CONTENTS

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Editorial/Business Office
161 Lake Circus, Kalabagan (Ground floor)
Dhaka-1205, Bangladesh
E-mail: thepharmaworld2012@gmail.com

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Published by
Muhammad Masud
161 Lake Circus, Kalabagan (Ground floor)
Dhaka-1205, Bangladesh, Tel/Fax: +88 02 9122777

ACME

Brand Name: Laxogol
Generic Name: Macrogol & Electrolytes
Dosage Form: Oral solution
Strength: Each 25ml Laxogol contains, Macrogol (3350) BP 13.125 gm, Sodium Bicarbonate BP 178.5mg, Sodium Chloride BP 350.7mg , Potassium Chloride BP 46.6mg
Indications: Chronic constipation and fecal impaction.

Brand Name: **Logibac**
Generic Name: Ceftibuten INN
Dosage Form: Capsule & Powder for Suspension
Strength: 400mg & 90mg/5ml
Indications: Acute Bacterial Exacerbations of Chronic Bronchitis, Acute Bacterial Otitis Media, Pharyngitis, Tonsillitis, Pneumonia, Urinary Tract Infections & Typhoid fever .

Brand Name: Butacit
Generic Name: Butamirate Citrate INN
Dosage Form: Syrup
Strength: 7.5mg/5ml
Indication: Dry cough.

Brand Name: Cortimax 24
Generic Name: Deflazacort INN
Dosage Form: Tablet
Strength: 24mg
Indications: Rheumatoid arthritis, juvenile chronic arthritis, polymyalgia rheumatica, anaphylaxis, asthma, severe hypersensitivity reactions, chronic dermatoses, Ulcerative colitis, Immune suppression in transplantation.

Aristopharma

Brand Name: Dicliz Plus 20
Generic Name: Doxylamine Succinate USP + Pyridoxine Hydrochloride BP
Dosage Form: Tablet
Strength: 20mg+20mg
Indications: Treatment of nausea and vomiting during pregnancy

Brand Name: Soneta 30 gm Ointment
Generic Name: Mometasone Furoate
Dosage Form: Ointment
Strength: 0.1%
Indications: Relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses, such as psoriasis and atopic dermatitis.

Brand Name: Fusithal sterile Eye Drops
Generic Name: Fusidic Acid
Dosage Form: Sterile Eye Drops
Strength: 1%
Indications: Bacterial conjunctivitis, Blepharoconjunctivitis, Blepharitis, Sty and Keratitis. It may also be used for the management of corneal and conjunctival abrasions and foreign body injuries.

Brand Name: Optimox Eye Ointment
Generic Name: Moxifloxacin Hydrochloride
Dosage Form: Ointment
Strength: 0.5%
Indications: Treatment of bacterial conjunctivitis caused by susceptible strains

Brand Name: Rejoin-D
Generic Name: Glucosamine Sulfate USP + Diacerein BP
Dosage Form: Tablet
Strength: 750mg + 50mg
Indications: Treatment of Osteoarthritis, Rheumatoid arthritis, Bone & joint injuries

Brand Name: TCL-R 40
Generic Name: Atorvastatin Calcium Trihydrate USP
Dosage Form: Tablet
Strength: 40mg
Indications: Indicated for the reduction of elevated total cholesterol, LDL-cholesterol, apolipoprotien B and triglycerides.

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, 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, 60mg/2ml
Indications: Post-operative pain, acute pain, Moderate to severe pain management.

Beximco

Brand Name: Tezolin
Generic Name: Tedizolid phosphate
Dosage Form: Tablet
Strength: 200mg
Indications: Acute Bacterial Skin and Skin Structure Infection (ABSSSI) – Cellulitis, Abscess, Wound infection (lesion size more than 0.75 cm2 with swelling and redness).

Brand Name: Dextrim
Generic Name: Dextromethorphan + Phenylephrine + Triprolidine
Dosage Form: Syrup
Strength: 20mg + 10mg + 2.5mg/5ml
Indications: Temporarily relieves– dry cough, Nasal congestion, Allergic disorder i.e. sneezing, runny nose, itching etc.

Brand Name: Tuspel
Generic Name: Guaifenesin + Dextromethorphan + Menthol
Dosage Form: Syrup
Strength: 200mg + 15mg +15mg / 5ml
Indications: Fast, effective relief of– cough with phlegm, Chest congestion and Sore throat.

Concord

Brand Name: Farin
Generic Name: Warfarin Sodium
Strength: 1mg, 2mg & 5mg
Dosage Form: Tablet
Indication: Venous thromboembolism, Stroke prevention, deep vein thrombosis.

Brand Name: Relikof
Generic Name: Citric Acid Monohydrate
Strength: 125mg/5ml
Dosage Form: Syrup
Indication: Dry-cough, Irritating sore throat.

Brand Name: Relikof Kidz
Generic Name: Citric Acid Monohydrate
Strength: 31.25mg/5ml
Dosage Form: Syrup
Indication: Dry-cough, Irritating sore throat.

Brand Name: Vildaglip
Generic Name: Vildagliptin INN
Strength: 50mg
Dosage Form: Tablet
Indication: Type-2 Diabetes Mellitus

Brand Name: Vildaglip M
Generic Name: Vildagliptin INN + Metformin
Strength: 50mg + 500mg
Dosage Form: Tablet
Indication: Type-2 Diabetes Mellitus

Eskayef

Brand Name: Zeefol M
Generic Name: Iron polymaltose complex, Folic acid and Zinc
Dosage Form: Tablet
Strength: Elemental Iron 47mg, Folic acid 0.5mg, Element Zinc 22.5 mg
Indications: Prevention and Treatment of Iron, Folic acid and Zinc deficiency.

Brand Name: Ulicon
Generic Name: Ulipristal Acetate
Dosage Form: Tablet
Strength: 30mg
Indication: Emergency Contraception.

Brand Name: Ostocal D
Generic Name: Calcium and vitamin D_3
Dosage Form: Chewable Tablet
Strength: Elemental calcium 500mg as Calcium carbonate USP, vitamin D_3 200 IU as cholecalciferol USP
Indications: Pregnancy and lactation, osteoporosis, osteomalacia, rickets, parathyroid disease, kidney disease.

Brand Name: Ostocal DX
Generic Name: Calcium and vitamin D_3
Dosage Form: Chewable Tablet
Strength: Elemental calcium 600mg as Calcium carbonate, vitamin D_3 400 IU as cholecalciferol
Indications: Osteoporosis and calcium and vitamin D deficiency.

Brand Name: Losectile MUPS
Generic Name: Omeprazole magnesium
Dosage Form: MUPS Tablet
Strength: 20mg
Indications: Gastric Acidity, GERD, NSAID Inducedulcer, heartburn andregurgitation, Halitosis.

General

Brand Name: Arnigen
Generic Name: Sacubitril & Valsartan
Dosage Form: Tablet
Strength: 50mg & 100mg
Indication: Chronic Heart Failure.

Brand Name: Fematos
Generic Name: Ferric Carboxymaltose
Dosage Form: Intravenous Injection
Strength: 100mg/2ml
Indication: Treatment of Iron Deficiency Anemia in adult patients – when Oral Iron preparations are ineffective or cannot be used. Who have Non-Dialysis dependent Chronic Kidney Disease.

Brand Name: Fematos
Generic Name: Ferric Carboxymaltose
Dosage Form: Intravenous Injection
Strength: 500mg/10ml
Indication: Treatment of Iron Deficiency Anemia in adult patients – when Oral Iron preparations are ineffective or cannot be used. who have Non-Dialysis dependent Chronic Kidney Disease.

Brand Name: Pentazo
Generic Name: Pentazocine
Dosage Form: Intravenous/ Intramuscular/ Subcutaneous Injection
Strength: 30mg/1ml
Indication: For the relief of moderate to severe pain. It also is used for Preoperative or Pre-Anesthetic medication and as a supplement to Surgical Anesthesia.

Brand Name: Proval CR
Generic Name: Sodium Valproate & Valproic Acid Controlled Release Tablet
Dosage Form: Tablet
Strength: 200, 300 & 500mg
Indication: Epilepsy & Bipolar Dirorder.

Brand Name: Glytear
Generic Name: Polyethylene Glycol
Dosage Form: Eye drop
Strength: Polyethylene Glycol 400 USP 4 mg & Propylene Glycol USP 3 mg.
Indication: Indicated for the temporary relief of burning and irritation due to dryness of the eye.

Navana

Brand Name: Artiforte™ Sterile & Pyrogen free
Generic Name: Glycerin 0.2%, Hypromellose 0.36%, Polyethylene glycol 400 1%, Tetrahydrozoline Hydrochloride 0.05%, Zinc Sulfate 0.25%.
Dosage Form: Eye Drops
Strength: 2mg, 3.6mg, 10mg, 0.5mg, 2.5mg.
Indications: Relief of discomfort and redness of the eye due to minor eye irritations, for relief of dryness of the eye, for the temporary relief of burning and irritation due to exposure to wind or sun, for protection against further irritation

Brand Name: Cinagen-D Sterile
Generic Name: Moxifloxacin 0.5% & Dexamethasone Phosphate 0.1%
Dosage Form: Eye Drops
Strength: 5mg & 1mg.
Indications: Treatment of eye infections caused by susceptible microorganisms and prevention of inflammation and bacterial infection occured after ocular surgery.

Brand Name: Eytob Sterile
Generic Name: Tobramycin USP 0.3%
Dosage Form: Eye Drops
Strength: 3mg
Indications: Treatment of external infections of the eye and its adnexa caused by susceptible bacteria.

Brand Name: Nafgal
Generic Name: Naftifine Hydrochloride USP 2%
Dosage Form: Cream
Strength: 20mg.
Indications: Treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organism Trichophyton rubrum.

Brand Name: Fixcef Plus & Fixcef Plus
Generic Name: Cefuroxime & Clavulanic Acid
Dosage Form: Tablet
Strength: 250mg, 62.5mg+ 500mg, 125mg.
Indications: Pharyngitis/tonsillitis, Acute bacterial otitis media, Acute bacterial maxillary sinusitis. Acute bacterial exacerbations of chronic bronchitis and secondary bacterial infections of acute bronchitis, Uncomplicated skin and skin-structure infections, Uncomplicated urinary tract infections. Uncomplicated gonorrhea (urethral and endocervical), Early lyme disease (erythema migrans).

Brand Name: Bonacerin
Generic Name: Glucosamine Sulfate & Diacerein
Dosage Form: Tablet
Strength: 750mg & 50mg
Indications: Treatment of Osteoarthritis, Rheumatoid arthritis & Joint injuries.

NIPRO JMI

Brand Name: Empa 25
Generic Name: Empagliflozin INN
Dosage Form: Tablet
Strength: 25mg
Indications: Type-2 Diabetes Mellitus & to reduce the risk of cardiovascular (CV) death.

Brand Name: Meroxin
Generic Name: Meropenem USP
Dosage Form: Injection
Strength: 500mg IV & 1g IV
Indications: RTIs, UTIs, Intra-abdominal Infections, Gynaecological Infections, SSTIs, Meningitis, Septicaemia, Pulmonary infections in cystic fibrosis & Infections in patients with febrile neutropenia.

Brand Name: Roxcef
Generic Name: Cefuroxime
Dosage Form: Injection
Strength: 750mg IM/IV & 1.5g IV
Indications: RTIs, SSTIs, UTIs, Bone & Joint infections, Gonorrhea, Meningitis & Surgical Prophylaxis.

One Pharma

Brand Name: Onlac 100 ml
Generic Name: Lactulose
Dosage Form: Oral Solution
Strength: 3.35gm/5ml
Indications: Constipation, Hepatic Encephalopathy, Hemorrhoids or Piles & preventing Gallbladder Stone formation.

Brand Name: NX-1
Generic Name: Naproxen Sodium
Dosage Form: Tablet
Strength: 500mg
Indications: Rheumatoid arthritis, Ankylosing spondylitis, Osteoarthritis, Acute gout, mild to moderate pain, Tendonitis, Bursitis and Dysmenorrhea.

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.

Square

Brand Name: Olistat 60
Generic Name: Orlistat
Dosage Form: Capsule
Strength: 60mg
Indications: Management of Overweight & Obesity.

Brand Name: Solodex Baby IV
Generic Name: Sodium Chloride & Dextrose
Dosage Form: Infusion
Strength: 0.225% w/v & 5% w/v
Indications: For replenishment of water, electrolytes & calories in neonate & infants.

Brand Name: Solodex JR IV
Generic Name: Dextrose & Sodium Chloride
Dosage Form: Infusion
Strength: 5% w/v & 0.45% w/v
Indications: For replenishment of water, electrolytes & calories in children.

Brand Name: Ocof
Generic Name: Dextromethorphan HBr, Phenylephrine HCl and Triprolidine HCl
Dosage Form: Syrup
Strength: 20mg + 10mg + 2.5mg
Indication: Common cold.

Brand Name: Deflacort
Generic Name: Deflazacort
Dosage Form: Suspension
Strength: 6mg/5ml
Indication: Severe Asthma & Allergic disorders.

Brand Name: Alice
Generic Name: Ivermectin
Dosage Form: Lotion
Strength: 5mg/gram
Indication: Topical treatment of head lice infestations in patients 6 months of age and older.

Brand Name: Cefopen
Generic Name: Cefoperazone
Dosage Form: IM/IV Injection
Strength: 1gm/Vial
Indication: Biliary Infection

Brand Name: Isodex IV
Generic Name: Dextrose Anhydrous & Sodium Chloride
Dosage Form: Infusion
Strength: 4.30% & 0.18% w/v
Indications: For maintenance & replacement of water, electrolytes & calories in pre & post-operative period.

Brand Name: Efaxim
Generic Name: Rifaximin
Dosage Form: Tablet
Strength: 200mg, 550mg
Indications: Treatment of traveler's diarrhea, hepatic encephalopathy, irritable bowel syndrome.

Ziska

Brand Name: Salitic
Generic Name: Salicylic Acid BP & Lactic Acid BP
Dosage Form: Solution
Strength: 16.7 % + 16.7 %
Indications: Warts, corns & calluses

Brand Name: MaxD 20000
Generic Name: Cholecalciferol USP
Dosage Form: Capsule
Strength: 20000 IU
Indications: Treatment & prevention of vitamin D deficiency.

Centeon Pharma

Brand Name: Domixon 10
Generic Name: Domperidone BP
Dosage Form: Tablet
Strength: 10mg
Indications: Prevention & symptomatic relief of Acute Nausea &Vomiting, Stimulate gut mobility.

Brand Name: Centokast 10
Generic Name: Montelukast BP
Dosage Form: Tablet
Strength: 10mg
Indications: Asthma, Seasonal Allergic Rhinitis.

Brand Name: Napoxol 500
Generic Name: Naproxen BP
Dosage Form: Tablet
Strength: 500mg
Indications: Rheumatic Disorder, Acute Gout and other painful conditions.

Brand Name: Ciproton 500
Generic Name: Ciprofloxacin BP
Dosage Form: Tablet
Strength: 500mg
Indications: Lung or airway Infections, Bone Infections, Urinary Tract Infections.

First Nationwide Digital Patient Registry in Bangladesh

A nationwide electronic diabetes patient registry will be introduced in Bangladesh, the first of its kind, with a view to delivering quality care for patient living with diabetes through analysing epidemiology and treatment outcomes. The electronic registry will be implemented through the institutions of Diabetic Association of Bangladesh (BADAS) and its affiliated associations across the country with the support of Novo Nordisk.

Diabetic Association of Bangladesh's (BADAS) President Prof. A.K Azad Khan and Novo Nordisk's Senior Vice President Frederik Kier signed an agreement to develop the registry.

"In Bangladesh there is no conclusive study or survey which provides an exact number or figure of the diabetic population", said Prof. Azad Khan. "The new nationwide registry will generate data on patient numbers, blood glucose level before and after meal, three-month average of glucose in blood (HbA1c), renal and cardiac history of patients living with diabetes and other relevance. Quality care will be ensured through analysing these data," he said.

Improving the understanding of diabetes and the need for its prevention is critical, which is why Novo Nordisk works to raise awareness for the diabetes epidemic and its impact in Bangladesh, said Frederick Kier. As a global leader in diabetes care, Novo Nordisk has a responsibility to work for improving understanding of diabetes and the need for its prevention, he said.

"The new nationwide registry will provide health outcome data to monitor patient needs and identify health problems that need prompt attention. It will also help to address the rising burden of diabetes to achieve sustainable development goals (SDGs)," he added.

The United Nations has recognised diabetes among other non-communicable diseases as a major challenge for achieving SDGs.

Novo Nordisk in partnership with BADAS has taken many initiatives to ensure access to quality care for patients, said Anand Shetty, Managing Director of Novo Nordisk. Changing diabetes® barometer, changing diabetes® in children (CDiC) programme and changing diabetes® brand ambassador (One-day cricket captain Mashrafe Bin Mortaza) are to name a few, Shetty said.

