and Drug Administration (FDA) has requested that a boxed warning about the risk of hepatitis B virus (HBV) reactivation is added to the drug labels of direct-acting antivirals for hepatitis C (DDAs). This warning should also be included in the patient information leaflets or medication guides for these medicines. The FDA identified 24 cases of HBV reactivation from reports submitted to the FDA. Of the cases reported, two patients died and one required a liver transplant. Healthcare professionals are recommended to screen all patients for evidence of current or prior HBV infection before starting treatment with DAAs, and to monitor patients using blood tests for HBV flare-ups or reactivation during treatment and post-treatment follow-up.

Levetiracetam and methotrexate

Health Canada has recommended that the product information for levetiracetam and methotrexate products is updated to provide information about drug-drug interaction, which could lead to greater amounts of methotrexate in the blood. Product labelling now recommends that blood methotrexate and levetiracetam levels should be carefully monitored in patients treated with the two drugs at the same time. The manufacturer of levetiracetam provided 13 international reports of a potential interaction between levetiracetam and methotrexate. Of these 13 reports, five noted that patients who were taking both levetiracetam and methotrexate at the same time had greater amounts of methotrexate in their blood. Health Canada's safety review concluded that there is a potentially greater risk of adverse effects when levetiracetam and methotrexate.

FDA issues warning for anesthetic drug use in young children

The USFDA has issued a drug safety communication for young children and pregnant women regarding the use of general anesthetic and sedation drugs during surgeries or procedures. The new warning indicates that these drugs may cause damage to the development of children's brains with repeated or lengthy use. Label warnings will now be required by the FDA to inform the public about the potential risk to children's brain development. The use of general anesthetic and sedation drugs will continue to be monitored by the FDA for further information about adverse events. The FDA encourages health care professionals to assess appropriate use of these drugs and balance the benefits against potential risks with each patient, especially for procedures taking longer than 3 hours or in multiple procedures required for children younger than 3 years old.

PPIs may increase risk of CAP

Proton pump inhibitors (PPIs) are commonly prescribed for certain gastrointestinal conditions. It is suspected, however, that in altering the acidity of the stomach, the drugs may promote bacterial overgrowth and colonization leading to pneumonia. U.K. and Saudi researchers teamed up to investigate this potential association. The study population included 160,000 adults with a new PPI prescription and individually matched control patients. Observational data was analyzed using three different analytic approaches. While a multivariable Cox regression model indicated that risk for community–acquired pneumonia (CAP) was 1.67 times higher among PPI users than non–users, a self–controlled case series and a prior event rate ratio analysis pointed to lower risk in the 30 days and 12 months, respectively, after PPI prescription than in the 30 days and 12 months before.

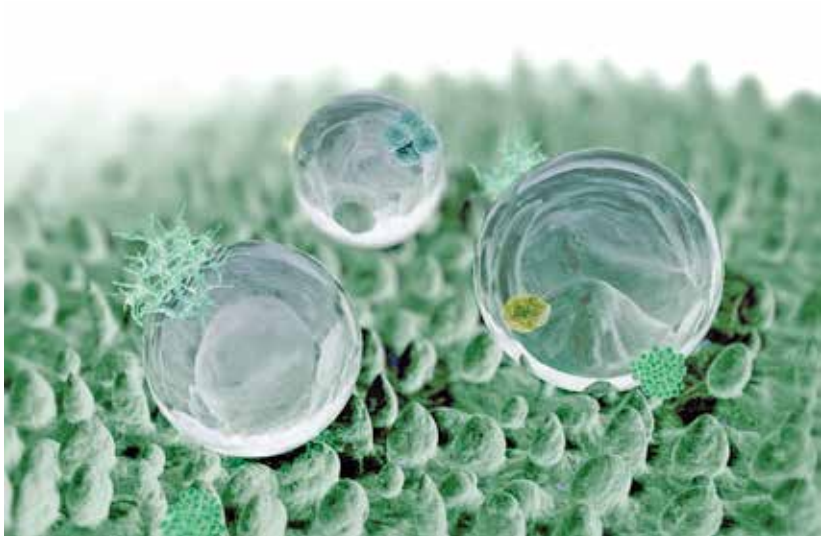
Aspirin-containing over-the-counter antacid products

The US FDA has warned consumers about the risk of serious bleeding when using over-the-counter (OTC) aspirin-containing antacid products to treat heartburn, sour stomach, acid indigestion, or upset stomach. A search of the FDA Adverse Event Reporting System (FAERS) database identified eight cases of serious bleeding events associated with these products after the warning was added. All of these patients were hospitalized. As a result, the FDA will continue to evaluate this safety concern and plan to convene an advisory committee of external experts to provide input regarding whether additional actions are needed.

Increased risk of Bladder Cancer in Pioglitazone-containing medicines

As a result of an updated review, the FDA has concluded that use of the type 2 diabetes medicine pioglitazone (Actos, Actoplus Met, Actoplus Met XR, Duetact, Oseni) may be linked to an increased risk of bladder cancer. FDA alerted the public about the possible risk of bladder cancer in September 2010 and June 2011 based on interim results from a 10-year epidemiologic study. Health care professionals should not use pioglitazone in patients with active bladder cancer, and should carefully consider the benefits and risks before using pioglitazone in patients with a history of bladder cancer.

