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NEW ARRIVALS

ACME

Brand Name: Logibac
Generic Name: Ceftibuten INN
Dosage Form: Capsule
Strength: 400mg
Indication: RTI, UTI

Brand Name: Cortimax
Generic Name: Deflazacort INN
Dosage Form: Tablet
Strength: 6mg & 24mg
Indications: Asthma, Allergy & Rheumatoid Arthritis, Anaphylaxis, Chronic Dermatoses.

Aristopharma

Brand Name: Dexamox
Generic Name: Moxifloxacin + Dexamethasone Phosphate
Dosage Form: Sterile Eye Drops
Strength: 0.5% + 0.1%
Indications: Post-op and other inflammation associated with infection.

Asiatic

Brand Name: R-20
Generic Name: Rabeprazole Sodium INN
Dosage Form: Tablet
Strength: 20mg
Indications: Erosive or Ulcerative GERD, Reflux Esophagitis, Peptic Ulcer, Zollinger-Ellison Syndrome, Barrett's esophagus and Malignancy.

Brand Name: Fenimex
Generic Name: Pheniramine Maleate BP
Dosage Form: IM/IV Injection
Strength: 45.5mg/2ml
Indications: Hay Fever, Urticaria and Pruritus.

Brand Name: Aceptin-R
Generic Name: Ranitidine
Dosage Form: IM/IV Injection
Strength: 50mg/2ml
Indications: Peptic Ulcer, Reflux Esophagitis, Post-operative Ulcer and Zollinger-Ellison Syndrome.

Brand Name: Asiclin
Generic Name: Clindamycin
Dosage Form: IM/IV Injection
Strength: 300mg/2ml
Indications: LRTIs, SSTIs, Dental infections, Gynecological Infections, Intra Abdominal Infections, Bone & Joint Infections.

Brand Name: Surpim
Generic Name: Ketorolac Tromethamine USP
Dosage Form: IM/IV Injection
Strength: 30mg/ml
Indications: Post-operative pain, acute pain, and Moderate to severe pain management.

Beximco

Brand Name: Traneta M
Generic Name: Linagliptin plus metformin hydrochloride
Dosage Form: Film Coated tablet
Strength: 2.5mg, 500mg, 850mg and 1000mg
Indications: Adjunct therapy to diet and exercise in type 2 diabetes.

Brand Name: Nitrosol SR
Generic Name: Nitroglycerin
Dosage Form: Tablet
Strength: 2.6mg
Indications: Nitrosol SR tablet is indicated for the management of angina pectoris. The onset of action is not sufficiently rapid for this form to be useful in aborting an acute angina episode.

Brand Name: Penomer
Generic Name: Meropenem
Dosage Form: IV Injection
Strength: 500mg & 1g Inj.
Indications: Community acquired pneumonia, Surgical site infections, Gynecological infections, Nosocomial pneumonia, Intra-abdominal infections and Meningitis.

Biopharma

Brand Name: Dialina 5
Generic Name: Linagliptin
Dosage Form: Tablet
Strength: 5mg
Indication: Treatment of Type 2 diabetes mellitus to improve glycemic control in adults.

Brand Name: Gloucium-D
Generic Name: Glucosamine sulfate & Diacerein
Dosage Form: Tablet
Strength: 75mg & 50mg
Indication: Osteoarthritis, Lumber degenerative joint pain, Bone and Joint injuries and post knee surgery.

Eskayef

Brand Name: SOLBION
Generic Name: Vitamin B1+B6+B12
Dosage Form: Oral tablet
Strength: Vitamin B1= 100mg, B6= 200mg, B12= 200mcg
Indications: Chronic painful conditions e.g. Low Back Pain, Neck Pain & Diabetic Peripheral Neuropathy

Brand Name: XINC OT
Generic Name: Zinc Orotate Dihydrate
Dosage Form: Oral tablet
Strength: Zinc Orotate Dihydrate INN equivalent to Elemental Zinc 10mg
Indications: Improving wound healing, Treatment and prevention of Zinc deficiency, Improving testosterone level, Fighting colds, Herpes simplex etc.

Brand Name: Facid tablet
Generic Name: Sodium Fusidate
Dosage Form: Oral tablet
Strength: Sodium Fusidate BP 250mg
Indications: Osteomyelitis, SSTI, post-surgical infection, complicated *S. aureus* infection

Brand Name: Lotrel G
Generic Name: Loteprednol Etabonate and Gatifloxacin
Dosage Form: Ophthalmic Suspension
Strength: 0.5% & 0.3%
Indications: Steroidal Anti-inflammatory and Anti-infective Eye Drop

NEW ARRIVALS

Brand Name: Noclog
Generic Name: Clopidogrel
Dosage Form: Film Coated Tablet
Strength: 75mg
Indication: Ischaemic Stroke, Myocardial Infarction, Peripheral Artery Disease.

Brand Name: Edenil
Generic Name: Spironolactone + Furosemide
Dosage Form: Film Coated Tablet
Strength: 50mg + 20mg
Indications: Edema, Hypertension, and CHF

Brand Name: Rupaday Oral Solution
Generic Name: Rupatadine
Dosage form: Oral Solution
Strength: Each 5ml oral solution contains Rupatadine Fumarate INN equivalent to Rupatadine 5mg.
Indications: Seasonal allergic rhinitis, Perennial allergic rhinitis and Chronic idiopathic urticaria

Brand Name: ZEEFOL-M
Generic Name: Ferric Polymaltose, Folic Acid, Zinc
Dosage form: Oral tablet
Strength: Elemental Iron 47mg, Folic Acid 0.5mg, Elemental Zinc 22.5mg
Indication: Iron deficiency anemia (IDA).

General

Brand Name: Rupoma
Generic Name: Rupatadine Fumarate
Dosage Form: Tablet
Strength: 10mg
Indication: Symptomatic treatment of seasonal & perennial allergic rhinitis & urticaria.

Brand Name: Rupoma
Generic Name: Rupatadine Fumarate
Dosage Form: Oral Solution
Strength: 5mg/5ml
Indication: Symptomatic treatment of seasonal & perennial allergic rhinitis & urticaria.

Brand Name: Oceancal-D
Generic Name: Calcium Carbonate (from Coral Source) + Vitamin D_3
Dosage Form: Tablet
Strength: 500mg + 200IU
Indication: Osteoporosis, Osteomalacia, Rickets, Tetany, Parathyroid Disease, Pregnancy & Lactation to meet the increased demand.

Brand Name: Oceancal-DX
Generic Name: Calcium Carbonate (from Coral Source) + Vitamin D_3
Dosage Form: Tablet
Strength: 600mg + 400IU
Indication: Osteoporosis, Osteomalacia, Rickets, Tetany, Parathyroid Disease, Pregnancy & Lactation to meet the increased demand.

Brand Name: Misopil
Generic Name: Misoprostol
Dosage Form: Tablet
Strength: 200mcg
Indication: Prevention of postpartum hemorrhage (PPH), Treatment of postpartum hemorrhage (PPH), Induction of labor, Cervical ripening pre-instrumentation.

Brand Name: Kit-63
Generic Name: Mifepristone & Misoprostol
Dosage Form: Tablet
Strength: 200mg & 200mcg
Indication: Termination of pregnancy up to 9 weeks (63 days) of gestation/Early menstrual regulation (MR).

Brand Name: Prebalin
Generic Name: Pregabalin
Dosage Form: Capsule
Strength: 25mg
Indication: Neuropathic pain, Fibromyalgia, Peripheral diabetic neuropathy.

Brand Name: Mirabeg
Generic Name: Mirabegron
Dosage Form: Extended release tablet
Strength: 50mg
Indication: Over active bladder (OAB).

Brand Name: Tiapine XR
Generic Name: Quetiapine
Dosage Form: Extended release tablet
Strength: 50mg
Indication: Schizophrenia, Bipolar disorder.

Brand Name: Tiapine XR
Generic Name: Quetiapine
Dosage Form: Extended release tablet
Strength: 200mg
Indication: Schizophrenia, Bipolar disorder.

Brand Name: Olmepres
Generic Name: Olmesartan Medoxomil
Dosage Form: Tablet
Strength: 40mg
Indication: Mild to moderate essential hypertension.

Globe

Brand Name: Bonmax
Generic Name: Ibandronic Acid INN
Dosage Form: Tablet
Strength: 150mg
Indications: Treatment and prevention of osteoporosis in postmenopausal women.

Brand Name: Pralidot
Generic Name: Pralidoxime Chloride USP
Dosage Form: Lyophilized Powder for IV Injection
Strength: 1gm/Vial
Indications: An antidote in the treatment of organophosphate pesticides and chemicals poisoning which have anticholinesterase activity and in the control of over dosage by anticholinesterase drugs used in the treatment of myasthenia gravis.

Brand Name: Salison
Generic Name: Betamethasone & Salicylic acid
Dosage Form: Ointment
Strength: Betamethasone 0.05% & Salicylic acid 3% (in 10 gm laminate tube)
Indications: Treatment of inflammatory, dry and scaly skin disorders, such as Eczema & Psoriasis.

NIPRO JMI

Brand Name: Receca 10
Generic Name: Racecadotril BP
Strength: 10mg
Dosage Form: Granules for Suspension (GFS)
Indication: Diarrhea

Brand Name : Receca 30
Generic Name: Racecadotril BP
Strength: 30mg
Dosage Form: Granules for Suspension (GFS)
Indication: Diarrhea

Brand Name: Symbiotrin
Generic Name: Miconazole
Strength: 2% w/w USP
Dosage Form: Oral Gel
Indications: Fungal infections of Oropharynx & Gastrointestinal tract

Brand Name: Camphor Plus
Generic Name: Methyl Salicylate BP, Menthol BP and Camphor BP
Strength: 30%, 10% and 4%
Dosage Form: Cream
Indications: Fast relief of minor aches and pains of muscles and joints (i.e. Backache, Arthritis, Strains, Bruises and Sprains)

Brand Name: Cefracef DS
Generic Name: Cefradine
Strength: 250mg/5ml
Dosage Form: Powder for Suspension (PFS)
Indications: RTIs, SSTIs, ENT Infections, UTIs & Dental Infections

Brand Name: Empa 10
Generic Name: Empagliflozin INN
Strength: 10mg
Dosage Form: Tablet
Indications: Type 2 Diabetes Mellitus & to reduce the risk of cardiovascular (CV) death

One Pharma

Brand Name: Azikil 20ml
Generic Name: Azithromycin Dihydrate
Dosage Form: Powder for Suspension
Strength: 200mg/5ml
Indications: Respiratory tract infections including Sinusitis, Pharyngitis, Tonsillitis, Otitis media, Typhoid fever & Diarrhea.

Brand Name: Kelorac
Generic Name: Ketorolac Tromethamine
Dosage Form: Injection (IM/IV)
Strength: 30mg/ml
Indications: Ketorolac Tromethamine is indicated for the short-term (<5 days) management of moderately severe acute pain that requires analgesia at the opioid level, (usually in postoperative setting).

Brand Name: Taxiclot 500
Generic Name: Tranexamic acid
Dosage Form: Capsule
Strength: 500mg
Indications: Menorrhagia, Prostatectomy and bladder surgery, Epistaxis, Conisation of the cervix, Management of dental extraction in patients with coagulopathies, Ulcerative colitis, Haematuria, Gastrointestinal haemorrhage.

Brand Name: P-lock 40
Generic Name: Pantoprazole Sodium Sesquihydrate
Dosage Form: Tablet
Strength: 40mg
Indications: Peptic ulcer disease, Gastro esophageal reflux disease, Treatment of ulcer resistant to H_2 receptor antagonists, Treatment of ulcers induced by non-steroidal anti-inflammatory drugs (NSAIDs).

Opsonin

Brand Name: Depodrol®
Generic Name: Methylprednisolone USP
Dosage Form: Tablet
Strength: 8mg & 16mg
Indications: Autoimmune disorder associated with Rheumatoid Arthritis, Adrenocortical insufficiency, Asthma, Multiple Sclerosis, Cancer & Ankylosing Spondylitis.

Brand Name: Ciclex ® Nasal Spray
Generic Name: Ciclesonide INN
Dosage Form: Nasal Spray
Strength: 50mcg per Spray
Indications: Seasonal Allergic Rhinitis & Perennial Allergic Rhinitis.

Brand Name: Zeltas®
Generic Name: Azelastine hydrochloride BP + Fluticasone propionate BP
Dosage Form: Nasal Spray
Strength: 137mcg + 50mcg
Indications: All kinds of rhinitis, asthma with persistant rhinitis, sinusitis, nasal congestion.

Brand Name: Movex® SR
Generic Name: Aceclofenac BP
Dosage Form: Tablet
Strength: 200mg
Indications: Osteoarthritis, Rheumatoid arthritis & Ankylosing spondylitis.

Brand Name: Dionem®
Generic Name: Doripenem
Dosage Form: IV Injection
Strength: 500 mg
Indications: Complicated intra-abdominal infections, complicated urinary tract infections including pyelonephritis & Nosocomial pneumonia including ventilator-associated pneumonia.

Popular

Brand Name: Dexogut
Generic Name: Dexlansoprazole INN
Dosage Form: Capsule
Strength: 30mg & 60m
Indications: Healing of erosive esophagitis (EE), Maintenance of Healed EE and relief of heartburn, Symptomatic Non-Erosive Gastro-esophageal reflux disease (GERD).

Brand Name: Toramax
Generic Name: Ketorolac Tromethamine
Dosage Form: Tablet & IM/IV Injection
Strength: 10mg, 30mg & 60mg
Indications: Toramax (Ketorolac Tromethamine) is indicated for the short-term management of moderate to severe acute pain, including post-surgical pain and acute musculoskeletal trauma pain.

Brand Name: Fexoral
Generic Name: Fexofenadine Hydrochloride USP
Dosage Form: Tablet & Suspension
Strength: 120mg & 180mg and 50ml
Indications: Fexoral is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older.Fexoral is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older.

Brand Name: Fexoral
Generic Name: Fexofenadine Hydrochloride USP
Strength: 120 mg & 180 mg tab and 50 ml suspension
Indication: Fexoral is indicated for the relief of symptoms associated with seasonal allergic rhinitis in adults and children 2 years of age and older.Fexoral is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in adults and children 6 months of age and older.

Brand Name: Dexogut
Generic Name: Dexlansoprazole INN
Strength: 30 mg& 60 mg capsule
Indication: Healing of erosive esophagitis (EE), Maintenance of Healed EE and relief of heartburn, Symptomatic Non-Erosive Gastro-esophageal reflux disease (GERD).

Brand Name : Toramax
Generic Name: Ketorolac Tromethamine
Strength: 10 mg Tablet, 30 mg & 60 mg IM/IV Injection
Indication: Toramax (Ketorolac Tromethamine) is indicated for the short-term management of moderate to severe acute pain, including post-surgical pain and acute musculoskeletal trauma pain.

Square

Brand Name: Seclo MUPS
Generic Name: Omeprazole
Dosage Form: Multiple Unit Pellet System (MUPS)
Strength: 20 mg
Indications: GERD, Gastric ulcer, Duodenal ulcer, NSAID-induced ulceration, Reflux Oesophagitis, *H. pylori* eradication, Zollinger-Ellison Syndrome etc.

Brand Name: Eporen
Generic Name: Recombinant Human Erythropoietin
Dosage Form: Pre-filled syringe injection
Strength: 2000 IU/0.2 ml, 3000 IU/0.3ml, 5000 IU/0.5 ml
Indications: Anemia associated with Chronic Kidney Disease, chemotherapy in non-myeloid malignancy & Zidovudine therapy in HIV patients. Anemic patients scheduled to undergo elective, non-cardiac, nonvascular surgery.

Brand Name: Otelast
Generic Name: Apremilast
Dosage Form: Tablet
Strength: 10mg & 30mg
Indications: Psoriatic arthritis (PsA) & Plaque Psoriasis

Brand Name: Cefotil Plus
Generic Name: Cefuroxime & Clavulanic Acid
Dosage Form: Powder for suspension
Strength: 70ml
Indications: Pharyngitis, Tonsillitis, Impetigo, Sinusitis, Acute otitis media.

Brand Name: Giloba 120
Generic Name: Ginkgo Biloba
Dosage Form: Capsule
Strength: 120mg
Indications: Cerebral insufficiency, Multi-infarct Dementia, Alzheimer's disease, Vertigo, Tinnitus, Intermittent claudication.

Brand Name: Suvirux
Generic Name: Sofosbuvir
Dosage Form: Tablet
Strength: 400mg
Indication(s): For the treatment of chronic Hepatitis C virus (HCV) infection in combination with other direct acting antivirals.

Brand Name: Racedot 100
Generic Name: Racecadotril
Dosage Form: Capsule
Strength: 100mg
Indications: Racecadotril is indicated for acute watery diarrhea.

Brand Name: Cholenak IV Infusion
Generic Name & Strength: Sodium Chloride 0.5% w/v, Potassium Chloride 0.1% w/v and Sodium Acetate 0.393% w/v
Dosage Form: IV infusion
Indications: Cholera, Diarrhea, Severe vomiting & Fluid loss due to excessive sweating

Brand Name: Fodexil 1gm
Generic Name: Cefadroxil
Dosage Form: Tablet
Strength: 1gm
Indications: Skin and soft tissue infections, Respiratory tract infections & uncomplicated lower Urinary tract infections.

Ziska

Brand Name: Pilosol Ointment
Generic Name: Calcium Dobesilate BP, Dexamethasone Acetate BP & Lidocaine Hydrochloride USP
Dosage Form: Ointment
Strength: 4%, 0.025% & 2%.
Indications: Internal & external hemorrhoids, Pre & postoperative treatment for hemorrhoidectomy, Anal pruritus, Anal eczema, Anal fissure and Acute hemorrhoidal thrombosis.

Novo Nordisk support DRU to Award Best Health Report

Novo Nordisk has supported Dhaka Reporters' Unity to award the best report in the health sector. The award will be given in four categories: print, electronic, radio and online media.

Mohammad Nasim, Health and Family Welfare Minister, and Anand Shetty, Managing Director of Novo Nordisk has delivered the cheque to Shakhawat Hossain Badsha, President of DRU at the inauguration ceremony of DRU-Lions Club of Dhaka Health Camp 2017 recently. The minister praised Novo Nordisk for supporting DRU.

Anand Shetty, Managing Director of Novo Nordisk, said: "We are working in Bangladesh for about 60 years and 90 years globally. Our commitments and contribution for the patients living with diabetes will be continued in the future also. Our key contribution is to discover and develop better biological medicines, manufacture them to meet increasing global demand and make them accessible wherever they are needed."

Novo Nordisk is the market leader within insulin and GLP-1 portfolio, and is the world's largest producer of insulin, said Shetty, adding that, "In Bangladesh we have introduced entire range of products starting from human insulin, modern insulin, next generation insulin and GLP-1, which meet the needs of all type of patients' requirement."

AK Azad Khan, President of Diabetic Association of Bangladesh, Faruque Pathan, Head of the Department of Endocrinology at BIRDEM General Hospital, M A Samad, CEO and senior consultant at National Healthcare Network were also present and spoke on diabetes.

Beximco Pharma commences export to Canada

Beximco Pharmaceuticals Limited the fast-growing manufacturer of generic pharmaceutical products and active pharmaceutical ingredients, recently announced that it has commenced the export of Olopatadine, an ophthalmic product for treating the symptoms of eye allergy, to Canada. This follows the approval of Olopatadine (0.1% solution) by Health Canada in October 2016 and is the first time a pharmaceutical product from Bangladesh has been launched in this North American country.

According to IMS data, the current market size for Olopatadine eye drops (including all strengths) in Canada is $14 million. The first consignment was delivered recently and the product will be distributed through the Company's existing partner in Canada. Beximco Pharma's second prescription product for the Canadian market is currently under evaluation by Health Canada, with approval expected by the first quarter of 2018. There are also a number of products in the R&D pipeline which the Company expects to file in Canada.

Beximco Pharma Managing Director, Nazmul Hassan MP, commented that the "Entry into the Canadian pharmaceutical market, following the successful launch of our first product in the US last year, is a significant step forward in strengthening our presence in North America. This is the first time a pharmaceutical product manufactured in Bangladesh, notably a sterile ophthalmic product, has been exported to Canada. The launch of our second product in North America is another validation of our strength in offering specialised generic products in a global setting. We continue to focus on building a strong pipeline for prescription markets."

Beximco Pharma's ophthalmic unit is the only such facility in Bangladesh to be approved by the regulatory authorities of Europe, Australia and Canada. The Company has developed a global footprint, with sales to more than 50 countries.

Beximco Pharma to acquire majority stake in Nuvista

Bangladesh's leading medicine producer Beximco Pharmaceuticals Limited recently announced that it has entered into a non-binding Memorandum of Understanding (MoU) under which Beximco may acquire a majority shareholding (85.22%) in Nuvista Pharma, a leading pharmaceutical company in Bangladesh specialising in hormones and steroid drugs. The proposed acquisition remains subject due to diligence and negotiation and completion of a definitive sale and purchase agreement. It is expected that the proposed acquisition will be completed by the end of December 2017, company Press release said.

Nazmul Hassan MP, Managing Director of Beximco Pharma, and Akhter Matin Chaudhury, Chairman of Nuvista Pharma, signed the MoU recently. High officials from both the companies were present during the signing ceremony held at Beximco Pharma head office in Dhaka. Nuvista Pharma, formerly Organon (Bangladesh) Ltd, was a subsidiary of Netherlands-based Organon International. It was sold out to the current Bangladeshi Management in 2006. The company has been operating in Bangladesh since 1964, with a local manufacturing facility at Tongi, Dhaka. They also have a long-term manufacturing and marketing collaboration with Merck Sharp & Dohme (MSD). According to the QuintilesIMS Q2 2017 data of the retail pharma market in Bangladesh, Nuvista Pharma currently ranks as the 21st largest supplier to the market by volume. The directors believe that the proposed acquisition will, if completed, accelerate revenue growth and improve the earning potential for Beximco Pharma, the statement added. Beximco Pharma Managing Director, Nazmul Hassan MP, commented: "We believe that this proposed acquisition would be the first in our company's history and will serve as a strong foundation for sustainable growth in the future. In our view, Nuvista Pharma is a good strategic fit for Beximco Pharma as their strong position in hormones and steroids, with a unique portfolio of 50 generics, complements our existing product range." The company shall make further announcements on progress as appropriate, the MD also said. ●

Lions Club of Dhaka organise 2-day Health Camp at DRU

Lions Club of Dhaka in association with Dhaka Reporters Unity had organised a two day health camp recently to mark its 60th anniversary.