According to International Diabetes Federation, 6.9 million people are living with diabetes in Bangladesh and it will hit 13.7 million by 2045.

Novo Nordisk in partnership with Eskayef, owned by Transcom Group, has been manufacturing insulin in Bangladesh since 2012, while Transcom Distribution Company distributes the insulin products across the country. ●

Hamdard Annual Sales Conference- 2017

The Annual Sales Conference-2017 of Hamdard Laboratories (waqf) Bangladesh was held recently in Dhaka. The conference was inaugurated by Dr. Hakim Md. Yousuf Harun Bhuiyan, Hon'ble Chief Mutuwalli & Managing Director, Hamdard Laboratories (waqf) Bangaldesh, Founder of Hamdard University, Bangladesh was also present as chief guest. Dr. Hakim Rafiqul Islam, Mutuwalli & Senior Director Marketing presided over the conference.

Mohammad Zamal Uddin (Russell), Mutuwalli & Deputy Managing Director, Anisul Haque, Director of Accounts & Finance, Prfoessor Hakim Shiry Forhad, Director of Administration, Lt.Col (Retd) Mahbubul Alam Chowdhury, Mihir Chokroborty, Director of Production, Dr. Nargish Marjhan Shilpi, Mutuwali & Director of HRD, Hakim Saifuddin Murad, Director, Sales, Assistant Directors, Managers, staff of Hamdard and all Field Forces from the county were present in the conference.

Chief Guest Dr. Hakim Yousuf Haroon Bhuiyan mentioned that herbal medicines are going to be popular not only in the subcontinent but also around the world because herbal medicines has fewer side-effects. To uphold the popularity, he recommended, to strictly maintain the quality of these medicines. Bangladesh government is also playing an important role to develop this sector.

He said that Hamdard is continuously serving the mankind and also playing an important role for the benefit of health, education & culture. For this purpose, Hamdard has established 3 Unani Medical Colleges, Hamdard Public College and Hamdard University. These educational institutions are helping the poor but meritorious students. Beside this, each year Hamdard is providing free treatment and medicines to the people gathered in the World Ijthema, Tongi.

Dr. Hakim Rafiqul Islam in his speech thanked for all for the accomplishment of the target of 2017 and also urged everyone to work harder for the accomplishment of the target of 2018. At the end, he also expected that everyone would work enthusiastically for the betterment of this institution.

The day-long program ended with a colorful cultural program. Best performers and achievers were awarded for their performance in 2017. •

Beximco Pharma gets Scrip Award in London

Beximco Pharma has won the prestigious Scrip Award in the category of 'Best Company in an Emerging Market' at the 13th Annual Scrip Awards ceremony held in London recently.

This is the first time a Bangladeshi company has won this global award which recognizes company's operational excellence and continued growth in global market.

Beximco Pharma Chief Operating Officer Rabbur Reza, received the award on behalf of the company.

The Scrip Awards honour, the highest achieving companies and individuals in global pharma and biotech industry, recognizing their important roles in improving healthcare around the world.

A panel of 16 highly respected and independent judges from across diverse sectors evaluated the award entries to select the finalists, according to a company statement.

Scrip's Best Company in an Emerging Market Award seeks to reward the growing R&D-based pharmaceutical company founded in areas beyond its traditional geographic borders of North America, Western Europe and Japan. Previous winners in this category include globally reputed pharma companies like Dr Reddy's, Hikma, Glenmark and Mundipharma.

"We are setting a high standard for the country's pharmaceutical industry through our research and development initiatives, strategic partnerships, and expansion programs," the statement quoted Beximco Pharma Managing Director Nazmul Hassan MP as saying on the occasion. •

NOVO Healthcare held Annual Marketing and Sales Conference-2017

The Annual Marketing and Sales Conference-2017 of NOVO Healthcare and Pharma Ltd. was held recently in the city. The conference was inaugurated by Md. Shibbir Mahmud, hon'ble Chairman of NOVO Healthcare and Pharma Ltd.

Md. Fariduddin Kawsar Khan, Hon'ble Managing Director of NOVO Healthcare and Pharma Ltd. expressed his gratitude to all employees for the incredible growth of the company. He also expressed his profound gratefulness to the physicians and other stakeholders for their sincere support. Considering the huge demand he addressed to launch high tech products like biotech, steroids, sterile and hormones in the near future to uphold the company position in Bangladesh pharmaceutical industry.

Md. Mazaharul Islam, Manager, Marketing Strategy Dept. of the company highlighted the achievements of 2017 and placed the objectives and action plan for 2018. He also thanked all participants for making the conference successful.

Chairman of the organization revealed that NOVO Healthcare and Pharma has started exporting medicine in different countries of the world and it is growing day by day. Other Directors, foreign delegates and Managers alongwith around 350 Sales personals coming from different regions of the country were also present at the conference. •

Aristopharma held Annual Sales Conference-2017

Aristopharma, one of the leading pharmaceutical companies in Bangladesh, held its Annual Sales Conference recently in the city. Aristopharma ranks as one of the top 10 companies in overall Pharma market & no.1 in the Ophthalmic market of Bangladesh. Moreover, it also exports medicines to around 34 countries of all the major 5 continents of the world. In the conference, the Chairman & Managing Director of the company, M. A. Hassan, thanked all his employees for their united efforts which have brought the company to this current position. Other Directors & Senior Officials also shared strategies for future development of the company. The people of the company working in different parts of the country attended the conference. At the end, awards were given to the achievers in different categories. •

One Pharma Steps into 3rd Year of Journey

One Pharma Ltd., the next generation pharmaceutical company, recently arranged a program on the occasion of their "Beginning of 3rd Year Journey and Achievers' Celebration Program" in Dhaka.

The Hon'able Managing Director of One Pharma Ltd. KSM Mostafizur Rahman, Chairman Mst. Nazmun Naher, General Manager, Marketing, General Manager, Sales, Head Office & Factory personnel and Sales Team of One Pharma Ltd participated in the program. The program was inaugurated by the welcome speech of Hon'able Managing Director. He defined the vision, mission of the company & discussed about next 2 years goal of the company.

For optimizing the progress & advancement of the company, General Manager, Marketing delivered his direction on different marketing strategies & blueprint for 2018 and General Manager, Sales discussed about the distinctive sales road map for 2018.

Later, the achievers' were awarded in different categories for their outstanding performance. The Program ended with a vote of thanks and by cutting a celebration cake. ●

UniMed UniHealth holds Annual Sales Conference

UniMed UniHealth Pharmaceuticals organized its Annual Sales Conference for the year 2017, with the theme "Better Customer Satisfaction through Quality, Service and Value," recently in the city.

Among others, M M Eskander, Md Shamim Alam Khan, General Manager, Kawsar Ara Hossain, Director, M Mosaddek Hossain, Managing Director, Nazmul Hossain, Executive Director, Md Saimul Islam and Rakib H Bhuiyan, General Manager of UniMed UniHealth Pharmaceuticals were present in the conference.

The senior management and all the sales and marketing executives of the organization were present in the event. Executive Director Nazmul Hossain gave a brief account of the company's overall performance in 2017 and objectives for 2018.

Director Kawsar Ara Hossain thanked all the members of the organization, including the sales and marketing team for their wonderful efforts in achieving the company's goal and objectives in 2017. Managing Director M Mosaddek Hossain welcomed all the participants and highlighted the future directions of the organization for the year 2018. ●

150 rallies organised across the country be proactive to prevent diabetes

World Diabetes Day was observed in the country to raise awareness and promote early diagnosis to prevent this non-communicable disease.

To mark the day, Novo Nordisk has launched a nationwide diabetes awareness and education campaign until June of 2018.

As part of the campaign, Danish pharma giant Novo Nordisk in partnership with Diabetic Association of Bangladesh (DAB) and Padma Textiles organised 150 rallies across the country. The biggest rally of the country was organised in front of national museum in the capital.

It was participated by country's top healthcare professionals, adults and kids living with diabetes and changing diabetes® brand ambassador Mashrafe Bin Mortaza.

As this year's theme is 'women and diabetes', Novo Nordisk will screen 15,000 pregnant women and train 5,000 healthcare professionals including 2,000 gynecologists on the risk of diabetes and modern treatment options.

Novo Nordisk also organised a motivational programme for the children living with diabetes at changing diabetes® in children clinic in BIRDEM-2 hospital, the world's largest clinic for children living with diabetes.

To control and prevent diabetes awareness and education are the main catalysts, said AK Azad Khan, president of DAB. 'Our ultimate aim is to create awareness on diabetes and promote early diagnosis to ensure more people can live a life free of complications,' said Anand Shetty, Managing Director of Novo Nordisk.

The cricket icon Mashrafe said: 'To start a good innings in life, act today and change the future of diabetes. Say YES to quality medicine and insulin to live a happy and complication- free life'. Novo Nordisk wants to change the quality of life of those living with diabetes by offering them much more convenient treatment options and raising awareness, said Mohammad Saiful, Head of Marketing of Novo Nordisk.

In 2017, a total of 6.9 million people are living with diabetes in Bangladesh, according to International Diabetes Federation. ●

30th Annual Sales Conference of General Pharmaceuticals Limited

30th Annual Sales Conference of General Pharmaceuticals Ltd. was held on 30th December, 2017 at Hotel Sea Palace, Cox's Bazar. The daylong conference was inaugurated by the Managing Director Dr. Momenul Haq in presence of Director Dr. Sarah Momen, Director Marketing Mir Zaki Azam Chowdhury, Head of Marketing Md. Faruk Hossain & more than 2400 sales employees all over the country.

There is no alternative of quality medicine for the treatment of mass people said by Dr. Momenul Huq in his welcome speech. He mentioned that General Pharmaceuticals Ltd. meets the challenges successfully from the very beginning to provide quality medicine to mass people with affordable prices. Furthermore he promises that it will be continued for lifetime of the company. He respectfully recalled Ex-Health Minister and "Drug Ordinance Act 1982"- policy maker Late Major General (Ret.) M Shamshul Huq. Because of this act our pharma sector flourished and many local pharmaceuticals are now exporting medicines to 86 countries around the world. General Pharmaceuticals Ltd. is also exporting medicines to 29 countries. Then honorable Managing Director gave thanks to sales employees for their contribution and declared some lucrative policies for them.

Director Marketing Mir Zaki Azam Chowdhury analyzed the sales of 2017 & presented guideline of marketing for 2018. The conference ended in the evening with a colorful cultural program. ●

Annual Sales Conference of NIPRO JMI Pharma Ltd. held

NIPRO JMI Pharma Ltd. (NJP), a Japan Bangladesh Company, held their annual sales conference recently. Md. Abdur Razzaq, the founder Managing Director of JMI Group and NIPRO JMI Pharma, inaugurated the program and expressed his dream to see a small Bangladesh in every country of the world. Chairman of the company, Jabed Iqbal Pathan revealed that quality products and skilled people is the secret of success. Md. Mizanur Rahman, CEO of the company, expressed to overcome the limitations of conventional treatment approach by introducing new molecules and latest technologies in the market. He also thanked all employees for their contribution to establish NJP as fastest growing Pharmaceutical company in Bangladesh. Presence of other directors, foreign delegates and managers along with around 1200 sales personnel from different regions of the country made the conference a success. ●

Salem Azad Chowdhury and Shah Mohammad Jalal Uddin elected President & Secretary of ARAB

Salem Azad Chowdhury

Shah Mohammad Jalal Uddin

Salem Azad Chowdhury and Shah Mohammad Jalal Uddin were elected as new President and General Secretary (respectively) of Regulatory Affairs Society Bangladesh (ARAB) for the period 2017-2020.

The 6th Triennial General Meeting of the Society was held recently at the auditorium of National Press Club, Dhaka. The other members of the newly elected executive committee are: Executive Vice President: Md. Abdur Rahman & Md. Mostafizur Rahman, Joint Secretary: Md Farhad Hossain & Md. Ohedur Rahman, Organizing Secretary: Taslim Ahmed Dipu, Finance Secretary: Nur Mohammad Chowdhury (Mihir), Communication and Office Secretary: A. S. M. Jobayar. Members of the EC are: D. Md. Hasan Khan, Andaleeb Ibne Afaz, Kazi Neamat Farjanal Alam, Md. Ahmadul Haque Swapon, Md. Aminul Islam Bhuiyan, Md. Alauddin, Md. Ahadul Islam and Md. Ponir Mia.

A seven members' Advisory Body, nine members' Board of Directors and two Standing Committees are also elected along with Executive Committee.

On the occasion of conference, the society organized a seminar on "Safe use of drug and public awareness." Major General Md. Mostafizur Rahamn, the Director General of Drug Administration was present as chief guest and S M Shafiuzzman the General Secretary of Bangladesh Pharmaceutical Manufacturers Association was present as special guest. •

Workshop on Pharmaceutical Science Research held at BCSIR

Bangladesh Council of Scientific and Industrial Research (BCSIR) organized a "Workshop on the Role of BCSIR in the area of Pharmaceutical Sciences Research" at the center recently.

Md Faruque Ahmed, Chairman, BCSIR attended as the chief guest, other Members, Directors, Scientists, University Professors, Drug administration's Officer and Senior Officers from several reputed Pharmaceuticals Industries in Bangladesh contributed their expert opinion. Key note speaker was Dr. Md. Hossain Sohrab, PSO, BCSIR Laboratory Dhaka. •

Pharmacy students of Primeasia University visit Incepta Pharma Ltd.

A group of 21 senior B.Pharm. (Hons.) students of Primeasia University Pharmacy Department, led by two teachers of the Department, went on a Study Tour and visited the manufacturing factories of Incepta Pharmaceuticals Ltd. at Jirabo, Savar recently. Incepta Pharmaceuticals Ltd. is one of the top-class good quality drug manufacturers in the country. It is equipped with all modern instruments and machinery.

The principal aim of undertaking this tour was to acquaint the students with the practical aspects of drug manufacture, using state-of-the-art technology and machinery.

At the Factory premises, a colourful and informative presentation was made by an official of the company on the gradual development, progress, achievements, successes and future plans of the company. At the end of the presentation, the General Manager Production, S.M. Zillur Rahman and the Deputy Manager Quality Control, E.H. Sebin Ahmed took the visiting team around different departments of the factory and explained the activities of these departments. Visiting students were highly impressed and excited to see the practical application of their theoretical knowledge of the technology and machinery. During this visit the students got the opportunity to see the activities of a number of departments including production, quality control, microbiology, dispensing and packaging.

The tour ended at 3.00 PM after a sumptuous lunch offered by the Incepta Pharmaceuticals Ltd. •

Primeasia University Pharmacy Students undertake Study Tour

A group of 38 senior B.Pharm. (Hons.) students and 12 teachers of the Pharmacy Department of Primeasia University went on a Study Tour to the newly built modern Factory of Techno Drugs Ltd. at Gazipur recently.

An export-oriented Company, built on 40 bigha land area with plenty of open green space in and around, Techno Drugs Ltd. has built its modern factory at Gazipur with separate dedicated buildings for manufacturing different groups of drugs. The dedicated building for manufacturing hormonal drugs, which the team visited, is now almost ready to start production. Although not in operation and final touches are still being given, the Management of Techno Drugs Ltd. was kind enough to allow students and teachers to visit this factory.

On arrival at the site, the Managing Director, the Plant Manager, the GM, Quality Operations & Head of Quality Assurance, the Project Engineer and other officials and staff of the Factory welcomed the team and led them to the well-decorated Factory Canteen building for briefing and tea.

The Managing Director, Plant Manager and the GM, QA then briefed the students about the gradual growth and development, the current standing and future plans for this modern drugs manufacturing factory. They also discussed and replied to questions from the students about some academic and practical aspects of drug manufacturing, quality control and GMP maintenance in such a factory.

After a short tea break, the Managing Director, the Plant Manager and the GM, QA took the students and teachers inside the hormonal drugs manufacturing factory and guided them through different sections of the modern factory to show them the sophisticated technology and materials used in constructing the factory and the sophisticated high-tech machinery installed in it for manufacturing hormonal drugs. The Tour ended after a sumptuous lunch given by Techno Drugs Ltd. at the nearby Green Tech Resort & Convention Centre. •

Novo Nordisk to continue raise awareness

Frederik Kier
Senior Vice President, Novo Nordisk

Novo Nordisk will continue to increase awareness in Bangladesh to beat diabetes towards long-term sustainability, said a top executive of the Danish drugmaker.

Frederik Kier, Senior Vice President of the worlds' largest insulin producer, said, "In Bangladesh, we are in a situation where we have a big task at hand to make sure a bigger number of patients are getting a good control over their disease."