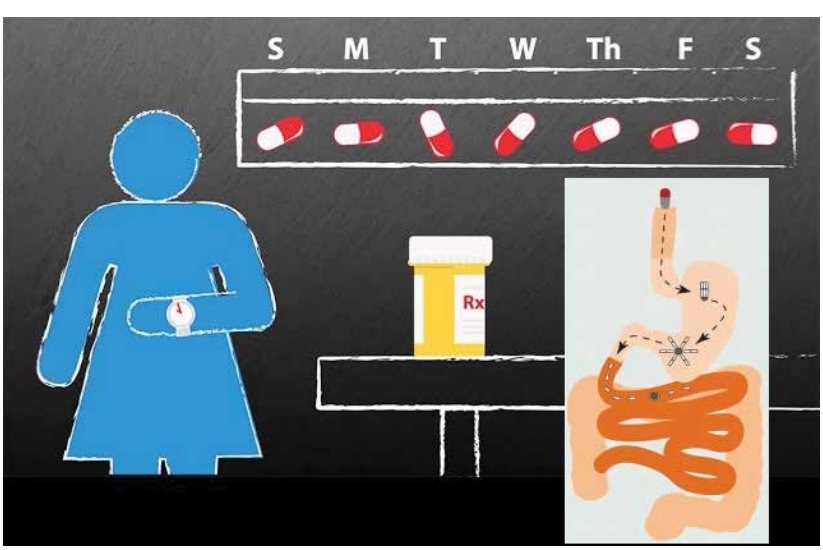
Slow-release hydrogel targets sites of inflammatory bowel disease



Researchers have developed a slow-release, inflammation-targeting hydrogel for patients with chronic inflammatory bowel disease (IBD), which could reduce uncomfortable, enema-based treatment from once-daily to once-weekly. Investigators from Brigham and Women's Hospital (BWH), Massachusetts General Hospital (MGH), and Massachusetts Institute of Technology (MIT) sought to deliver anti-inflammatory treatment directly to the surface of the colon. "We realized that if we could develop a disease-targeted hydrogel system that rapidly attaches to ulcers and slowly releases drugs at the site of inflammation, then we could create a better way to deliver medicine only where the drug is needed," said the co-corresponding author. For this study, the investigators developed hydrogel microfibers from ascorbyl palmitate, an FDA-approved compound that possesses both hydrophilic and lipophilic properties. This negatively-charged hydrogel can be disassembled by enzymes found only in inflamed tissue, which is positively charged. The investigators loaded the hydrogel with dexamethasone, which is commonly used to treat IBD. When the inflammation-targeting hydrogel drug meets such enzymes, the molecules that make up the gel begin to break apart, slowly releasing the dexamethasone.

Ultra-long acting pill releases daily doses of medicine for a month

The problem with pills is that you have to take them on a regular basis. Now, imagine swallowing a pill today that continues releasing the daily dose of a medicine you need for the next week, month or even longer. Investigators from Brigham and Women's Hospital and their collaborators from the Massachusetts Institute of Technology (MIT) have developed a long-acting drug delivery capsule that may help to do just that in the future. The capsule is about the size of a fish oil capsule when swallowed. Once inside the stomach, the capsule unfolds into a star-shaped structure too large to pass through the pylorus and exit the stomach, but designed to allow food to continue passing through the digestive system. The capsule contains polymers and other materials mixed with ivermectin to allow the drug to slowly diffuse out of the material over time. The team reports evidence of diffusion for up to two weeks, and is interested in continuing to develop the system so that it can provide the drug for one month or longer. In addition, they envision potential applications beyond infectious disease, including chronic diseases such as psychiatric disease, heart disease, renal disease and more. They plan to investigate the system's applications for these conditions as well.



Explore untapped potential of the strongest most pharma-economy of CWentral & West African pharma markets at 4th NIGERIA PHARMA MANUFACTURERS' EXPO 2017

4th Nigeria Pharma Manufacturers Expo 2017 (NPME 2017), an international exhibition on pharmaceutical industry is happening for the 4th time during August 30-31 to 01 September, 2017 at New Haven, Oba Akinjobi Street, GRA, Ikeja, Lagos NIGERIA. NPME 2017 is hailed as one of the biggest international pharma manufacturing exhibition of the Central & West Africa region attracting more than 150 exhibiting companies and nearly 3,500 pharma trade professionals from across the region including Nigeria, Ghana, Mali, Chad, Cameroon, EQ Guinea, Central African Republic, Senegal, The Gambia, Ivory Coast, Niger, Burkina Faso, Benin amongst others.

NPME 2017 is being jointly organized by the Pharmaceutical Manufacturers Group of Manufacturers' Association of Nigeria (PMG-MAN) and GPE EXPO PVT. LTD. The official media is PHARMA Pro&Pack magazine and official website of NPME 2017 is www.NigeriaPharmaExpo.com.

Largest most exhibitions on pharma manufacturing technologies for Central & West African pharma markets NPME 2015, an international exhibition will provide an unique platform to showcase Pharma Processing Machineries (Tablet / Capsule / Liquid / Injectables / Ointment / Dry Syrup), Packaging Machineries, Packaging Materials & Consumables, API, Bulk Drugs, Additives, Excipients, Pharma Finished Products, Formulations Lab Reagents, Glassware & Equipments, Analytical, R&D Equipments & Biotech Instruments, Environment Control Eqpts & Services, Utilities Products & Services, Turn-key Contractors, Project Consultants etc.