The health camp supported by Novo Nordisk has created the opportunity for testing diabetes on first day and eye test on second day for the members of DRU. The camp inaugurated by Mohammad Nasim, Health and Family Welfare Minister at DRU.

Mohammad Saiful, president of Lions Club of Dhaka, said to mark the club's 60th anniversary and its focus on diabetes, the health camp has been organised. "We serve is our philosophy. We want to serve more. We want to stand for the society," said Saiful. A total of nine eye patients had been selected for the operations at subsidised cost at Lions Hospital in Dhaka, while 260 people had tested diabetes.

AK Azad Khan, President of Diabetic Association of Bangladesh, Anand Shetty, Managing Director of Novo Nordisk, Faruque Pathan, Head of the Department of Endocrinology at BIRDEM General Hospital, M A Samad, CEO and senior consultant at National Healthcare Network were also present and spoke on diabetes. ●

Paracetamol (modified- or prolonged-release)

The EMA has recommended that modified- or prolonged-release paracetamol products should be suspended from the market. This is in view of the risks to patients from the complex way these medicines release paracetamol into the body after an overdose. Paracetamol is a medicine that has been widely used for many years to relieve pain and fever in adults and children. The review of modified-release paracetamol has been carried out by the EMA's Pharmacovigilance Risk Assessment Committee (PRAC). The PRAC evaluated published studies and reports of overdose with these medicines, consulted experts in the management of poisoning and assessed how overdose with paracetamol is managed in the EU and other parts of the world. In many cases, it may not be known whether an overdose of paracetamol involves immediate-release or modified-release products, making it difficult to decide what type of management is needed. The committee could not identify a way to minimise the risk to patients, or a feasible and standardised way to adapt the management of paracetamol overdose across the EU to allow for treatment of cases that involve modified-release preparations. It concluded that the risk following overdose with these medicines outweighs the advantage of having a longer-acting preparation.

Warfarin

The MHLW and the PMDA have announced that the package insert for warfarin has been updated to include the risk of calciphylaxis as a clinically significant adverse reaction. Warfarin is used for treatment and prevention of thromboembolism (including venous thrombosis, myocardial infarction, pulmonary embolism, brain embolism and, slowly progressive cerebral thrombosis). Eleven cases associated with calciphylaxis have been reported in Japan and there is an overseas report published in the literature describing calciphylaxis with the use of warfarin. In addition, package inserts in Europe and the US have been revised.

Desloratadine

Health Canada has carried out a safety review to look at the potential risk of QT interval prolongation with the use of over-the-counter (OTC) desloratadine-containing products. This safety review was triggered by a signal publication in the WHO Pharmaceuticals Newsletter No.2, 2015, describing cases of abnormal heart rhythm suspected to be associated with the use of loratadine and desloratadine. Desloratadine is used to relieve symptoms of seasonal allergy or allergy caused by pollen or dust (hay fever). At the time of the review, Health Canada had received 10 Canadian reports of abnormal heart rhythm suspected to be associated with desloratadine use. In addition, Health Canada reviewed 13 international reports of abnormal heart rhythm suspected to be associated with the use of desloratadine that were provided by the manufacturer. A search in the WHO database of Individual Case Safety Reports, VigiBase identified 35 cases of abnormal heart rhythm suspected to be associated with desloratadine use. A link between the use of desloratadine and the abnormal heart rhythm could not be established, as there was not enough information in the reports to draw conclusions. Published scientific studies have shown that desloratadine is not associated with abnormal heart rhythm in humans.

Azithromycin

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have announced that the package insert for azithromycin (Zithromax®) has been updated to include the risk of acute generalized exanthematous pustulosis as a clinically significant adverse reaction. Azithromycin is an antimicrobial used for a number of bacterial infections caused by strains of genus *Staphylococcus*, *Streptococcus*, *Pneumococcus*, Neisseria gonorrhoeae, *Moraxella (Branhamella) catarrhalis*, *Haemophilus influenzae*, *Legionella pneumophila*, *Peptostreptococcus*, *Prevotella*, *Chlamydia*, and *Mycoplasma*. One case of acute generalised exanthematous pustulosis has been reported in Japan. A causal relationship could not be excluded in this case. In addition, the company core datasheet (CCDS) has been updated.

Doxycycline

The Saudi Food and Drug Authority (SFDA) has updated the summary of product characteristics and patient information leaflet for doxycycline to include the risk of fixed drug eruptions (FDE). Doxycycline is a tetracycline broad-spectrum antibiotic with bacteriostatic characteristics. It is used as treatment or prophylaxis against a wide range of susceptible strains of gram-negative and gram-positive bacteria and other microorganisms. The SFDA initiated the investigation based on a signal observed in a published case report examining potential associations between doxycycline and risk of FDE. As a result, the SFDA reviewed the available evidence related to this safety issue including screening of the WHO global database of Individual Case Safety Reports, VigiBase. In addition, a literature review was conducted. The SFDA concluded that the available evidence suggests a probable association between doxycycline and FDE.

Relief Handover Ceremony to Health Minister, MOHFW for Rohingyas

BAPI's Humanitarian response to DGDA call

Bangladesh Association of Pharmaceuticals Industries (BAPI) came forward with expanded assistance in accordance with the initiatives taken by DGDA participating in the relief donation for the Rohingya refugees. The Relief handover ceremony took place in the conference room of DGDA recently. Hon'ble Minister Mohammad Nasim MP, Ministry of Health & Family Welfare was present as the chief guest of the ceremony. A total amount of Tk. 56 crore, Medicines worth Tk. 2 crore & dry foods worth Tk. 7 lac was handed over to the chief guest by Major General Md Mustafizur Rahman, Director General, DGDA along with Secretary General BAPI. Hon'ble Health Minister highly appreciated this noble effort in his speech.

Major Activities Performed by DGDA during July - September 2017

1.	No of Total Drug License (Retail & Whole sale)	123836
2.	No of Renewal of Drug License (Retail & Whole sale)	8370
3.	No of Sample Collected for test	548
4.	No of sample test	972
5.	Issue of GMP Certificate	18
6.	Issue of CPP	1257
7.	Issue of FSC	145
8.	Issue Form-10	291
9.	Inaugurated Model Pharmacy (up to september)	128
10.	Inaugurated Model Medicine shop(up to september)	82

Case filed in Mobile Court, Magistrate Court and Drug Court

Month	Case filed in Drug Court	Case filed in agistrate Court
July 2017	0	0
August 2017	3	0
September 2017	1	2
Total	**4**	**2**

Global best practices on OTC drug regulations: A way forward for Bangladesh

A seminar was held recently in the conference room of Directorate General of Drug Administration chaired by Major General Md Mustafizur Rahman Director General of Drug Administration. Professor Syed Modasser Ali, Hon'ble Chairman, Bangladesh Medical Research Council (BMRC) adorned the chair of the chief guest.

First time in the history of Bangladesh, the very recently approved "National Drug Policy – 2016" introduced the OTC List of 39 multi-sourced Finished pharmaceutical products along with all system of medicines. The seminar primarily focused on the implementation strategy enabling stringent regulation over the OTC LIST cited in NDP-2016.Over The Counter (OTC) drug product is a drug product marketed for the consumers without the intervention of a health care professional in order to obtain the product. Over-the-counter (nonprescription) drug products play an increasingly vital role in the health care system of Bangladesh. Additional measures need to be taken to address the growth of prescription to OTC switches in recent years.

An overwhelming majority of the comments supported the agency's initiative to standardize the format of OTC drug product labeling and to make the labeling easier to read and understand by requiring a minimum type size, user-friendly headings, and other well-accepted visual cues. However, a number of specific points in the proposal generated extensive, and sometimes divergent, comment: (1) Whether pharmacists, nurses, or other health professionals should be specifically referenced in some of the proposed headings; (2) an appropriate minimum type size for the required labeling information; (3) application of the proposed labeling format to products traditionally marketed in small containers and products marketed as both drugs and cosmetics. The labeling regulations/ Guidance should cover all OTC drugs marketed. Affixing Color code on the label will ease the consumers identification.

Several comments recommended permitting voluntary/mandatory use of symbols or pictograms in addition to required warning language. Some stated that symbols and pictograms may confuse consumers because they may have different meanings for different people. Solution to this issue came up and decided that USP type pictograms should be adopted.

The active ingredients and the labeling of different therapeutic classes of drugs, for example analgesics or antacids, instead of individual drug products. For each category, an OTC drug monograph need to be developed and published in the *BDNF*. OTC drug monographs are a kind of "recipe book" covering acceptable ingredients, doses, formulations and labeling. These monographs define the safety, effectiveness, and labeling of all marketing OTC active ingredients.

All the Educational & Training Institutions should incorporate the OTC facts into their course curriculum.

STRATEGIES FOR IMPLEMENTING THE NATIONAL DRUG POLICY

> "THE MAJORITY RECOMMENDED FOR AN ACTION PLAN FOR IMPLEMENTING THE NDP-2016 WHICH SHALL FOCUS ON EFFECTIVE DRUG MANAGEMENT PROCESSES, SUCH AS RATIONAL DRUG SELECTION, PROPER QUANTIFICATION OF DRUG NEEDS AT ALL LEVELS OF HEALTH CARE DELIVERY, AND EFFECTIVE PROCUREMENT PRACTICES

A seminar discussing on the strategies that shall be used to implement the National Drug Policy-2016 held recently in presence of Hon'ble Minister Mohammad Nasim MP , Ministry of Health & Family Welfare, stakeholders from different levels.

The issues introduced for the second time in the NDP-2016 was discussed on the open floor. The majority recommended for an Action Plan for Implementing the NDP-2016 which shall focus on effective drug management processes, such as rational drug selection, proper quantification of drug needs at all levels of health care delivery, and effective procurement practices. Others shall include assurance of quality of drugs at all levels, appropriate storage, proper costing and effective distribution of drugs, promotion of local drug manufacture, appropriate legislation, product registration, research and development, human resources development, monitoring and evaluation. Furthermore, the strategies shall emphasise proper accountability and rational use of drugs by health workers and consumers. In view of the fact that these activities are purely technical, government at all levels - federal, state and local governments, shall be required to employ pharmacists and other relevant personnel to ensure satisfactory implementation of the Policy.

Hon'ble Health Minister gave his bold consent for facilitating sky-high for the implementation of NDP-2016. In pursuant to that, he directed Major General Md Mustafizur Rahman, Director General of DGDA, to circulate a public notice stating 4 months waiver to the Pharmacies still in operation without Drug License. The Pharmacies failing criteria to be on the standards (Model Pharmacy, Medicine Shop) formulated by DGDA will be shut down forever by enforcement action.

He also stated the empowerment of Director General as much as he needs to make DGDA comparable to Global Stringent Regulatory Authorities (SRAs). ●

'Our commitments for the patients living with diabetes will be continued'

Sebnem Avsar Tuna
Corporate Vice President
Novo Nordisk Pharma Operations (BASEA)

Q&A

What are the key contributions of Novo Nordisk for the patients living with diabetes?

Novo Nordisk has been working as a leader in diabetes care for about 60 years in Bangladesh and more than 90 years globally. Our commitments and contribution for the patients living with diabetes will be continued in the future also. Our key contribution is to discover and develop better biological medicines, manufacture them to meet increasing global demand and make them accessible wherever they are needed.

In Bangladesh ~400,000 patients depend on Novo Nordisk insulins; every second patients is taking Novo Nordisk's insulin. Novo Nordisk is the market leader within insulin and GLP-1 portfolio, and is the world's largest producer of insulin. In Bangladesh we have introduced entire range of products starting from human insulin, modern insulin, next generation insulin and GLP-1, which is meeting the needs of all type of patients' requirement.

In addition to that as part of our long-term commitments, Novo Nordisk has transferred state-of-the-art technology from Denmark to produce Human Insulin vials in partnership with Eskayef since 2012. Today, around 70 percent of total demand of Novo Nordisk's insulin is locally produced. Transcom Distribution Company Limited (TDCL) is our partner in insulin distribution to reach within 2 hours to any corner of the country maintaining strict cold chain.

Novo Nordisk is doing the training and educational activities related to diabetes. We are introducing innovative and simpler devices with benefits like simplifying the self-injection of insulin compared with durable pens.

As part of our continuous innovation, Novo Nordisk has also introduced world class Human Insulin FlexPen® devices in Bangladesh to ensure more benefits and safety for patients at affordable price.

We know that there are 7.1 million people living with diabetes in Bangladesh and 52 percent don't know they have it. Novo Nordisk in association with Diabetic Association of Bangladesh is working very hard to create awareness among mass people to beat diabetes.

Would you please tell us about the diabetes challenges globally and locally?

I think diabetes is a big challenge globally. We call it's a kind of a slow motion epidemic. The size of the diabetic population is big. It is a burden to the public. Being working partnering together, how we can find a sustainable solution for the diabetic patient to get to reach to treatment option and care, I think it's a biggest challenge for nation.

But, treating diabetes is not so expensive. But, "Not Treating" diabetes will cost much more. It is a progressive disease that goes with complications. For instance, if you don't get a treatment on time, you can get blind, your kidney may doesn't work, can affect your food habit and heart also. Treating these complications is much more expensive than treating diabetes having once or twice daily insulin. According to research, the total cost of diabetes only 7 percent accounts for drugs and other 93 percent cost for the complications.

International Diabetes Federation data: Diabetes affects 415 million people worldwide and the number is expected to increase to 642 million

> "NOVO NORDISK IN ASSOCIATION WITH DIABETIC ASSOCIATION OF BANGLADESH IS WORKING VERY HARD TO CREATE AWARENESS AMONG MASS PEOPLE TO BEAT DIABETES

by 2040. Two-thirds of all people with diabetes live in urban areas. In Bangladesh 7.1 million people living with diabetes in 2015 putting it among top 10 countries in the world and it will hit 13.6 million by 2040. The prevalence of diabetes in Bangladesh is 7.4 percent. Approximately 129-313 people died in Bangladesh due to diabetes in 2015.

What does "Changing Diabetes" means to Novo Nordisk?

Diabetes is a lifelong disease. In different term it needs to get different treatment and the extreme term you need to get insulin by injections which is not certainly easy. We are trying to change the quality of life by our 'Changing Diabetes' activities. For instance: giving better treatment and better opportunities, educations on how to cope with the diseases or some inspirations on healthy life styles.

At Novo Nordisk, we are driven by a core belief: that the alarming rise of diabetes is not inevitable. We can change its trajectory – and we must act now. We are working for changing diabetes. We must ensure that people are diagnosed earlier, improve diabetes care and tackle the rise of the diabetes in cities.

In a country like Bangladesh can our poor people afford your products?

I think they can. Because the level of the price we are providing is quite affordable. It is less than a cup of coffee. We are the only company who has entire range of products starting from HI, MI, NGIs and GLP-1, which meet the needs of all type of patients' requirements based on affordability.

What is your triple bottom line business philosophy?

Triple bottom line means three components: financial, environmental and social responsibilities. Being financially responsible, we are aware of our responsibility in terms of providing and supplying life-saving insulin globally. If we do continue this, we sustain, we need to have financial support so that we can continue our research and manufacture and sell those products.

Being environmentally responsible, we only use green energy and wind energy; we don't harm environment. Being socially responsible, Novo Nordisk is doing business in a responsible and sustainable way, with a focus on improving public health, benefits patients, society and shareholders. We believe that a healthy economy, environment and society are fundamental to long-term business success.

For instance, being socially responsible, we want to be a part of this society. If there is flooding we have to make sure that our insulin are there. We have distribution partner. We are ready to face challenges.

What is in your next pipeline for the country?

We would like to continue to bring more innovative treatment options for Bangladesh. We will introduce Fiasp, Xultophy, Saxenda way forward to ensure more patient benefits.

It takes more than medicine to defeat diabetes. Please elaborate?

Diabetes is a life-long disease and patients should take treatment on time and need to be aware about drugs and need to know how to cope with that. It requires lot of services to be professional as well as the patients in terms of education and to learn how to cope with that kind of non-communicable disease. It's a part of our "Changing Diabetes" and we committed to our educational activities and get more physicians trained to treat diabetes.

However, to defeat a serious chronic condition, we need to do more than supply the right medicine. This is why we work in partnership with patients, policymakers, healthcare professionals and non-governmental organisations to raise awareness, improve prevention, promote earlier diagnosis and expand access to care.

In Bangladesh, we have launched changing diabetes® in children (CDiC) programme in partnership with DAB and World Diabetes Foundation (WDF) to increase access to diabetes care for children with type 1 diabetes so that they can live better lives.

Globally, Novo Nordisk has launched Cities Changing Diabetes® – a cross-disciplinary and cross-sector partnership programme to identify and address the root causes of the rise in type 2 diabetes in urban area and we want to introduce the same project in Dhaka.

Team Novo Nordisk, a global all-diabetes sports team, spearheaded by a professional cycling team, works to inspire, educate and empower people affected by diabetes.

Would you please enlighten me on your activities for changing diabetes?

We are doing many activities with the partnership of Diabetic Association of Bangladesh (DAB). We have supported DAB to initiate Distance Learning Programme (DLP) on 2003 to create trained diabetologists with a view to ensuring better access to care to people living with diabetes. DLP is now a self-sustainable programme and now developing skilled doctors to treat diabetes better. It has already trained more than 12,000 doctors.

Recently, National Cricket Captain Mashrafe Bin Mortaza has joined with Novo Nordisk as Brand Ambassador to fight against diabetes. He is working as a "Changing Diabetes® Brand Ambassador" to create awareness on the prevention, detection, management and control of diabetes. He is also focusing on the benefit of healthy lifestyle and diet to prevent diabetes.

In addition to that we have trained 55 journalists on non-communicable disease and sustainable development goals. We have organised more than 100 awareness campaigns on World Diabetes Day last year and Novo Nordisk Half Marathon- run for changing diabetes to motivate on healthy lifestyle and diet. ●

'Hypertension can cause both acute and chronic complications'

Dr. A. B. M. Abdullah
Dean, Faculty of Medicine
Professor of Medicine
Bangabandhu Sheikh Mujib Medical University, Dhaka

Q&A

As an eminent physician, would you please tell us, in brief, about the overall scenario of Hypertension in Bangladesh?

Hypertension (HTN) is an increasingly important medical and public health problem globally. Bangladesh is passing through a phase of epidemiological transition from different communicable diseases to non-communicable diseases and currently has a double burden of the disease. This means that though the prevalence of Hypertension is modest now, probably it will show a rising trend.

There is a significant lack of data regarding the prevalence of Hypertension in Bangladesh. However in a recent study, it has been shown that approximately 20% of adult and 40 to 65% of elderly people have been suffering from HTN in Bangladesh.

Although awareness against Hypertension has tremendously increased and patients are adhering to healthier and disciplined lifestyle, it is still one of the major causes of death worldwide. What is the reason behind that?

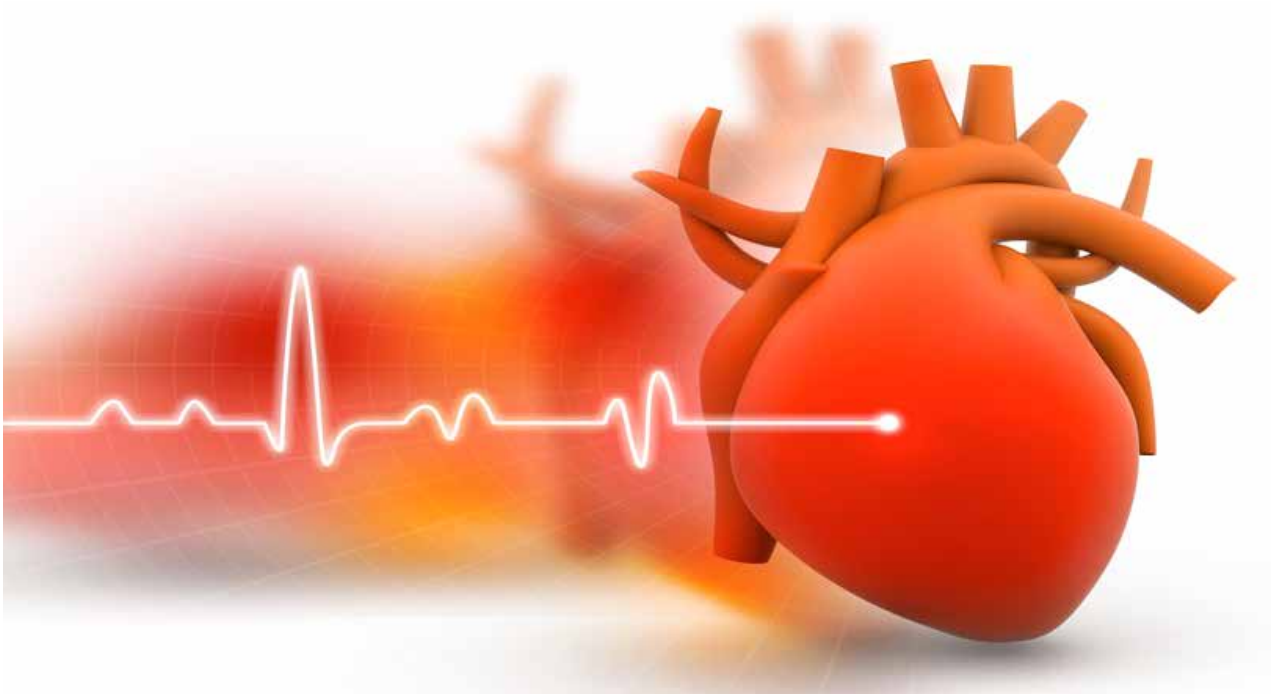
Hypertension is one of the leading causes of death worldwide. Hypertension and its complications account for an estimated of 9.4 million deaths every year. Though awareness against Hypertension is progressively increasing among general people, still the number of deaths per year is very high due to its fatal complications and poor drug compliance. Hypertension is such a disease which affects almost all the major organs of body like heart, kidney, brain, eye etc. As a result, death rate remains significantly higher.

What is the status of Bangladesh compared to the developed countries so far as the prevalence of Hypertension is concerned?

There are very limited data regarding prevalence of Hypertension in Bangladesh. However in a survey conducted in Bangladesh in 2010, the overall prevalence of Hypertension was estimated to be 17.9% for the whole country (17.9% in urban and 15.9% in rural areas) among the population aged 25 years and above. United States Census Bureau information demonstrated 28 to 30 percent prevalence of hypertension in the age 1-8 years and older population of the United States.

We know Hypertension as a 'silent killer'. What measures can be taken before to prevent this disease?