Novo Nordisk in partnership with Diabetes Association of Bangladesh (DAB) is working in the country over 60 years to address the challenges patients are facing and living with diabetes, he said. "There is still a lot to be done," he told The Pharma World in an interview in Dhaka.

The Danish national was in the capital in December last year to sign a Memorandum of Understanding with the DAB. The MoU aims at developing a nationwide electronic diabetes patients' registry in Bangladesh this month. The data will be recorded through DAB's institutions and affiliated organisations with support from the insulin maker.

Kier said the registry will give a full overview of medical records of the patients who are being treated by these hospitals. It will generate data on the number of patients, blood glucose level before and after meal, three-month average of glucose in blood, renal and cardiac history of patients living with diabetes and the medicines they are taking.

As a result, the registry will help treat the patients in a better way throughout their lifetime. "I think it is a significant improvement because you will have the history of an individual patient and will know what he or she has undergone and hence a much more dedicated and individualised treatment can be decided."

The registry is already a part of the healthcare system in many countries. So, Novo Nordisk together with BIRDEM has decided to introduce the system, he said.

According to the International Diabetes Federation, 69 lakh people are living with diabetes in Bangladesh and the figure will double to 1.37 crore by 2045. DAB believes that the number is underestimated. It would probably be around 8 to 9 million and will be double in the next 25 years, Kier said.

"We are seeing the same challenges in Bangladesh what we have seen at the global level. We have to do something about it."

He said the disease probably cannot be reversed. The company wants to make sure that many more of these 8 to 9 million people are diagnosed properly. Many people do not even know that they have diabetes, he said. "We can make them aware and help them get proper treatment."

Kier said, education, awareness, understanding of the disease and a change in lifestyle are mandatory to improve the diabetes scenario. The prime focus of Novo Nordisk has centred around education, awareness and training of doctors during its 50 years of collaboration with the DAB, he said.

"We have seen that people go to doctors too late. By that time, they have already developed complications and made it even worse for individuals and the society." "In the worst case scenario, you can lose your capabilities to work which has high societal and economic impact," he said.

With the "Changing Diabetes" slogan, Kier says Novo Nordisk wants to change the quality of life of those living with diabetes by offering them much more convenient treatment options and raising awareness.

Novo Nordisk's investment in Bangladesh is not limited to only sales and marketing activities but also production activities with local partner Eskayef Bangladesh, one of the leading healthcare solution providers in the country, he said.

Since 2012, Eskayef Bangladesh has been producing human insulin vial at its high-tech plant for Novo Nordisk – a unique partnership from its viewpoint.

Transcom Distribution Company distributes the insulin products across the country.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. It markets its products to more than 165 countries and caters to half of the demand of insulin globally.

Novo Nordisk has 56 percent share in Bangladesh's insulin market. It employs more than 200 people in Bangladesh. ●

Pharmaceutical products named 'Product of the Year 2018'

Pharmaceutical products have been named 'Product of the year 2018' by Hon'ble Prime Minister Sheikh Hasina. Prime Minister Sheikh Hasina made this announcement while she was inaugurating this year's 23rd Dhaka International Trade Fair (DITF) in the city on 1st January, 2018.

The pharmaceutical sector is a high-tech industry. Not only the industry meet the demands of 98 percent of the local demand, it currently exports to 145 countries, including the US, the UK, the EU and Australia and it can reach the same level of international recognition and respect as RMG.

DGDA congratulated Prime Minister Sheikh Hasina and arranged a meeting on 8th January, 2018. The Chief Guest was Mohammed Nasim MP, Minister, Ministry of Health and Family Welfare. Special Guest was Salman F Rahman, Advisor to Hon'ble PM for Private Sector Development and Vice Chairman of Beximco Group and Nazmul Hassan, MP, Managing Director, Beximco Pharmaceuticals Ltd., President, BAPI and Chairman Bangladesh Cricket Board (BCB).

Board (BCB) and the pharmaceuticals sector was recognized as product of the year at the time as it keeps booming with about 1458 generics and 28,063 brand named products and gradually entering to 145 countries of the world given its full potentials.

As a Least Developed Country, Bangladesh can manufacture generic drugs with an exemption from obligations to implement patents and data protection for pharmaceutical products until 2033.

Bangladesh's pharmaceutical output has grown by a thousand times to $2 billion since 1982 - or around 1% of GDP - making it one of the largest white collar employers in the country.

The industry is the second highest contributor to the national exchequer

with a total of 268 registered pharmaceutical companies.

Salman F Rahman said that it is a very good initiative by Hon'ble Prime Minister to declare the pharma sector as the product of the year 2018 to facilitate growth and export of the pharmaceuticals products. However, it needs strengthening DGDA and to improve their capacity.

Nazmul Hassan, MP appreciated Hon'ble Prime Minister to declare pharma product as the Product of the Year 2018. He said that this declaration will encourage pharmaceutical manufacturer as well as facilities export. To strengthen, DGDA is needed to export pharmaceutical products in stringent regulatory countries.

In that meeting S. M. Shafiuzzaman, Secretary General, BAPI said "We have the potentials to earn billions of dollars through exports but the sector needs fiscal benefits and policy support to do so."

DG, DGDA said, "Declaring it the 'Product of the Year' is not enough. The government needs effectively patronize it to utilize its full potentials. Government should strengthen DGDA which will increase the export potentiality .The industry is now exporting pharmaceutical products and raw materials to 145 countries and the number can increase further if the embassy officials, i.e. ambassadors, economic ministers, or councilors of different countries can help to connect and promote Bangladesh pharmaceutical products to the individual country where they are posted.

Bangladesh earned $399.5 million from exporting pharmaceutical goods in the Year 2017. Now 54 Pharmaceutical companies are exporting pharmaceutical products.

Hon'able Minister said in his speech that Government is supporting pharmaceutical industry to grow more and capture foreign markets so that export volume could be increased in double digit growth. He told Government has declared 20% cash incentives for exporting API (Active Pharmaceutical Ingredients). Government is now establishing API Park which will facilitate export.

DGDA Celebrate World Antibiotic Awareness Week 13-19 Nov, 2017

DGDA focuses on this year's theme: "Seek advice from a qualified healthcare professional before taking antibiotics"

Antibiotics are drugs used for treating infections caused by bacteria. Also known as antimicrobial drugs, antibiotics have saved countless lives.

Misuse and overuse of these drugs, however, have contributed to a phenomenon known as antibiotic resistance. This resistance develops when potentially harmful bacteria change in a way that reduces or eliminates the effectiveness of antibiotics.

When antibiotics don't work, the result can be

- Longer illnesses
- More complicated illnesses
- More doctor visits
- The use of stronger and more expensive drugs
- More deaths caused by bacterial infections

To raise awareness about the importance of better and appropriate use of antibiotics, the hon'ble Director General of DGDA instructed all of his offices to celebrate World Antibiotic Awarness Week 13-19 November, 2017. As per his instruction, 55 of his district offices along with Head Office have taken different initiatives to celebrate World Antibiotic Awareness Week.

DGDA is combating antibiotic resistance through activities that include-Labeling regulations, addressing proper use of antibiotics, Partnering to promote public awareness through arranging rally, awareness seminar.

DGDA distributed almost 1 lac posters including the following instructions:

1. Antibiotic can only be dispensed as per prescription supplied by registered physician (in special cases as per national guidelines antibiotics can be prescribed by the Government trained health workers)
2. Take antibiotic as per time and instruction given in the prescription.
3. Complete the full course of antibiotic even you feel better before it is finished.

DGDA has inaugurated 289 Model Pharmacy and Model Medicine shop in 20 districts of the country. Inauguration of Model Pharmacy and Model Medicine shop in Bogra, Gaibandha and Rangpur.

Case filed in Mobile, Magistrate and Drug Court

Month	Case filed in Drug Court	Case filed in Magis-trate Court
Oct'17	2	5
Nov'17	1	0
Total	**3**	**5**

Two Months Activities of DGDA (October'17- November'17)

1.	No of Total Drug License (Retail & Whole sale)	123836
2.	No of Renewal of Drug License (Retail & Whole sale)	6323
3.	No of Sample Collected for test	101
4.	No of sample test	83
5.	Issue of GMP Certificate	08
6.	Issue of CPP	832
7.	Issue of FSC	78
8.	Issue Form-10	264
9.	Inaugurated Model Pharmacy (up to December)	169
10.	Inaugurated Model Medicine shop(up to December)	120

DGDA fixes up MRP of Pacemaker & Heart Valve

On 19 December 2017, a meeting was held at the office of DGDA where the price of (MRP) of pacemaker was discussed under the chairmanship of Major General Md. Mostafizur Rahman.

The meeting was participated by the Cardiac Surgeon, Intervention Cardiologist, representative of National Board of Revenue, Bangladesh Medical Association, Bangladesh Association of Pharmaceutical Industries & President of Medical Device Association & General Secretary & the Importer of Heart Valve, Pacemaker respectively.

Due to non-fixation of the price of pacemaker, the pacemakers were sold at different prices in the hospitals. On this plea, BAPI took the initiative to fix the maximum price of Cardiac Device. In this context Major General Md. Mostafizur Rahman had a meeting recently in his office to exchange views with the Cardiac Surgeons & Cardiologists from different hospitals, Medical Device Importer Association.

On the basis of exchange of views, the price of Pacemaker & Heart Valve was discussed.

The chart of the maximum price of Heart Valve is as follows. Earlier, in different hospitals, the medical Heart Valve were sold at different prices. From now, every hospital will sell the mechanical heart valve as per the table below:

Sl No.	Name of Medical Device	No	Brand Name	Price limit of supply in hospital (Tk.)	Maximum Price (Tk.)	Decreased Price (Tk.)
a)	Mechanical Heart Valve	1.	SJM Mechanical Heart Valve (Rotatable Arotic)	58,000-74,000/-	58,000/-	16,000/-
		2.	SJM Mechanical Heart Valve (Rotatable Mitral)	58,000-74,000/-	58,000/-	16,000/-
		3.	REGENT Mechanical Heart (Rotatable Arotic)	58,000-74,000/-	75,000/-	16,000/-
		4.	SJM Mechanical Heart Valve Conduit Valve	1,50,000-1,76,000/-	1,50,000/-	26,000/-
		5.	Medtronic Open Pivot Heart Valve (Mitral)	58,000-74,000/-	58,000/-	16,000/-
		6.	Medtronic Open Pivot Heart Valve (Aortic)	58,000-74,000/-	58,000/-	16,000/-
		7.	On-X Prosthetic Heart Valves (Heart Valves)	55,000-59,800/-	55,000/-	4,8,00/-
b)	Tissue Heart Valve	8.	TRIFECTA SJM (Tissue Heart Valve (Aortic)	2,50,000/-	2,50,000/-	

It has been seen that in different hospitals the Heart Valve has been decreased from Tk. 4,800/- to Tk. 26,000/-.

The maximum price of pacemaker (MRP) has been fixed as per the table below.

Sl. No.	Types of pacemaker	Price in Different Hospital (Taka)	Maximum price (Taka)	Decreased price (Taka)
1.	VVI-Single Chamber	65,000/– to 75,000/-	65,000/-	10,000/-
2.	VVI-Single Chamber with Rate Responsive	1,00,000/- to 1,10,000/-	95,000/- to 1,00,000/-	5,000/- to 10,000/-
3.	VVIR (Single Chamber with Rate Responsive) with MRI compatible	2,00,000/- to 2,30,000/-	1,40,000/-	60,000/- to 90,000/-
4.	DDDR (Dual Chamber with Rate Responsive)	1,65,000/- to 2,00,000/-	1,52,000/-	13,000/- to 48,000/-
5.	DDDR (Duel Chamber) with MRI compatible	3,00,000/- to 3,50,000/-	2,80,000/-	20,000/- to 70,000/-
6.	CRT-P (Cardiac resynchronization therapy with Pacing-Bi-Ventricular Pacemaker)	4,00,000/- to 6,50,000/-	4,00,000/- to 4,80,000/-	1,70,000/-
7.	ICD-VR (Implantable Cardioverter Defibrillator – Single Chamber)	4,50,000/- to 6,20,000/-	4,20,000/- to 5,00,000/-	30,000/- to 1,20,000/-
8.	ICD-DR (Implantable Cardioverter defibrillator Single Chamber)	7,50,000/- to 9,00,000/-	6,50,000/- to 9,00,000/-	1,00,000/-
9.	CRT-D (Cardiac resynchronization therapy with defibrillator)	9,00,000/- to 14,07,000/-	8,50,000/- to 10,00,000/-	50,000/- to 4,07,000/-

It may be mentioned that at the time of use of Screw in Lead instead of Tine Lead, the patient has to pay Tk. 5,000/- More.

Export of Medicine Statistics 2016–2017

Sl. No.	Company Name	Taka
1	Beximco Pharmaceuticals Ltd.	1795732300.00
2	Square Pharmaceuticals Ltd (Pabna)	846844882.02
3	Square Pharmaceuticals Ltd (Gazipur)	497328709.32
4	Square Pharmaceuticals Ltd (Chemical Division)	175329560.34
5	Square Formulation Ltd.	30047959.30
6	Square Herbal Division Ltd.	2782433184.00
7	Incepta Pharmaceuticals Ltd. (Savar Unit)	1123776939.78
8	Incepta Pharmaceuticals Ltd.(Dhamrai Unit)	2208497.40
9	Incepta Herbal Nutriceticals Ltd.	762210.00
10	Novartis (BD) Ltd	746926188.00
11	Radiant Pharmaceutical Ltd.	2746411.11
12	Glaxosmithkline (BD) Ltd.	24855149.49
13	Healthcare Pharmaceuticals Ltd.	139565901.00
14	Popular Pharmaceuticals Ltd.	113660874.05
15	Orion Pharmaceutical Ltd.	223459259.44
16	SK+F Pharmaceutical Ltd (Mirpur)	243445862.48
17	SK+F Pharmaceutical Ltd (Gazipur)	
18	General Pharmaceutical Ltd.	95427176,00
19	General Pharmaceutical Ltd (Unit-2)	5953313.00
20	Techno Drugs Ltd.	2326656.00
21	Beacon Pharmaceuticals Ltd.	926225180.00
22	Nipro JMI Co. Ltd.	645553173.02
23	Nipro JMI Pharmaceutical Ltd.	30602595.20
24	JMI Syringes & Medical Devices Ltd.	5324088.00
25	Renata Ltd. (Mirpur)	518527417.60
26	Renata Ltd. (Gazipur)	35392582.40
27	Aristopharma Ltd.	494729208.16
28	The Acme Laboratories Ltd.	454422131.98
29	Global Cap. Ltd.	169466435.25
30	Opsonin Pharmaceutical Ltd.	101295724.00
31	ACI Ltd. (Pharma)	169245659.49
32	Delta Pharmaceutical Ltd.	105278571.00
33	Jayson Pharmaceutical Ltd.	76834629.60
34	Drug International Ltd.	3822560.00
35	Drug International Ltd. (Unit-2)	42050800.00
36	Drug International Ltd. (Herbal Division)	5412800.00
37	Navana Pharmaceutical Ltd.	103653201.00
38	Navana Healthcare Ltd.	4561116.00
39	The IBN Sina Pharmaceutical Ind. Ltd.	45300000.00
40	SanofiAventis Ltd.	46051692.00
41	Remon Drug Ltd.	21511933.85
42	ALCO Pharmaceutical Ltd.	13937843.00
43	Kemiko Pharmaceutical Ltd.	13600937.60
44	Concord Ph. Ltd.	6313140.00
45	Medicon Ph. Ltd.	18700480.00
46	Al-Madina Pharmaceutical	5698720.00
47	Astra Biopharma Ltd.	7893120.00
48	Essential Drugs Chemical Ltd.	30257718.08
49	Biopharma Ltd.	84277360.00
51	Active Fine Chemicals Ltd.	14175600.00
52	Globe Pharmaceuticals Ltd.	185275769.64
53	Globe Drug Ltd.	982800.00
54	Ziska Pharmaceuticals Ltd.	18100000.00
55	Edruc Limited	16567494.00
Total		**13273873523.60**

EXPORT STATISTICS (IN MILLION TAKA)

Year	Finished Products	Raw materials	Total Export	In million USD	No. of Countries
2001	311.80	11.00	322.8	4	17
2002	406.91	43.00	449.91	5.6	32
2003	545.46	87.32	632.78	7.9	51
2004	1400.00	138.97	1538.97	19.2	62
2005	1421.00	147.57	1568.57	19.6	67
2006	2519.98	143.41	2663.39	33.2	61
2007	2347.10	130.31	2477.41	30.9	67
2008	3131.07	146.12	3277.19	40.9	71
2009	3352.07	119.62	3471.69	43.4	73
2010	3274.32	51.19	3325.51	41.6	83
2011	4212.25	49.27	4261.52	53.3	87
2012	5396.21	116.03	5512.24	68.9	87
2013	6038.71	160.56	6199.27	77.4	87
2014	7139.81	190.73	7330.54	91.6	95
2014-15	7683.46	168.00	7851.46	98.1	113
2015	8125.07	195.58	8320.65	104	113
2016	22456.0	14.00	22470.50	280.8	127
2017	31924.57	38.66	31963.23	399.5	145

Our slogan to control Asthma as well as COPD is Education, Caution, Medication and regular follow up

Prof. Dr. Mohammad Rashidul Hassan
Ex-Director
National Institute of Diseases of the Chest and Hospital, Mohakhali, Dhaka
President Bangladesh Lung Foundation

As an eminent Chest Specialist of the country, how do you assess the facilities available in Bangladesh for treatment of chest diseases?