Brief about the Organizers:

Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN): PMG-MAN is the umbrella body of the local manufacturers of the medicines and healthcare products in Nigeria with over one hundred members having established factories that manufacturing life-saving medicines to support the Healthcare Delivery System. The major target of the PMG-MAN is to realize Government objective of making Nigeria self-sufficient in essential medicines through local manufacturing of Drugs. The Group also focuses on the exports drive of locally manufactured quality medicines to the West African region. The pharmaceutical manufacturing sector of Nigeria contributes to nation building with aggregate investments in excess of N300 billion, paying taxes and other tariffs and employing over 600,000 persons. In collaboration with relevant stakeholders, PMG-MAN established the 1st special Exhibition / Expo starting in June 2008 in Abuja, which sensitized and showcased the resources, contributions and breakthrough pharmaceutical products – Proudly Made – in – Nigeria to Nigerian citizenry, policy makers and the international community.

4th Nigeria Pharma Manufacturers' Expo 2017 coming up in August 30-31 & 1 September 2017, is an opportunity for stakeholders in the health sector to exchange information, products, services and ideas towards achieving the Health related Millennium Development Goals and other developmental initiatives in Nigeria and West African region.

GPE EXPO PVT. LTD.: Established in 1997, GPE has attained an international recognition worldwide including, India, Malaysia, Syria, Bangladesh, Pakistan, Nepal, and have become specialized in providing event organizing, planning and consultation services, event marketing & management for country specific international Exhibitions, along with for corporate, associations and individual organizations of pharmaceutical, healthcare, chemical sectors. The core strength is in the logistical details of organizing and executing large events involving multiple players, while integrating diverse services. Based on the experience in the industry, GPE has established an expertise, which enables to produce a top rated event in all areas including decor, food and beverage, entertainment and timely execution. We pride ourselves on having a professional commitment to each aspect of a client's project.

GPE enjoys the credit of highly successful organization (marketing, management, and execution) of several country specific international exhibitions for pharmaceutical industry, includes; PHARMA Pro&Pack Expo (India), Asia Pharma Expo (Malaysia & Bangladesh), Nigeria Pharma Manufacturers' Expo (Nigeria), Kenya Pharma Expo (Kenya), Pak Pharma Expo (Pakistan), Nepal Pharma Expo (Nepal), PHARMA Pro&Pack Expo (India) & Global Pharma Expo (India), and many more to emphasize the significance of the local pharma industry on the global platform. GPE is having co-ordeal relationship with various national trade associations of these countries. Besides servicing pharmaceutical industry, GPE has been also associated with Healthcare and Chemical segments, including Association of Surgeons of India, Society of Gastroenterology (India), Society of Gastrointestinal Endoscopy of India, Association of Colon and Rectum Surgeons of India, Research Society for the Study of Diabetes in India, Indian Society of Knee and Hip Surgeons, Association of Physicians of India, Urologist Society of India, etc.

For further information, please visit: www.NigeriaPharmaExpo.com or contact at: info@NigeriaPharmaExpo.com

CAN YOUR OWN IMMUNE SYSTEM FIGHT OFF CANCER?

Sharyn Mackay and John Pattison belong to an extraordinary club - people told they have terminal cancer only for their tumours to disappear inexplicably, to the astonishment of patient and doctor alike. It's tempting to see these stories as medical miracles. But drug companies are hard on the trail of a more rational answer - that the tumours were 'killed off' by the patient's own immune system - and are developing new therapies to harness this power

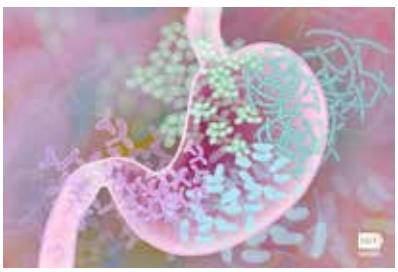
Sharyn was suffering from pain in the right side of her stomach when she was diagnosed with a cancerous tumour on her kidney, which proved be spindle cell sarcoma, which is normally a bone cancer. But, the doctor told her that the cancer had metastasized through the kidneys and lungs. Three months later, scans showed the cancer was gone. Now let's take a look at John Pattison's story. When he was diagnosed with Hodgkin's disease, he, too, was told his case was terminal. The doctors decide on palliative care, to make him feel more comfortable, rather than a cure. However, after two months the astonishing miracle happened. John was told he had gone into spontaneous remission.

Not a fairy tale: The power of human immune system

A New York surgeon, William Coley was one of the first scientists to try to recruit the immune system to fight cancer in the 1890s. He was inspired by a patient who recovered from sarcoma after suffering a serious bacterial infection. In 2006, Dr Wolf Fridman, working in Paris, analysed colon tumour cells. He found the level of white blood cells inside their tumours was a strong predictor of recovery. Those with the highest number of the cells rarely relapsed; those with the fewest almost always did. Cancer Research UK Centre in Southampton is examining ways of creating vaccines that stimulate patients' immune systems to produce antibodies that kill tumour cells. The journal Lung Cancer reported on a man whose tumours had spontaneously disappeared. They found his blood had high levels of an antibody to a molecule called NY-ESO, which was found where his tumours had been.