There are multiple risk factors for Hypertension which can be controlled by proper life style modifications to prevent Hypertension. Correcting obesity, restricting salt intake reducing alcohol intake, taking regular. physical exercise an increasing consumption of fruits and vegetables can lower blood pressure. Moreover quitting smoking and adopting a diet that is low in saturated fat may produce further reduction in development of Hypertension.



What other complications are associated with Hypertension which may prove fatal?

Hypertension can cause both acute and chronic complications which as may prove fatat such heart attack, stroke, long term kidney problems even kidney failure, visual difficulty blindness etc.

Research on management of Hypertension has always been in progress globally. Where Bangladesh stands so far as the research on Hypertension is concerned? Is BSMMU working on this?

Different types of research activities are going on in Bangladesh at different levels. BSMMU is taking active participation in these activities both in personal and institutional level.

What is the standard of drugs manufactured in Bangladesh for management of Hypertension?

Quality of drugs manufactured in Bangladesh for the treatment of Hypertension are quite good and effective to control Hypertension.

Between male and female, who are more prone to this disease? Does it also prevail in children and adolescents?

High blood pressure is more common in men as compared to women before the age of 50. However, after the age of 55 years. High blood pressure is almost equal in both women and men. Studies have shown that acute complications of Hypertension life heart attack and stroke are significantly lower in women, especially in those who have not undergone menopause. Between these two complications, the reduction in heart attacks is much more prominent in females.

An estimated 3% of children have high blood pressure. In babies, it's usually caused by prematurity or problems with the kidneys or heart. While Hypertension is far more common among adults, the rate among children is on the rise, a treat that experts like to the increase in childhood obesity. Many children and adolescents with high blood pressure have no other health problems but do have a family history of Hypertension and an unhealthy lifestyle like a bad diet, excess weight, stress and insufficient physical activity.

Lastly, what are your suggestions for a patient with Hypertension to lead a normal life?

Firstly, I would like to say that every person should lead a healthy lifestyle which includes proper diet and avoiding rich food, doing sufficient physical exercise, giving up smoking and restricting alcohol and salt intake. Secondly, if any patient is diagnosed with Hypertension, he or she must take the prescribed medicines regularly and should have proper follow up to avoid any unwanted complications. He or she must not stop the drug without consulting the doctor. ●

'Hypertension leads to many complications & is associated with many co-morbidities'

Prof. Dr. M A Rashid
CEO & Senior Consultant
Ibrahim Cardiac Hospital & Research Institute, Dhaka

Q&A

As an eminent physician, would you please tell us, in brief, about the overall scenario of Hypertension in Bangladesh?

Hypertension (HTN) is an increasingly important medical and public health problem. In Bangladesh, approximately 20% of adult and 40–65% of elderly people suffer from HTN.

According to Non Communicable Disease risk factors survey, one third of the Bangladeshi population never measured their blood pressure. Among Bangladeshi patients, high incidence of metabolic syndrome, and lifestyle-related factors like obesity, high salt intake, and less physical activity may play important role in the pathophysiology of HTN.

Although awareness against Hypertension has tremendously increased and patients are adhering to healthier and disciplined lifestyle, it is still one of the major causes of death worldwide. What is the reason behind that?

Hypertension is associated with many co-morbidities and is an important component of metabolic syndrome, and also leads to accelerated atherosclerosis leading to stroke and myocardial infarction, eventually death. One of the most important problems with HTN control is the lack of awareness among people about the importance of compliance and adherences to medication. Many patients whose BP is well-controlled on medications, sometimes stop their medicine after a while, because they are unaware of the importance of medication compliance in BP control. Also a number of hypertensive patients have multiple co-morbidities and are taking a lot of medication anyway, it may be another reason for lack of compliance. Although there is a general perception that patients are adhering to healthier lifestyles, this is rather relative. They may be consciously working out, but food habits and work-related stress are all contributors to hypertension, and as such, these factors must also be considered in the overall treatment and control of hypertension.

In Bangladesh, studies have found that non-adherence to antihypertensive treatment was found in 85% of cases; factors determining such non-adherence included lower level of education, low family income, duration of illness, perception related to the disease, lack of accompanying person, and insufficient information from the service provider.

So it's important that the physician explains these issues clearly to the patients, and stresses on continued medication and regular follow up.

What is the status of Bangladesh compared to the developed countries so far as the prevalence of Hypertension is concerned?

This is difficult to say exactly due to lack of accurate data on prevalence of HTN in Bangladesh. Globally, the overall prevalence of adult hypertension is around 40%. Bangladesh data have found that the prevalence of HTN was found to be within 15-

20% among the adult population of Bangladesh. Across the WHO regions, the prevalence of hypertension was highest in the Africa region, around 40%. The lowest prevalence of raised blood pressure was in the WHO Region of the Americas at 35% for both sexes.

We know Hypertension as a 'silent killer'. What measures can be taken before to prevent this disease?

Hypertension leads to a number of complications and is associated with many co-morbiditites so it's important to establish good control of hypertension with treatment targets. In those genetically prone to the disease, prevention may not be possible but we can certainly control hypertension, and maintain target BP so that end organ involvement is delayed and deterred. Good lifestyle modification, regular exercise, improved dietary habits and less salt intake are practical measures that can be adopted. Also adhering to medication and regular follow-up is important.

What other complications are associated with Hypertension which may prove fatal?

Hypertension, when uncontrolled can lead to life-threatening complications such as stroke, myocardial infarction, hypertensive retinopathy and papilloedema, acute left ventricular failure and chronic renal failure.

Research on management of Hypertension has always been in progress globally. Where Bangladesh stands so far as the research on Hypertension is concerned? Is Ibrahim Cardiac Hospital & Research Institute working on this?

There are many groups of anti-hypertensive drugs, both traditional and new ones like angiotensin receptor neprilysin inhibitor (ARNI) and the novel calcium channel blocker cilnidipine. In current practice calcium-channel blockers and ACE-inhibitors and ARB's are the most commonly prescribed antihypertensive drugs; diuretics and beta-blockers are also commonly used. Most of the anti-hypertensive drugs are also produced locally in Bangladesh, some at par with international standards, and are even exported to other countries.

What is the standard of drugs manufactured in Bangladesh for the management of Hypertension?

In Bangladesh, there have been many small scale researches, however, large studies representative of the population as a whole are somewhat lacking.

A recent study using data from the nationally representative 2011 Bangladesh Demographic and Health Survey (BDHS) including a total of 7,839 (3,964 women and 3,875 men) Bangladeshi adults aged 35 years and older are found that the overall prevalence of hypertension was 26.4 %, and the prevalence was higher in women (32.4 %) than men (20.3 %). Studies have also found that the risk of hypertension was significantly associated with older age, sex, education, place of residence, working status, wealth index, BMI, and diabetes.

A study conducted by Ibrahim Cardiac Hospital among 1915 patients with acute coronary syndrome found that HTN was highly prevalence among ACS patients, with 1421 (74.24%) of the patient population reported as hypertensive. This shows that HTN is a significant risk factor among patients with ACS. However, large scale preferably, nation-wide survey, and clinical research studies should be conducted to identify genetic components to HTN, role of hypovitaminosis D, salt intake and also best response to drug therapy including ACE gene polymorphism are needed. The data yielded from such large scale studies would help to formulate a national policy to combat hypertension efficiently and effectively.

Between male and female, who are more prone to this disease? Does it also prevail in children and adolescents?

That is difficult to say as various recent data have yielded different results in terms of gender related prevalence. WHO data have found that men have slightly higher prevalence of HTN than women. But as I mentioned before, one study in Bangladesh did find that HTN prevalence was higher in women (32.4 %) than men (20.3 %).

As for children and adolescents, the exact prevalence of HTN in children in Bangladesh is not known. One study involving 6–16-year-old school children of Dhaka city found a prevalence of 0.55%, but this is probably an underestimate of the true prevalence. The increasing prevalence of childhood obesity and sedentary lifestyle among children could be a contributing factor in addition to genetic components. Especially the altered perception to childhood obesity by the parents in south Asian population, makes the situation even worse .

Lastly what are your suggestions for a patient with Hypertension to lead a normal life?

Good lifestyle habits, regular exercise and dietary control, limited salt intake, and most importantly adherence to medication and being on regular follow up are important. Hypertension is certainly a disease that can be well-controlled and with good control, patients can lead an almost normal life without complications. ●

'Illness to Wellness: Paradigm Shift in Healthcare Industry'

Dilip Ghosh

Introduction

The healthcare industry itself is undergoing functional and structural changes from a 'fee-for-service' to 'value-based' services at a national level in various countries. This movement is currently experiencing renewed impetus as several food components are being employed as medicines, either directly or as prodrugs. Indeed, there are areas in which the border between "food" and pharma" is not well defined, as the former often contains several bioactive compounds including secondary plant molecules (polyphenols), fibers, friendly bacteria, essential fatty acids, probiotics, and other contributions. Furthermore, several current drugs are derived from natural products including those to which humans have been exposed via diet. Indeed, it is sometimes difficult to distinguish between bioactive molecules termed as 'drugs' and other substances classified as 'nutrients'.

Optimal health and prevention of chronic diseases can be attained (to a certain extent) by modulating the intake of macro- and micronutrients, often in pharmacological doses as in the case of supplements, nutraceuticals, and functional foods. Classic pharmacotherapy can also be accompanied by adjunct treatments with nutrition-derived remedies that are often able to decrease the doses of medicines and/or lessen their side effects. In summary, the border between pharma and food is becoming less distinct, and companies are marketing affordable, fast-moving nutraceutical products, with a focus on fortified foods and beverages [1].

Paradigm Shift: From Illness to Wellness

It is generally accepted worldwide that modern pharmaceuticals will remain out of reach of many people and "health for all" may only be materialized by the use of adequately assessed nutraceutical/phytomedicinal products. The human has been using food bioactive and/or herbal medicine for healing purpose from the beginning of human civilization. In recent times, use of herbal medicine for healthcare has increased steadily all over the world although it was neglected for decades by Western societies. However, the gaps in relation to the safety, claimed efficacy, and quality of herbal products used as herbal medicine, nutraceuticals, health foods, and cosmetics are being realized and addressed by many companies in their product development framework. The combination therapy of pharmaceuticals and food bioactive in disease prevention and treatments is one of the most discussed topics in recent time. A unique example is ezetimibe, which is used together with lifestyle changes (diet, weight loss, exercise) to reduce the amount of cholesterol (a fatlike substance) and other fatty substances in the blood.

Challenges

Nutraceutical market is one of the most promising ones all over the world. But this market is not without its share of challenges. One of the most important needs today is the need to have evidence-based nutraceuticals. These are also referred to as the third-generation nutraceuticals. When deriving evidence-based nutra products, it is vital that they be studied scientifically, supported on a clinical level, and has standardized new ingredients derived from plants, foods, etc.

The pharmaceutical and food sectors have independent as well as shared challenges as both are introduced at different stages in a life cycle. The pharma sector is at a maturity stage, while the nutraceutical and food sectors in some countries are still at the growth and infancy stages. The challenges become even intense for the pharmaceutical industry because of difficult economic conditions in the past years and also huge fall of existing patents. Today, pharmaceutical industry requires total reforms right from developing alternate revenue models, to derive new focus on investments and behavior.

Transition of Pharmaceutical Industry

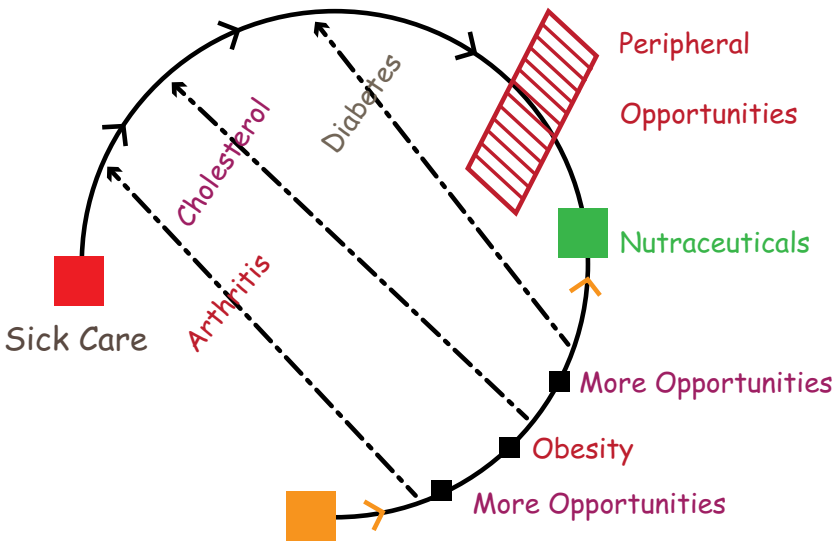
The transition of the pharmaceutical industry from its traditional business model is ongoing and interest-

ing to see how their next blockbuster molecule could be derived through different routes.[2] It is proposed [3] that the industry is challenged with three interrelated tipping points referring to what the industry sells (service models vs. therapies), to whom (mass markets vs. niche), and how it should organize itself (making connections vs. integration). The transition from current 'high-risk, high-margin' business model to 'low cost high volume' nutra business model is dependent on many factors and also advised to move into less regulated markets like animal and consumer health [4].

Diversification

Companies have started to look for alternatives to the blockbuster philosophy, which is simply diversification. As for example, Pfizer and Merck, being world leaders in consumer healthcare and animal health, follow diversification into their new business areas. The 2009 acquisitions of Wyeth and Schering-Plough, respectively, have consolidated their market position. Pfizer Consumer Healthcare is one of the top five over-the-counter (OTC) companies in the world. It sells two of the ten top selling OTC brands worldwide and accounted for revenues of €2093 million after the acquisition of Wyeth (from Pfizer website http://press.pfizer.com/press-release/pfizer-acquire-wyeth-creating-worlds-premier-biopharmaceutical-company-accessed on 8 July 2016). The acquisition has also allowed Pfizer to gain a foothold into the nutraceutical market, whose infant nutritionals have brought revenues of €1410 million for 2010. Pfizer Nutrition is expected to grow due to the less strict regulated market and face competition from other diversifiers as well as the established food industry. A clear trend here is the move into delivering of not just treatments, but outcomes. An example of an outcome management is the Changing Diabetes program of Novo Nordisk (from Novo Nordisk website http://www.novonordisk.com/ about-novo-nordisk/ changing-diabetes.html), which provides support such as specialized training for healthcare professionals, support for diabetes patient organizations, free blood sugar screening services, and equipment supply for diabetes clinics.

Geographical diversification is pursued through the numerous contributions from the world's fastest-growing, emerging markets, such as those in China, India, Brazil, Argentina, Turkey, and Romania. Despite high variations in their characteristics and stability, business in these areas offers important opportunities for growth over time. The most important strategic move is to relocate the expensive R&D activities into a lower-cost country and secure a front position in the largest emerging market through local partnerships.



Conceptial Model by Dr. R.B. Smarta

Conclusion

The present model of nutraceutical or medical food industry is pharma-driven. It emphasizes on the cure for diseases or ailments for their customers in the sick care sector. To be successful, the focus of the nutraceutical model will have to shift from illness to wellness domain (Figure 1) i.e., preventive and promotional aspects. In the nutraceuticals domain, peripheral opportunities are also exist for managing chronic lifestyle diseases and ailments. With the emergence of lifestyle-related diseases such as obesity, tuberculosis, diabetes, arthritis, malaria, and cholera, which can be managed through preventive efforts. ●

Acknowledgement

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References

1. Alice S (2015) Food as pharma: Marketing nutraceuticals to India's rural poor. Crit Publ Health 25(3): 361-372.
2. Rusu A, Kuokkanen K, Heier A (2011) Current trends in the pharmaceutical industry-A case study approach. Eur J Pharm Sci 44: 437-440.
3. Anscombe J, Wise M, Cruickshank C (2009) Pharmaceuticals out of balance. Reaching the tipping point. AT Kearney, Chicago, IL, USA.
4. Danner S, Hosseini M, Rimpler M (2010) Fight or flight. Diversification vs. Rx focus in Big Pharma's quest for sustained growth. Roland Berger Strategy Consultants, Munich, Germany.

'A diabetic patient with hypertension'

Dr. Subrata Maitra

A 54-year-old male suffering from Type II diabetes mellitus, attended the clinic for routine checkup. He gave a history of hypertension detected I year back. He was taking oral anti-diabetic medication regularly, he used to skip his blood pressure tablet and he felt that high BP was not causing any problem to him. Examination revealed BP of 166/100 mm Hg, rest of the examination was satisfactory.

Hematological and biochemical parameters were satisfactory random glucose was 186 mg% with an HbA1C of 7.1%. His lipids were satisfactory. Urine examination showed trace of protein.

Diagnosis: Uncontrolled hypertension in Type II diabetes mellitus Hypertension is a common accompaniment of Type II diabetes mellitus and a cause of significant morbidity and mortality. 80% of the diabetics die of macro vascular disease (MI and CVA) and hypertension is a significant risk factor.

Trials like DCCT and UKPDS have shown that strict control of diabetes mellitus can reduce micro vascular complications like retinopathy, nephropathy etc. but has negligible effect on macro vascular complications whereas control of hypertension can reduce it. So, it is very important that clinicians should pay meticulous attention in controlling BP in their Type II diabetic patients.

The question would arise whether control of BP helps in diabetes - In three trials on hypertension (SHEP HDFP and Syst Eur) where different anti-hypertensive were used, there was evidence of reduction of cardio vascular mortality and morbidity in a subset of patients with diabetes mellitus.

The next question we need to answer what is the optimum BP in a diabetic patient - Results from the studies like HOT and UKPDS indicate that probably the target BP in diabetic patient IS 135/80 mm/Hg at which level the patient will derive maximum benefit.

The choice of agent is also important.

Three trials compared ACE inhibitors with calcium channel blockers (FACET, ABCD STOP II). In these trials–

- ACE inhibitors fared better compared to calcium channel blockers.
- In UKDS, ACE inhibitors and b blocker were equipotent although b blocker caused more weight gain.
- In INSIGHT, calcium channel blocker nifedepine and diuretics were found to be the same
- In NORDIL, b blocker and calcium channel blocker were found to be equally effective.
- In ALLHAT- diuretic chlorathalidone, ACE Inhibitor iisinopril and caldum channel blocker amlodipine were equally effective although the incidence of heart failure was more with amlodipine. Chlorthalidone was particularly effective in Black Americans.

In the diabetic subgroup of LIFE study, Losartan treated patients had less event rates compared to b blocker (atenolol) treated patients.

> HYPERTENSION IS A COMMON ASSOCIATION WITH TYPE II DIABETES MELLITUS; 80% MORTALITY IN DIABETES OCCURS DUE TO MACROVASCULAR COMPLICATION; METICULOUS CONTROL OF DIABETES REDUCES MICROVASCULAR COMPLICATIONS WHEREAS CONTROL OF HYPERTENSION REDUCES MACROVASCULAR COMPLICATIONS

Although so far ACE inhibitors and P blockers have been the drugs of choice, from the above discussion it is evident that one can extend the choice of drugs further depending on the clinical situation, like diuretics in African population, beta blockers and ca+channel blockers in IHD, ACE inhibitors and or A T2 receptor blockers in renal impairment, with other drugs suitably added to the regime depending on the BP level, Calcium channel blocker should be used as a third line agent. If needed a blockers may also be added but they do not alter the prognosis in such patients.

It is important to remember that most of the patients are asymptomatic and would try to avoid medication. It is incumbent on the clinicians to stress on the importance of controlling the BP meticulously. On many occasions the patients might need combination of 2 to 3 antihypertensive medication to achieve the target BP.

One should remember control of blood glucose will reduce the microvascular complication only, whereas simultaneous control of BP will reduce the macrovascular complication the main cause of morbidity and mortality in diabetic patients while treating hypertensive without diabetes similar principle should be adopted be adopted (However the target BP is slightly higher compared to diabetes). In patients of less than 50 years of age, ACE Inhibitor and or beta blocker should be tried first.

In patients above 50 years, low dose diuretic and or calcium channel blockers should be the drugs of choice. In the event of poor control these group of drugs can be suitably added or substituted for one another.

While treating isolated systolic hypertension, calcium channel blocker has a special edge over the other agents. The recent guideline of the British Hypertension Society has been outlined below:

	Younger<55 yrs and Non Black	Older>55 yrs and Black
Step-I	A or B	C or D
Step-II	A or B +	C or D
Step-III	A+C	D

(Resistant)Add and blocker or spironolactone.

A-ACE Inhibitor, B-b blocker, C-Calcium Channel blocker, D-Diuretic

In addition to drug therapy, life style modification, regular exercise, weight reduction, low salt intake, will also help the patient in controlling BP.

What is New?

Updated classification from J.N.C. on prevention, Detection, Evaluation and Treatment of High BP.

B.P.	Systolic BP (MM/Hg)	Diastolic BP (mm/Hg)	Therapy
Normal	>120	And<80	Treat BP <130/80 in diabetes and renal disease
Prehypertensive	120-139	80-89	
Stage-I hypertensive	140-159	90-99	Diabetics unless specific disease
Stage-II hypertensive	>160	>100	2 drugs in most cases

ACE Inhibitors in diabetes, IHD, kidney disease, heart disease B blockers in IHD.

Combination of ACE inhibitor with AT2 receptor blocker in no diabetic renal disease with proteinuria delays the progression of renal disease.

Key points

Hypertension is a common association with Type II diabetes mellitus; 80% mortality in diabetes occurs due to macrovascular complication; Meticulous control of diabetes reduces microvascular complications whereas control of hypertension reduces macrovascular complications.

The target of BP control is 130/85 mm/Hg one needs to use combination therapy to achieve the target.

Although ACE inhibitors and beta blockers are still the drugs of choice, one can extend the list depending upon the clinical situation.

Science hypertension is asymptomatic in most patients, primary care physicians should stress the need of tight BP control as a preventive strategy to the patient via individual consultation, group discussion and seminars.

Source: Stethoscope

'Need of Pharmacovigilance Education and Awareness in Bangladesh'

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Introduction

Pharmacovigilance (PV) is - *"The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems"*- World Health Organization (WHO, 2002). It is concerned with Adverse Drug Reactions or ADR, which is also described by WHO as *"a response to a drug which is noxious and unintended, and which occurs at doses normally used for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function"* (Suke *et al.*, 2015). Searching of harms or risks in approved drugs and to take right measures for protection is the main goal pharmacovigilance. It is one of the nine functions WHO requires for a functional National Drug regulatory Authority (NRA) of a country.