We can divide our facilities into two components:

1. Facilities for diagnosis of chest disease
2. Treatment facilities

In Bangladesh, most of the diagnostic facilities are available in Dhaka City as our country is mainly Dhaka oriented. Some investigation facilities are very costly in our country. For example PET scan is available now for staging of Lung Cancer. But, only a few patients can afford it.

Treatment facilities depend on availability of Pulmonologist, and Thoracic Surgeon. After creation of different posts of chest disease in different Public Medical College Hospitals, treatment facilities are now available in many peripheral centers of Bangladesh.

Would you please tell us about the prevalence of COPD in Bangladesh and its management?

According to first National COPD Prevalence Survey 2007 (BOLD-BD) prevalence of COPD in 40 years or more population was about 21.24%, i.e. about 6.5 million people are suffering from COPD in Bangladesh. It was seen than 86% COPD patients were symptomatic, 63% sufferers were male and 37% were female. 62% sufferers were from urban population, 88% COPD patients were associated with smoking, whereas 80% female COPD were associated with exposure to smoke related to Bio-mass fuel.

Do you think Bangladesh has all the state-of-the-art facilities to diagnose chest disease ailment? Do common people have access to such facilities?

Yes, all facilities are available only in Dhaka city, for example body Plethysmography, PET CT is now available in Dhaka. End bronchial ultrasound (EBUS) is still now only available in National Chest Diseases Institute and Hospital (NIDCH). All types of investigations should be available in peripheral hospitals.

Does NIDCH organize awareness building campaign for the COPD patients?

While I was the Director, NIDCH, and now working as President of Bangladesh Lung Foundation. We (Bangladesh Lung Foundation) are providing training of our doctors by two days master class on COPD and hands on training on spirometry. We want to orient our Physicians on spirometry as main diagnosis of COPD depends on spirometry. But, in our country, spirometry is not so popular among general practitioner as well as among specialist Physicians due to lack of awareness. Even in Europe & USA, 30% COPD patients are not diagnosed early due to less use of spirometry for diagnosis of COPD. It is important to create

> GOVERNMENT HEALTH SERVICES HAS VERY BIG INFRASTRUCTURE WITH HUGE LOGISTICS. PRIVATE SERVICES ALWAYS FOLLOW OUR GOVERNMENT FACILITIES. UNLIKE GOVERNMENT SERVICE, THERE IS NO SUBSIDY IN PRIVATE SECTOR. THAT'S WHY EVERYTHING IS COSTLY IN PRIVATE SECTOR

awareness among General Physicians as 80% people in our country under the treatment of general Practitioners and Specialists Physicians. It is important to understand that control of COPD depends on understanding of this chronic disease.

Do you have all the modern facilities in NIDCH to cater to the needs of Asthma and COPD patients?

National Asthma Center was established in 2005 to serve people with asthma and COPD patients. Those patients attended the center they got diagnostic facilities including pirometry, Arterial blood gas analysis, Bronchoprovocation tests, 6 minutes' walk test and etc. We are trying to give flu vaccine free of cost to all Asthma and COPD patient during early winter season. This year Director General of Health Services supplied 6000 PFS Flu vaccines for our patient and staff.

In addition, we have 70-bedded indoor and 10-bedded ICU to control Asthma & COPD Patients. Non-Invasive ventilator support is unique for our ICU.

What are the challenges in Asthma and COPD care in Bangladesh?

Our slogan to control Asthma as well as COPD is "Education, Caution, Medication and regular follow up are the key words of treatment of Asthma & COPD". We should educate our patients to control Asthma & COPD. 30% patients are still very much concerned to use Inhaler medicine. In 1999, according to 1st National Prevalence Study of Asthma (NAPS) demonstrated that 90% of our people are reluctant to use inhaler. But after 10 years, it is now about 30% people still not using Inhaler devices.

What are your suggestions to the Asthma and COPD patients to lead a normal life despite his being Asthma or COPD?

1st advice: is to live in a smoke free environment. Indoor pollution is most important which triggers pollution and is most important which triggers Asthma and exposure to smoke (including cigarette, Bidi Hukka smoke as well as wood smoke) is most important risk factors for COPD.

2nd advice: Flu Vaccine and Pneumococcal vaccine are available in Bangladesh. All COPD patients should take one of Injection of flu vaccine every year & one pneumococcal vaccine every 3 years interval. Special 10 valent conjugated pneumococcal vaccine (Synflorix) is also available for 6 weeks to 5 years of age.

3rd advice: for COPD patient, if cough exacerbation or color of sputum changed, then take a course of antibitic like Co-Amoxiclav or Azithromycin. But Antibiotic has little role in asthma exacerbation as 90% exacerbation of Asthma is due to virus infection.

4th advice: Asthma patient should continue corticosteroid based inhaler during asymptomatic period as inflammation control is our goal in Asthma. But maximum bronchodilation is our goal in COPD.

5th advice: After control of Asthma and COPD, we should encourage patient for free hand exercise.

6th advice: Always importance to other co-morbidities like allergy, hypertension, diabetes, IHD, peptic ulcer disease, depression, insomnia, anorexia along with treatment of Asthma and COPD.

Compared to government hospitals, charges in private Asthma Care Centres are very expensive. What are the reasons behind this? How can we make it affordable for the common people?

It is not possible to compare government health services with private services. Government health services has very big infrastructure with huge logistics. Private services always follow our government facilities. Unlike government service, there is no subsidy in private sector. That's why everything is costly in private sector.

It is clear that General Physician can manage most of Asthma and COPD patients, if they are oriented properly by appropriate short training program. It is the way to make treatment affordable for the common people. •

Prevent Respiratory Infections

Our lungs have a natural defense system that protects them from dirt and germs. But that isn't enough to prevent all cases of lung disease.

- The American Lung Association says here's what you can do to keep your lungs healthier:
- Don't smoke. If you do, quit.
- Avoid air pollution. On smoggy days, stay inside.
- Wash your hands often with soap and water. An alcohol-based sanitizer may be used in a pinch.
- Practice good oral hygiene. Brush your teeth at least twice daily and see your dentist at least every six months.
- Get the annual flu shot, and ask your doctor about whether the pneumoniavaccine is right for you.
- If you get sick, stay home from work or school until you're feeling better.

Understanding COPD

Chronic obstructive pulmonary disease (COPD) is the third-leading cause of death in the United States, affecting some 16 million Americans and potentially millions more who don't know they have it. According to the National Heart, Blood, and Lung Institute, COPD can make it difficult for people to breathe and harm their quality of life. In COPD, less air flows in and out of the lung's airways due to one or more of these factors:

- The airways lose their elastic quality.
- The walls between some of the air sacs are destroyed.
- The walls of the airways become thick and inflamed.
- The airways make more mucus than usual and become clogged.

Could skipping breakfast feed Heart Disease?

Middle-aged adults who routinely skip breakfast are more likely to have clogged heart arteries than those who enjoy a big morning meal, a new study finds. The findings are the latest to link breakfast to better heart health. They suggest that people who eat breakfast -- especially a hearty one -- are less likely to harbor plaques in their arteries. Plaques are deposits of fat, calcium and other substances that can build up in arteries, causing them to harden and narrow -- a condition called atherosclerosis. Atherosclerosis can lead to heart attacks, strokes and other complications. The new study does not prove that skipping breakfast directly harms people's arteries. "It's not that you skip breakfast, you get plaques," said senior researcher Jose Penalvo, of Tufts University's Friedman School of Nutrition Science and Policy in Boston. But, he said, there are several reasons that forgoing the morning meal could contribute to the risk of atherosclerosis. For many people, skipping breakfast is part of a "cluster" of bad habits, said

Penalvo. These people tend to eat out a lot, and opt for nutritionally dubious convenience foods, for instance. On top of that, Penalvo said, skipping breakfast may have negative effects on appetite-regulating hormones, blood sugar and insulin (a hormone that regulates blood sugar). Prior studies have shown that breakfast fans are less likely to be obese or have diabetes or heart disease.

In all respects of diagnosis and management of asthma in Bangladesh, we do not lag behind the developed countries

Prof. Dr. Md. Ali Hossain
National Institute of Diseases of the Chest and Hospital, Mohakhali, Dhaka

Would you please tell us about the prevalence of COPD in Bangladesh and its management?

Asthma is a one of the most common chronic conditions affecting both children and adults. In Bangladesh about 7 million people (5.2% of total Population) are suffering from asthma (First National Prevalence Study/1999). Among them 5.86% are adult and 7.3% are children. But, day by day numbers of patients are increasing. Study done in 2010 shows 11.6 million people suffering from asthma.

Management of Asthma

Management of asthma include treatment of acute asthmatic episodes and control of chronic symptoms, including nocturnal and exercised induced asthmatic symptoms. Pharmacologic management includes the use of preventers such as Inhaled corticosteroids, Inhaled cromulyn or Nedocromil, Long acting bronchodilators, Theophylline, Leukotriene modifier, and recent strategies such as the use of Anti IgE antibodies (Omalizumab) immunotherapy and bronchial thermoplasty. Prevention and control of asthma risk factors are the important tools of asthma management.

What are the factors that trigger Asthma? Is it curable?

Asthma is a multifactorial disease. Genetic, environmental, social, emotional factors are responsible for developing asthma.

A. Environmental: Allergens

i. Outdoor allergens (pollens, molds or fungus)

ii. Indoor allergens (House dust Mite, Dander, molds, insects-cockroach, hairy doll)

iii. Food allergens (beef, prawn, hilsha and other shell fishes, sea food, eggs, cow's milk, vegetables, nuts and food additives)

B. Irritants

Tobacco smoke, wood smoke, strong odors, perfumes and spray, cosmetics, paints, air pollutants, toxic gases from vehicles and factories

C. Upper Airways Infections:

Viral infections, recurrent common cold.

D. Exercise

E. Certain Drugs

B-Blockers, aspirin, NSAIDs.

Is it curable? Actually asthma is not curable, but would be in remission. If an asthma patient get all the preventer drugs regularly and avoid risk factors, he or she will be free from asthma symptoms, and even, can maintain his/her normal life with or without minimum drugs.

Compared to developed countries, do we have all the facilities for treatment of Asthma patient?

Management of asthma done in Bangladesh is same as in other parts

of the world. The basic principle of management of asthma is:

i. Avoidance of risk factors
ii. Use of preventer drugs regularly
iii. Use of reliever drugs as required basis
iv. Use of recent drugs (Anti IgE anti-bodies)

Is there any research work going on Asthma in Bangladesh?

Yes, a lot of research is going on in Bangladesh, especially in NIDCH. All the doctors who are in MD (Chest Diseases) course are involved in research activities. All research papers are of high standard and published in national and international journals.

> "ALL NECESSARY DRUGS ARE MANUFACTURED BY LOCAL PHARMACEUTICALS COMPANIES IN OUR COUNTRY FOR REMEDY OF ASTHMA. THESE DRUGS ARE IN GOOD QUALITY AND AVAILABLE THROUGHOUT THE COUNTRY. COMPARED TO OTHER COUNTRIES, THESE ARE CHEAPER.

A few years back, we were a bit behind the developed countries in the management of asthma. But for the last 3-4 years, because of excellent growth of our pharmaceutical companies, we acquired all the latest medicine required to control asthma and we have got well equipped laboratory facilities to diagnose asthma from other diseases. So, in all respects of diagnosis and management of asthma in Bangladesh, we do not lag behind the developed countries.

Do we have any specialized hospital to treat patients?

Yes, In Dhaka, National Institute of the diseases of the chest and hospital and National Asthma center is mother organization for treatment of asthma patients. Also in periphery in all medical college we have got well equipped respiratory unit to render services for asthma patients. Respiratory specialist in all these respiratory unit are quite competent enough to combat asthma attack among the asthmatics.

Which group or segments of people are more vulnerable to this disease and why?

Asthma is a global burden, prevalence is increasing day by day. Paediatric population are more vulnerable for developing asthma due to:

i. Early exposure to environmental pollutants such as, particulate matter, ozone concentration, sulphur dioxide etc.
ii. Recurrent respiratory tract infections i.e. Respiratory syncytial virus, Rhinovirus.
iii. Overcrowded population
iv. Low birth weight baby
v. Maternal smoking habit
vi. Indiscriminate use of antibiotics in early age
vii. Family h/o asthma and atopy

What advice you have for Asthma patients to enable them to lead normal life?

Living with asthma can be challenging, but if one pays full attention, he can lead an active, healthy normal life. For these, Asthma patients will be able:

i. To learn about the natural h/o disease, trigger factors, management plan of exacerbations and self-management plan.
ii. To learn how to monitor his asthma severity by recording peak flow with peak flow meter
iii. To learn regular use of preventer drugs and rescue medications during exacerbations
iv. To learn life style modifications and environmental changes care

Do you think our local pharma companies are manufacturing all the necessary drugs for remedy of Asthma? What about quality of these drugs?

Yes, all necessary drugs are manufactured by local pharmaceuticals companies in our country for remedy of asthma. These drugs are in good quality and available throughout the country. Compared to other countries, these are cheaper.

What role of Govt. or NGO or Media can play in building awareness about Asthma?

Asthma is a non-curable but easily controllable disease. So, awareness about the disease is very important. Early diagnosis and treatment can help near total control. In all sector, Govt., NGO or media can play an important role for asthma awareness. Such as:

i. Govt. can formulate law against use of tobacco
ii. Health insurance card for all patients
iii. Development of echo-friendly housing for homeless people
iv. Asthma education topics in primary books
v. Development of residential and industrial town in different places
vi. Organizing regular seminar, symposium about asthma
vii. Print and Electronic Media can show how to use asthma medication
viii. To overcome of fear about inhaler. ●

Defining Medical Negligence

Dr. C.M. Francis
MBBS, Ph. D

Negligence is a careless act and may result in harm. A person is said to be negligent when he/she acts without care in regard to the possible harmful consequence of his/her action. "Negligence is the omission to do something which a reasonable man, guided upon these considerations which ordinarily regulate the conduct of human affairs, would do, or doing something which a prudent and reasonable man would not do." (Salmond, Law of Torts, 19th edition)

Halsbury's Laws of England (4th edition) gives the general principles of negligence: "Negligence is a specific tort and in any given circumstances is the failure to exercise that care which the circumstances demand... it may consist in omitting to do something which ought to be done or in doing something which ought to be done either in a different manner or not at all."

Where there is a duty to exercise care, reasonable care must be taken to avoid acts or omissions which can be reasonable foreseen to be likely to cause personal injury to persons or property."

Lord Wright said: In strict legal analysis, negligence means more than heedless or careless conduct, whether in omission or commission; it properly connotes the complex concept of duty, breach and damage thereby suffered by the person to whom the duty was owing." Medical negligence occurs when there is want of reasonable degree of care and skill on the part of a member of the medical profession (or hospital or other health care institution) leading to harm. When a member of the medical profession (or a hospital or other health care institution) falls short of the standard of ordinary skilled person and the patient suffers harm, the patient (or the heirs) has a right of action for damages.

Manusmriti says: ''All physician who treat their patients wrongly shall be liable to pay fine." (Sacred Books of the East, Vol.2.5)

BrihaspathiShruti has the following: "A physician who, though unacquainted with drugs and their effects or is ignorant of the nature of diseases, yet takes money from the sick (for giving treatment), shall be punished like a thief."
(Sacred Books of the East, Vol. 15)

What are the duties of the doctor?

Law imposes a duty of care upon every individual to take reasonable care for the protection of others. This is so in the relation of doctors to their patients. When consulted by a person, the doctor owes the person a duty of care in deciding

- Whether to undertake the care of the person
- What advice or treatment to give; and
- Administration of treatment

The duty of a medical practitioner arises from the fact that, unless it is done with proper care and skill, it can cause physical harm. There is no warranty of success when treatment is given. A practitioner is held liable, i.e. his/her diagnosis/treatment is so palpably wrong as to prove negligence (AIR 1975 Bombay 306)

What is the degree of care required by a doctor?