GlaxoSmithKline, Bristol-Myers Squibb, Sanofi-Aventis and Pfizer are developing drugs to boost the immune system to fight cancer. GlaxoSmithKline has just recruited more than 2,200 patients worldwide for final-stage tests of a vaccine to prevent lung cancer and skin cancer melanoma. A series of injections is given to stimulate the immune system to destroy cells that carry a molecule called MAGE-A3. This is not present in normal tissue, but found most commonly in lung cancer and melanoma. Preliminary results in small trials suggest the vaccine can boost survival rates by up to 27%. Meanwhile, a drug called Ipilimumab is being developed by Bristol-Myers Squibb and Medarex. In one trial, it shrank tumours in 10% of melanoma patients. The drug is also being tested in men with prostate cancer. The key is to encourage antibodies to attack only a person's own cancer cells, leaving the rest unscatched. After all, why use devastatingly strong drugs to kill cancer cells if you can recruit the body's own defences to do it?

Sleep loss tied to changes in Gut Bacteria



Getting too little sleep alters the balance of bacteria in the gut, a change that's linked to certain metabolic conditions, including obesity and type 2 diabetes, new research shows. For the study, European researchers limited the sleep of nine healthy men who were a normal weight to examine how sleep loss affects the number of types of bacteria in the gut. For two days in a row, the men slept only four hours a night. The study showed the diversity of gut bacteria didn't change but sleep loss did alter the balance of the existing groups of bacteria. The sleep-deprived participants were also 20 percent less sensitive to the effects of insulin. These changes parallel some of the differences seen when obese people have been compared with normal-weight people in other studies, said the senior study author. The study authors said more research is needed to assess sensitivity to the effects of sleep loss and how it affects brain function and metabolic health

Benefits of daily aspirin outweigh risk to stomach

Stomach bleeds caused by aspirin are considerably less serious than the spontaneous bleeds that can occur in people not taking the drug, concludes a study led by Cardiff University. The extensive study of literature on aspirin reveals that while regular use of the drug increases the risk of stomach bleeds by about a half, there is no valid evidence that any of these bleeds are fatal. Heart disease and cancer are the leading causes of death and disability across the world, and research has shown that a small daily dose of aspirin can reduce the occurrence of both diseases by around 20-30%. Recent research has also shown that low-doses of aspirin given to patients with cancer, alongside chemotherapy and/or radiotherapy, is an effective additional treatment, reducing the deaths of patients with bowel, and possibly other cancers, by a further 15%.

Groundbreaking research finds fungus plays a central role in Crohn's disease

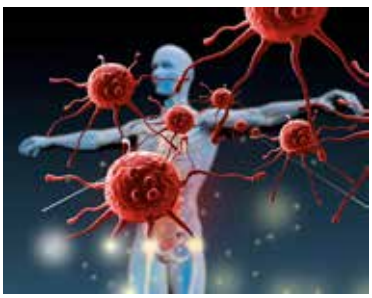
Researchers reported for the first time that the fungus Candida tropicalis appears to play a critical role— along with elevated levels of Serratia marcescens and Escherichia coli bacteria in the intestinal tracts of patients with Crohn's disease, which suggested that these organisms interact. This is the first study to find that a fungus is associated with Crohn's disease in humans and also the first to include S. marcescens in the analysis of the intestinal bacteriome of Crohn's patients. The researchers also discovered that E. coli cells fused to C. tropicalis cells, while S. marcescens used bridge-like fimbriae to link to the two other microbes. "Interestingly, in biofilms formed by the three organisms, S. marcescens cells interacted with both C. tropicalis and E. coli through these fimbriae," the authors wrote. "Specific interkingdom microbial interactions may be key determinants in Crohn's disease."

Breath test could diagnose irritable bowel syndrome

Researchers have identified a combination of 16 volatile organic compounds (VOCs) in the breath that, when measured together, can accurately identify patients with irritable bowel syndrome (IBS).The authors express that this study can be considered an important first step forward in the design and development of reliable non-invasive biomarkers for IBS. The investigators reasoned that because exhaled human breath contains hundreds of VOCs, metabolic differences may indicate certain states of disease, in this case, IBS. After analyzing the collected breath samples with gas chromatography, the researchers found a pattern of 16 VOCs that indicated IBS, with a sensitivity of 89.4% and specificity of 73.3%. The researchers also found that the VOCs moderately correlated with severity of GI symptoms—the worse the results of the breath test, the worse the patient's symptoms. This finding could not only help identify disease severity, but could also be used to monitor the effects of treatment, the researchers predicted.

Modified virus could turn immune system on liver cancer

A modified form of Reovirus could be used to launch an immune attack on liver cancer cells, a new study has revealed. The study also found that the virus can stop the hepatitis C virus,

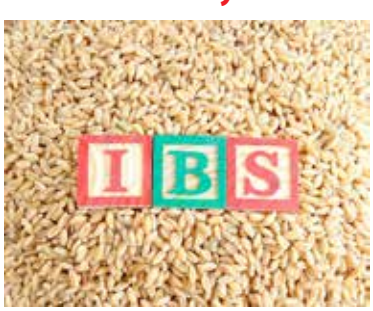


which is a cause of liver cancer, from growing. The researchers suggest that the virus' double blow may be a more effective treatment than what is currently available for liver cancer. The team also found that the modified virus works as a type of immunotherapy, kick–starting the immune system into action against the cancer. This causes the release of an immune molecule called interferon, which activates natural killer cell. The natural killer cells then recognise and destroy the tumour cells, while interferon blocks hepatitis C virus growth. Studying mice with liver cancer, treatment with the modified Reovirus caused the tumour cells to die. And those that had liver cancer caused by the hepatitis C virus, the viral treatment stopped the harmful virus from reproducing.