Aims and Scope of PV

Patient Care	• **To improve patient care & safety in relation to medicines**
Public Health	• **To monitor and improve public health & safety in relation to the use of medicines** • **Early detection of unknown safety problems**
Risk Benefit Assessment	• **To contribute to the identification, assessment of benefit, harm, effectiveness, safety and risk of medicines**
Communication	• **To promote understanding & effective communication to health professionals, pharmaceutical manufacturers & the public** • **Prevent patients from being affected unnecessarily**

Partners in Pharmacovigilance

The management of the risks associated with the use of medicines demands close and effective collaboration between the key players in the field of pharmacovigilance. Sustained commitment to such collaboration is vital if the future challenges in pharmacovigilance are to be met, and if the discipline is to continue to develop and flourish. Those responsible must jointly anticipate, describe and respond to the continually increasing demands and expectations of the public, health administrators, policy officials, politicians and health professionals. However, there is little prospect of this happening in the absence of sound and comprehensive systems which make such collaboration possible. The constraints typically include lack of training, resources, political support, and especially scientific infrastructure. Understanding and tackling these are an essential prerequisite for future development of the science and practice of pharmacovigilance.

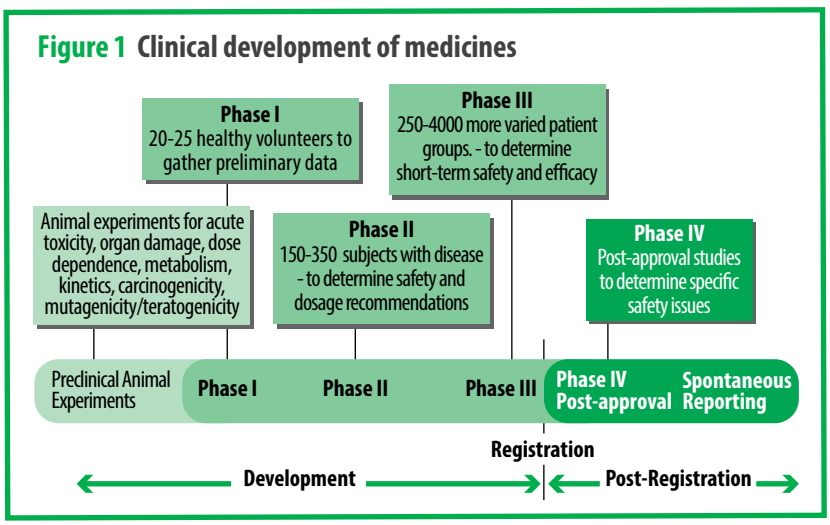
Key partners for monitoring the safety of medicines:

- Government
- Medicine Industry and Importer
- Hospitals and Academia
- Medical and Pharmaceutical Associations
- Medicines information centres
- Health Professionals
- Patients and Consumers
- The Media
- World Health Organization

Limitations of Clinical development of drugs.

50% of the approved drugs have serious adverse effects not detected

Figure 1 Clinical development of medicines



prior to approval **(US Dept. of HHS, FDA : May-1999).** The process involved in the clinical development of medicines are illustrated in Fig. 1.

Once put onto the market, a medicine leaves the secure and protected scientific environment of clinical trials and is legally set free for consumption by the general population. At this point, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals. In some cases as few as 500 subjects, and rarely more than 5000, will have received the product prior to its release.

For good reason, therefore, it is essential that new and medically still evolving treatments are monitored for their effectiveness and safety under real-life conditions. More information is generally needed about use in specific population groups, notably children, pregnant women and the elderly, and about the efficacy and safety of chronic use, especially in combination with other medicines. The information collected during the pre-marketing phase of a medical drug is inevitably incomplete with regard to possible adverse reactions:

a. Tests in animals are insufficiently predictive of human safety.
b. in clinical trials patients are selected and limited in number, the conditions of use differ from those in clinical practice and the duration of trials is limited.
c. Information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available.

Even very severe ADRs, such as liver damage, are often undetected because study populations are small. Post market surveillance uses tools such as data mining and investigation of case report to identify the relationships between drugs and ADRs (Suke *et al.*, 2015; Yao *et al.*, 2013).
Experience has shown that many adverse effects, interactions (i.e. with foods or other medicines) and risk factors come to light only during the year after the release of a medicine (Table 1).

Table 1 Classical examples of serious and unexpected adverse reactions

Medicine	Adverse reaction
Aminophenazone (amidopyrine)	Agranulocytosis
Chloramphenicol	Aplastic anaemia
Clioquinol	Myelooptic neuropathy (SMON)
Erythromycin estolate	Cholestatic hepatitis
Methyldopa	Haemolytic anaemia
Oral contraceptives	Thromboembolism
Practolol	Sclerosing peritonitis
Reserpine	Depression
Statins	Rhabdomyolysis
Thalidomide	Dongenital malformations

PV is needed in every country

Pharmacovigilance is needed in every country, because there are differences between countries (and even regions within countries) in the occurrence of adverse drug reactions and other drug-related problems. This may be because of differences in:

a. drug production.
b. distribution and use (e.g. indications, dose, availability).
c. genetics, diet, traditions of the people.

d. pharmaceutical quality and composition (excipients) of locally produced pharmaceutical products.
e. the use of non-orthodox drugs (e.g. herbal remedies) which may pose special toxicological problems, when used alone or in combination with other drugs.

Data derived from within the country or region may have greater relevance and educational value and may encourage national regulatory decision-making. Information obtained in a certain country (e.g. the country of origin of the drug) may not be relevant to other parts of the world, where circumstances may be different. When information from a region itself is not available, it may take longer before a problem becomes known to drug regulatory authorities, physicians, pharmacists, patients and pharmaceutical companies.
On the other hand, international monitoring such as the WHO International Drug Monitoring Programme may provide information on possible safety issues which may not yet have emerged within the country's data. So, pharmacovigilance activities and related studies are needed for prevention of drug-induced human sufferings.

Current position of PV in Bangladesh

Pharmacovigilance has been started in Bangladesh at Directorate General of Drug Administration (DGDA) in 1996 with the support of WHO. Then adverse drug reaction monitoring (ADRM) Cell was established and some steps were taken to build awareness & communication. But the initiatives became dormant due to lack of adequate support, legislation, funding, knowledge and attitude of the stakeholders.

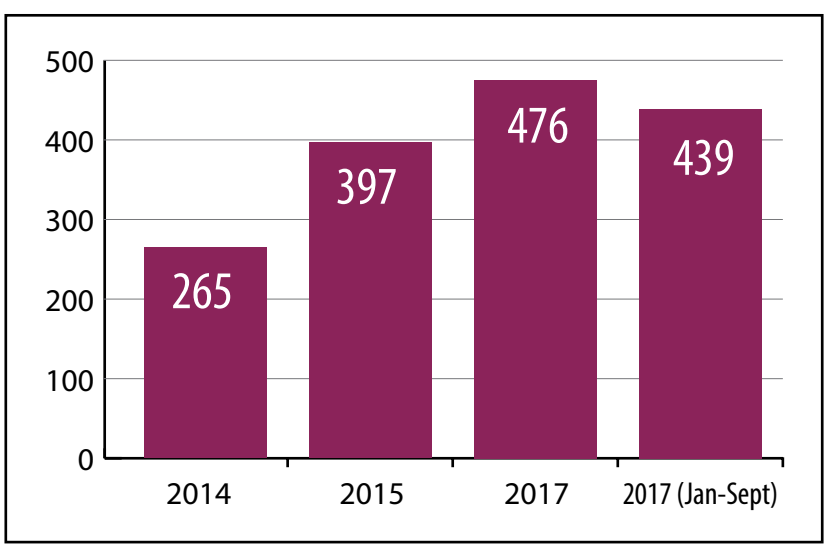
ADRM Cell at DGDA was re-started in 2013 with technical support of USAID funded MSH/SIAPS program and functioning well now. It is doing as a National PV Center in Bangladesh. DGDA is receiving suspected ADE reports from the primarily selected top selling 30 pharmaceutical industries and 32 different types of government & private hospitals in the country. The Cell is also receiving reports from a Public Health Program (Kala-azar) & some other health facilities of the country. For PV activities Bangladesh has achieved the 120th full membership of WHO–Uppsala Monitoring Centre (UMC), Sweden.

Suspected ADE Reporting form is available in DGDA web site. Easily one can download, fill-up and send it through mail or post to the ADRM Cell. On-line reporting system is also going to be launched very soon. ADRM Cell and ADR Advisory Committee (ADRAC) are performing as well. Number of reports received are going up gradually, but the figure is not yet up to the standard as per WHO.

International studies show that-

ADRs constitute the top ten leading causes of death (WHO, pharmacovigilance: ensuring the safe use of medicines, Geneva,

Fig-2.Total 1577 Suspected ADE Reports received at National PV Centre (ADRM Cell) from 2014 to 2017 (Up to Sept)



Total 517 reports have been reviewed by ADRAC up to March, 2017. and uploaded to WHO-UMC database.

Table-2 : Sources of Reports received

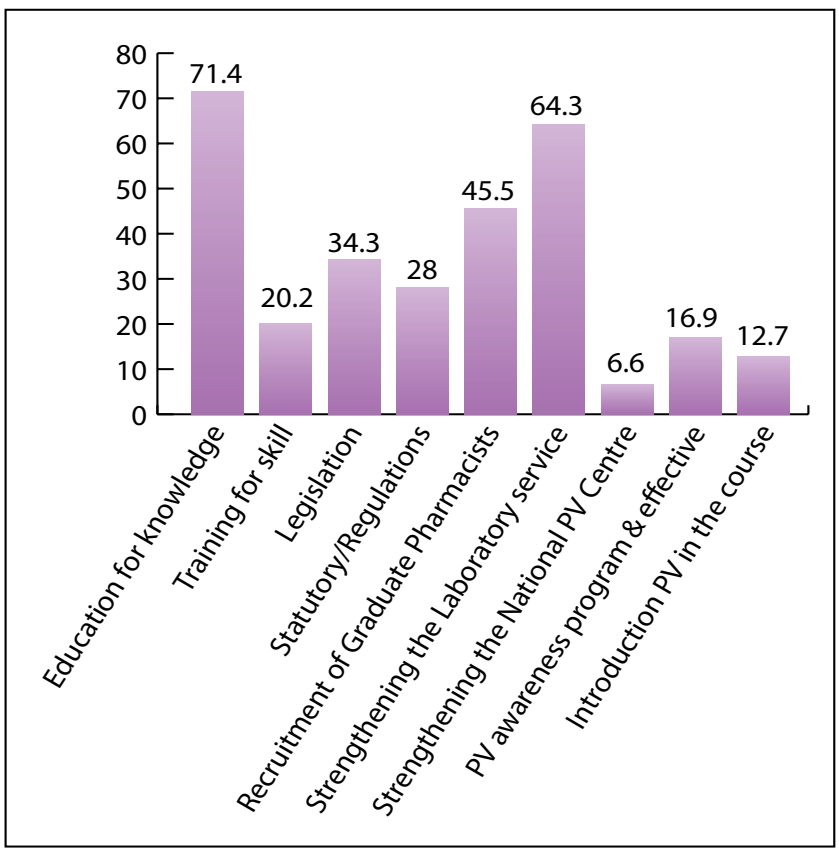
Sources	Number of Reports	Percent(%)
Pharmaceutical Industries & Importers	1110	70.39
Hospitals	223	14.14
Health Program(Kala-Azar)	244	15.47

2004) . Reports from GPs are the backbone of ADR reporting with total reporting from doctors contributing to almost 50% (UK-MHRA 2014). 3.19% of patients were admitted to hospital because of an adverse drug reaction. (Pouyanne et al.1998). A review of 17 studies show that overall incidence of ADRs among hospitalized children of 9.53% when compared with Le et al. (2006) with severe reactions accounting for 12.29% of the total. The overall rate of pediatric admissions due to ADRs was 2.09% with 39.3% of the ADRs being severe reactions. Functional PV (ADR monitoring) systems can improve these situations. '... and more importantly 30.7% of admissions due to ADRs were preventable, providing a potential savings of 175 million Euro' (Goettler et al. 1997).

Studies in Bangladesh

Author conducted a questionnaire based study on Pharmacovigilance in 2016 among 496 educated (66.9% Masters and above degree) populations to find out the main components required for sustainable PV in Bangladesh. Respondents were Academicians, Doctors, Pharmacists, Medicine Manufacturers and DGDA inspectors. Area of study was Dhaka, Rajshahi and Khulna division.

Figure 3: Components of the PV require immediate action for sustainable PV (Multiple response up to 3)



Result shows that the top most prioritized component is Education for Knowledge (71.4%) in this regard. Then the others are strengthening the laboratory service (64.3%) and recruitment of Graduate Pharmacists in all the Hospitals & Pharmacies (45.5%).

Another study has been conducted from December 2009 to December 2010 to find out response of reporting ADRs in one teaching hospital and 10 private chambers which revealed that response of reporting of ADR from private chamber was very poor (29%) whereas response from teaching hospital was more (55%) (Nahar *et al.*, 2011)

Demographic Category of Survey	Number	%
Respondent	203	69.5
Pharmacy technicians	152	74.9
Pharmacist	37	18.2
Master of science	2	0.98
Others	12	5.9
Respondent experienced ADR at their pharmacy	72	35.5
Respondent were not familiar with the existence of an ADR reporting body in Bangladesh	105	51.7

General ADR practices of respondent

Findings of the study is shown in table 1 (Amin et al., 2015). From this study it is clear that more than half of them were not familiar with the existence of ADR reporting body of Bangladesh though they were experienced ADRs. Many did not even know how to report, some were afraid of legal liabilities associated with reporting to ADRs.

So it is very urgent to strengthen the pharmacovigilance practice and reporting system in our country for the safety of medication system, especially in case of self medication which is very common in our country.

Challenges of PV activities in Bangladesh

- Lack of adequate knowledge, skill and awareness.
- Health care professionals are over burdened.
- Tendency of self-medication and poly pharmacy.
- Lack of collaboration with Industry and Academia.
- Medication errors and multi disease complicacy.
- Improper storage and distribution of drugs.
- Aggressive promotion and push sale of drugs.
- Unhealthy food, environment and others.
- Irrational use of antibiotics, steroids, hormones and other drugs.
- Inadequate legislation, logistics & financial support for PV, etc.

Importance of PV education and awareness

The first day a new drug is on the market should mark the start of a systematic ongoing evaluation of how wisely doctors are prescribing it, how thoroughly patients are taking it, what adverse events it causes in routine care, and (eventually) whether its promised benefits are actually being realized with routine use. Additionally, beyond licensure for marketing, there is also a need for comparative studies assessing both pharmaceutical risks and benefits at different dosing levels between drugs of the same class (or drugs used for the same purpose) across broad end-user populations. Failure to make such post-marketing studies remains therefore perhaps the single biggest challenge in public regulation of drug 'safety' at present.

Conventional methods of communication of pharmacovigilance knowledge such as letter writing, label wording and package insert warnings have very limited success in achieving the goal of an informed prescriber ready to apply pharmacovigilance intelligence in their everyday practice (Belton *et al.*, 1995; Smalley *et al.*, 2000). Similarly with the general public, largely ineffective communication has been observed using these conventional tools (Berry*et al.*, 2002).

When does a side effect of a drug become an adverse event, an ADR or a medication-related error? Clearly different players in the healthcare system will have different perceptions on this point. The relationship between medication errors and adverse drug events is complex, with medication errors being generally more common than adverse drug events. It has been estimated that about a third of a half of adverse drug events are typically associated with medication errors: however, of course, not all adverse drug events necessarily spring from medication errors (Morimoto *et al.*, 2004).

For a clinician management of an adverse drug effect and filling the ADR report represents an important opportunity for learning. Local institutional settings, discussion of, and interaction about ADR reports may become a matter of routine. Such arrangements need to be purposefully fostered. Multi-disciplinary hospital drug and therapeutics advisory committees can be a useful forum for such learning.

Necessity of more study on PV in Bangladesh

Bangladesh is an underdeveloped country. Bangladesh is now exporting wide range of products to 140 countries of the world. It includes all major therapeutic class & dosage forms along with high-tech products like inhalers, nasal sprays, suppositories, IV fluids, injectables etc. (Mustansir *et al.*, 2013). On the other hand, a major portion of the people of Bangladesh are unconscious about the health and the drug they intake during diseases. They have limited ideas about their health and medicines. They face many serious health hazard (several drug induced diseases like- kidney damage, liver disease etc.). Due to these reasons pharmacovigilance study must be required for the safety of the people. It is very urgent to strengthen the pharmacovigilance practice and reporting system in our country for the safety of medication system, especially in case of self medication which is very common in our country. (*Jahan et al.,2017).* Education for PV knowledge of the stakeholders and building awareness can improve the present situation resulting sustainable & effective Pharmacovigilance system in Bangladesh.

Conclusion

Pharmacovigilance is very much crucial and important to ensure safety of marketed drug products. DGDA is working to ensure safe, quality and effective medicines for safeguarding the human and animal health. So, nationwide Good PV Practice is essential. Basics of PV may be introduced in course-curriculum for healthcare professionals (Doctor, Pharmacist & Nurse) in Bangladesh. All stakeholders should be aware about PV-activities. WHO definition of PV has evolved considerably during the period 1961– 2000 and includes, through the term 'prevention', a clear call for knowledge gained through pharmacovigilance

activities to be influencing and improving outcomes from use of medicines. This call is reflected in contemporary expert commentary on the importance of surveillance and drug safety (Edwards, Faich and Tilson, 2005): *A general effort to improve risk communication both in particular instances and in the general education of the public, should be a high priority*. For the individual healthcare professional learning and incorporating pharmacovigilance in their routine patient care is now a key challenge. ●

References:

1. Amin, M.N., Khan, T.M. and Dewan, S.M.R. 2016. Cross sectional study exploring barriers to adverse drug reactions reporting in community pharmacy settings in Dhaka, Bangladesh. *Br. Med. J. Open*. 6.
2. Yao, B., Zhu, L., Jhing, Q. and Xia, H.A. 2013. Safety monitoring in clinical trials. *Pharmaceutics*. 5, 94-106.
3. Amran, M.S. Introduction to Pharmacy. January 2015.pp. 159-161.
4. Jahan et al. / Bangladesh Pharmaceutical Journal 20(1): 105-114, 2017)
5. Olsson S. (ed.) (1999). National Pharmacovigilance Systems. Uppsala: The Uppsala Monitoring Centre.
6. Begum, Z.A., Sultana, S., Umar, B.U., Ferdous, A.H., Uddin, M.K. and Islam, S.M.H. 2012. Study of adverse drug
7. Reactions in out-patient department of a teaching hospital. *Bangladesh J. Pharmacol.* 7, 104-107.
8. Edwards, R. 2012. An agenda for UK clinical pharmacology, pharmacovigilance. *Br. J. Clinical Pharmacol.* 73, 979-982.
9. Helali, A.M., Iqbal M.J., Islam, M.Z. and Haque, M. 2014. The evolving role of pharmacovigilance and drug safety: The way forward for Bangladesh. *Int. J. Pharm. Res* .6, 31-37.
10. Khondkar, L. and Khan, M.S.I. 2014. Clinical profile of cutaneous drug reactions. *J. Pakistan Associ.*
11. *Dermatologist.* 24, 160-163.
12. Mustansir, M.A., Saha, D., Paul, S., Rahim, Z.B. and Hosen, S.M.Z. 2013. Studies on pharmacovigilance in
13. Bangladesh: Safety Issues. *Int. J. Pharm. Teachi Practice*. 4, 613-621.
14. The importance of pharmacovigilance, Safety monitoring of pharmaceutical products, 2002.
15. WHO. Pharmacovigilance ensuring the safe use of medicines.
16. Practical Experience in Teaching Pharmacovigilance, R.E. FERNER AND S.E. MCDOWELL, UK
17. Suke, S.G.,Kosta, P. and Negi, H. 2015. Role pharmacovigilance in India: An overview. *Online J.Public Health*
18. *Informatics.*7, p. 223.

DRUG SAFETY UPDATES BY WHO

Sl. No	Name of Medicine	Indication	Adverse Drug Reaction	Regulatory actions/ recommendation taken by NRAs
1.	Fluoro-quinolones	a. Urinary tract infection b. Respiratory tract infection c. Skin and soft issue, bones and joint infection. d. Abdominal cavity infection	Retinal detachment.	Singapore. The HSA has instructed to update the package inserts of uoroquinolones containing products. .
2.	Selective serotonin reuptake inhibitors (SSRIs)	Antidepressants	a. Risk of suicidal thinking and behavior. b. Potential risk of autism in child whose mothers used elective Serotonin Reuptake Inhibitors (SSRIs) during pregnancy. (Canada)	a. Australia. The TGA has issued a reminder to health-care professionals relating to suicidal thinking and behavior in children and adolescents & directed to include in the Product Information documents of all SSRIs registered for use in Australia. b. Canada. Health Canada has aware Potential risk of autism in child whose mothers used SSRIs.
3.	Carbamazepine	Epilepsy and other conditions such as bipolar disorders, alcohol-withdrawal syndrome, trigeminal neuralgia, diabetic neuropathy and diabetes insipidus.	Severe cutaneous adverse reactions (SCARs).	Singapore. The HSA has recommended health-care professionals for HLAB* 1502 genotyping prior to the initiation of Carbamazepine therapy in patients of AsianAncestry, to minimize that risk.
4.	Pioglitazone containing Drugs	Control of Blood sugar Along with diet and exercise, in adults with type 2 diabetes.	Risk of bladder cancer	USA. The US FDA has updated the product information for pioglitazone-containing medicines to include an additional Adverse effect to existing warnings, about the increased risk of bladder cancer.

SOURCE: PHARMACOVIGILANCE NEWSLETTER

'Management of Hypertension – Bangladesh Perspective'

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Introduction

Blood pressure is a very important physiologic component in human body. In fact no one can survive without maintaining his or her blood pressure. By definition it is the pressure of blood over the blood vessel while flowing through it. Blood pressure has two components namely systolic and diastolic which have their own normal ranges. Either of these two separately or together can go up above these normal ranges. If it is a persistent rise- blood pressure turns to hypertension.

Hypertension is a long-term medical condition in which the blood pressure in the blood vessels is persistently elevated. When this persistent rise is in the arteries then it is called Arterial Hypertension. Though other vessels like veins, pulmonary arteries can have hypertension too but the term "Hypertension" usually refers to arterial hypertension if not specified otherwise.

Epidemiology

Hypertension is a global problem, let alone Bangladesh. It is one of the largest non-communicable disease as around 25% of the world population is suffering from it. The bad news is its increase in prevalence. A large number of these people live in developing countries.