It is the law that a practitioner must bring to his/her task a reasonable degree of care. The standard required will be that of an average practitioner of the class to which he/she belongs or holds to belong. In the case of a specialist, a higher standard is expected.

"Law imposes a duty on everyone to conform to certain standards of conduct for the protection of others. Persons who undertake work requiring special skill must not only exercise reasonable care but measure up to the standard of proficiency that can

The duties which a doctor owes to his patient are clear. A person who holds himself out ready to give medical advice and treatment impliedly undertakes that he is possessed of skill and knowledge for the purpose. Such a person when consulted by a patient owes him certain duties, namely, a duty of care in deciding what treatment to give or duty of care in the administration of that treatment.

be expected from persons of such profession. Failure to conform to the required standard of care resulting the material injury is actionable negligence, if there is proximate connection between the defendant's conduct and the resultant injury. A surgeon or anesthetist will be judged by the standard of an average practitioner of the class to which he/she belongs or holds himself/herself out to belong. In the case of specialists, a higher degree of skill is called for."

The law does not exact of the members of the medical profession utmost degree of care and skill attainable or known to the profession but they should possess and exercise reasonable degree of skill, knowledge and care ordinarily possessed and exercised by members of their profession under similar circumstances. However, the law does not recognize that medicine is a progressive science; therefore, in determining the degree of care and skills, regard will be had to the state of advancement of the profession at the time and place of treatment.

Mc Nair. J, in Bolam vs. Friern Hospital committee (AIIE. R. 118, 1957 (2) enunciated the law: "A doctor is not guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art... At the same time, that does not mean that a medical man can obstinately and pigheadedly carry on with some old technique if has been proved to be contrary to what is really substantially the whole of the informed medical option."

Liability

Liability arises when there is a breach of duty resulting in injury. Three factors have to be proved to establish liability by a doctor, where there is alleged deviation from normal practice:

- There is a usual and normal practice
- The defendant (doctor) has not adopted the practice
- The course the doctor adopted is one which no professional ordinarily would have taken, if he/she had been acting with ordinary skill.

Negligence would not be inferred merely because there was body of opinion which took another view. There may be more than one perfectly proper standard; if the medical professional conforms with one of those standards, then he/she is not negligent.

Vicarious liability

Ordinarily, the person who is negligent is held responsible. But the employer (hospital or other health care institution) may be responsible for the negligence of the employee. The responsibility of hospital authorities includes the obligation to treat; they are liable, if the persons employed by them to perform the obligation on their behalf act without due care.

Negligence of other health cares

Ordinarily, we think of the medical professional but other health care professionals and workers may be negligent and the hospitals become liable. The most important among them are the nurses. A nurse may be negligent in

- Mistaking and administering a wrong drug;
- Breaking a needle while giving injection, leaving a piece in the body;
- Manipulating a bed, without warning the patient of the possible danger;
- Failing to call the obstetrician in time for delivery;
- Failing to test a patients' broken leg for sufficiency of circulation and
- Not bestowing care while applying hot- water bottle making a wrong sponge count, leaving one in the patient's abdomen after operation is not uncommon. The overall responsibility to ensure that the swaba and Instruments are not left in the body of the patient rests with the surgeon.

"As it is the task of the surgeon to put swabs in, so it is the surgeon's task to take them out."

[If it is one that would not have been made by a reasonably competent professional man professing to have the standard and type of skill that the defendant holds himself/herself out as having, and acting with ordinary care, then it is negligence. If on the other hand, it is an error that such a person, acting with ordinary care, might have made, then it is not negligence.]

Error of judgment

Sometimes a plea is made that the injury was caused as a result of an error of judgment and not due to negligence. An error of judgment may or may not be negligent.

"The true position is that an error of judgment may or may not, be negligent; it depends on the nature of the error. If it is one that would not have been made by reasonably competent professional man

professing to have the standard and type of skill that the defendant holds himself/herself out as having, and acting with ordinary care, then it is negligence. If on the other hand, it is an error that such a person, acting with ordinary care, might have made, then it is not negligence."

(Lord Fraser, 1981, I All ER 267, quoted by Hon 'ble S. Sabir Ahmed & G B Pattanaik, JJ, AIR 1998 Se 1801)

Misadventure

Occasionally, injury may be caused to the patient by an unintentional or accidental act, even after taking all due precautions and care. It is an inevitable hazard of medical practice; there is no negligence, if due care has been exercised and there is no breach of duty.

Onus of proof

The onus of proof of negligence rests squarely on the plaintiff. Justice Chagla and Baghawati of the Bombay high court stated: "The law on the subject is really not in dispute. The plaintiff has to establish that there had been a want of competent care and skill on the part of the defendant to such an extent as to lead to a bad result. The plaintiff has also to establish the necessary connection between the negligence leading to harm in all common situations, there can be circumstance in which the defendant will have to establish that there was no breach of duty.

Neither the very highest nor a very low degree of care and competence, judged in the light of the particular circumstances of each case is what the law requires and a person is not liable in negligence because someone else of greater skill and knowledge would have prescribed different treatment or operated in a different way; nor is he guilty of negligence if he has acted in accordance with a practice accepted by a responsible body of medical men skilled in that particular art, even though a body of adverse opinion also existed among medical men.

... Whenever they (local authorities, governing boards or any other corporation) accept a patient for treatment, they must have reasonable care and skill to cure him of his ailment. The hospital authorities cannot, of course do it by themselves; they have no ears to listen through the stethoscope and no hands to hold the surgeon's knife. They must do it by the staff which they employ and if their staff are negligent in giving treatment they are just as liable for their negligence as is anyone else who employs others to do his duties for him... it is no answer for them to say that their staff are professional men and women who do not tolerate any interference by their lay masters in the way they do their work... because they employ the staff and have chosen them for the task and have in their hands the ultimate sanction for good conduct, the power of dismissal.

Legal remedy

Recourse may be had by the person affected in various ways. It depends on the type of liability of the law under which claim is made.

Criminal liability: Section 304A, IPC, provides for punishment for grossly rash or grossly negligent act, which is proximate, direct or substantive cause of patients death. Sections 337 and 338 also provide for punishment for rash or negligent act endangering human life or the personal safety of others.

Law of Torts: This is a judge-made law and it comes into effect whether the patient pays or not.

Consumer Protection Act 1986: This is a comprehensive piece of legislation and provides for quicker remedy and without incurring large expenses as court fee etc.

Damages: If the negligence cause harm to the patient, then the patient (or his/her heirs) is the entitled to compensation or damages. The damages may be for

- Pecuniary losses (special damages) &
- Non-pecuniary losses (general damages)
- Special damage include
- Expenses incurred for treatment as a result of negligence
- Loss of earning &
- Future momentary losses, because of disabilities The special damages must be pleaded and proved
- General damages include payment for
- Pain & suffering
- Loss of amenities of the life, and
- Shortened expectation of life

The general damages will be decided by the court. •

Source: Health Action

NIDCH involved in various research activities in the field of Chest Diseases

Prof. Dr. MD. Shahedur Rahman Khan
Director
National Institute of Diseases of the Chest and Hospital (NIDCH), Dhaka

As Director of NIDCH, please tell us about the services available in your organization

Q&A

NIDCH is a tertiary institute, a Center of Excellence in Bangladesh representing chest disease treatment and also an institute for higher degrees, post-graduation degrees in chest medicine and surgery. We offer 5 post-graduate degree-DTCD, MD chest, FCPS pulmonology, MS thoracic surgery, and FCPS thoracic surgery. You see our outdoor services are attended by respective unit chief (Professor/ Associate Professor) with his team doctors besides the resident physician and resident surgeon's team. Outdoor services are open from 8 am to 2 pm. Our emergency services are open for 24 hours round the clock. Emergency medical officer with his staff and logistic support control the emergency situation for both Medical and Surgical patients. Our indoor service includes Medicine, Thoracic Surgery, Pathology and microbiology, Radiology & Imaging Transfusion Medicine, Anesthesia, ICU, RCU & Physical Medicine. In 16 separate blocks, the hospital has accommodation of 690 patients suffering from Pulmonary Tuberculosis and allied diseases of the chest. Of the total 280 beds are allotted for Non-Tubercular Chest diseases and 390 for Tuberculosis cases. The Hospital has 10 beds each for ICU and RCU. In order to facilitate management of patients, the Hospital beds are divided and put in 10 medical units & 8 surgical units with care of highly experienced Professor or Associate Professor as unit chief. It has some specialized investigational facilities like CT Scan Chest, CT-guided FANC, USG, Pleural Biopsy, FOB, EBUS-TBNA, Fluoroscopy, VATS, Sleep Lab. NIDCH is also involved in various research activities in the field of chest diseases. You see, NIDCH is the only institute of Bangladesh which extend modern specialized medical and surgical treatment to complicated chest and TB patients and also offer training of medical manpower in the specialization of tuberculosis and chest disease. We have 4 professional organizations to gear up the medical science related to chest disease & chest surgery i.e. Asthma Association of Bangladesh, The Chest & Heart Association of Bangladesh, Bangladesh Lung Foundation, Bangladesh Society of Allergy and Immunology. Two journals are being published by our affiliated associations Bangladesh Journal of Pulmonology & Chest & Heart Journal. We also published the 5th edition of the standard national guidelines earlier this year on Asthma & COPD management. At the same time, we are performing CME (Continuous Medical Education) Program all over the country to disseminate the latest knowledge among the physicians.

What are the common Chronic Respiratory Diseases prevalent in Bangladesh? What is the status of management of these diseases in our country?

The most prevalent chronic respiratory diseases in our country are Pulmonary Tuberculosis, Asthma & COPD. Chronic bronchitis & emphysema are two diseases which often coexist in COPD. Tubercular Pleural effusion is another common chronic disease, which is the build-up of excess fluid between the layers of linings outside the lungs. Other diseases like pulmonary fibrosis, ILD bronchiectasis, occupational lung diseases including occupational Asthma pneumoconiosis, silicosis etc. Actually, management of the diseases I mentioned is almost in parallel with the world standard. We are no more lagging behind in the management of these diseases. But, problem is that our people are less aware of their conditions. So they make delay to consult the physicians, thereby making the diseases more complicated. Otherwise, the standard of treatment in our country is at par with the developed countries, at least in this institute.

As an eminent Chest Specialist of the country, how do you assess the facilities available in Bangladesh for treatment of Chronic Respiratory diseases?

Bangladesh is a densely populated country, with a population of 16 crore people according to government statistics. The number of qualified doctors and specialists in proportion to the patients is very low. So, we are facing a very poor doctor-patient ratio in our country. We need more and more specialists, we need more & more centers with proper treatment facilities and

diagnostic tools. We have many centers here in Dhaka, including NIDCH. There are district level Chest hospitals also. But in upazila level, there is no organized dedicated chest hospital and asthma medications, especially essential inhalers and facilities are not easily available. We have sputum examination facility, GeneX-pert investigation throughout Bangladesh. It is possible to give treatment to the patients. Even the rural dispensaries offer some asthma medications & full range of anti-tuberculosis medication. A network still exists, but we need a much stronger network. The treatment of chronic respiratory disease in the rural level needs to be more updated. The patients also need to be more aware and educated about their illness, so that they go to the doctors without wasting time.

What are the challenges in Asthma & COPD Care in Bangladesh?

Let me highlight some important points. Firstly, the lack of education and awareness among the mass population. Although literacy is increasing, people are still not aware. People should come early to the doctors to avail treatment. Secondly, risk factors of COPD and asthma i.e. pollution, smoking & other occupational hazards are not strictly monitored or controlled. So, we are lagging behind in taking preventive measure as well. Thirdly, the medications for prevention & management of asthma and COPD are very costly. The cost of various inhalers ranges from about 200 taka to 4000 taka. So, these are tough for the general people to buy and to use regularly. Chronic respiratory illnesses require years of treatment or even lifelong. So, to ensure regular use of medication, people need support from the government & NGO's, as well as from affluent class of the society.

Do we have any specialized facilities in Bangladesh dedicated to Chronic Respiratory diseases?

National Institute of the Diseases of the Chest and Hospital is a specialized institute. We have the state-of-the-art treatment and diagnostic facilities. For Interventional Pulmonology, we offer Rigid Bronchoscopy, Medical Thoracoscopy, Autofluorescence Bronchoscopy (AFB), Endobronchial Ultrasound-Transbronchial Needle Aspiration (EBUS-TBNA), Bronchial provocation test (BPT), Complete Pulmonary Function Test (CPET), Cardiopulmonary Exercise Testing (CPET).

In the near future, we'll also provide airway dilatation, laser surgery, argon plasma coagulation (APC), cryosurgery, airway sending, bronchoscopic lung volume reduction (BLVR) etc. We also have a fully equipped sleep laboratory for diagnosis & the treatment of sleep disorders. Alongwith that, we are doing CME and free medical camps. Asthma Association is planning to establish an Asthma Bank where all the expensive medicines will be collected from donors, NGOs and affluent society, to be distributed all over the country. It is our will to render service to the people one step further.

Which group or segments of people are more vulnerable to this disease and why?

You see, our respiratory system is an open one. Our circulatory system is closed, our gastrointestinal system is closed but the respiratory system is open to the environment just like our skin. When you are taking a breath, you are taking the surrounding air, fresh or polluted is a crucial risk factor. People who are exposed to pollutants become vulnerable to respiratory diseases. Occupational environment may contain huge factors contributing to respiratory diseases. People working in chemical factories, tanneries, sand blasting, sand crushing, asbestos manufacturing, garment factories etc., who work without proper safety measures are more at risk. They are vulnerable to occupational lung disease, occupational asthma and different types of pneumoconiosis. Chronic respiratory diseases are also common in immune -compromised patients i.e. those who are diabetic, those who have chronic kidney disease, those who have undergone transplantation, people with chronic liver disease, people with auto- immune diseases etc. as they are defenseless against pollution and inflammation. The same is true for cancer patients undergoing chemotherapy who are immunosuppressed. However, in Bangladesh, smoking is the number one cause of such diseases. Non-smokers who are exposed to second hand smoking are also at risk for developing COPD. In rural areas, women are being affected by the smoke from cooking which are not ventilated. These are the way our people are becoming exposed to risk factors so that respiratory illness even COPD, asthma, bronchial carcinoma they are increasing and getting more and more prevalent.

How life style, pollution and smoking are responsible for triggering the respiratory disease?

Life style is very important. Although we need plenty of food now due to decreased poverty, people are still malnourished. Because of abundance of fast food, rich people even do not get proper and balanced nutrition. So, despite eating more, they get malnutrition. If you live in a congested or overcrowded area, you are more at risk than people who live in well-ventilated area surrounded by greenery. You see smoking is also a way of air pollution. Smokers and non-smokers who are exposed to passive smoking, both are susceptible to COPD. It is also one of the causes of the exacerbation of asthma. Then there are pollution from auto-vehicles. Before introduction of CNB, the concentration of lead in the air of Dhaka city was all time high. On the other hand, the industries pollute the environment more than anything. When you go to the Buriganga River, you will see the water is totally polluted due to the disposal of both industrial and domestic wastes. Labors who are working in the industries are not provided with proper safety measures.

Unknowingly, they are taking the sand and dust particles to their lungs and thus become stone and in certain stage the silicosis develops.

Government is already taking different steps including prevention of air pollution, restriction of smoking. But, the real results depend on how the rules are implemented and practiced among general people. ●

We have national guidelines for treating Asthma, COPD and Tuberculosis patients

Prof. Dr. Bashir Ahmed
Professor, Respiratory Medicine
National Institute of Disease of the Chest & Hospital
Mohakhali, Dhaka

As an eminent Chest Specialist of the country, how do you assess the prevalence of chest diseases in Bangladesh?

I am a Chest diseases specialist working for about 33 years in different hospitals of Bangladesh like Union Health Centres, Upazilla Health Complexes, District Sadar Hospitals, Chest Diseases Clinic, Dhaka Medical College hospital and National Institute of Diseases of the Chest and Hospital. In case of respiratory diseases, we don't have any definite prevalence study. We have only Asthma & COPD prevalence study. But we have so many other diseases of respiratory system like pneumonia, lung abscess, bronchiectasis, lung cancers, occupational lung diseases and pulmonary TB etc in our society. As an experienced chest physician, from my observation in different hospitals and private chamber patients, I can say prevalence of chest diseases in our country is not less than 30% among all diseases.

Do you think Bangladesh has all the state-of-the- art facilities to manage chest diseases? Does common people have access to such facilities?