Novel HCV Drug Combo Shines in CKD Patients

An investigational combination of antiviral agents was almost universally successful in curing hepatitis C (HCV) patients with severe kidney disease, according to a new study. The combination, glecaprevir/pibrentasvir cleared HCV in 98% of patients after 12 weeks of treatment. Patients all had stage 4 or 5 kidney disease and 82% were on dialysis, a population of people at high risk for HCV and regarded as difficult to treat. Also, current recommended therapies for people with HCV and chronic kidney disease are only aimed at a few of the HCV genotypes. So there is an "unmet medical need" that is satisfied by the new combination. The drug is co-formulated so that both medications are in a single pill; patients take three of them together once a day. The most common adverse events were pruritus, fatigue, and, nausea. Grade 3 or higher lab abnormalities were rare. The study, known as EXPEDITION-4, is one of several in drugmaker AbbVie's series of trials leading up to marketing applications.

Genetic carbohydrate digestion defects Linked to irritable bowel syndrome



Irritable bowel syndrome (IBS) is the most common gastrointestinal disorder. People with IBS often connect their symptoms to certain foods, particularly fermentable carbohydrates. Now an international research team led by scientists from Karolinska Institutet in Sweden have identified defective sucrase-isomaltase gene variants that increase the risk of IBS. The researchers studied DNA variants in the gene encoding the enzyme sucrase-isomaltase (SI), due to the observation that SI mutations are often found in hereditary forms of sucrose intolerance, whose main characteristics diarrhea, abdominal pain and bloating are also common in IBS. "Significant decrease in the enzymatic activity of sucrase-isomaltase would be compatible with poor carbohydrate digestion in the intestine, possibly leading to malabsorption and bowel symptoms" says co-senior author. The results provide rationale for novel nutrigenetic studies in IBS, with potential for personalizing treatment options based on SI genotype.

Certain high blood pressure drugs block cancer invasion

Researchers have identified a new way of blocking the spread of cancer. Calcium channel blockers, which are used to lower blood pressure, block breast and pancreatic cancer invasion by inhibiting cellular structures. By screening already approved drugs, the team in University of Turku has discovered that calcium channel blockers can efficiently stop cancer cell invasion in vitro. Cancer kills because of its ability to spread throughout the body and form metastases. Therefore, developing drugs that block the ability of cancer cells to disseminate is a major anti-cancer therapeutic avenue. Identification of anti-hypertension drugs as potential therapeutics against breast and pancreatic cancer metastasis was a big surprise. The targets of these drugs were not know to be present in cancer cells and therefore no one had considered the possibility that these drugs might be effective against aggressive cancer types.

TOP 25 GLOBAL MEDICINE BRANDS

HUMIRA adalimumab

Manufactured by AbbVie Inc. – Rheumatoid Arthritis and other inflammatory conditions
Annual Sales $14,021M
Annual Growth 11.8%

HARVONI ledipasvir/sofosbuvir 90 mg/400 mg tablets

Manufatured by Gilead Sciences, Inch (US) –Hepatitis C
Annual Sales $13,864M
Annual Growth 551.8%

Enbrel etanercept

Manufactured by Amgen Inc. (US)- Rheumatoid Artritis, psoriasis and other inflammatory conditions
Annual Sales $*9.027M
Annual Growth 1.2%

Remicade INFLIXIMAB

Manufactured by Johnson & Johnson (US), Merck & Co. (US), Mitsubishi Tanabe Pharma Corporation (Japan), - Anti-TNF alpha drug for inflammatory disorders
Annual Sales $*8,957M
Annual Growth -9.4%

LANTUS insulin glargine injection 100 Units/mL

Manufactured by JSanofi S.A. (France)- Diabetes
Annual Sales $7,209M
Annual Growth 0.7%

AVASTIN bevacizumab

Manufactured by JF. Hoffmann-La Roche AG (Switzerland), Cancer
Annual Sales $6,905M
Annual Growth 4.2%

Herceptin trastuzumab Precision • Power • Promise

Manufactured by JF. Hoffmann-La Roche AG (Switzerland)-Anti-HER2 for breast Cancer
Annual Sales $6,754M
Annual Growth 4.2%

Prevnar 13 Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein)

Manufactured by Pfizer Inc. (US) Pneumococcal Vaccine
Annual Sales $6,254M
Annual Growth 39.9%

MabThera Rituximab

Manufactured by JF. Hoffmann-La Roche AG (Switzerland)- Cancer
Annual Sales $5,827M
Annual Growth 0.7%

Revlimid

Manufactured by Celgene Corporation (US)- Multiple Myeloma
Annual Sales $5,801M
Annual Growth 16.5%

CRESTOR rosuvastatin calcium

Manufactured by AstraZeneca Plc (UK), Shionogi & Co. Ltd. (Japan)- Diabetes
Annual Sales $5,427M
Annual Growth -8.2%

SOVALDI SOFOSBUVIR 400 mg TABLETS

Manufactured by Gilead Sciences, Inc. (US)- Hepatitis C
Annual Sales $5,176M
Annual Growth -48.7%