Bangladesh has no large scale data but those so far found, have come up with around 26.4% overall prevalence with female preponderance. Another study by Islam et.al. depicted that incidence of hypertension increases with age as 40-65% of elderly people suffer from hypertension. A large number of hypertensive patients live in the rural areas according to these studies. Chowdhury et,al. has shown in their study that hypertension in Bangladesh community is associated with older age, sex, education, place of residence, working status, wealth status BMI and diabetes.

Types and risk factors of hypertension

Primary or essential hypertension

The exact cause of hypertension is not known among almost 95% of hypertensive patients and it is termed as primary or essential hypertension. However, there are some risk factors that are linked to developing hypertension in this group. These are lack of physical activity, obesity, recent weight change, dietary habit, smoking, positive family history. All these risk factors are getting more prominent among our people putting them at more risk to develop hypertension.

Secondary hypertension:

This is the type of hypertension that develops secondary to a disease that cause is known. Only 5% of the hypertensive patients experience secondary hypertension. Common causes are renal disease, thyroid disorder, due to some drugs and sleep disorder. Recently some studies have found relation in-between hypertension and arsenicosis which has common cause of water pollution in parts of Bangladesh. Hypovitaminosis D might be another cause that might play a role in causing hypertension among Bangladesh people.

Coexistence with other Diseases

Though at the younger ages and at initial stages hypertension may remain alone but in course of time it may coexist with other diseases. These are commonly, kidney disease, cardiovascular disease, cerebrovas-

cular disease, lipid disorder, metabolic syndrome, COPD, eclampsia. In all these comorbid situations, management of hypertension becomes complicated and choice of antihypertensive is driven by the compelling indication.

Stages of Blood pressure

Since Bangladesh doesn't have any of its own guideline on Hypertension, therefore, we follow the other guidelines, namely those of JNC 7, European Society of Hypertension and British Hypertension Society. All have categorized hypertension almost similarly with slight differences. JNC 7, the most popular of these have categorized blood pressure in the following way:

Table: Stages of Hypertension: JNC 7

Stage of Blood Pressure (BP)	Systolic BP	Diastolic BP
Normal	< 120	And <80
Prehypertension	120-139	80-89
Stage 1 Hypertension	140-159	90-99
Stage2 Hypertension	≥160	≥100

The majority of the people in Bangladesh, especially those living in the rural areas have no idea about these numbers. Those with more education have some conception about the ranges, but very few of us know regarding 'Prehypertension' and its importance. Though not today's focus of discussion, our community deals with another blood pressure related complain which is termed by the patients " Low Pressure".

Complications

Hypertension though a silent disease by itself can invite various complications for the body, more rapidly when it is not well controlled by the patient. Ischemic heart disease, acute coronary syndrome, left ventricular failure, cardiomyopathy, arrhythmia, chronic kidney disease, cerebrovascular disease (brain stroke) retinopathy, peripheral vascular disease, dementia etc. are recognized complications of hypertension. Our hypertensive patients do not know well about these complications. So, many of the hypertentensive patients attend the physicians with the clinical features of the complication and come to know about their hypertension status for the first time.

A group of hypertensives may fall into conditions like resistance hypertension, hypertensive urgency and hypertensive emergencies warranting more vigorous treatment, urgent hospitalizations and management.

Diagnosis

Hypertension initially is largely a silent disease, therefore, remain undiagnosed in many patients. In a large group of patients hypertension is asymptomatic while in others there are nonspecific symptoms like headache, weakness, palpitation, breathlessness, nasal bleeding, vision disturbance and so forth. As the disease progresses silently there comes a time when body's vital organs are damaged and symptoms of complications surface.

This is relatively a common phenomenon in Bangladesh; hypertensive patients presenting with complications. Health System in Bangladesh is not supported by widespread health insurance and health checkup is not routinely practiced here.

Lack of education, health awareness is also responsible for non-diagnosis or late diagnosis of hypertension. People come to know about their hypertension while measuring blood pressure somewhere or attending a health facility for some other reasons.

Trend of Measuring Blood Pressure

Blood pressure measurement is the key way to diagnose hypertension. In Bangladesh, blood pressure measurement is available in health facilities like hospitals, clinics, chambers. Now a days, beside such office BP measurement out of office BP measurement in pharmacies (medicine stores) is commonly seen. Road side temporary facilities with blood pressure machine , glucometer and weight machine in and around places where people visit for regular exercise are also seen now a days.

Home BP monitoring (HBPM) is getting popularity in this country. However there should be definite scientific and logical approach to home blood pressure monitoring. Otherwise, misuse or overuse of HBPM produces confusion, anxiety and lead the patient and family members to wrong treatment.

All these approaches in spite of their limitations have positive impact in the diagnosis and management of hypertension.

Types of Sphygmomanometer (Blood Pressure Machines)

Aneroid BP Machine: The most popular type is the aneroid sphygmomanometer due to its availability, cost efficacy, easy handling. In addition to its use in office BP measurement it is widely used in home BP monitoring.

The Mercury BP Machine: Many people still unaware of the fact that mercury sphygmomanometer is losing its position as the gold standard because of chance of mercury toxicity.

Automated Digital BP Machine: People have doubt about the measurement efficacy of automated digital blood pressure machine though it is the sphygmomanometer that has been advocated by recent guidelines. Compared to other auscaltatory methods this automated digital BP machines measure blood pressure by means of oscillometry. Therefore, it can be operated alone. Excessive cost is another reason for its less use in Bangladesh community.

Ambulatory blood pressure monitor: Though it has an important role in the diagnosis of hypertension but its use is still very limited in

our community due to unavailabity, higher cost and unawareness- even among the physicians.

Other investigations

Diagnosis and assessment of hypertension status include some other investigations like creatinine, urine, lipids, ECG, Echo, which the patients are reluctant to do due to unawareness and expenses.

Treatment

Treatment of blood pressure comprises of life style modification and antihypertensive medication. For all groups of hypertensive patients, life style modification is an inevitable component and in prehypertensives and stage1 without compelling indication it is infact the initial and only treatment.

Life style modification

Life style modification comprises of diet, reduction of obesity, regular exercise, cessation of smoking, abstinence from alcohol and stress management.

Diet

Diets include healthy eating habit like Dietary approach to stop hypertension (DASH), Mediterranean diet etc. All diets have a common basic concept that is a diet with required calorie according to patient's body weight, rich in vegetable, fruit, fiber and less in animal fat, carbohydrate and no added salt (that is low in sodium) and rich in potassium. But it's a common practice in Bangladesh to indulge in a diet rich in carbohydrate and extra salt.

So as a part of management of hypertension our diet needs healthy change – diet that is amicable with our culture as well as healthy enough to control hypertension. The traditional practice of taking extra salt, specially among the rural people must be discouraged by different approaches of health awareness program. Mass awareness campaign should also be launched to lower down the consumption of excess salt. Salt low in sodium is widely available in developed countries and should be instituted in Bangladesh.

Obesity Reduction:

With the growing economy, obesity in Bangladesh is expanding as well. Our community should have more institutional facility like health center, counselor , nutritionist, treatment facility for morbid obesity, drugs to reduce obesity for obesity reduction.

Exercise:

No doubt, awareness for doing exercise has increased among Bangladesh people though a lot more needed to control no communicable diseases. Facilities like roads, pavements, parks friendly enough for walking and other exercises are not at all enough for us and should be increased at any cost. Exercise should also include mental relaxation techniques like prayer, meditation, yoga etc.

Cessation of Smoking:

Cigarettes and other forms of tobacco are very easily available on the streets everywhere in Bangladesh which should be discouraged by making stringent laws and their implementation in addition to mass health awareness program. Special programs to quit smoking should be advocated in the community.

Moderation of alcohol use should also be a part of lifestyle management among patients with hypertension.

Treatment with Antihypertensive Drugs

One of the mentionable developments that Bangladesh has achieved in local production of almost 95% of the drugs used in health sector, thanks to the booming

pharmaceutical sector. Almost all types of antihypertensive drugs are locally produced and marketed cost effectively by the pharmaceutical industries. These are the combination drugs also available here making the treatment more patient-friendly. Antihypertensives are even crossing the border as pharmaceuticals are now a days exporting these drugs to other countries

South Asians respond to antihypertensive therapy in similar manner with the others. Since it is a lifelong treatment, most patients find comfort with cost effective antihypertensives. Single daily dose is preferred to twice daily dosing and increases patient's compliance with the treatment. In most cases, at least two drugs are needed at one stage of treatment to control hypertension. Calcium-channel blockers (45%) and beta blockers (40%) are the two most popular drugs used for hypertension treatment in Bangladesh. Still the age old beta blockers are on popularity list though recent guidelines have discouraged the use of beta blockers due to its inability to lower down central blood pressure. Side-effects are sometimes troublesome for the patients and another reason for non-compliance with drug treatment. Prescription survey study found irrational drug prescribing, lack of

Table: Antihypertensive drugs

First Line Antihypertensive Drugs	Diuretcs, ACE Inhibitors (ACEI), Angiotensin II Receptor blocker (ARB), Calcium Channel Blocker (CCB)
Combination Antihypertensive	ACEI OR ARB +Diuretics, ARB+ CCB, CCB+ BB, BB+ Diuretics
Second Line Antihypertensive Drugs	Beta blocker (BB), Alpha Blocker, Hydralazine
Drugs used in Hypertensive Emergency	Hydralazine, Nitroprusside, Labetalol, Clonidine, Methyldopa,Furosemide, Nitrate

quality in prescribing, dosing and biasness due to the influence by the pharmaceuticals.

Misconception regarding Antihypertensive drugs:

There are several misconceptions regarding treatment of hypertensive patients in Bangladesh. Many people believe regarding treatment, there is no other option but to take antihypertensive drugs. Some do not want to start antihypertesnsives because they believe it is not required since the disease is not producing any symptom. Some do not start the drug because they think it cannot be stopped once started so it's better not to start at all.

Some people discontinue the drug once the blood pressure is normalized because they think the drug is no more needed. In a study, non-adherence to antihypertensive treatment was found in 85% of cases. Many people keep taking the drug continuously without attending the physician further or measuring there blood pressure from time to time.

Factors determining non-adherence included lower level of education, low family income, duration of illness, perception related to the disease, lack of accompanying person, and insufficient information from the service provider.

Prevention

The primary prevention of hypertension include healthy lifestyle in such a manner so that blood pressure remains in normal range. The secondary prevention includes good control of blood pressure among the hypertensive patients and avoidance of complications. Lifestyle modification, antihypertensive drugs, regular health checkup, health education all these in concert can achieve the purpose of prevention. Bangladesh needs its own guideline, strong health policy, robust strategy, large scale research works, mass awareness program to achieve its target on management of hypertension. ●

FAST FACTS

- *An estimated 17.5 million people died from CVDs in 2012, representing 31% of all global deaths. Of these deaths, an estimated 7.4 million were due to coronary heart disease and 6.7 million were due to stroke.*
- *Out of the 16 million deaths under the age of 70 due to non-communicable diseases, 82% are in low and middle income countries and 37% are caused by CVDs.*
- *Most cardiovascular diseases can prevent by addressing behavioral risk factors such as tobacco use, unhealthy diet and obesity, physical inactivity and harmful use of alcohol using population wide strategies.*

'Hypertension - A Global burden'

Professor Dr. Md. Zakir Hossain
President (Honorary)
Hypertension and Research Centre, Rangpur
Professor & Head of Medicine
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Global Burden of Hypertension

- More than 25% of the world adult population is already hypertensive
- The number is projected to increase to 29% (1.56 billion) by 2025
- Almost 75% of the worldwide population with HTN will be in developing countries
- In Bangladesh, prevalence of raised blood pressure among adults aged ≥ 18 years in 2014 was 25.1% & 26.1% in male & female respectively
- is most prevalent risk factor for cardiovascular and renal diseases worldwide, contributing to -
  - one half of the IHD, and
  - ≈ two thirds of stroke
- Worldwide,**7.1 million deaths** occurs from hypertension per year
- *In 2002, it was named 'the number one killer'* by WHO in The World Health Report

Why Hypertension is so important?

A term, triple paradox is helpful to understand the importance of it. It is-

- Easy to diagnose but often remains undetected
- Simple to treat but often remains untreated
- Despite availability of potent drugs, treatment often is ineffective

How Hypertension is defined?

Any definition of HTN is arbitrary. **According to JNC 7, a** most acceptable guidelines for hypertension noted **Hypertension** as-

A systolic blood pressure **(SBP) ≥140 mmHg** and/or a diastolic **(DBP) ≥90 mmHg** based on the average of **two or more** properly measured, seated BP readings on each of **two or more** office visits.

Blood Pressure Categories:

According to JNC VII, level of Hypertension is classified as below:

Stage	SBP mm Hg	DBP mmHg
Normal	<120	and <80
Prehypertension	120-139	or 80-89
Stage 1 hypertension	140-159	or 90-99
Stage 2 hypertension	>_ 160	>_100

Types of Hypertension

- **Primary Hypertension:**
  - also known as essential HTN
  - accounts for about 95% of cases of HTN
  - no universally established cause known
- **Secondary Hypertension:**
  - less common cause of HTN (5%)
  - secondary to other potentially rectifiable causes

- **Causes of Secondary HTN:**
  - ✓ **Common**
    - Renal disorder
    - Drug induced
    - Thyroid disorder
    - Sleep apnea
  - ✓ **Uncommon**
    - Pheochromocytoma
    - Cushing's Syndrome
    - Coarctation of Aorta
    - Primary Aldosteronism

Risk factor:

- Family and personal H/o HTN, CVD, dyslipidemia and diabetes
- Smoking habits
- Dietary habits
- Recent weight change; obesity
- sedentary lifestyle (lack of physical activity)
- Snoring, sleep apnea
- Low birth weight

Diagnostic Procedures

- Positive presentation with risk factor
- History and Physical examination including BP measurements
- Laboratory investigations
- Further diagnostic tests

Presentation:

A patient with Hypertension is frequently ***Asymptomatic*** until the development of complication. Many patients may be incidentally found as hypertensive during their visit with the doctor for another health related problem. But some patient may present with symptoms as:

- Headache
- Breathlessness
- Bleeding from nose
- Fatigue
- Sleepiness
- Profuse sweating
- Blurred vision.

Investigations:

Laboratory investigations is not mandatory for diagnosis of Primary hypertension. But limited investigations may be necessary for evaluation of patients status during initial visit.

Occationally extensive investigations may be required when secondary cause of hypertension is sustected. Routine investigations includes:

- Urine for blood, protein and glucose
- Urea,electrolyte and creatinine
- Blood glucose
- Lipid profile
- Thyroid function test
- ECG

Treatment:

Treatment is based on Non-Pharmacological and pharmacological approach.

➲ **Non-Pharmacological:**

By Life style modification. It includes:

- Physical activity.
- Weight reduction.
- Moderation of alcohol
- Smoking ceasation
- DASH diet: DASH diet includes plenty of fruits and vegetables, low fat dairy product, whole grain, fish, lean poultry, and nuts, diet low in saturated fat low sodium and adequate potassium.

➲ **Pharmacological:**

- Choice of pharmacological treatment depends on variety of factor which includes
- Age, Race, pregnancy, stage of HTN, therapeutic target, drug cost, dosing side effect and contraindication, associated co-morbid condition needed to be treated-compelling indication.
- Initial drugs for control of Hypertension are:
  - ACE inhibitor
  - Angiotensin receptor blocker
  - Thiazide diuretics
  - Calcium Channel blocker

Target BP:

Eligible population	Target BP
General population upto age 79	BP<140/90 mmHg
General population aging 80 or above	BP<150/90 mmHg
Any age with: DM, CKD, PVD, CAD, Cardiac failure, aortic aneurysm, secondary prevention of stroke and TIA	BP<130/85 mmHg

Target organ:

Epidemiological data suggests that hypertension remains a major modifiable risk factor for cardiovascular disease through target organ damage. Major target organ that involves are -**Heart, Brain, Kidney, Peripheral arteries, Retina.**

Complications:

- **Blood vessels:**
  - Smooth muscles hypertrophy
  - Hyaline arterio-sclerosis
  - Aortic aneurysm
  - Aortic dissection
  - Wide spread atheroma develops may lead to coronary artery disease and or / CVD
  - Increased peripheral resistance that aggravate hypertension
- **Central nervous system:**
  - CVD
  - TIA is more common
  - Hypertensive encephalopathy
- **Eye:**
  - Hypertensive retinopathy
- **Heart:**
  - Excess cardiac mortality and morbidity
  - Left ventricular hypertrophy
  - AF Common due to left ventricular diastolic dysfunction.
  - LVF
- **Kidneys:**
  - Protenuria
  - Progressive renal failure by damaging renal vasculature

Benefits of lowering BP:

Average percent reduction-

o Stroke reduction	35-40%
o Myocardial infarction	20-25%
o Heart failure	50%

Follow up:

Patients taking antihypertensive therapy require follow up at 3 monthly intervals to maintain BP, minimize side effects & reinforce lifestyle advice. Patients with target organ damage require more frequent follow up.

Conclusion:

Hypertension is the most recognised treatable risk factor for cardiovascular mortality and morbidity. The asymptomatic nature of hypertension and the inherent variability in blood pressure can delay the diagnosis and treatment. Effective management requires continuity of care by a physician, awareness of the patient and active involvement of educated person of the society. As well as, institutional care is very much important to establish a regular follow up & extensive care as per need. Hypertension & Research Centre, Rangpur is such an institution that provide all the facilities that is needed for a hypertensive patient with or without target organ damage. ●

HEALTH CARE

Hypertension & Research Centre, Rangpur

An Overview

Hypertension and Research Centre, Rangpur is a sister-concern of Dr. Wasim-Waleda Foundation.

Milestones:

- Established on 14th November 2008, Rangpur, Bangladesh.
- Registered by ministry of social affairs, Bangladesh.
- Started lab facilities as a part of expansion of activities.
- Research work started from July, 2011
- Hypertension detection center started from 2011.

Necessities for HTN care centre:

- High burden of hypertensive patients
- Low resource community
- Least awareness of HTN
- Silent killer disease
- Social responsibility

Prerequisite of registration of patient

Only Hypertensive patients can be registered this centre. Besides, any disease accompanied with hypertension as like as stroke, ischaemic heart diseases, paralysis etc are treated here.

Registration subscription fee

- Registration (including a guideline & prescribing book): 50tk.
- Subsequent follow-up fee: 40tk.

Flow chart of treatment:

- Registration & Personal Data fill-up
- Providing a guideline & prescribing book
- Counseling
- Treatment by a Senior Medical officer
- If needed or as per patients wish consult with a consultant
- If needed or as per patients wish consult with chief consultant
- If needed medical board is formed for better management

All the above mentioned process need no additional free.

Patient profile:

- Total patient: 20073 (up to 27.10.17)
- Daily patients: 40-50
  - New patient: 5-10 Daily
  - Follow up patients: 30-40 daily.

MYTH VS REALITY

Myth: **I don't use table salt, so I'm in control of my sodium intake and my blood pressure.**

Reality: In some people, sodium can increase blood pressure. But controlling sodium means more than just putting down the salt shaker. It also means checking labels, because up to 75 percent of the sodium we consume is hidden in processed foods like tomato sauce, soups, condiments, canned foods and prepared mixes. When buying prepared and prepackaged foods, read the labels. Watch for the words "soda" and "sodium" and the symbol "Na" on labels. These words show that sodium compounds are present.

Myth: **People with high blood pressure have nervousness, sweating, difficulty sleeping and their face becomes flushed. I don't have those symptoms so I'm good.**

Reality: Many people have high blood pressure for years without knowing it. It's often called "the silent killer" because it usually has no symptoms. You may not be aware that it's damaging your arteries, heart and other organs. Know your numbers and don't make the mistake of assuming any specific symptoms will let you know there's a problem.

Myth: **I was diagnosed with high blood pressure, but I have been maintaining lower readings, so I can stop taking my medication.**

Activities of HTNCRp:

- At very beginning only treatment of hypertensive patients in low cost
- Create awareness for HTN & its consequences
- Detection of HTN
- Preserve the data of hypertensive patients
- Research activities about HTN
- Provide comprehensive service to the hypertensive patients; including quality investigation facility, target organ care facilities

Activities performed yet:

- Arrangement of free medical camp: 31
- Awareness generation program: 218
- Free blood pressure check up camp: 73
- Scientific seminars: 26
- Publications of health magazine yearly: 03
- Observation of various remarkable day like world hypertension day

Achievement:

Within about 9 years of establishment-

- Over 20,073 (upto 27 October 2017) hypertensive patients have registered in the center from northern zone of Rangpur division.
- Research done: 06
- Research ongoing: 06
- Thesis done: 07
- Publications: 09
- Scientific paper presentation-15
  - Home 11
  - Abroad 04.

Visions of HTNCRp:

- Development of guideline in management of hypertension & its complication.
- Establishment of complete laboratory facilities.
- Establish branches throughout the country
- Act as a partner organization in collaboration with Gov and NGO's in NCD study & control program
- Establishment of target organ damage management centre
  - Stroke care corner
  - Kidney care centre
  - Heart care corner

Reality: High blood pressure can be a lifelong disease. Follow your healthcare professional's recommendations carefully, even if it means taking medication every day for the rest of your life. By partnering with your healthcare team, you can successfully reach your treatment goals and enjoy the benefits of better health.

Myth: Blood pressure is controlled, so I can stop taking pills.

Reality: Unfortunately like many other NCDs, HTn cannot be cured, once diagnosed, it can only be controlled/ managed. The moment treatment is withdrawn there are high possibilities HTn bounce back.

Myth: All HTn pills have side effect and nothing can be done for that.

Reality: Gone are the days when HTn pills had major side effects and nothing could be done but now scenario has changed, now doctors prescribe pills which are practically without side effects. But, yes exceptions are there a pill which suits one might have some side effect for other, like ACE inhibitors might induce dry cough in some, but these effects are of mild nature, do inform about even any slight change you notice.

Myth: Old age means HTN.

Reality: Age has no specific relation to HTN. There are many factors which cause hypertension-genetic, stress, lifestyle, kidney impairment, etc. Collecting in simple words, HTN is caused when due to some reasons heart has to work harder to pump blood to different parts of body.

Myth: High cholesterol levels means definitive HTN.