Yes, Bangladesh has all the facilities to manage chest diseases. We have one National Institute of Diseases of the Chest and Hospital, 4 divisional Chest Disease Hospitals, 44 Chest Diseases Clinics, eight -20 bedded Chest Disease Hospitals & respiratory units in some of our medical colleges to treat chest disease patients. Besides, internists are also giving treatment to chest disease patients. We have no post of chest disease specialists in District Sadar Hospitals and in all medical colleges. We have no chest disease specialists to act at Upazilla Hospitals. Due to lack of posts in above hospitals, our people are not getting services from these chest disease specialists. We have national guidelines for treating Asthma, COPD and Tuberculosis patients and we are giving treatment according to these guidelines- which are internationally recognized. By creating posts of chest disease specialist in District Sadar Hospitals and all medical colleges, we can give all facilities of treatment to common people.

Would you please tell us about the prevalence of COPD in Bangladesh and its management?

In 2007, a study on COPD known as BOLD- BD (Burden of Obstructed Lung Disease in Bangladesh) revealed the prevalence of COPD in general population as 4.32%. Treatment includes advice to quit smoking, immunization against influenza and pneumonia. Other treatment includes, use of long acting bronchodilators in oral and inhalation forms and use of inhaled corticosteroids on the basis of severity. During exacerbation antibiotics and systemic steroid are also given. Rehabilitation programme for COPD patients includes selection of diet, breathing exercise and chest physiotherapy has great importance. •

> OUR PHARMACEUTICAL COMPANIES ARE PRODUCING ALMOST ALL TYPES OF DRUGS FOR THE MANAGEMENT OF CHEST DISEASES. THE QUALITY OF THESE DRUGS ARE UP TO THE INTERNATIONAL STANDARD. ONLY A FEW DRUGS FOR ASTHMA, MDR AND XDR TB TREATMENT ARE YET TO BE PRODUCED LOCALLY

What are the factors that trigger Asthma? Is it curable?

Asthma is a chronic inflammory disease and multi-trigger factors includes domestic or occupational allergens (e.g., house dust mite, pollens cockroaches), tobacco smoke, exercise, cold, viral infection, stress etc can trigger the disease. These responses are more likely when asthma is uncontrolled. Some drugs can trigger asthma, e.g., beta- blockers, and (in some patients) aspirin or other NSAIDs. Asthma can be controlled. With modern treatment an Asthma patient can lead a normal life.

Which group or segments of people are more vulnerable to this disease and why?

Asthma is more prevalent in children and young adults (5-21 years). But almost in the young teens (12- 14 years) the prevalence is highest (10.3%). Exact cause is yet to be known. Poor and low socio- economic people are easy victims of asthma and other chest diseases. Garment workers, and people living in overcrowded area are easy victims of asthma and TB.

What are the challenges in Asthma & COPD care in Bangladesh?

Increasing air pollution, high cost of inhaler drugs, easy availability of tobacco products, superstition regarding these diseases are main challenges. Strong campaign against tobacco is also a challenge.

How life style, pollution and smoking are responsible for triggering the respiratory diseases?

A number of studies have reported associations between air pollution exposures and asthma. For example, researchers have found an association between increased hospital admissions for asthma and particulate matter, an outdoor air pollutant. Air pollution, such as ozone and particle pollution, can make asthma symptoms worse and trigger attacks. Adults and children with asthma are more likely to have symptoms when ozone and particle pollution are in the air. Ozone is often found in smog and particle pollution is often found in haze, smoke, and dust. Ozone is often worst on hot summer days, especially in the afternoons and early evenings. Particle pollution can be bad at any time of year, even in winter.

What advice do you have for Asthma patients to enable them to lead normal life?

People living with asthma have to accommodate their long- term condition within the context of their daily life. They may need to remember to use regular medication to keep a supply of inhalers, avoid their triggers where possible, cope with the variability of asthma and the impact of this has on them and their family's lifestyle. Crucially they have to recognize when their asthma is deteriorating, and make decisions about when to adjust their medication, when to use emergency treatment and when to seek physicians' help.

What is the status of Tuberculosis disease in our country?

Bangladesh ranks 6th in the world TB burden countries. We have achieved a lot of our goal in treatment and control of TB in our country. Now number of smear + ve pulmonary TB patients are 225/ lac and number of total TB patient in one lac are 405. Last year i.e in 2016 total number of TB patients were 223000. Among them pulmonary TB patients were 180000, Smear + ve new pulmonary TB 130000, retreatment smear + ve cases 15000, Smear – ve pulmonary TB 350000. Extra pulmonary TB patients were 43000 and Multidrug Resistant (MDR) TB patients were 800, XDR were TB 10 in number. Amongst pulmonary TB patients, cure rate is 93% and amongst MDR TB patients, cure rate is 73% in our country.

Do you think our local pharma companies are manufacturing all the necessary drugs for management of chest diseases? What about the quality of these drugs?

Our Pharmaceutical Companies are producing almost all types of drugs for the management of chest diseases. The quality of these drugs are up to the international standard. Only a few drugs for Asthma, MDR and XDR TB treatment are yet to be produced locally. •

Quality management – A way forward

'Success is the sum of small efforts repeated day-in and day-out'

Dr. Raman Mohan Singh[1] & **Smt. Sujata S. Kaisare**[2]

For a laboratory to achieve its quality goals true level of sincere efforts, intelligent direction and skillful execution should be put in their work each day. Doing the right thing comes from an organization that instills quality into the fabric of work culture. The organization which is committed to its target creates a culture where people understand and respect the significance of following quality norms. As Henry Ford has correctly said "Don't find fault, find remedy", it is necessary to find the solution to the issues prevailing than focus on the source of the issues. The idea of quality as perceived by the industry is of the QA manager and QA department or some specified personnel directly or officially concerned with the management. But Quality can be managed if any only if all members feel equally responsible to achieve the quality goals.

Laboratory is subject to various national and local requirements and it is very complicated to track compliance with all the listed specifications. Hence, the need of a road map is essential for quality that ensures that each laboratory contributes its best in continually meeting all the norms. An ideal model of a laboratory is one which meets the important relation between quality activities designed and supported by the technical activities to produce 'Good Laboratory Practiced".

Quality Management ensures that an organization or services rendered are consistent. It has four main components: Quality planning, Quality Assurance, Quality Control and Quality Improvement. Quality Management utilizes quality assurance and control of processes to achieve more consistent and reliable quality results.

Customer satisfaction is the backbone of quality management. Knowledge management is an important tool which enables a laboratory/organization in promoting and achieving quality standards. Sustained success is attained when an organization attracts and retains the confidence of customers understanding present and future needs of the industry and contributes to sustained success of the organization. Many aspects which attribute in enhancing the organizations results are:

- Continuous Improvement
- Relationship Management
- Rational Leadership
- Customer Focus
- Factual approach to decision
- System approach to management

The term 'quality' has a relative meaning. The ISO defines it as "The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs." When projected on analytically work, quality can be defined as "Delivery of reliable information within an agreed span of time under agreed conditions at agreed cost and aftercare" Laboratory quality means accuracy, reliability and timeliness of test results. All aspects of the laboratory operations must be reliable in order to be useful in a clinical or public health setting. Quality Management is considered as a wider interpretation.

Sound management of quality will enable the laboratories to attain trust globally for the test results generated.

Source: The Pharma Review

DID YOU KNOW ?

Medicines for teeth may lead to diarrhea

Antibiotics prescribed by dentists can allow the growth of serious and potentially deadly bacteria that cause severe diarrhea, a study warns. Antibiotics kill bad and good bacteria in the gastrointestinal (GI) system. Wiping out the protective bacteria can allow the growth of Clostridium difficile (C diff) bacteria, leading to severe and potentially deadly diarrhea. C diff can occur after just one dose of antibiotics and is one of the top tree most urgent antibiotic resistance threats identified by the US Centers for Disease Control and Prevention (CDC). Researchers from Minnesota Department of Health (MDH) in the US interview 1,626 people with community associated C diff between 2009 and 2015.

- Eating high-potassium food such as avocados and bananas can protect against vascular clacification or hardening of the heart's arteries which is a risk factor for heart attack and stroke.

Source: Health Action

ACE inhibitors and Angiotensin II Receptor Blockers

L'Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) France has reminded health-care professionals that the use of angiotensin converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs) are contraindicated during the second and third trimesters of pregnancy and not recommended for use during the first trimester. ACE inhibitors and ARBs are indicated for the treatment of hypertension in adults.

Statins: Additional Adverse Effects Found

Recent data suggests a number of additional side effects of statins, namely: ● Treatment with any statin may be associated with depression, sleep disturbances, memory loss and sexual dysfunction. ● Statin therapy is associated with a slightly increased risk of development of diabetes. ● Statins may rarely be associated with interstitial lung disease. Patients should advised to seek medicalattention if they symptoms such as dyspnea, non-productive cough or detgerioration in general health (e.g. fatigue, weight loss and fever). ● Simvastatin Dose: (a) Due to increased risk of serious, life-threatening myopathy, no patient should be initially started on 80mg dose. (b) Use other treatments if patients' LDL targets aren't met with the 40mg daily dose. (c) Patients concurrently on amiodarone, or verapamil or diltiazem should not be prescribed more than 10mg daily. (d) Patients concurrently on amlodipine or ranolazine must not receive more than 20mg daily. € Concurrent use of itraconazole, ketoconazole, posaconazole, erythromycin clarithromycin, telithromycin, HIV protease inhibitors, nefazodone, gemfibrozil, cyclosporine, and danazole is contraindicated.

Febuxostat

The US Food and Drug Administration (FDA) has alerted the public that preliminary results from a safety clinical trial showed an increased risk of heart-related death with febuxostat (Uloric®). Febuxostat is approved to treat gout in adults. The product information for febuxostat already carries a warning about cardiovascular events, based on information from clinical trials that showed a higher rate of heart-related problems in patients treated with febuxostat compared to an alternative treatment, allopurinol. These problems included heart attacks, strokes and heart-related deaths. As a result, the FDA required an additional post market safety clinical trial to increase understanding of these differences.

Intraocular injections of a compounded triamcinolone, moxifloxacin and TMV formulation

The US FDA has stated that the prophylactic use of intraocular vancomycin, alone or in a compounded drug combining multiple active ingredients such as triamcinolone, moxifloxacin, and vancomycin (TMV) formulation, is generally not recommended for use during cataract surgery because of the risk of haemorrhagic occlusive retinal vasculitis (HORV). Intraocular vancomycin is used by many ophthalmologists during cataract surgery with the intent of preventing postoperative endophthalmitis. There is no FDA-approved vancomycin formulation for intraocular injection. The formulation is usually prepared at the surgical site or obtained in advance of surgery from a compounding pharmacy.

Hyoscine butylbromide ampoule

The Therapeutic Goods Administration (TGA) has updated product information for hyoscine butylbromide (Buscopan®) to include a caution regarding the use of hyoscine ampoules in patients with pre-existing cardiac conditions (for example cardiac failure, coronary heart disease). The Australian product information for hyoscine butylbromide already lists tachycardia, decreased blood pressure and anaphylaxis as potential adverse effects, but the product information has been updated to include a stronger warning in the precautions section because these adverse events can be more serious in patients with cardiac conditions. Monitoring of these patients is advised and emergency equipment and personnel trained in its use must be readily available.

Ibrutinib

The Medicines and Healthcare Products Regulatory Agency (MHRA) has updated the product information of ibrutinib (Imbruvica®) to include ventricular tachyarrhythmia (common) and hepatitis B virus reactivation (uncommon) as adverse reactions. Opportunistic infections are already listed in the product information of ibrutinib. Ibrutinib is indicated for the treatment of adult patients with: • mantle cell lymphoma who have received at least one prior therapy • chronic lymphocytic leukaemia (CLL), including CLL with deletion 17p • Waldenström's macroglobulinaemia.

Cleanrooms assure quality as per cGMP norms

P Mandal

The manufacturing processes in pharmaceutical sector should be well controlled to prevent contamination from raw materials, finished products and workforce as well as accommodating services, such as processing unit and equipment. The key purpose of a cleanroom is to provide the quality assurance of product according to current good manufacturing practices. The cleanroom facility should prevent contamination of the product and should be equipped with sophisticated monitoring devices.

The need for cleanrooms

The cleanroom is a modern phenomenon. The dirt-free conditions provided by the cleanrooms are essential for manufacturing electronic components and dirt and bacteria-free conditions are essential for manufacture of drugs and other medicinal products. Without clean conditions, products get contaminated and either malfunction or become hazardous to people. For these reasons cleanrooms are widely used in pharmaceutical industries and also in electronic industries.

Cleanrooms are also now used for the manufacturer of items used in computers, cars, aeroplanes, spacecraft televisions, disc players and many other electronic and mechanical devices, besides the production of medicines, medical devices and convenience foods.

In recent years there has been a considerable increase in the number of cleanrooms. This rapid increase in the use of cleanrooms has created a demand for good quality information about cleanrooms that is free from the intensive publicity of sales and marketing jargon. Information is also required to teach production personnel about their working environment, and how to conduct themselves within the cleanroom to minimize contamination.

In a cleanroom, the introduction, generation and retention of particles are minimized. This is achieved, firstly, by supplying it with exceptionally large qualities of air that has been filtered with high efficiency filters.

This air is used to:

- Dilute and remove the particles and bacteria dispersed from personnel and machinery with the room;
- Pressurize the room and
- Ensure that no dirty air flows into the cleanroom.

Secondary, a cleanroom is built with materials that do not generate particles and can be easily cleaned. Finally, cleanroom personnel use clothing that envelope them and minimizes their dispersion of particles and micro-organisms. According to the process, cleanrooms can also control the temperature, humidity, sound, lighting and vibration.

The primary purpose of a cleanroom is to ensure production of a product with high quality. The cleanrooms range from very small chambers, called micro-environments, to large scale rooms, called ballrooms. They are used in pharmaceutical industry as well as in other industries such as biotechnology, nanotechnology, microelectronics etc.

Production process need to be controlled effectively:

Cleanrooms are designed to control and limit temperature, humidity, air pressure and particles. As of late, cleanrooms have become crucial as pharmaceutical products should be manufactured under the requirements of good manufacturing practices. A cleanroom can be termed as a room in which the concentration of air borne particles is well regulated and is built and used in a manner to minimize the introduction, generation, and retention of particles inside the room and in which other relevant parameters, viz. temperature, humidity, and pressure are controlled as per requirement. The basic function of a cleanroom is to protect the manufactured product from contamination. In the pharmaceutical production, the economical survival of the manufacturing company depends on the safety of the finished product. So, it is necessary to know the potential sources of contamination, which could include the working environment itself.

Bacteria

Bacteria – in microbiology is a single-celled or non-cellular spherical or spiral or rod-shaped organism lacking chlorophyll that reproduce by fission. Important as pathogens and for biochemical properties, bacteria are the most significant contaminant in a pharmaceutical cleanroom. Normally, bacteria

enters a clean room through the equipment and materials which are taken in and taken out from the cleanroom.

The workforce is also responsible in spreading the contamination in a cleanroom. So, it is important to know the number of work-force employed in a cleanroom. Health, hygiene and clothing of the workforce are very significant factors to maintain the desired quality of specifications in a clean room and airborne contamination is very common source, which occur during transfer of materials from cleanroom to environment and vice-versa. Special attention is required to prevent airborne contamination. Airborne contamination from outside is a usual problem for cleanroom. To reduce the holes in cleanroom, construction should be minimized. It is possible to reduce contamination transfer to prevent an unacceptable flow of air from a lower area to a higher area.

Contamination

Contamination is a process that causes materials, surfaces or environment to be soiled or adulterated with contaminating substances. There are two broad categories of surface contaminants: film type and particulates. These contaminants can produce a killer defect in a miniature circuit. Film contaminants on only 10 nanometres can drastically reduce coating adhesion on a wafer or chip. It is widely accepted that particles of 0.5 microns or larger are the target. The generated contaminants must be continually removed from the air. There are several sources of contamination such as process equipment, personnel and surfaces. An important source of particulate contamination is process equipment.

Cleanroom design

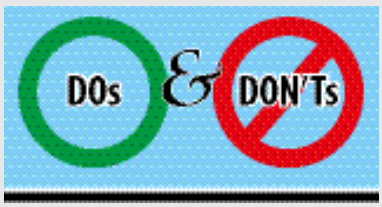
Cleanrooms are designed to maintain positive pressure, preventing unclean (Contaminated) air from flowing inside and less-clean air from flowing into clean areas. The idea is to ensure that filtered air always flows from cleanest to less-clean spaces. In a multi-chambered cleanroom, for instance, the cleanest room is kept at the high pressure.

Pressure levels are set so that the cleanest air flows into space with less clean air. Thus, multiple pressure levels may need to be maintained. A differential air pressure of 0.03 to 0.05 inches water gauge is recommended between spaces. In order to ensure that pressure differentials remain constant when doors are opened, or other events occur, control systems must be in place.