Seretide

Manufactured by GlaxoSmithKlnie Plc (UK) Asthma
Annual Sales $5,228M
Annual Growth -13.0%

COPAXONE (glatiramer acetate injection)

Manufactured by Teva Pharmaceutical Industries Ltd.-Multiple Sclerosis
Annual Sales 5,213M
Annual Growth -6.5%

Courtesy: Igea the Hub forMedicine, Pharma & Health

Symbicort (budesonide/formoterol fumarate dihydrate) Inhalation Aerosol

Manafactured by AstraZeneca Plc (UK)-Asthma
Annual Sales 3,394M
Annual Growth -10.7%

SPIRIVA® (tiotropium)

Manufactured by Boehringfer Ingelheim GmbH (Gemany)-Bronchospasm
Annual Sales $3,201M Annual Growth -12.3%

Neulasta® (pegfilgrastim)

Manufactured by Amgen Inc. (US)
Leukocyte Growth Factor
Annual Sales $4,715M
Annual Growth 2.6%

Januvia (sitagliptin, MSD)

Manufactured by Marck & Co (US)-Diabetes
Annual Sales $3,864M
Annual Growth -1.7%

Nexium® esomeprazole / esoméprazole

Manafactured by AstraZeneca plc (UK) Daiichi Sankyo Company Ltd. (Japan), Gastroesophageal Reflux Disease
Annual Sales $*3,196M
Annual Growth -25.5%

gleevec™ imatinib mesylate

Manufactured by Novartis AG (Switzerland- Cancer
Annual Sales $4,658M
Annual Growth -1.9%

LYRICA® PREGABALIN

Manufactured by Pfizer Inc. (US)-Anti-Epileptic
Annual Sales $3,655M
Annual Growth 9.1%

Truvada®

Manufactured by Gilead Sciences, Inch (US)-HIV
Annual Sales $3,459M
Annual Growth 3.6%

Xarelto® rivaroxaban

Manufactured by Bayer AG (Germany), Johnson & Johnson (US)-Anticoagulant
Annual Sales $4,409M
Annual Growth 29.1%

LUCENTIS® RANIBIZUMAB

Manufactured by Novartis AG (Switzerland), F. Hoffmann La Roche AG (Switzerland)- Macular Degeneration
Annual Sales $3,630M
Annual Growth -13.5%

ATRIPLA®

Manufactured by Gilead Sciences, Inc (US), HIV
Annual Sales $3,134 Annual Growth -9.7%

UPCOMING EVENTS

TITLE	VENUE	SCHEDULE
Arab Health 2017	Dubai, UAE	Jan. 30-Feb. 02, 2017
Health Tech India 2017	New Delhi, India	February 02-04, 2017
MedLab 2017	New Delhi, India	February 06-09, 2017
Bio Asia 2017	Hyderabad, India	February 06-08, 2017
India Pharma 2017	Bengaluru, India	February 09-11, 2017
MediTech Healthcare Asia 2017	Gujarat, India	February 10-12, 2017
Medical Japan 2017	Osaka, Japan	February 15-17, 2017
4th Africa Healthcare Summit 2017	London, UK	February 21-22, 2017
Asia Pharma Expo 2017	Dhaka, Bangladesh	February 23-25, 2017
Medhealth Kenya	Nairobi, Kenya	February 24-26, 2017
Medex Algeria 2017	Algiers, Algeria	March 02-04, 2017
CPhI Istanbul	Istanbul, Turkey	March 08-10, 2017
CPhI South East Asia 2017	Jakarta, Indonesia	March 22-24, 2017
CPhI Russia	Moscow, Russia	March 28-30, 2017
Medical Fair India 2017	New Delhi, India	April 06-08, 2017
Medeiconex 2017	Cairo, Egypt	April 08-10, 2017
Korea Lab & Korea Pharma 2017	Seoul, Korea	April 18-17, 2017
China International Health Care Fair 2017	Xiamen, China	April 20-24, 2017
Vietnam Medi-pharm 2017	Hanoi, Vietnam	May 10-13, 2017
Medexpo Ethiopia 2017	Addis Ababa, Ethiopia	May 12-14, 2017
Radiology Asia 2017	Singapore	May 19-20, 2017
6th Pharmaceutical Sciences World Congress	Stockholm, Sweden	May 21-24, 2017
KIHE 2017	Almaty, Kazakhstan	May 24-26, 2017
MediPharm Expo 2017	Yangon, Myanmar	May 25-27, 2017
ProPak Asia 2017	Bangkok, Thailand	June 14-17, 2017
26th China (Guangzhou) International Health Industry Expo (IHE 2017)	Guangzhou, China	June 16-18, 2017
In Pharma Japan 2017	Tokyo, Japan	June 28-30, 2017
Interphex Japan 2017	Tokyo, Japan	June 28-30, 2017
Myanmar Phar-Med Expo 2017	Yangon, Myanmar	July 05-07, 2017
MediPharm Expo 2017	Ho Chi Minh City, Vietnam	August 17-19, 2017
Medexpo Tanzania 2017	Dar es Salaam, Tanzania	August 22-24, 2017
Pharmacon Asia 2017	Singapore	Sept 12-15, 2017
Combodia Phar-med Expo 2017	Phnom Penh, Combodia	Sept 15-17, 2017
MEDEXPO KENYA 2017	Nairobi, Kenya	Oct 26-28, 2017

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.