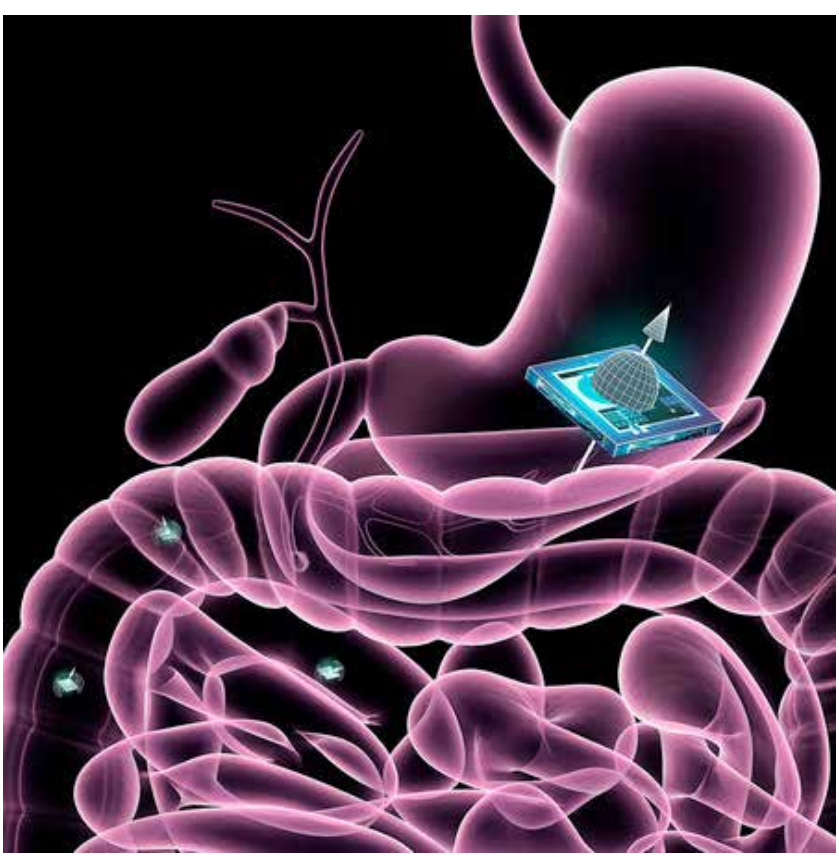
Reality: Poor eating habits with sedentary life style may increase may increase both but not necessarily that high cholesterol means also high BP.

Medicine of the future: New Microchi Technology could be used to track smart pills

Researchers at Caltech have developed a prototype miniature medical device that could ultimately be used in "smart pills" to diagnose and treat diseases. A key to the new technology - and what makes it unique among other micro scale medical devices - is that its location can be precisely identified within the body, something that proved challenging before.

"The dream is that we will have microscale devices that are roaming our bodies and either diagnosing problems or fixing things," said Azita Emami, the Andrew and Peggy Cherng Professor of Electrical Engineering and Medical Engineering and Heritage Medical Research Institute Investigator, who co-led the research along with Assistant Professor of Chemical Engineering and Heritage Medical Research Institute Investigator Mikhail Shapiro. "Before now, one of the challenges was that it was hard to tell where they are in the body."

A paper describing the new device appeared in the September issue of the journal Nature Biomedical Engineering. The lead author is Manuel Monge (MS '10, PhD '17), who was a doctoral student in Emami's lab and a Rosen Bioengineering Center Scholar at Caltech, and now works at a company called Neuralink. Audrey Lee-Gosselin, a research technician in Shapiro's lab, is also an author.



Called ATOMS, which is short for addressable transmitters operated as magnetic spins, the new silicon-chip devices borrow from the principles of magnetic resonance imaging (MRI), in which the location of atoms in a patient's body is determined using magnetic fields. The microdevices would also be located in the body using magnetic fields - but rather than relying on the body's atoms, the chips contain a set of integrated sensors, resonators, and wireless transmission technology that would allow them to mimic the magnetic resonance properties of atoms.

"A key principle of MRI is that a magnetic field gradient causes atoms at two different locations to resonate at two different frequencies, making it easy to tell where they are," said Shapiro. "We wanted to embody this elegant principle in a compact integrated circuit. The ATOMS devices also resonate at different frequencies depending on where they are in a magnetic field."

"We wanted to make this chip very small with low power consumption, and that comes with a lot of engineering challenges," said Emami. "We had to carefully balance the size of the device with how much power it consumes and how well its location can be pinpointed." ●

New scan developed to predict stroke risk

Researchers at the University of Oxford have developed a new type of MRI scan to predict the risk of having a stroke, thanks to funding from the British Heart Foundation (BHF).

The non-invasive technique, produces a quantitative result that can accurately indicate whether plaques in the carotid arteries – those that supply the brain with blood - are rich in cholesterol, and therefore more likely to cause a stroke.

The rupture of fatty plaques can block the arteries and cause potentially debilitating and life-threatening strokes as the brain is starved of oxygen.

At present, the risk of stroke is measured by the size of the plaque in the carotid artery. If the plaque is deemed to be too big, people are treated surgically to remove it. However, this method can miss fatty plaques that are not big, but have a high risk of rupturing.

The new MRI technique was developed to differentiate between the risky plaques that contain a lot of cholesterol, and those that are more stable.

In the study, the researchers used the new MRI scan to measure the amount of cholesterol in the carotid plaques of 26 patients scheduled for surgery. After the plaques were surgically removed, the team looked at the actual cholesterol content in each plaque and found that the new technique was accurate and the more cholesterol they detected within the plaque, the greater the risk.

The work was a collaboration between researchers at the University of Oxford and surgeons working within the John Radcliffe Hospital and was supported by the BHF Centre of Research Excellence in Oxford and the NIHR Oxford Biomedical Research Centre. ●

DID YOU KNOW ?

Top 10 things you need to know about high blood pressure

1. **High blood pressure is a very common medical condition.** By the time you reach 55 to 65 years of age, you will have about a 40% chance of having high blood pressure. And even if you don't have high blood pressure when you are 55 to 65 years of age, you will have a 90% chance of developing it in the next 20 years.

2. **High blood pressure is known as the silent killer.** In most cases, high blood pressure presents no symptoms, and nearly 20% of people who have high blood pressure don't even know they have it! While you might not feel symptoms of your high blood pressure, it could be silently causing serious problems inside of your body.

3. **You should know your blood pressure target.** For most people, the ideal blood pressure reading is 140/90. If you have diabetes, your target would be less than 130/80.

4. **You shouldn't leave high blood pressure untreated.** If you do not treat or control your high blood pressure, you will be at an increased risk of stroke, heart attack, blood vessel disease, and heart failure. Your risk of heart-related diseases and death approximately doubles for every 20 mm Hg (millimetres of mercury) increase in systolic blood pressure (the top number in your blood pressure measurement) and 10 mm Hg increase in diastolic blood pressure (the bottom number in your blood pressure measurement).

5. **There are some high blood pressure risks you cannot control.** High blood pressure may run in your family. If it does, you are also at higher risk yourself. Know your family medical history so you can have your blood pressure checked regularly.

6. **But there are some high blood pressure risks you can control!** You can reduce your high blood pressure risk by taking steps to improve your lifestyle habits. Eat a healthy diet that is low in sodium. Get regular exercise. Limit your intake of caffeine. Lose weight if you are overweight. And if you smoke, quit.

7. **Salt is small, but it carries big blood pressure risks.** Experts estimate that about 30% of all high blood pressure is caused by consuming too much salt! Something as simple as reducing your salt intake can help to reduce your blood pressure. Get simple tips for reducing salt in your diet.

8. **Your medicine cabinet could be putting you in danger of high blood pressure.** Did you know that some common over-the-counter medications can increase your blood pressure? Some of the ones to watch for are pain medications like ibuprofen and naproxen and cold medications that contain pseudoephedrine. If you already have high blood pressure, talk to your doctor or pharmacist before using any over-the-counter medications.

9. **You may need to take more than one blood pressure medication.** Researchers have found that using lower doses of more than one medication can help to control blood pressure better and cause fewer side effects than taking higher doses of one medication. This does not necessarily mean that you will have to take a handful of different pills, since some combination high blood pressure medications are available.

10. **Whether your blood pressure medication works may depend on you.** That is because in order for your medication to work properly, you must take it regularly. This can be tricky, especially since high blood pressure often causes no symptoms. You may feel fine and simply forget to take your medication. If you find it difficult to remember to take your medication or if you do not want to take it - for example, if you experience side effects - speak to your doctor or pharmacist.

GLOSSARY OF TERMS
HYPERTENSION

Angina: chest pain

Beta-Blockers: one kind of medication used to treat high blood pressure, chest pain, and irregular heartbeat and to help protect a person from heart disease. Beta-blockers work by blocking the effects of adrenaline in various parts of the body. Beta-blockers relieve stress on the heart so that it requires less blood and oxygen. As a result, the heart doesn't have to work as hard and blood pressure is lowered.

Calcium Channel Blockers: one kind of high blood pressure drug that slows the movement of calcium into the cells of the heart and the walls of the arteries (blood vessels that carry blood from the heart to the tissues). This relaxes the arteries and reduces the pressure in the blood vessels and makes it easier for the heart to pump blood.

Congestive Heart Failure: the inability of the heart to adequately pump blood. This can be caused by a number of problems, including untreated high blood pressure, heart attacks, or infections.

Diastolic Blood Pressure: the pressure of blood against the walls of the arteries when the heart relaxes between beats. It is the "bottom" number when referring to a specific blood pressure. For example, if your blood pressure is 120 over 80 or 120/80, the diastolic measurement is 80.

Diuretics: Diuretics act on the kidneys to remove excess salt and fluid from the blood. This increases the flow of urine and the need to urinate, which reduces the amount of water in the body. This can help lower blood pressure and can be used to treat high blood pressure and heart failure.

Echocardiogram: a test that uses a device to bounce sound waves off the heart to create an image of the heart. The ultrasound image details the blood flow in the heart's chambers and evaluates heart chamber size and how the heart valves are functioning.

Electrocardiogram (EKG or ECG): a diagnostic test that measures the electrical activity, rate, and rhythm of the heartbeat via electrodes attached to the arms, legs, and chest

Essential Hypertension: high blood pressure that does not have an apparent cause, but is associated with such conditions such as obesity, smoking, and/or diet. The vast majority (95%) of people with high blood pressure have essential hypertension -- also known as primary hypertension.

Exercise Stress Test: a test in which electrocardiogram readings are taken while the patient exercises (on a treadmill or stationary bicycle) to increase heart rate to a predetermined point. It's used to diagnose heart disease or abnormal heart rhythms.

Systolic Blood Pressure: the highest force of blood against the walls of the artery when the heart contracts or squeezes blood into the blood vessels. It is the "top" number when referring to a specific blood pressure. For example, if your blood pressure is 120 over 80 or 120/80, the systolic measurement is 120.

Ischemic Heart Disease: a condition caused by a decrease in blood flow to the heart. This decrease is usually the result of narrowed coronary arteries, which impede the blood flow.

Stent: a small tube that can open blocked blood vessels during a heart catheterization. Stents are usually made of metal and are permanent. It can also be made of a material that the body absorbs over time. Some stents have medicine that helps keep the artery from getting blocked again.

Stroke: an interruption of the blood supply to the brain, resulting in damaged brain tissue. An interruption can be caused by clots that block blood flow, or by bleeding in the brain from a ruptured blood vessel or a significant injury.

FACTS ON **FINGER TIPS**
DIABETIC NEUROPATHY

Diabetes can harm your nerves. That damage, called neuropathy, may be painful. It can happen in several ways, and they all seem to be related to blood sugar levels being too high for too long. To prevent it, work with your doctor to manage your blood sugar. You may hear your doctor mention the four types of diabetes-related neuropathy: peripheral, autonomic, proximal, and focal.

Peripheral Neuropathy

This type usually affects the feet and legs. Rare cases affect the arms, abdomen, and back.

Symptoms include:

Tingling, Numbness (which may become permanent), Burning (especially in the evening) and Pain
Early symptoms usually get better when your blood sugar is under control. There are medications to help manage the discomfort.

What you should do:

Check your feet and legs daily, Use lotion on your feet if they're dry, Take care of your toenails. Ask your doctor if you should go to a podiatrist and Wear shoes that fit well. Wear them all the time, so your feet don't get injured.

Autonomic Neuropathy

This type usually affects the digestive system, especially the stomach. It can also affect the blood vessels, urinary system, and sex organs.

In your digestive system:

Symptoms include:
Bloating, Diarrhea, Constipation, Heartburn, Nausea and Vomiting
Feeling full after small meals
What you should do: You may need to eat smaller meals and take medication to treat it.

Symptoms include:

Blacking out when you stand up quickly, Faster heartbeat, Dizziness, Low blood pressure, Nausea, Vomiting and Feeling full sooner than normal.
If you have it: Avoid standing up too quickly. You may also need to wear special stockings (ask your doctor about them) and take medicine.

In Men:

Symptoms include: He may not be able to have or keep an erection, or he may have "dry" or reduced ejaculations.
What you should do: See your doctor, because there are other possible causes than diabetes. Treatment includes:
Counseling, Penile implant or injections, Vacuum erection device and Medication.

In Women:

Symptoms include: Can include less vaginal lubrication and fewer or no orgasms.
What you should do: See your doctor. Treatments include:
Vaginal estrogen creams, suppositories, and rings
Medications to help sex not feel painful
Lubricants

In the Urinary System:

Symptoms include:
Trouble emptying your bladder
Bloating
Incontinence (leaking urine)
More bathroom trips at night
What you should do: Tell your doctor. Treatments may include:
Medication
Inserting a catheter into the bladder to release urine (self-catheterization)
Surgery

USFDA approves MRI especially for newborns

The US Food and Drug Administration approved the first magnetic resonance imaging (MRI) device that can be specifically used in neonates or newborn babies. These MRI devices would be used for imaging of the brains and head in neonates who are admitted to the neonatal intensive care units (NICU) where they are necessary.

MRI or magnetic resonance imaging is a form of radiological imaging technique where the scanners use strong magnetic fields to produce the images of the inner structures. The protons in fat and water molecules in the body help form an image of the insides of the body. MRI brain is indicated in several conditions some of which are life threatening and MRI can help detect these conditions. Newborns admitted to the NICU may also require an MRI scan as part of their investigations whereby important decisions may be made.

Vasum Peiris, chief medical officer for pediatrics and special populations at FDA's Center for Devices and Radiological Health, said that till date whenever MRI brain was indicated for neonates in the NICU, the babies had to be taken to the MRI units. Traditional MRI images thus were possible but the challenges of moving a sick newborn out of the NICU to the MRI suite would often be a challenge. This new system is exclusively for neonates and now it would be safer and more convenient for imaging the brains of these ill newborns. He said that this approval ensures "safer imaging for this vulnerable patient population".

The newly approved MRI system for neonates is called the Embrace Neonatal MRI System. It can measure the heads of the neonates only. Babies with a head circumference up to 38 centimeters and weight between 1 and 4.5 kilograms can be imaged in this machine. Larger babies and children cannot be imaged in this machine. Those with metallic implants within their bodies also cannot be imaged using this system much like traditional MRI machines.

Embrace Neonatal MRI System. Image Credit: Aspect Imaging

To make the transition from the NICU cots to the MRI machine comfortable as well as less risky for the ill newborn, this new system also has a temperature-controlled incubator inside the MRI system. This makes the baby comfortable and ensures that the baby moves less. In case of an emergency where the baby needs immediate attention, the baby can be removed from the machine within 30 seconds and resuscitated. The system can be placed inside a NICU safely.

The machine is safe with no risk of radiation release and thus need not be in a radiation-safe room. Further the Embrace Neonatal MRI System is completely enclosed and thus it does not mandate what is around it. Most MRI machines cannot allow metallic elements around or within them. The objects that can be allowed inside traditional MRI machines are termed "MR safe" and those less safe are termed "MR conditional".

The approval of the machine comes from non-clinical testing and the system has not yet been tried on actual neonates. This was done to avoid putting the vulnerable patients at risk. Electrical and mechanical safety of the system was thoroughly examined before approval. The Embrace Neonatal MRI System clearance was granted to Aspect Imaging Ltd. by the FDA. ●

Medtronic HeartWare HVAD System for Destination Therapy

Patients with end-stage heart failure now have new options for care

Medtronic HeartWare HVAD System as a destination therapy for patients with advanced heart failure who are not candidates for heart transplants. The HVAD System, a left ventricular assist device (LVAD), helps the heart pump and increases the amount of blood that flows through the body.

"LVADs are an effective and well-established treatment for patients who have progressed to advanced heart failure," said Joseph Rogers, M.D., interim chair of the Department of Medicine at Duke University, and a co-principal investigator for the ENDURANCE and ENDURANCE Supplemental trials. "In addition to its use as a bridge to heart transplantation, the HVAD System offers a promising option for a growing number of patients who are ineligible for transplant."

FDA said that the ENDURANCE and ENDURANCE Supplemental trials, which enrolled nearly 1,000 destination therapy patients. The data support the safety and effectiveness of the HeartWare HVAD System for patients with advanced, refractory left ventricular heart failure as a bridge to cardiac transplantation (BTT), or myocardial recovery, or as destination therapy (DT) in patients for whom subsequent transplantation is not planned.

The HVAD System features the world's smallest centrifugal-flow VAD, according to Medtronic, and is designed to reduce surgical invasiveness, improve patient recovery times and enhance patient outcomes. Weighing only 160 grams, the HVAD System's continuous flow pump is 30 percent thinner and has 38 percent less volume than other centrifugal devices. The pump features a unique integrated inflow cannula that is designed to treat more complex patients while maintaining stable inflow position and eliminating the need for abdominal surgery and device pockets.

The ENDURANCE Supplemental trial was a prospective, randomized, controlled, multicenter evaluation of the incidence of neurologic events in patients receiving the HVAD System as destination therapy who received improved blood pressure management. Between October 2013 and August 2015, 465 patients were randomly selected to receive either the HVAD System or, as part of a control group, an alternative LVAD approved by the FDA for destination therapy, in a two-to-one ratio. Patients will be followed long-term, up to five years.

This trial was a follow-up to the ENDURANCE Destination Therapy trial that implanted 445 patients between 2010-2012 who received either the HVAD System or an alternative LVAD approved by FDA for destination therapy in a two-to-one ratio. The ENDURANCE trial met its primary endpoint, demonstrating non-inferiority of the HVAD System to the control device; results were published in The New England Journal of Medicine. ●

Use of ACE inhibitors with ARBs Risky

Combined use of two drugs that act on renin angiotensin system (RAS) i.e. a member of ACE inhibitors along with a member of Angiotensin II Receptors Blockers (ARBs) is associated with increased risks of hypotension, hyperkalaemia and changes in renal function (including acute renal failure) compared to monotherapy. Most patients receiving the combination of two RAS inhibitors (such as enalapril or lisinopril with losartan or telmisartan) do not obtain any additional benefit compared to monotherapy. Hence, combined or concurrent use of Ace inhibitors with ARBs should be avoided. Use of drugs that act on the RAS during second and third trimesters of pregnancy reduce foetal renal function and increase foetal and reonatal morbidity and death.

Do not use Repaglinide & Clopidogrel together

Health Canada has warned prescribers and patients against concurrent use of Repaglinide (indicated in the treatment of diabetes sold under trade names of Regan, Repilin etc.) and Clopidogrel, (a medication meant to prevent heart attacks & strokes sold in India under the trade names of Plavix, Clopilet, Clopid, Noklot etc.) under any circumstances due to risk of severe hypoglycaemia levels due to a drug-drug interaction. In a study conducted with healthy volunteers, co-administration of clopidogrel (300mg on day 1, followed by 75mg daily for 2 consecutive days), and repaglinide (single dose of 0.25mg on day 1 and day 3) resulted in an increase in repaglinide systemic exposure by 5.1 fold and 3.9 fold on day 1 and day 3 respectively. Hypoglycaemia was noted in health volunteers on day 1 (3.3mmol/L) and on day 3 (3.9mmol/L).

Sildenafil should be avoided in valve disease with residual pulmonary hypertension

Sildenafil should not be used to treat residual hypertension in patients with valvular heart disease, according to a latest research find up. Pulmonary hypertension refers to increased blood pressure in the pulmonary artery. In patients with long-standing valvular disease, the high pressure in the left side of the heart is transmitted backwards to the lung vessels which react by thickening. This process may not revert after valve treatment, resulting in persistent pulmonary hypertension.

Ibuprofen associated with blood pressure rise in arthritis patients at cardiovascular risk

Ibuprofen is associated with increased blood pressure and hypertension compared to celecoxib in patients with osteoarthritis or rheumatoid arthritis and increased risk of cardiovascular disease, according to a new research findings. Nonsteroidal anti-inflammatory drugs (NSAIDs), both non-selective and selective cyclooxygenase-2 (COX-2) inhibitors, are among the most widely prescribed drugs worldwide, but are linked with increased blood pressure and adverse cardiovascular events.

No benefit of Paracetamol with Ibuprofen FDC

The Fixed Dose Combination (FDC) of paracetamol with Ibuprofen is no better than either paracetamol or ibuprofen taken alone in relief of musculo-skeletal pain according to a double blind, randomized controlled trial undertaking at the Department of Emergency Medicine, Stony Brook University, New York. A total of 90 patients were administered either ibuprofen 800mg or paracetamol 1g or FDC of both. There was no difference in the relief of pain among the three groups. Side effects of FDC are more by consuming two drugs together than individual ingredients.

Oral Ketoconazole banned in Europe

Due to risk of severe liver injury oral ketoconazole has been banned in all the member states of the European Union. The decision was taken after detailed review following the drug's ban by the French medicine regulator, the National Agency for the Safety of Medicines and Health Products (ANSM). Though hepatotoxicity is a class effect with azole antifungals but incidence and seriousness is higher in case of ketoconazole including hepatitis, cirrhosis and liver failure with fatal outcome requiring liver transplantation. The onset of hepatotoxicity has been reported as early as one month after use. The efficacy studies on ketoconazole are limited. Safer alternatives are available.

FDA approves Mvasi (bevacizumab-awwb), a Biosimilar to Avastin

The US Food and Drug Administration approved Mvasi (bevacizumab-awwb) as a biosimilar to Avastin (bevacizumab) for the treatment of multiple types of cancer. Mvasi is the first biosimilar approved in the U.S. for the treatment of cancer. Mvasi is approved for the treatment of adult patients with certain colorectal, lung, brain, kidney and cervical cancers.