Conclusion

The production processes in pharmaceutical industries required to be controlled effectively to prevent various types of contaminations from people, raw materials, finished products as well as accommodating services, process plant and equipment. The requirements that are available are involved in the overall design and a complex construction process and cleanrooms guarantee a high standard and quality of product. The successful cleanroom operation can be achieved by developing a team including all relevant personnel from production, quality, logistics, maintenance and engineering departments at the early stage of a design to develop the initial user requirement specification. The user requirement specification gives criteria pertaining to process, equipment, operations, capacities and the environment for the new cleanroom. Various international standards of designing cleanrooms are available and the cleanrooms should be designed according to process requirements and standards. ●

Source: Chronicle Pharmabiz



Do's for asthma patients

Asthma patients must

Keep away from things that cause asthma.

Maintain a healthy sleep routine i.e. Go to bed early and get up early in the mornings.

Take morning walks and if possible perform yoga.

Don't smoke and avoid passive and second hand smoking.

Take a simple diet at regular hours.

Keep the house clean and dust free.

Keep away from smoke and dust.

Try and stay in pollution free environment.

Regularly consult the doctor.

Keep inhalers in hand.

Take medicines regularly and without fail.

Don'ts for asthma patients

Asthma patients must not disrupt their regular routine.

Asthma patients must refrain from smoking and drinking.

Asthma patients must avoid hard drinks.

Asthma patients must not over eat and avoid taking spicy food.

Asthma patients must not forget to take their medications and ensure to take these at correct times.

Good Distribution Practice (GDP) in Pharmaceutical Companies

Vinay Phatak, Chetan Jadhav & **Sandeep Deshmukh**

Introduction: Distribution is an essential activity in the integrated supply-chain management of pharmaceutical products. Various individuals and entities are generally responsible for the handling, storage and distribution of such products.

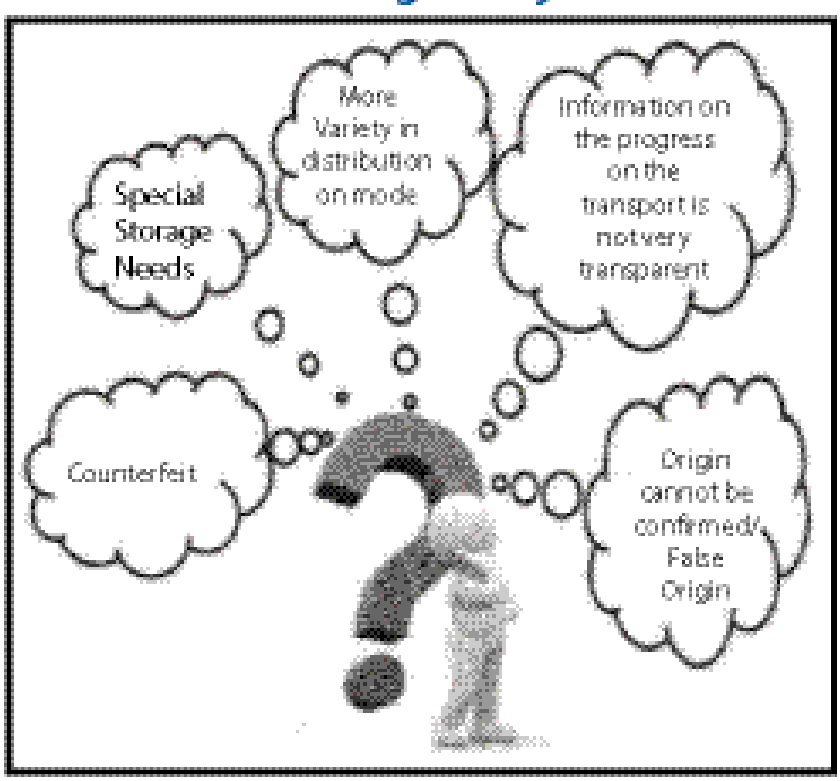
So it's very important to have adequate controls over the entire chain of distribution' To maintain the original quality of Pharmaceutical products, every party involved in the distribution chain has to comply with the applicable requirement' Each activity in the distribution of pharmaceutical products shall be caned out according to the principles of Good Distribution Practice (GDP)' The nature of the risks involved is likely to be similar to that for risk countered in the manufacturing environment, e.g. mix-ups, adulteration, contamination' cross-contamination' spurious

besides inherent potential for degradation of such products if not maintained and distributed under specified storage conditions. Good Distribution Practice (GDP) is much more than just the distribution of products. The MHRA (the UK authority) defined GDP as "the sum of all of the processes and activities designed and implemented to ensure that the quality of medicines is maintained throughout the distribution chain from manufacturer to patient, ensuring compliance with regulatory requirements at all relevant stages. It includes the storage and transportation of APIs, other ingredients and packaging components used in the production of the medicines."

The World Health Organization defines GDP as "that part of quality assurance that ensures that the quality of pharmaceutical product, is maintained by means of adequate control of the numerous activities which occur during the distribution process as well as providing a tool to secure the distribution system from counterfeits, unapproved, illegally imported, stolen counterfeit sub-standard, adulterated, and/or misbranded pharmaceutical products". The critical need to establish controls at all points the supply chain is an increasing challenge for all pharmaceutical companies and their partners in handling and transporting medicines globally.

The global growth of counterfeiting, not only of finished products but also of APIs, is a major issue for the industry. The implementation of GDP is essential for

Need of GDP and Regulatory Concerns



keeping counterfeits out of the legitimate supply chain/distribution network chain vulnerable to counterfeits.

Hence, good distribution practice remains an essential aspect of compliance for all pharmaceutical products as raw material and products are transported and delivered on a global and local basis.

Need of GDP and Regulatory Concerns

In the pharmaceutical industry, good distribution is not just a case of guaranteeing that a patient's supply of medicine made available on time when needed.

It is a case of ensuring that the entire supply chain and distribution network is focused on supplying a quality product that complies at every point with regulatory requirements and is fit for its purpose, when it reaches the patient.

Failure to comply, within the pharmaceutical supply chain can seriously compromise the quality of the product and hence patient safety.

In this context, the supply chain extends well beyond the vehicles used to take bulk pharmaceutical (such as APIs) and medical components to the manufacturing facility and finished products from the manufacturing facility to distributors/wholesalers.

It also must ensure compliant delivery to hospitals, pharmacies and even super markets where patients receive their medicines

We (as manufacturing pharmacist/chemist as patients) would like to know that the excellent quality under which medicines are made in the manufacturing facility also extends all along the legitimate supply chain to ensure that self and our families are always safe.

The supply chain is becoming more complex and global, raising serious practical questions about where the supply chain starts and ends, and precisely where control must be focused to guarantee quality all the way from ingredients to the final medicine. The more global and complex the distribution network, the more difficult it is to ensure that goods follow approved routes, are transported by approved and trained delivery drivers, and that records are properly maintained and quality is assured at every point along the pharmaceutical supply chain.

Counterfeit Pharmaceutical Products are a real threat to public health and safety:

Consequently, it is essential to protect the pharmaceutical supply chain against the penetration of such products. Weak points in the distribution processes of pharmaceutical products provide an avenue for counterfeit as well as illegally imported, stolen and substandard medicines to enter the supply chain.This is a concern in both developed and developing countries.

The methods by which such products enter the supply chain have become increasingly complex and have resulted in the development of thriving secondary and grey markets throughout the world. The involvement of unauthorized entities in the distribution and sale of pharmaceutical products is a particular concern. Only a joint approach including all parties involved in the supply chain can be successful in the fight against counterfeit pharmaceutical products and, therefore, all parties active in the market should take an active part in collaborative activities.

Scope of GDP

The storage, sale and distribution of pharmaceutical products are often carried out by various companies, institutions and individuals.

GDP explores different aspects of the distribution process within the supply chain and to avoid the introduction of counterfeits into the market place via the distribution chain. The nature of the risks involved in distribution is likely to be similar to that for risks encountered in the manufacturing environment, e.g. mix-ups, adulteration, contamination and cross contamination.

When the distribution chain is interrupted by manufacturing steps, such as repackaging and re-labeling, the principles of good manufacturing practices (GMP) should be applied to these processes.

Regulatory Overview:

Worldwide, there are a number of international Regulatory Guidelines, which toss light over the requirement, and importance of GDP. These are more or less aligned, but some have specifics e.g. Argentina, Brazil, Saudi Arabia etc.

Few highlights are as below:

0n March 1,2013, the European Commission finalized and published the Good Distribution Practice (GDP) guideline which replaces the GDP Guideline published in 1994 (941C 63/03) and will apply to not only to the wholesalers and manufacturers of pharmaceuticals, but it also incorporates the specific requirements for brokers dearing with pharmaceutical products. Its requirements (Ref: 2O13lC 6g/0.1) will enter into force on 8 September 2013.

The revised guidelines introduce the following changes:

The maintenance of a quality system setting out responsibilities, processes and risk management

> GDP IS APPLICABLE TO ALL PERSONS AND OUTLETS INVOLVED IN ANY ASPECT OF THE STORAGE AND DISTRIBUTION OF PHARMACEUTICAL PRODUCTS FROM THE PREMISES OF THE MANUFACTURER OF THE PRODUCT TO THE PERSON DISPENSING OR PROVIDING PHARMACEUTICAL PRODUCTS DIRECTLY TO A PATIENT OR HIS OR HER AGENT

principles in relation to wholesale activities;

- Suitable documentation which prevents errors from spoken communication;
- Sufficient competent personnel to carry out all the tasks for which the wholesale distributor is responsible;
- Adequate premises, installations and equipment so as to ensure proper storage and distribution of medicinal products,
- Appropriate management of complaints, returns, suspected falsified medicinal products and recalls;
- Outsourced activities correctly defined to avoid misunderstandings;
- Rules for transport in particular to protect medicinal products against breakage, adulteration and theft, and to ensure that temperature conditions are maintained within acceptable limits during transport;
- Specific rules for brokers (person involved in activities in relation to the sale or purchase of medicinal products).

World Health organization has released WHO technical Report Series, No. 957, 20.1 0, Annex 5 – WHO good distribution practices for pharmaceutical products.

This document lays down guidelines for the distribution of pharmaceutical products. Depending on the national and regional legislation on pharmaceuticals, these guidelines may apply equally for human and for veterinary use. WHO has also released, model requirements for the storage and transport of time and temperature sensitive Pharmaceutical Products TRS No. 961, Annexure 9 (2011).

The National Regulatory Body Government Pharmaceuticals and Medical Devices in India, Central Drugs Standard Control Organization (CDSCO) has released the Guidelines on Good Distribution Practices for Biological Products.

CDSO also released the Guidelines on Good Distribution Practices for Pharmaceutical Products. This draft CDSO Regulations covers a broad range of issues and activities are intrinsic to a validated supply chain:

- Appropriate organization and management of suppliers
- Personnel and training
- Quality systems and self-inspection in keeping with ISO or other accepted national or international guidelines
- Warehousing and storage
- Temperature control of both products and the storage environment
- Inventory control
- Transportation
- Dispatch and receipt of goods
- Documentation and record-keeping
- Complaint mechanisms
- Recalls and returns
- Counterfeit pharmaceutical products
- Importation
- Contractual obligations.

GDP is applicable to all persons and outlets involved in any aspect of the storage and distribution of Pharmaceutical products from the premises of the manufacturer of the product to the person dispensing or providing pharmaceutical products directly to a patient or his or her agent. This includes all parties involved in trade and distribution of pharmaceuticals, including the manufacturers of bulk, finished products, wholesalers as well as others such as suppliers, distributors, government institutions, international procurement organization , donor agencies and certifying bodies, logistics providers, traders, transport companies and forwarding agents and their employees as well as health workers.

It also includes ensuring the quality and identity of pharmaceutical products during all aspects process. These aspects include, but are not limited to, procurement, purchasing, storage, distribution, transportation, repackaging, re-labeling, documentation and record-keeping practices. ●

Source: The Pharma Review

Cancer blood test finds eight kinds of tumours

A new blood test for cancer has shown promise toward detecting eight different kinds of tumors before they have spread elsewhere in the body, offering hope of early detection, researchers said.

Further study is needed before the test – called CancerSEEK – can be made widely available for its projected cost of about $500, said the report in the Journal Science.

The study, led by researchers at Johns Hopkins University, involved 1,005 patients whose cancer – already pre-diagnosed based on their symptoms – was detected with an accuracy rate of about overall 70 percent.

Cancers were detected in the ovaries, liver, stomach, pancreas, esophagus, colorectal, lung and breast.

For five of these cancer types – ovary, liver, stomach, pancreas and esophagus – there are no screening tests available for people of average risk.

The test was able to detect these five with a sensitivity range of 69 to 98 percent.

In 83 percent of cases, the test was even able to narrow down where the cancer was anatomically located.

The test is noninvasive and based on combined analysis of DNA mutations in 16 cancer genes as well as the levels of 10 circulating protein biomarkers.

"The ultimate goal of CancerSEEK is to detect cancer even earlier -- before the disease is symptomatic," said the report.

Outside experts said more research is needed to uncover the true accuracy of the test, and whether it would be able to detect cancers before they cause symptoms.

"This looks promising but with several caveats and a significant amount of further research is needed before we can even contemplate how this might play out in screening settings," said Mangesh Thorat, Deputy Director of the Barts Clinical Trials Unit at Queen Mary University of London.

"The sensitivity of the test in stage I cancer is quite low, about 40 percent, and even with stage I and II combined it appears to be around 60 percent. So the test will still miss a large proportion of cancers at the stage where we want to diagnose them."

Nicholas Turner, Professor of Molecular Oncology at The Institute of Cancer Research, London, pointed out that the test's one percent false positive rate may sound low but "could be quite a concern for population screening. There could be a lot of people who are told they have cancer, who may not have it."

However, Turner described the paper as "a step along the way to a possible blood test to screen for cancer, and the data presented is convincing from a technical perspective on the blood test."

Many other efforts are under way to develop blood tests for cancer.

"I do not think that this new test has really moved the field of early detection very far forward," said Paul Pharoah, Professor of Cancer Epidemiology at the University of Cambridge.

"It remains a promising, but yet to be proven technology." ●

MYTH VS REALITY

Myth: **Allergies aren't dangerous.**
Reality: A lot of people have allergies that are not dangerous. Hay fever is annoying, and the hives that some people get when exposed to certain plants or chemicals are merely itchy. However, an extreme reaction can cause anaphylactic shock which is a condition where the throat and airways swell shut and blood pressure plummets. It can be life-threatening if not treated promptly. Reactions to bee stings, nuts and shellfish are the most likely to be severe and dangerous. Carrying a pre-loaded, self-injectable syringe of the drug epinephrine is the most common precaution that these severe allergy sufferers take.

Myth: Indoor house plants and flowers cause allergic rhinitis
Reality: Allergic rhinitis is usually triggered by outdoor grass and tree pollens. Dull wind-pollinated plants and grasses cause more allergies than brightly coloured outdoor insect-pollinated flowers. However indoor cut flowers such as Lilies give off brightly coloured pollens and can cause conjunctivitis symptoms in sensitised individuals.

Myth: Smoking does not trigger asthma
Reality: Babies who are born to smoking mothers have a greater chance of developing asthma than children of non-smoking mothers. Smoking is also a known trigger of asthma attacks and should not be ignored. So if you must smoke, do it outside and away from your children.

Myth: Allergy testing is dangerous and should not be performed in young children
Reality: Occasionally skin testing for allergies can trigger a slight skin reaction or wheezing, but this is very rare. Blood RAST testing for allergies is safer in highly allergic people. Children can and should be allergy tested from 4 months of age if an allergy is suspected.

Myth: Asthma inhalers can make your allergies worse and you should rather use breathing exercises (Buteyko)
Reality: Asthma is due to inflamed airways, breathing exercises will not clear this inflammation, only low-dose steroid inhalers can do this and control the asthma. Breathing exercises may have a complementary effect but it's the airway inflamation that needs attention in asthma.

What Change are in the Future of Pharma?

Emil W. Ciurczak

Introduction: Some years ago, the "Dean of Science Fiction writers" (Isaac Asimov) was complaining that many of his newer "fiction" stories were being placed on the shelves of libraries' "science" reference sections. The "march of science" had become a full sprint and was running ahead of his whimsy. In a similar mode, many of what I may feel are "future" improvements are, most likely, already in place in any number of locations. Nonetheless, they remain a secret to most practitioners or, at best, a rumor.

Many "Future" improvements are, most likely, already in place in any number of locations

Since the USFDA began encouraging Pharma to come into the 21st Century (part of the title of a Guidance), a number of forward- thinking groups within larger companies have taken the FDA at its word. However, the inertia in the pharmaceutical industry is greater than most industries. This is natural, considering that the USFDA came into existence for the sole purpose of halting abuses and excesses of the drug producing industry; in other words, a policeman. Over the years, thousands of complicated and arcane rules have become "the law." It did not help that the most common answer from Agencies to "how should this section (of an NDA or ANDA) be written?" was "Just give us something and we'll tell you if it's OK."