Dos & Don'ts

- Do consider raising the head of your bed. Elevating your head keeps the contents of the stomach from sliding up against the LES (the sphincter that separates the esophagus from the stomach) while you sleep.
- Do chew thoroughly. Chewing aids digestion by breaking down food and mixing it with digestive enzymes and probiotics in the mouth.
- Do consider chewing gum after meals. Gum stimulates saliva production, which is alkaline. The saliva goes down the esophagus and helps protect the food tube and neutralize some of the acid in the stomach. (Avoid peppermint-flavored gum, which can actually increase the odds of reflux.)
- Do eat smaller meals. The greater the volume of your meal, the higher the odds it will give you heartburn simply because of the mechanical pressure the weight of the food puts on the LES.
- Do encourage the proliferation of dietary enzymes and good bacteria by eating fermented foods rich in probiotics, such as yogurt, cheese, lassi, miso etc.

- Don't eat mindlessly. Eat plenty of fruits and vegetables to keep things moving. When cooking meat, choose to grill, broil or bake instead of pan fry or deep fry.
- Don't eat junk food. Processed foods are filled with chemicals designed to delay degradation and extend shelf life.
- Don't eat within two hours before vigorous exercise. Too much vigorous exercise (like jumping rope or fast-paced jogging) can induce acid reflux, even in people who usually don't suffer from the condition.
- Don't lie down within two to three hours of eating. Gravity is your friend. Give the stomach plenty of time to empty its contents before you get horizontal.
- Don't suck on peppermints to combat the sour taste in your mouth. Peppermint can relax the esophageal sphincter muscle, which could exacerbate your problem

HISTORY MAKER

PROFESSOR DAME SHEILA PATRICIA VIOLET SHERLOCK, a British physician, is considered one of the world's leading authorities on liver disease and a pioneer in the science of hepatology. She was born in Dublin in 1918. She went to Edinburgh University in 1936, where she studied the biochemistry of the liver and its disorders. When Dr. Sherlock began her medical career in the early 1940's, very little was known about liver disease, and hepatology was not even a recognized branch of medicine. Her classic reference work, "Diseases of the Liver and Biliary System", now in its 11th edition and used throughout the world, was the first standard textbook on clinical liver disease. Throughout her career, she conducted clinical research that led to improved diagnosis and treatment of liver disease and that helped establish and later enhance the field of hepatology. In 1959, she became the first woman to be promoted to a professorship of medicine at the Royal Free Hospital in London, where she helped set up and direct a world famous clinical, research and training center on liver disease. In 1966, she helped create what is now a standard test in diagnosing primary biliary cirrhosis. A few of her contributions to hepatology are, the role of the hepatitis B virus in the development of cirrhosis and liver cancer, autoimmunity as the cause of primary biliary cirrhosis, and the great benefit of corticosteroid therapy for autoimmune hepatitis. Throughout her career Dr. Sherlock published more than 600 papers on the liver. In 1986, she received the Distinguished Service Award of the American Association for the Study of Liver Diseases, which is awarded only on a special basis. She died on 30 December 2001, aged 83, from pulmonary fibrosis.

WISH TO EXPORT TO ETHIOPIA?

Ethiopia is consistently investing in its health sector. The Democratic Republic of Ethiopia, on 14 July 2015, launched an ambitious 10-year national strategy and plan of action to develop local pharmaceutical manufacturing capacity in order to increase access to locally manufactured, quality-assured medicines. Currently, there are 12 pharmaceutical companies operating in the country, and only six of them at full capacity. Cadila, Julphar Ethiopia, the Ethiopian Pharmaceutical Manufacturing Company and Pharmacure are some of the major players. There are also approximately 200 importers of pharmaceutical products and medical consumables in Ethiopia. In 2014, the local companies supplied products to the value of 44,225 million USD. According to Pharmaceutical Fund and Supply Agency (PFSA Ethiopia), Ethiopian private pharmaceutical market is estimated to be worth between 400 and 500 million USD and said to be growing at an impressive rate of 25% per annum. Studies also suggest that the market could witness a slightly 14% growth rate to reach an approximate value of just under 1 billion USD in the year 2018. Things are moving fast, with state support and a vibrant local market.

Food, Medicine and Health Care Administration and Control Authority of Ethiopia (FMHACA) Guidance:

1. Paper size should be A4. Margins for top, bottom, header, and footer are 12.5 mm, and left and right margins are 25mm. Paragraph: Single line spacing. Font: Times New Roman, letter space 0%, type size 12point.

2. *Cover:* hard cover and labeled with the name of product, dosage form, strength, and name of the manufacturer.

3. The color of the dossier folder for a new, normal application should be black; for a new drug application by a stringent regulatory authority(SRA) should be red; for re-registration should be blue; for variation, furtherance, and amendment should be yellow or light yellow.

4. One hard copy of the PD should be submitted along with electronic copy.

5. The attached data and documents should be in the English language.

6. Any abbreviation should be clearly defined.

7. The compilation of the document should be outlined according to the respective modules and should be indexed or annotated as described in this Guideline in the

Common Technical Document (CTD) format.

8. *Evaluation and Notification:* The application submitted for registration will be screened chronologically according to date of submission to the Authority, and the applicant will be notified of the results of its evaluation within 30 days of its submission to the Authority.