FDA Approves Vosevi (sofosbuvir/velpatasvir/voxilaprevir)

The USFDA has approved Vosevi (sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg) tablets, a single-tablet regimen for the re-treatment of Chronic Hepatitis C Virus (HCV) infection in adults with genotype 1, 2, 3, 4, 5 or 6 previously treated with an NS5A inhibitor-containing regimen, or with genotype 1a or 3 previously treated with a sofosbuvir-containing regimen without an NS5A inhibitor. The approval is based on data from the Phase 3 POLARIS-1 and POLARIS-4 studies, which evaluated 12 weeks of Vosevi in direct-acting antiviral-experienced chronic HCV-infected patients without cirrhosis or with compensated cirrhosis. Vosevi has a boxed warning in its product label regarding the risk of hepatitis B virus (HBV) reactivation in HCV/HBV coinfected patients.

FDA approves Vabomere (meropenem and vaborbactam)

The USFDA recently approved Vabomere for adults with complicated urinary tract infections (cUTI), including a type of kidney infection, pyelonephritis, caused by specific bacteria. Vabomere is a drug containing meropenem, an antibacterial, and vaborbactam, which inhibits certain types of resistance mechanisms used by bacteria. The safety and efficacy of Vabomere were evaluated in a clinical trial with 545 adults with cUTI, including those with pyelonephritis. At the end of intravenous treatment with Vabomere, approximately 98 percent of patients treated with Vabomere compared with approximately 94 percent of patients treated with piperacillin/tazobactam, another antibacterial drug, had cure/improvement in symptoms and a negative urine culture test. Approximately seven days after completing treatment, approximately 77 percent of patients treated with Vabomere compared with approximately 73 percent of patients treated with piperacillin/tazobactam had resolved symptoms and a negative urine culture.

FDA approves Kymriah (tisagenlecleucel) CAR-T Gene Therapy for acute Lymphoblastic Leukemia

The U.S. Food and Drug Administration issued a historic action making the first gene therapy available in the United States, ushering in a new approach to the treatment of cancer and other serious and life-threatening diseases. The FDA approved Kymriah (tisagenlecleucel) for certain pediatric and young adult patients with a form of acute lymphoblastic leukemia (ALL). Kymriah is a genetically-modified autologous T-cell immunotherapy. Each dose of Kymriah is a customized treatment created using an individual patient's own T-cells, a type of white blood cell known as a lymphocyte. The patient's T-cells are collected and sent to a manufacturing center where they are genetically modified to include a new gene that contains a specific protein (a chimeric antigen receptor or CAR) that directs the T-cells to target and kill leukemia cells that have a specific antigen (CD19) on the surface. Once the cells are modified, they are infused back into the patient to kill the cancer cells.

Sanofi receives tentative FDA approval of Admelog (insulin lispro injection) 100 units/mL

Sanofi announced that the U.S. Food and Drug Administration (FDA) granted tentative approval for Admelog® (insulin lispro injection) 100 Units/mL, a rapid-acting human insulin analog. Admelog is indicated to improve glycemic control in adults and children with diabetes mellitus. The tentative approval is based on physicochemical, non-clinical and clinical similarity to another insulin lispro 100 Units/mL as currently approved in the U.S., including data from a clinical development program involving more than 1,000 adults living with type 1 or type 2 diabetes. Admelog is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to insulin lispro or one of its other ingredients.

FDA clears Novo Nordisk's diabetes drug to treat heart disease

Novo Nordisk announced that the US Food and Drug Administration (FDA) approved its diabetes drug as a treatment to reduce the risk of three major cardiovascular diseases. This is the first time the FDA has cleared a diabetes drug to treat heart–related diseases in patients with type 2 diabetes, the company said in a statement. Type 2 diabetes, closely linked to obesity, accounts for more than 90% of all diabetes cases, the company said. Victoza's expanded label follows a successful trial that showed the drug significantly reduced the risk of cardiovascular death, non–fatal heart attack or non–fatal stroke by 13% when compared to a placebo.

WHO report highlights lack of treatment options for antibiotic-resistant infections

A World Health Organization (WHO) report highlighted a lack of new antibiotics under development to combat the growing threat of antimicrobial resistance.

The report found few potential treatment options for antibiotic-resistant infections identified by WHO as posing the greatest threats to health, including drug-resistant tuberculosis, which kills around 250,000 people each year.

Most drugs currently in the clinical pipeline are modifications of existing classes of antibiotics and are only short-term solutions, said the report titled 'Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline, including tuberculosis.".

"Antimicrobial resistance is a global health emergency that will seriously jeopardize progress in modern medicine. There is an urgent need for more investment in research and development for antibiotic-resistant infections including TB, otherwise we will be forced back to a time when people feared common infections and risked their lives from minor surgery," said Tedros Adhanom Ghebreyesus, Director General of WHO.

In addition to multidrug-resistant tuberculosis, WHO has identified 12 classes of priority pathogens – some of them causing common infections such as pneumonia or urinary tract infections – that are increasingly resistant to existing antibiotics.

The report identifies 51 new antibiotics and biologicals in clinical development to treat priority antibiotic-resistant pathogens, as well as tuberculosis and sometimes deadly diarrhoeal infection Clostridium difficile.

Among all these candidate medicines, however, only eight are classed by WHO as innovative treatments that will add value to the current antibiotic treatment arsenal.

"Pharmaceutical companies and researchers must urgently focus on new antibiotics against certain types of extremely serious infections that can kill patients in a matter of days because we have no line of defence," said Suzanne Hill, Director of the Department of Essential Medicines at WHO.

Research for tuberculosis is seriously underfunded, with only two new antibiotics for treatment of drug-resistant tuberculosis having reached the market in over 70 years, said Mario Raviglione, Director of the WHO Global Tuberculosis Programme.

"If we are to end tuberculosis, more than $800 million per year is urgently needed to fund research for new anti-tuberculosis medicines," Raviglione said.

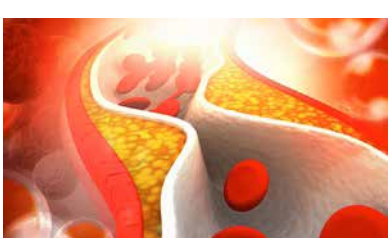
New treatments alone, however, will not be sufficient to combat the threat of antimicrobial resistance, WHO said. The apex health organization is also developing guidance for the responsible use of antibiotics in human, animal and agricultural sectors. ●

Brand Name	Generic Name	Manufacturer	Date of Approval	Treatment
Trelegy Ellipta	Fluticasone Furoate, Umeclidinium & Vilanterol	GlaxoSmithKline	September 18, 2017	Chronic Obstructive Pulmonary Disease
Adzenys ER Extended-Release Liquid Suspension - formerly NT-0201	Amphetamine	Neos Therapeutics, Inc.	September 15, 2017	Attention-Deficit Hyperactivity Disorder (ADHD)
Solosec Oral Granules	Secnidazole	Symbiomix Therapeutics, LLC	September 15, 2017	Bacterial Vaginosis
Aliqopa	Copanlisib	HealthCare Pharmaceuticals Inc.	September 14, 2017	Follicular Lymphoma
Mvasi formerly ABP 215	Bevacizumab-Awwb	Amgen Inc.	September 14, 2017	Non-Small Cell Lung Cancer, Colorectal Cancer, Glioblastoma Multiforme, Renal Cell Carcinoma, Cervical Cancer
Mylotarg	Gemtuzumab Ozogamicin	Pfizer Inc.	September 1, 2017	Acute Myeloid Leukemia
Kymriah Suspension for Intravenous Infusion - formerly CTL019	Tisagenlecleucel	Novartis Pharmaceuticals Corporation	August 29, 2017	Urinary Tract Infection
Vabomere **Injection - formerly** Carbavance	Meropenem and Vaborbactam	The Medicines Company	August 29, 2017	Urinary Tract Infection
Benznidazole **Tablets**	Nitroimidazole	Chemo Research, S. L.	August 29, 2017	Chagas Disease
Cyltezo Injection	Adalimumab-Adbm	Boehringer Ingelheim Pharmaceuticals, Inc.	August 25, 2017	Rheumatoid Arthritis, Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Crohn's Disease – Acute, Crohn's Disease –Maintenance, Ulcerative Colitis, Plaque Psoriasis
Gocovri **Extended-Release Capsules - formerly ADS-5102**	Amantadine Hydrochloride	Adamas Pharmaceuticals, Inc.	August 24, 2017	Levodopa-Induced Dyskinesia
KedRAB **Injection**	Rabies Immunoglobulin Human	Kamada Ltd. and Kedrion S.p.A.	August 23, 2017	Rabies Prophylaxis
Duzallo **Tablets**	Allopurinol and Lesinurad	Ironwood Pharmaceuticals, Inc.	August 18, 2017	Gout
Besponsa **for Injection**	Inotuzumab Ozogamicin	Pfizer Inc.	August 17, 2017	Acute Lymphoblastic Leukemia
CaroSpir **Oral Suspension**	Spironolactone	CMP Pharma, Inc.	August 4, 2017	Congestive Heart Failure, Edema, Hypertension
Vyxeos **Injection**	Cytarabine and Daunorubicin	Jazz Pharmaceuticals plc	August 3, 2017	Acute Myeloid Leukemia
Mavyret **Tablets**	Glecaprevir and Pibrentasvir	AbbVie Inc.	August 3, 2017	Chronic Hepatitis C
Idhifa **Tablets**	Enasidenib	Celgene Corporation	August 1, 2017	Acute Myeloid Leukemia

High blood pressure: Sodium may not be the culprit

Salt has long been vilified as the harbinger of hypertension. However, as research into the condition has delved deeper, it is becoming clear that the story is more complex. The latest study in this arena goes some way toward absolving sodium. Following a raft of large-scale studies showing that a high salt intake leads to high blood pressure, the Dietary Guidelines for Americans set the recommended sodium intake at 2,300 milligrams per day. However, a new batch of studies are bringing this guideline into question, and researchers are now asking whether the relationship between hypertension and salt is so clear cut.

Statins may help people with COPD live longer



Drugs known as statins may have benefits beyond lowering "bad" LDL cholesterol levels. A new study suggests people with chronic lung disease who take these drugs may extend their survival. The study included nearly 40,000 people with Chronic Obstructive Pulmonary Disease (COPD). One in five patients was taking a statin, and those individuals had a 21 percent lower risk of dying from any cause, and a 45 percent reduced risk of dying from lung-related issues, the researchers found. This study comes on the heels of a separate large-scale investigation that found no link between statin use and the number of COPD exacerbations people experienced.

Could folic acid fight a cause of Autism?

By taking folic acid around the time of conception, mothers-to-be may reduce their child's risk of pesticide-related autism, a new study suggests. "We found that if the mom was taking folic acid during the window around conception, the risk associated with pesticides seemed to be attenuated," said study author. Autism risk was higher among children whose mothers were repeatedly exposed to pesticides or whose mothers had low folic acid intake and exposure to agricultural pesticides between three months preconception and three months afterward, the findings showed. Those two factors combined were associated with higher risk of autism than either low folic acid intake or pesticide exposure alone.

New 'Biologic' drug may help severe Asthma

A "biologic" drug in development to treat severe asthma reduces the rate of serious attacks by about two-thirds compared to a placebo drug, according to preliminary research findings. If approved, the drug, tezepelumab, could join a group of costly medications that appear to offer relief when nothing else curbs respiratory distress. The new research was funded by the drug's developers, Amgen and MedImmune, a subsidiary of AstraZeneca. Asthma is a chronic lung disease. Study said an estimated 15 percent of asthma patients can't control the disease with current inhaled medications. Tezepelumab, an injectable drug, is a monoclonal antibody – a term that refers to how it's made.

Doctor-Patient dialogue may boost use of blood pressure drugs

Doctors can help boost use of high blood pressure medications by

their poor patients simply by talking to them, a new study suggests. Many people fail to take their blood pressure-lowering drugs, putting them at higher risk of heart attack and stroke, the American Heart Association says. But by communicating more effectively and talking to patients about their specific challenges, physicians may improve medication use, researchers found. If important issues go undiscussed, doctors may never figure out why patients are not taking their medications.

Kidney Disease may boost risk of abnormal Heartbeat

People with failing kidneys are at increased risk of developing a life-threatening abnormal heart rhythm, a new report suggests. Chronic kidney disease can as much as double a patient's risk of atrial fibrillation, a quivering or irregular heartbeat that can lead to stroke or heart failure, said a study. The risk of atrial fibrillation increases as kidney function declines, said researcher. A poorly functioning kidney can alter blood levels of a number of nutrients needed to maintain proper heart function, such as potassium, vitamin D, calcium and phosphorus, said the study. The kidneys also are responsible for maintaining a steady volume of blood in your body, removing excess fluid by way of urination.

Blood Pressure Fluctuations tied to Dementia risk in study

If your blood pressure varies from day-to-day, you may be at higher risk for dementia or Alzheimer's disease, new research from Japan suggests. People whose systolic blood pressure (the top reading) fluctuated from day-to-day were more than twice as likely to develop any type of dementia or Alzheimer's disease compared to those with more stable day-to-day blood pressure, the researchers found. And the study – which was based on home-monitorings -- also reported that the participants were nearly three times more likely to develop vascular dementia, caused by hardening of the arteries.

Painkiller prescriptions more prone to errors if handwritten

Mistakes are much more likely to occur with handwritten prescriptions for opioid painkillers than with electronic ones, a new study finds. Researchers analyzed prescriptions for opioids – such as oxycodone (Oxycontin, Percocet) and hydrocodone (Vicoprofen). The investigators found that 42 percent of the prescriptions contained an error.

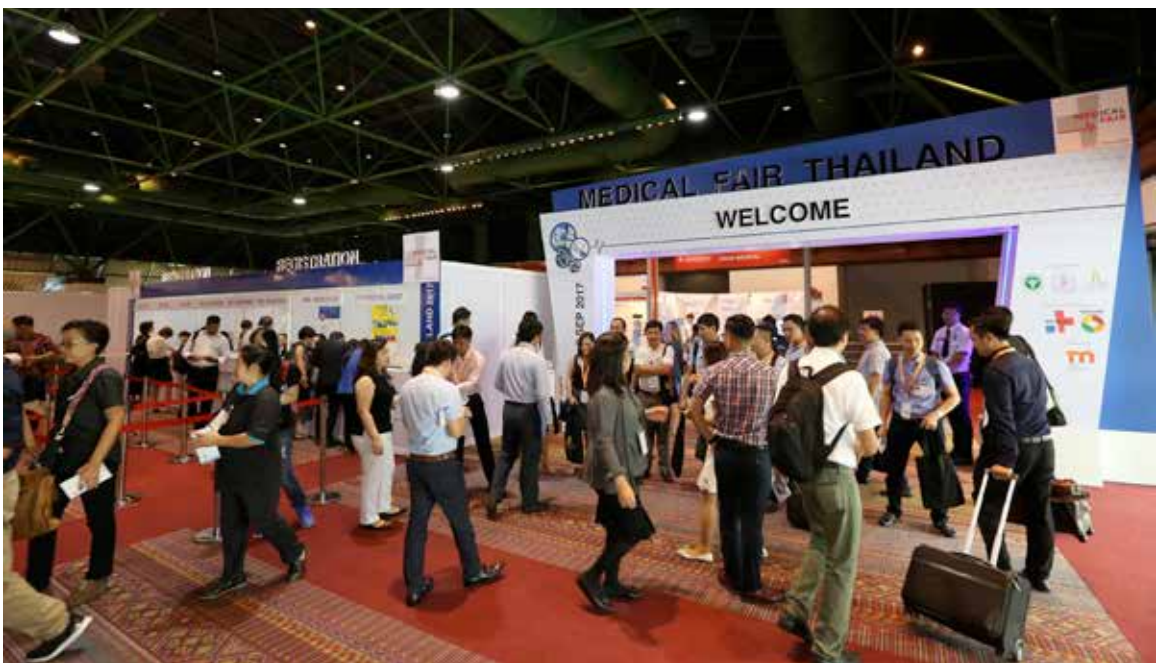
Can an Aspirin a day keep a pregnancy complication away?

Something as simple as taking a low-dose aspirin every day may protect pregnant women from the life-threatening condition known as preeclampsia, new research suggests. "Preeclampsia is one of the most serious complications of pregnancy, with a high risk of death for the mother and baby," said the study. The new study looked at an aspirin dose of 150 milligrams (mg) per day because some past studies with smaller daily doses of aspirin have produced conflicting results, according to the study. A baby aspirin dose is 81 milligrams. In those studies using smaller doses, the reduction in preeclampsia risk hovered around 10 percent, he said, but the higher dose in this latest study was linked to a 62 percent reduction in risk.

Hypertension during pregnancy may affect women's long-term cardiovascular health

Women who experience hypertension during pregnancy face an increased risk of heart disease and hypertension later in life, according to a new study. "The study highlights the need for long-term follow-up of women with a history of hypertension during pregnancy to provide early management of risk factors for cardiovascular disease".

MEDICAL FAIR THAILAND SETS RECORD AGAIN!



Biennial exhibition sees a 25% increase in visitor attendance

18 national pavilions, with 5 new country groups showcasing for the first time

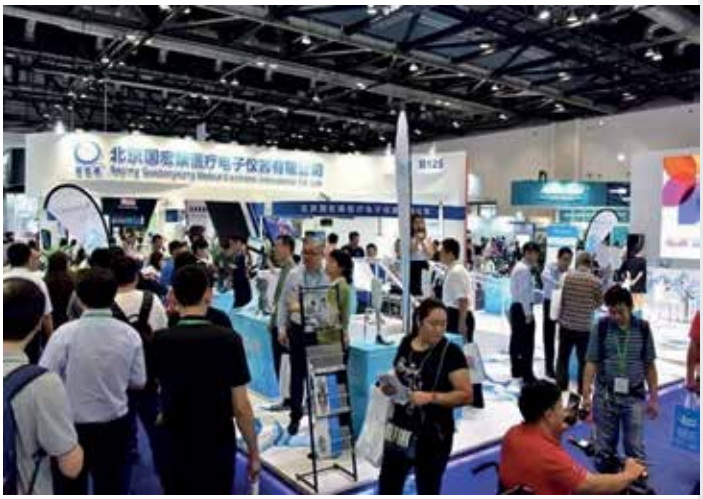
MEDICAL FAIR THAILAND 2017 concluded its most successful edition to date. It saw 830 companies from 66 countries, 18 national pavilions and country groups, and welcomed more than 9,000 quality trade visitors from over 70 countries.

MEDICAL FAIR THAILAND 2017 is the region's premier medical and healthcare exhibition with leading exhibitors showcasing their latest medical innovations to the show. There were many opportunities for networking and business matching, with 13,000 meetings requested through the free business matching service. MEDICAL FAIR THAILAND also hosted many industry-leading concurrent conferences and seminars that were well-attended throughout the three days with 650 attendees.

Gernot Ringling, Managing Director of Messe Düsseldorf Asia, organizer of MEDICAL FAIR THAILAND said: "The exhibition is a record-breaking edition, with a strong showcase of innova-tions from leading exhibitors as well as highly satisfied visitors. MEDICAL FAIR THAILAND certainly serves the booming medical market of Southeast Asia. We also welcomed 25% more visitors than the 2015 edition, of which 33% were from overseas, indicative of the increasing interest from regional healthcare professionals. "

This record-breaking edition is greatly indicative of the exhibition's influence on the region's burgeoning and fast-growing medical and healthcare industry. Companies from all around the world continue to bring in their innovative products and best sellers to MEDICAL FAIR THAILAND, solidifying the exhibition as the industry's must-attend exhibition.

Following the success of this exhibition, the much-anticipated 12th edition of MEDICAL FAIR ASIA will return to Singapore from 29 – 31 August 2018 at Marina Bay Sands. While, MEDICAL FAIR THAILAND will return for its 9th edition from 11 to 13 September 2019 at the Bangkok International Trade and Exhibition Centre (BITEC). More information on MEDICAL FAIR THAILAND 2019 can be found at www.medicalfair-thailand.com



Conclusion of CR Expo 2017 with Breakthroughs in Technology Showcase and Business Match-making

The Care & Rehabilitation Expo China 2017, a three-day event to showcase the latest technologies, products and solutions in the fields of assistive devices as well as rehabilitation and medical treatment, successfully concluded at China National Convention Center on September 15, 2017.

Compared with previous sessions, CR Expo 2017 records new height in the number of visitors, exhibitors as well as the total exhibition area. This year's expo had an expanded area of up to 20,000 square meters and creates an ideal platform of visiting, purchasing, and cooperation for almost 300 exhibitors from 22 countries and regions and more than 50,000 experts and professional buyers coming from around the globe. The Expo had grown into a one-stop platform where professional insiders get information on industrial and market trends and more importantly, communicate and conduct business. CR Expo is now acting as the benchmark of the industries of assistive device, rehabilitation and medical treatment.

See you next year at CR Expo from October 11 to 13, 2018!

Quiz ON HYPERTENSION

Please take this quiz to test your knowledge and awareness of high blood pressure.
Score 7-9 Excellent! 4-7 Very good!
Below 3- Can do with more updates!

1. ***Which is the most desirable blood pressure (taken as average of 2 consecutive measurements at one point in time)?***
   a) 180/110mmHg
   b) 140/80mmHg
   c) 130/90mmHg
   d) 120/80mmHg
   e) 80/60mmHg

2. ***Select the true statement from the following.***
   a) The older we get, the greater is our risk to develop high blood pressure.
   b) Hypertension shows symptoms in most people.
   c) Hypertension is inherited so the best way is to take medicines.
   d) Sea salt contains lots of mineral so it is good for hypertension.
   e) Being overweight is not related to hypertension.

3. ***The risk of developing high blood pressure can be reduced by: (choose all that apply)***
   a) Reducing salt intake
   b) Eating a balanced diet
   c) Avoiding harmful use of alcohol
   d) Taking regular physical activity
   e) Maintaining a healthy body weight
   f) Avoiding tobacco use

4. ***What organs are affected by high blood pressure? Choose all that apply.***
   a) Eyes
   b) Kidney
   c) Heart
   d) Brain
   e) Lungs
   f) Stomach

WHO report shows world is running out of antibiotics

> PHARMACEUTICAL COMPANIES AND RESEARCHERS MUST URGENTLY FOCUS ON NEW ANTIBIOTICS AGAINST CERTAIN TYPES OF EXTREMELY SERIOUS INFECTIONS THAT CAN KILL PATIENTS IN A MATTER OF DAYS BECAUSE WE HAVE NO LINE OF DEFENCE

A report, *Antibacterial agents in clinical development – an analysis of the antibacterial clinical development pipeline, including tuberculosis*, launched recently by WHO shows a serious lack of new antibiotics under development to combat the growing threat of antimicrobial resistance.

Most of the drugs currently in the clinical pipeline are modifications of existing classes of antibiotics and are only short-term solutions. The report found very few potential treatment options for those antibiotic-resistant infections identified by WHO as posing the greatest threat to health, including drug-resistant tuberculosis which kills around 250 000 people each year.

"Antimicrobial resistance is a global health emergency that will seriously jeopardize progress in modern medicine," said Dr Tedros Adhanom Ghe-

breyesus, Director-General of WHO. "There is an urgent need for more investment in research and development for antibiotic-resistant infections including TB, otherwise we will be forced back to a time when people feared common infections and risked their lives from minor surgery."

In addition to multidrug-resistant tuberculosis, WHO has identified 12 classes of priority pathogens – some of them causing common infections such as pneumonia or urinary tract infections – that are increasingly resistant to existing antibiotics and urgently in need of new treatments.

The report identifies 51 new antibiotics and biologicals in clinical development to treat priority antibiotic-resistant pathogens, as well as tuberculosis and the sometimes deadly diarrhoeal infection *Clostridium difficile*.

Among all these candidate medicines, however, only 8 are classed by WHO as innovative treatments that will add value to the current antibiotic treatment arsenal. There is a serious lack of treatment options for multidrug- and extensively drug-resistant M. tuberculosis and gram-negative pathogens, including *Acinetobacter* and *Enterobacteriaceae* (such as *Klebsiella* and *E. coli*) which can cause severe and often deadly infections that pose a particular threat in hospitals and nursing homes.

There are also very few oral antibiotics in the pipeline, yet these are essential formulations for treating infections outside hospitals or in resource-limited settings.

"Pharmaceutical companies and researchers must urgently focus on new antibiotics against certain types of extremely serious infections that can kill patients in a matter of days because we have no line of defence," said Dr. Suzanne Hill, Director of the Department of Essential Medicines at WHO. ●

Source: Chronicle Pharmabiz

Top 50 Global Pharma Companies 2017

Annual ranking published by Pharmaceutical Executive. The Top Global Pharma Companies ranking is based on sales in the previous year.

Sl	Company Name	Sl	Company Name
1	Pfizer	26	CSL
2	Novartis	27	Merck KGaA
3	Roche	28	Valeant Pharmaceuticals International
4	Merck & Co Inc	29	Otsuka Holdings
5	Sanofi	30	Sun Pharmaceutical Industries
6	Johnson and Johnson	31	Eisai Co
7	Gilead Sciences	32	Les Laboratories Servier
8	GSK	33	Endo Health Pharmaceuticals
9	AbbVie	34	UCB
10	Amgen	35	Abbot
11	AstraZeneca	36	Fresenius
12	Allergan	37	Chugai Pharmaceutical
13	Teva Pharmaceutical Industries	38	Grifols
14	Bristol-Myers Squibb	39	Regeneron Pharmaceuticals
15	Eli Lilly	40	Dainippon Sumitomo Pharma
16	Bayer	41	Alexion Pharmaceuticals
17	Novo Nordisk	42	Mallinckrodt Pharmaceuticals
18	Boehringer Ingelheim	43	Menarini
19	Takeda	44	Mitsubishi Tanabe Pharma
20	Celgene	45	Lupin
21	Astellas Pharma	46	Actelion
22	Shire	47	Aspen Pharmacare Holdings
23	Mylan	48	Kyowa Hakko Kirin
24	Biogen Idec	49	Ono Pharmaceutical
25	Daiichi Sankyo	50	Ferring Pharmaceuticals

WISH TO EXPORT TO BAHRAIN?

The agent or the company representative should provide the following documents for the registration of a pharmaceutical manufacturer or its site.

Item 1

1. Full profile of the Company including kinds and scope of activities.
2. Number of manufacturing sites owned by the company and their addresses.
3. The kind of legal and commercial relationship the company holds with these different sites.
4. Manufacturing licence number and its date in country of origin
5. List of all products marketed by the company
6. Agency Contract
7. GMP certificate from the health authorities in the country of the site
8. Number of employees in the different sections and their qualification.
9. Graphic design of the site and flow of manufacturing lines
10. List of all products the site produces either on its vicinity, or through contract manufacturing with or for other marketing authorization holders (NIAH's)
11. Clarification of the relationship with the MAH.
12. Any inspection visit report by GCC health authorities or Arab Health Authorities, except for country of origin if it is an Arab country/site. Otherwise, a GMP inspection visit should be arranged.

Registration does not cover wholesalers and distributors. Marketing authorization holders should have a manufacture licence issued by the health authorities in country of origin.

Item 2

In case of failure to meet GMP requirements after a GMP inspection visit, a 12-month period should elapse before reconsidering the case.

Item 3

MOH authorities should be informed about any sale, merge, take or take over or any legal or commercial action concerning the company or its site within 90 days of the action.

PRODUCTS

The applicant should submit a description of the submitted documents as follows:

1. Number of submitted files
2. Number of samples submitted along with a brief description of these
3. Full index of contents of the files

The files should contain the following:-

A CPP form according to WHO certification scheme authenticated by health authorities in the country of origin. If, for any reason the certificate cannot be provided from that particular EU country than from any EU country where the product is marketed with clarification for the reason. Legalization of this certificate by any GCC embassy is requited.

The CPP should contain the following:

- registration number in country of issue
- name and address of the applicant
- name of the country issuing the certificate
- name of the country for which the certificate is issued.
- name and address of the manufacturing Licence holder
- the proprietary name of the product if available.
- non-proprietary name (rINN or any common name)
- pharmaceutical formula (in details attachments)
- name and address of manufacturer of finished product
- commitment of health authorities signatory to the certificate to GMP periodic inspection
- statement specifying if the leaflet is the same in country, issuing the certificate, and the reason(s) if different
- date and number of registration of the product in the country issuing the CPP, and if this is not available then the reason
- name and address of health

authority, issuing the certificate

2. Summary of Product Characteristics (SPC). This should contain the following:-
   - Proprietary name of the medicinal product
   - Qualitative and quantitative composition of product stating the generic names of common flames of the active ingredient and important ingredient(s)
   - pharmaceutical form
   - Clinical particulars such as:-
   - therapeutic indication(s)
   - Posology and method of administration
   - Contraindications
   - Special warnings and precautions
   - interactions with other medicaments and other forms of interactions
   - use during pregnancy and lactation
   - Effects on ability, to drive and operate machinery
   - Undesirable effects
   - Overdose
   - Pharmacological properties
   - Pharmacodynamic properties
   - Pharmacokinetic properties
   - Preclinical Safer data
   - Pharmaceutical particulars such as
   - list of excipients
   - incompatibilities
   - shelf life
   - Special precautions for storage
   - Nature and content of containers
   - Instructions for use/handling
   - Manufacturing authorization holder
   - Manufacturing authorization number
   - Date of first authorization/renewed authorization
   - Date of revision of the text
   - Legal category
3. A separate file for the quality control laboratory including the following:
   - Method of analysis for finished product
   - Certificate of analysis for finished product (physical, chemical, biological and microbiological)
   - Finished Product Specifications
   - Validation of analytical test methods
   - Certificate of analysis of standards and specifications
   - Safety measures
   - Reference standards (sufficient quantity)
   - Related substance reference standards (sufficient quantity)
4. Full description of the active ingredient(s) and excipients including colouring agents, flavouring agents, presentations, emulsifiers, and other pharmaceutical means.
5. Full description of vehicles and carriers of the product e.g., gelatin capsules, pessaries, rectal enemas etc.
6. Method of manufacture of the finished product
7. Names and addresses of any pharmaceutical manufacturing site involved if any step(s) of manufacturing of the finished product
8. Products that are still protected by patent tights will not be registered if submitted by other than the holder of the patent rights
9. Full description of the outer pack and all accessories included to give the proper dose such as syringes, pipettes etc.
10. The concentration of the product should be clear and specific per unit mass or volume.
11. Pharmacological studies including pharmadynamics and pharmacokinetic studies
12. Toxicological studies (new products including newly introduced generics)
13. Clinical studies (new products including newly introduced generics) (for well established generic products reference articles and documents are enough)

Item 4

Source of starting material should be clarified.

Item 5

The product label should carry the following information on external and internal pack in English/Arabic-

- Proprietary name followed by common name of active ingredient(s)
- Pharmaceutical form and strength
- Contents by common flame and quantities per dose
- Pack size by weight, volume, or number of doses.
- List of excipients with certain pharmaceutical function
- For injectables, eye drops, and external use products all excipients should be mentioned
- method of use
- warnings
- expiry date by month & year
- Special storage requirements
- marketing authorization holder
- manufacturer of the finished products
- batch number
- In case of OTC drugs, clear method of use should be specified.
- In case of blisters, proprietary name, common name, marketing authorization holder, batch number and expiry date should be mentioned
- In case of small containers such as ampoules the following should appear on the label (as minimum requirement)
- name of drug, strength, route of administration
- manufacturer name and/or logo
- method of use
- expiry date
- batch number
- contents by weight, volume or units

Item 6

The product patient leaflet should contain the following in English/Arabic

- brand name followed by common name

- pharmaceutical form and concentration or strength
- qualitative and quantitative information about active ingredient(s) and excipients in common name
- pack size and contents by volume, weight or number of dosage
- pharmacotherapeuetic group in clear understandable language.
- MAH and manufactudnglicence holder
- therapeutic indication(s)
- contra indication(s)
- precautions
- drug-drug interaction, food interaction, alcohol drug interaction and others.
- any special precautions
- use during pregnancy, lactation, elderly, children and other patient categories
- effect on driving and machinery operating
- probable allergy-producing addresses
- dose and dose regimens
- clear description of administration method
- antidote and treatment of overdose
- any information related to period of use, skipping or forgetting doses, abrupt withdrawal, best time of administration of doses, etc.
- side effects and advice on reporting any adverse reaction to doctors and pharmacists
- warning against use after expiry date on Pack
- number of leaflet and date of last revision

Item 7

A full bioequivalence study report or equivalent, from an independent lab should be submitted whenever a generic product is submitted for registration. For registration of under-licence products for out-of-patent molecules a bioequivalence study comparing it with the parent product is required.

Item 8

Products imported for government outlets and in large pack sizes should carry the full medical profession leaflet. In case this could not be met and patient leaflets ate supplied in the pack, extra medical profession leaflets should be submitted to the Ministry of Health for distribution upon request.

Item 9

If the pharmaceutical product contains an animal product the source and kind of animal should be specified.

Item 10

Only approved colouring substances, flavouring substances, diluents and additives should be used in the manufacturing process as approved by major drug regulatory agencies, WHO and other international organizations.

Item 11

Price certificate authenticated by the health authorities in country of origin stating the following:-

- ex-factory price.
- wholesale price in country of origin
- public sale price in country of origin
- CIF price GCC countries
- suggested CIF price to Bahrain

Item 12

1. Stability studies should be attested by quality assurance section and authorized by manufacturer. Stability studies should be conducted on the product in the same container closure system intended for marketing in Bahrain.
2. Stability studies should be provided for at least 3 production batches, the following should be clarified at the beginning of the document
   - batch numbers, dates of expiry of batches tested
   - Storage conditions of T & RH used during the study protocols
   - temperature and relative humidity
   - Samples should be taken for analysis at certain points of time i.e. every 3 months at least during the first year and every six months thereafter
   - analysis method
   - parameters tested
   - conclusion of the studies pertinent to stability and suggested shelf-life and storage condition (the conclusion could be added at the end of the document)
3. Tests should cover physical, chemical, biological and microbiological attributes.
4. For accelerated stability studies, testing should be done at certain time points: initial, 3 and 6 months at least. If there is a change in the specifications, then testing should be done at intermediate conditions at four points of time: kiital, 6, 9 and 12 months (this includes initial and final readings)
5. Real time should cover at least 12 months duration at long term and at least 6 months data at intermediate storage condition. For zones I and II, /long term conditions are 25ºC±2 ºC and 60%±5% RH. For Zones III and IV, long terms conditions are term conditions are 25ºC±2 ºC 60%±5% RH. Which is the same as the intermediate conditions
6. Stability studies conditions: Long-term

REGISTRATION

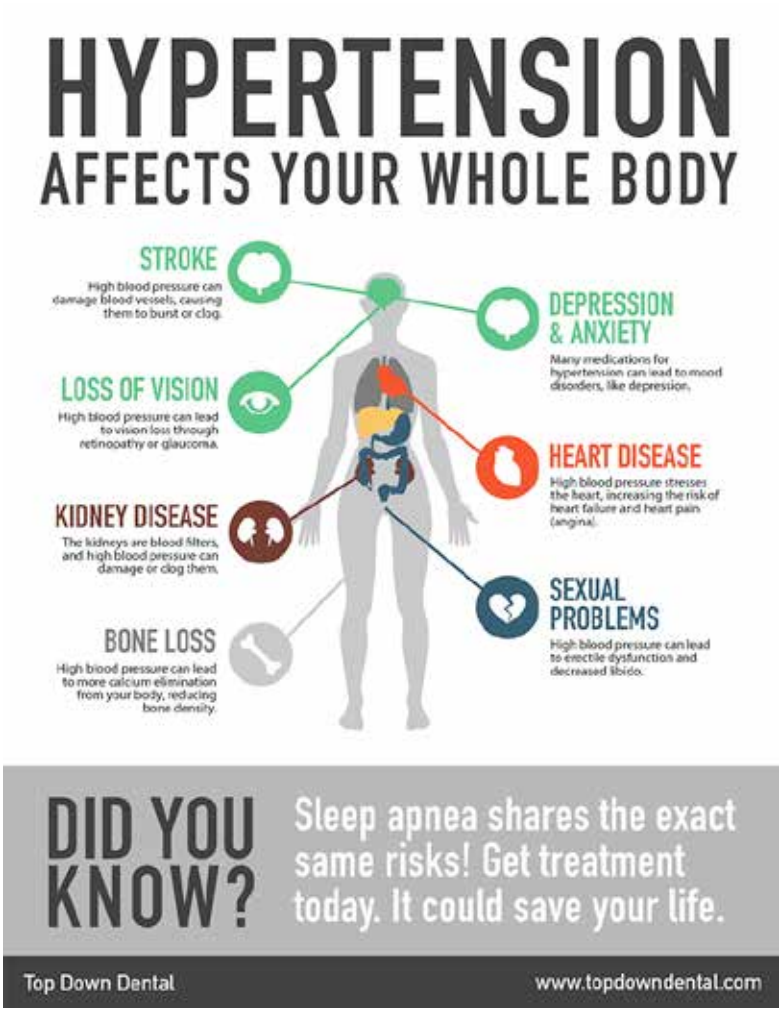
The cancellation of a manufacturer's registration is done under any of the following conditions:

1. If it has not submitted any of its products for registration within a year of the company registration.
2. If forgery in its papers and documents has been proven.
3. If it has violated the regulations and guidelines of GMP. ●

TITLE	VENUE	SCHEDULE
4th European Biopharma Congress	Vienna, Austria	Nov 09-11, 2017
25th Global Diabetes Summit and Medicare Expo	Dubai, UAE	Dec 04-05, 2017
22nd World Cardiology Conference	Rome, Italy	Dec 11-12, 2017
2nd International Conference on Generic Drugs and Biosimilars	Rome, Italy	Dec 14-15, 2017
15th Annual Scientific Meeting of the Malaysian Society of Hypertension	Kuala Lumpur, Malaysia	Jan 19–21, 2018
1st International Congress of Hypertension in Children and Adolescents	Valencia, Spain	Feb 09–11, 2018
Pharmaceutical Sciences 2018	London, UK	Feb 26- 27, 2018
The 6th World Symposium on Pulmonary Hypertension	Geneva	Feb 27–Mar 01, 2018
9th World Congress on Bioavailability & Bioequivalence	Dubai, UAE	March 19-21, 2018
Pharmaceutica 2018	Berlin, Germany	March 19-21, 2018
NanoPharma 2018	Amsterdam, Netherlands	April 09-11, 2018
5th Annual Congress on Chemistry In Drug Discovery & Designing	Dubai, UAE	April 16-17, 2018
4th International Conference on Antimicrobials and Antibiotics Resistance	Las Vegas, USA	April 20-21, 2018
2nd World Heart Congress 2018	Tokyo, Japan	May 14-16, 2018
International Conference on Diabetes and its Complications	Osaka, Japan	May 21-22, 2018
International Conference on Pharmaceutical Research and Development	Baltimore, USA	June 06-07, 2018
27th European Diabetes Congress	Rome, Italy	June 11-12, 2018
Pharmacovigilance 2018	London, UK	June 21-22, 2018
2nd Annual Hypertension, Diabetes and Dyslipidemia Conference 2018	Charleston, USA	June 22-24, 2018
Global Cardiology Summit 2018	Kuala Lumpur, Malaysia	June 25-26, 2018
3rd International Conference on Cardiovascular Medicine and Cardiac Surgery	Berlin, Germany	July 05-06, 2018
20th Asia Pacific Diabetes Conference	Sydney, Australia	July 9-11, 2018
28th World Congress on Diabetes, Obesity & Heart	Tokyo, Japan	Aug 20-22, 2018
3rdInternational Conference on Hypertension and Healthcare	Tokyo, Japan	Aug 24–25 , 2018
4th International Conference on Hypertension & Healthcare	Zurich, Switzerland	Sept 10-12, 2018
ISH 2018 Scientific Meeting - Beijing	Beijing, China	Sept 20–23, 2018
2nd International Conference on Clinical Diabetes, Diabetic Medication & Treatment	Montreal, Canada	Sept 27-29, 2018
23rd ASEAN Federation of Cardiology Congress (AFCC 2018)	Bangkok, Thailand	Sept 28–30, 2018
12th International Conference on Endocrinology, Diabetes and Metabolism	Osaka, Japan	Oct 15-17, 2018
23rd ASEAN Federation of Cardiology Congress 2018	Cape Town, S. Africa	Oct 18–21, 2018
6th Global Experts Meeting on Cardiology and Cardiovascular Pharmacology	Osaka, Japan	Oct 20-21, 2018

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

MOHAMMAD HANIF has recently joined Beacon Pharmaceuticals Ltd. as Executive Vice President in Marketing Division. In his 22 years of long career in Pharma Marketing, he has worked in different positions & applied his vast expertise in different core areas of operation. Prior to this, he worked as Chief Marketing Officer (CMO) in DBL Group & Deputy General Manager, Marketing in Square Pharmaceuticals Ltd. He is a well known personality in the arena of Pharmaceuticals Marketing by virtue of his strong leadership skills, interpersonal skills, team making ability and above all, with his pleasant personality & proven track. He has obtained MBA degree from Institute of Business Administration (IBA), University of Dhaka and M. Pharm from the University of Dhaka.



Which single behavior best prevents High Blood Pressure?

You probably already know that certain healthy lifestyle behaviors can reduce your risk of developing high blood pressure, but is any one behavior more important than the others? Maybe, as new research suggests maintaining a healthy weight is the No. 1 behavior to prevent unhealthy blood pressure levels.

TITLE	VENUE	SCHEDULE
Medica 2017	Dusseldorf, Germany	November 13–16, 2017
Kenya International Trade Exhibition	Nairobi - Kenya	November 24–26 2017
Cyber Security in Healthcare Malaysia Conf. '17	Kualalampur, Malaysia	November 26–27, 2017
Philippines Expo 2017	Manila, Philippines	November 27–28, 2017
CPhI India	Bombay, India	November 27–29, 2017
IndoMedicare Expo 2017	Jakarta, Indonesia	November 28–30, 2017
Algeria Health 2017	Alger, Algeria	December 04–07, 2017
SIMPEX 2017	Khartoum, Sudan	December 05–07, 2017
Zdravookhraneniye 2017	Moscow, Russia	December 04–08, 2017
MediPharma Expo 2017	Hanoi, Vietnam	December 07–09, 2017
India MedExpo 2017	Hyderabad, India	December 08–10, 2017
Nepal Medical Show 2017	Kathmandu, Nepal	December 14–16, 2017
18th ISE & SFEC 2018	Dhaka, Bangladesh	January 13–15, 2018
Arab Health 2018	Dubai, UAE	Jan. 29–Feb. 01, 2018
Asia Pharma Expo 2018	Dhaka, Bangladesh	February 08–10, 2018
Plastindia 2018	Gujarat, India	February 07–12, 2018
India Medical Device 2018	Bengaluru, India	February 15–17, 2018
Medical Japan 2018	Tokyo, Japan	February 21–23, 2018
Meditec 2018	Chandigarh, India	February 22–24, 2018
Medicall 2018	Hyderabad, India	February 23–25, 2018
IFM 2018	Dubai, UAE	February 26–28, 2018
Africa Healthcare Summit 2018	London, UK	March 01-02, 2018
MedHealth Kenya 2018	Nairobi, Kenya	March 03–05, 2018
5th Annual Africa Healthcare Week 2018	Olympia, London	March 06–07, 2018
Tunisia Health Expo 2018	Tunis, Tunisia	March 07–10, 2018
Future Healthcare UK 2018	London, UK	March 13–14, 2018
Intermed 2018	Moscow, Russia	March 13–15, 2018
Medical Fair India 2018	Mumbai, India	March 16–18, 2018
Expomed Eurasia 2018	Istanbul, Turkey	March 22–25, 2018
CPhI South East Asia 2018	Jakarta, Indonesia	March 27–29, 2018
Asia Health 2018	Suntec, Singapore	April 02-04, 2018
Rehacare & Orthopedic China 2018	Guangzhou, China	April 02-04, 2018
Kuwait Health 2018	Mishref, Kuwait	April 04–05, 2018
Lab Indonesia 2018	Jakarta, Indonesia	April 04–06, 2018
Nano Pharma 2018	Amsterdam, Netherlands	April 09–11, 2018
IDEM 2018	Singapore	April 13–15, 2018
Mediconex 2018	Cairo, Egypt	April 14–16, 2018
CPhI Japan	Tokyo, Japan	April 18–20, 2018
Exposanita 2018	Bologna, Italy	April 18–20, 2018
Analitika Expo 2018	Moscow, Russia	April 24-26, 2018

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FAST FACTS

- *Globally, 9.4 million people die every year and 1.5 billion people worldwide suffer because of high blood pressure or hypertension. It is the biggest single risk factor for death worldwide causing heart disease, stroke and kidney disease and diabetes.*
- *Hypertension affects approximately 6.3 million South Africans. About 130 heart attacks and 240 strokes occur daily in South Africa. This means that 10 people will suffer a stroke and five people will have a heart attack every hour.*
- *Hypertension affects 1 in every 5 adults, and is one of the leading causes of morbidity and death in adults over the age of 50/55.3.*
- *In the World Health Organization (WHO) Africa region up to 50% of adults in many countries are estimated to have high blood pressure and this proportion is increasing.*