9. Fast Track Registration: Antimalarial, antiretroviral, anti-tuberculosis medicines, reproductive health care products, anti-cancer drugs, vaccines, drugs for ~~–~~orphan diseases and drugs for emergent humanitarian aid shall have priority for evaluation and registration.

10. *Brand (Trade Name):* Generally, the first and last three letters of any trade name should not be identical with a registered product in Ethiopia.

The following Modular format of PDs in the CTD content should always be considered during dossier preparation for registration submission to the Authority:

Module 1 – Administrative information and prescribing information

1.1 Cover Letter
1.2. Table of Contents of the Application, including Module 1 (Modules 1-5)
1.3. Application Form
1.4. Agency Agreement
1.5. Good Manufacturing Practice Certificate and Certificate of Pharmaceutical Product.
1.6. Certificate of Suitability (CEP), if any
1.7. Product Information
1.7.1. Summary of Product Characteristics
1.7.2. Labeling Information (immediate and outer label)
1.7.3. Patient Information Leaflet (PIL)
1.8. Evidence for an Application Fee

Module 2 – Dossier Overall Summary of Product Dossier (DOS-PD)

2.1 PD Table of Contents (Modules 2-5)
2.2 PD Introduction
2.3 Quality Overall Summary of Product Dossier (QOS-PD)
2.4 Nonclinical Overview – generally not applicable for multisource products (some exceptions may apply)
2.5 Clinical Overview
2.6 Nonclinical Written and Tabulated Summaries – generally not applicable for multisource products (some exceptions may apply)
2.7 Clinical Summary – generally not applicable for multisource products

Module 3 – Quality

3.1 Table of Contents of Module 3
3.2 Body of Data
3.3 Literature References

Module 4 – Nonclinical Study Reports – generally not applicable for multisource products (some exceptions may apply)

4.1 Table of Contents of Module 4
4.2 Study Reports
4.3 Literature References

Module 5 – Clinical Study Reports

5.1 Table of Contents of Module 5
5.2 Tabular Listing of all Clinical Studies
5.3 Clinical Study Reports
5.3.1 Reports of Biopharmaceutical Studies (mainly BE study reports for generic products)
5.3.7 Case Report Forms and Individual Patient Listings – generally not applicable for multisource products(some exceptions may apply)
5.4 Literature References.

Drugs Regulatory Authority:

Food, Medicine and Health Care Administration and Control Authority
Ministry of Health
Government of the Federation Democratic Republic of Ethiopia
P.O. Box 5681, Addis Ababa
ETHIOPIA
Telephone No: +251-11-5524122
Fax No.: +251-11-5521392
E-mail: regulatory@fmhaca.gov.et
Website: www.fmhaca.gov.et

APPOINTMENTS & PROMOTIONS

RAZIUL AMIN CHOWDHURY joined as the Chief Operating Officer of Labaid Pharmaceuticals Limited recently. He completed his Bachelor & Master's degree under Pharmacy Department of Dhaka University and he also took MBA degree from the Institute of Business Administration (IBA). After that he achieved MS in Management Information System from the University of Baltimore, Maryland, USA. He began his career in Square Pharmaceuticals Limited. Later on, he joined Roche Bangladesh Limited as a Senior Executive, Corporate Affairs & ended his journey at Roche as Managing Director & Country Manager.

KAZI MUSTANUR RAHMAN has recently been promoted as Manager, Production Planning and Scheduling in Square Pharmaceuticals Ltd. Prior to this, he was serving as Sr. Executive, Production in the same company. He joined Square Pharmaceuticals Ltd. as Executive, Production in the year 2006. He started his journey in the pharmaceutical industry as Quality Compliance Officer in ACI Pharmaceuticals Ltd. He obtained his Bachelor of Pharmacy degree from Khulna University and his MSc in Pharmaceutical Technology from University of Asia Pacific.

MAZAHARUL ISLAM has recently joined NOVO Healthcare and Pharma Ltd. as Assistant Manager, Marketing Strategy Department. Prior to this, he worked at One Pharma Ltd. as Product Manager, Product Management Department in different capacities. He started his carrier in Virgo Pharmaceuticals Ltd. He completed his B.Pharm from University of Science and Technology Chittagong (USTC) and M.Pharm from State University of Bangladesh.

IMRAN ISLAM NOYAN has recently joined ONE PHARMA LTD. as Assistant Manager, PMD. Prior to this, he worked in UAE based multinational Pharmaceutical Company, Julphar Bangladesh Ltd. as Group Product Manager, Marketing. He started his career from RAK Pharmaceuticals Ltd. as Product Executive in Product Management Department & served there for 7 years. Imran obtained his B.Pharm & M.Pharm degrees from University of Development Alternative (UODA). He has undergone a good number of training and has diversified experience in pharmaceutical marketing.

MD. KAWSER HOSSAIN has recently joined Julphar Bangladesh, a Joint Venture with Gulf Pharmaceuticals Industries, UAE and Hetero Drugs, India, the largest pharmaceuticals conglomerate in the world, as Product Manager. He looks after overall business of Chronic Care Portfolio. Prior to this, he has worked in marketing department of Concord Pharma and Apex Pharma. He started his career in Apollo Hospitals Dhaka after completion of his B. Pharm & M. Pharm. He obtained his MBA from AIUB. Kawsar has vast knowledge and expertise in managing Chronic Care Brands.