To be safe, Pharma companies simply took the most conservative pathways, namely:

1. Make each submission just like the last 200 submissions. ["Heck, it's worked for us for 60 years, why trifle with success?"]
2. Use the most advanced technologies [NMR, Raman, LCLC, LC-MS, etc.} to assure that the API is safe and active, then simply use USP or BP "wet" analysis methods for the final product, assuring speedy acceptance by the Agency (and retaining as much patent-protection as possible) since there will be less validation needed.
3. Since any "new" concept or production technology/monitoring needed to be arduously (read: time consuming and expensive) validated, manufacturers continued using 1950's approaches to development and production.
4. Since 21st century production is simply larger versions of mid-20th century techniques, minimum testing was considered "safer" than a higher number of tests.

The fourth point is, in essence, the main reason for resistance to the idea of PAT, namely that, if we test too much, we will find problems with every batch. This is a fair point as every batch has percent active, hardness, weight, etc. distributed as best can be described by a Gaussain curve. So, unless a process actually is a six-sigma process, there are a number of outliers that, for a million-dose run, could run into the hundreds or even thousands. This is, of course, based on the traditional "make-it-and-then-check-it" paradigm. If PAT is used to merely assay the old-fashioned method of production, its main outcome will be discovering all the weak points and outliers. But can/should PAT (and QbD) be used to speed up AND improve the quality of the product?

Actual PAT to QbD

While the idea of PAT goes back 15 or so years, it is still not a bad idea to adopt a PAT program. If we assume that a company is heavily invested in traditional batch-type manufacturing, then PAT can help in several ways:

The 1st part of PAT/QbD, ofttimes overlooked, is qualitative examination of incoming raw materials (both excipients and APIs) I also recommend 100% examination, to avoid potentially mislabeled or tainted conteners ("√n + 1" testing, commonly used, would imply only examining 11 out of every hundred containers, allowing potential errors in 89 of them).

The measured parameters of the raw materials allow the operators to estimate the mixing times, for example: smaller mean particle sizes equal to less time, on average, than larger ones.

Even if lots of incoming raw materials are found to be acceptable, the time saved in real-time qualification (e.g., an hour for 200 bags of lactose vs. a week in the QC lab) more than makes up for the time and expense of validating the program. [This doesn't even take into account labeling incoming materials as "in testing," quarantining them, relabeling them approved or destroy, and transferring them to a different part of the warehouse; they may be either used immediately or sent back on the truck that brought them.]

The physical information gleaned from incoming qualification may then be given to R&D/Pilot Plant/

Production to allow them to plan their blending, etc.

The next easiest step in PAT, putting an in-line, real-time blend uniformity unit allows for optimal mixing time. All too often, the blend is mixed longer than needed, just to "be sure." Over the course of a year, optimal blending can shave several minutes from each lot, effectively adding equipment without cost. [Blending generates heat which, in turn, could cause degradation, change in polymorphism, or simply grinding the particles to smaller sizes.]

In addition, active monitors at each production step fulfills the GMP requirement to "have meaningful in process tests." Not only will these data be meaningful, but obtained in a timely fashion, potentially avoiding lot failure.

Another oft-ignored GMP requirement is "a statistically significant number of dosage forms need to be tested." Clearly, 10, 20, or even 30 tablets from 3-5,000,000-unit run does not constitute a "significant number" in any statistics course taught on Earth. Using current HPLC testing is neither timely nor is it conducive to many samples per lot (potentially thousands?). Time and costs are reasons for not doing large number of HPLC samples, so we "wink-wink nod nod" and make believe we are properly sampling production runs. An inline spectrometer would give both control and a picture of the "goodness" of a batch from beginning to end.

One last point: any contract manufacturer, having this ability, makes itself more appealing to clients since they can produce better products, faster.

While the idea of PAT goes back 15 or so years, it is still not a bad idea to adopt a PAT program

Continuous Manufacturing

The logical conclusion to an effective PAT/QbD program is to take the batch-wise (moving from step one to step two to…)production, now "controlled" by PAT and simply link the steps together. [Not necessarily simple, but the ROI is so great, it is worth the trouble.] There are several larger companies engaging in CM currently (Vertex and Pfizer, to name two) and several more seriously working on the technology needed.

Since a well-designed PAT program already would assure that each step (mixing, granulating/ribbon, lubricating, granulating, coating is within proper parameters, it almost seems silly to drag several containers of powder and/or tablets from room to room, charging and discharging apparatuses, for days at a time. This "classic" approach requires more rooms, more cleaning/cleaning validation, more personnel, more lighting/heating/venting, and a larger footprint than simply "downsizing" each unit and placing them all in one room.

Since they're all in the same room, why not attach them and make a single entity? Since we are now skilled at ascertaining blend uniformity (in real time), let's just keep adding API and excipient, in the correct proportions, and continuously blend them (a screw blender seems the most logical choice). Granulating can be performed, but extruding a ribbon has been seen to be more amenable to CM and easily attached to the blender. The ribbon can be chipped and lubricated continuously and the lubricated mix easily tableted (or encapsulated) continuously. [The easiest approach in CM is seen to be direct compression, where possible. Since the mixture is small and continuously monitored, stratification, seen in large granulation feeders, is less common in CM.]

There are several excellent advantage in using CM in lieu of batch production:

One not immediately apparent advantage is when your company commits to true QbD, based on a well-run design of experiments. To perform the DoE correctly, full-sized batches should be run to account for physical interactions (mixing time, polymorph change, etc.). In a classic batch production, this would entail a lot of time, equipment, excipients and API. A small-ish DoE could take more than a month to complete (not including all the lab work needed). Using a CM unit, the ratios of API/excipients mixing time/speed, and all such combination could realistically be performed in a couple of days with all the analytical data available at the end of the experiments.

Batch size is only dependent on the time of a run. That is, a company can easily set up for a 500,000-unit run as a 10,000,000 run. Of course, it goes without saying that there is no waiting for lab results, as the entire batch has been monitored and, for all intents and purposes, analyzed in real-time.

Cleaning is much simpler, too. After conferring with several companies who use CM, it is seen that "appropriate" powder, run through the intact system, can efficiently clean the components as well, if not better than a water/alcohol/detergent approach, often the "go-to" cleaning approach today. This cuts even more time between products and increases throughput and eliminates almost all of the down-time associated with conventional cleaning.

The most obvious positive attribute is the footprint needed. Since there are no massive tableting machines, the massively thick floor (sometimes a meter thick) is unnecessary. The entire suite may be housed in a two story room, not much bigger than a small auditorium. This means less land, HVAC, electricity, personnel, warehousing, and all associated expenses.

CM is much like the automobile: horses and blacksmiths were nice and needed for many years, but very few people, now exposed to cars, would willingly ride a horse to work or shopping. As a co-instructor of mine once stated, "There is no law stating you must stay in business."

3-D Printing
Not likely to rapidly replace products that are either easily produced or are made in large numbers, this methodology is the answer to a number of complicated questions. At several recent meeting (e.g., IFPAC), I was thrilled to see actual products being made with 3-DP. These were usually low-volume batches, typically specialty drugs for small populations of patients, but there are also a number of more esoteric applications.

3-D printing is the answer to a number of complicated questions…
Special delivery systems (osmotic pumps) and even long duration (controlled-release) dosage forms benefit from 3-DP. Getting a 12-hour delivery system to repeat its performance via standard compression technology, even when aided by CM, can be more art than science. 3-DP give a far more reproducible dosage form than any other system.

Several other benefits are realized with 3-DP:
Cleaning, again, is simpler. Since the components are "sprayed" onto a platform (stationary of moving), the reservoirs can be dedicated to various excipients and APIs. The proper ones simply put into place for the production of the various products and seldom need cleaning (covered by SOP's, obviously).

Again, DoE is very inexpensive and rapid. The company can make even smaller experimental units via 3-DP, which can be important when the unit is complex and/or the API is rare or expensive.

Currently, 3-DP is mainly used for fabrication of medical devices, such as replacement knees, and work is being done on cells to form muscles and organs. The joints are a "slam-dunk" while organs are still down the road a bit. As the units fall in price and experience is gained, I would say this is the most interesting new technology to come along in decades.

Predictions
Of course, we are not saying that there will be a technological revolution over the next year or two. For decades after the automobile was introduced, many people complained that they were smelly, loud, there were no gasoline stations, no one knew how to repair them, and so forth. Horses were known, traditional, comfortably familiar, etc. How did that turn out?

Several students, over the years, have asked, "We covered that last year. Do we still need to know it?" My stock answer is, "If you are an English major, you do not need to remember Chaucer to study Shakespeare." However, if you are majoring in science, what was covered last year and the year before are important. Likewise, the Pharma (or BioPharma) industry cannot jump to continuous manufacturing without "prior knowledge" of PAT principles (risk management, design or experiment, statistical process control, etc.), which lead to QbD concepts (including lifecycle concepts, supply chain control, LEAN, six sigma).

When these concepts are understood, embraced, and mastered; when the proper personnel are in place; when upper management embraces the program (acknowledging that the process has been enhanced, with regard to speed and quality) are we prepared for CM. CM is the peak of the pyramid and, like the roof of a building, cannot be built without the base being strong.

Yes, technology will be a strong impetus for change, but, as always, economics is the largest driving force for change. As price controls are instituted in country after country, the pressure to make less expensive drugs will only increase. On top of that, the Agencies of all these countries are becoming increasingly strict, obviating the temptation to cut quality to cut costs.

Slowly, larger companies will move to 1) their own QbD/CM processing or 2) outsource to CMO's that are QbD/CM capable. Smaller/generic companies may have difficulty engaging the personnel/technology needed to move to successful QbD/CM manufacturing, so they will have three options: 1) close (there is no law forcing them to stay in business), 2) merge with one or more small companies, so they can afford/support QbD/CM, or 3) (happening now) the larger Pharma companies engage and support one or more smaller companies to produce their off patent, older (but still in-demand) brands.

So, will there be a tsunami or slow geological-speed change in Pharma? Like a garden, some seeds sprout early (larger, innovative companies like Pfizer, GSK, and Merck), some come later, but the last seeds face an existential choice: sprout or be crowded out by the other plants. There will be an entirely different looking industry in a decade: there will be fewer companies and the only ones making a profit will be the ones who understand and properly implement QbD.

Hint: If the US FDA and EMA were to announce that they would enforce the two parts of cGMPs I mentioned earlier by a set date (e.g., 2022),then line for purchasing PAT/QbD equipment, software, and experts would resemble the line at an Apple store when a new iPhone is introduced.

CM is the peak of the pyramid and, like the roof of a building, cannot be built without the base being strong. •

Source: The Pharma Review

The issue of counterfeit medicines an enduring problem, especially in lower income countries

The issue of counterfeit medicines is far more of a problem than most people believe. Counterfeit medicines are dangerous by their very nature – they are not produced under safe manufacturing conditions and are not inspected by regulatory authorities. It is impossible to know what ingredients counterfeit medicines actually contain. Sophisticated counterfeiters may put some of the active ingredient in the fake medicine and make it look very similar to the real medicine.

The primary danger in taking a counterfeit medicine is that you are putting something into your body that may not help your current condition, or in the worst cases, could harm or even kill you. Counterfeiting happens all over the globe, but it is most common in countries that lack stringent standards to regulate the production of medicine. The Centers for Disease Control estimates that 10%–30% of medicines sold in developing countries are counterfeit. In the industrialized world (countries such as the United States, Australia, Japan, Canada, New Zealand, and those in the European Union), estimates suggest that less than 1% of medicines sold are counterfeit. However, no country is immune to the threat of counterfeits as even these countries have seen counterfeit medicines enter the supply chain.

The issue of counterfeit medicines has been an enduring problem, especially in lower income countries, where an estimated 10 to 30 percent of medicines sold are believed to be counterfeit, according to the U.S. Centers for Disease Control and Prevention (CDC). In higher income nations with stricter regulations, including the United States and countries in the European Union, an estimated 1 percent of medicines sold are counterfeit, according to the CDC.

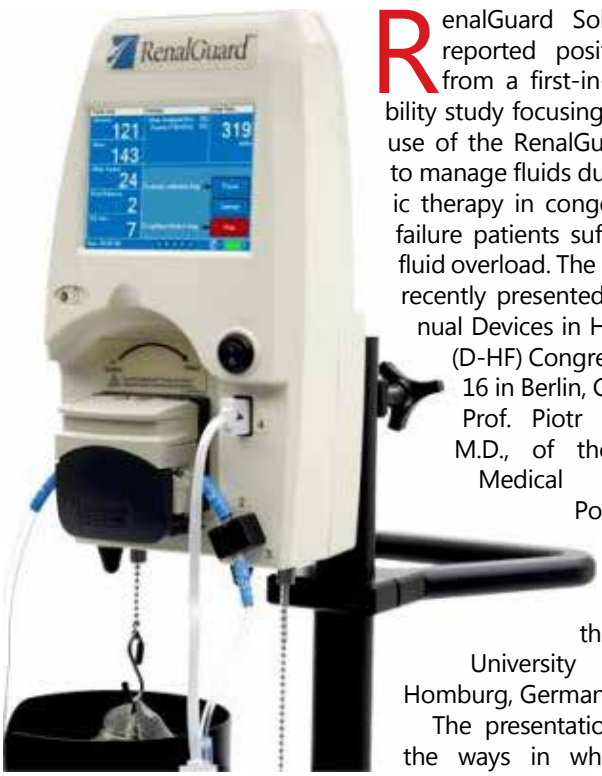
In addition to the economic impact, there's an added risk when it comes to counterfeit medicines because they can cause harm— both by failing to deliver the proper active ingredients that the patient expects and by possibly containing ingredients that may be harmful.

Making sure those counterfeit medicines don't get into the hands of unsuspecting patients is the mission of a team of scientists and investigators— and they have some state-of-the-art technology at their disposal to complement their shoe-leather detective work. •

Source: Pfizer

First-in-Man Renal Guard Promise for Heart Failure Patients

Novel fluid replacement and balance system featured in two presentations at Devices in Heart Failure Congress



RenalGuard Solutions Inc. reported positive results from a first-in-man feasibility study focusing on a novel use of the RenalGuard System to manage fluids during diuretic therapy in congestive heart failure patients suffering from fluid overload. The results were recently presented at the annual Devices in Heart Failure (D-HF) Congress, Dec. 15-16 in Berlin, Germany, by Prof. Piotr Ponikowski, M.D., of the Wroclaw Medical University, Poland, and Prof. Felix Mahfoud, M.D., of the Saarland University Hospital, Homburg, Germany.

The presentation reviewed the ways in which current treatment strategies for hospitalized patients with heart failure remain inadequate. Annual hospitalizations for heart failure exceed 1 million in both the United States and Europe, and more than 90 percent are due to symptoms and signs of fluid overload. Recurrent fluid overload in heart failure patients has uniformly been associated with worse outcomes independent of age and renal function; 25 percent of hospitalized patients will be re-hospitalized within three months, with a one-year mortality rate of 26 percent.

The presenters also identified the drawbacks of diuretic therapy, the cornerstone therapy for fluid overload, which acts primarily by inducing fluid loss. An individual patient's response to diuretic therapy is often variable and unpredictable. If the patient sees excessive urine output due to the diuretic, this rapid fluid loss can induce a condition termed "diuretic resistance," which blunts the continued function of diuretics and may result in acute kidney injury.

Originally developed for the treatment of contrast-induced acute kidney injury (CI-AKI), RenalGuard Therapy offers a potential solution to improve the impact of diuretic therapy in the treatment of fluid overload in heart failure patients. The results presented at D-HF followed the treatment of 10 diuretic resistant patients with heart failure symptoms receiving diuretic therapy while their fluid management was controlled by the RenalGuard System.

"None of the patients we treated experienced a fluid loss rate greater than the settings we established," said Ponikowski, who also serves as the Chairman of the European Society of Cardiology 2016 Heart Failure Guidelines Committee. "RenalGuard Therapy is remarkably simple and safe, and works automatically to carefully achieve and control the desired fluid balance."

The RenalGuard System measures the patient's urine output, then infuses a volume of saline to maintain the desired fluid balance. The clinician can set a maximum fluid loss rate, beyond which RenalGuard will not allow the patient's fluid balance to drop, thus limiting the potential of excessive fluid loss. This may allow clinicians to increase the dose of diuretic without increasing the risk of diuretic resistance.

"There is a clear unmet clinical need for alternative methods of fluid removal with superior efficacy in patients with heart failure. This first-in-man study demonstrated that RenalGuard can safely be used in these patients while maintaining the proper conditions to both prevent diuretic resistance, and increase the removal of excess fluid from the patient," said Mahfoud. "Our initial experience with the RenalGuard System in heart failure patients is very promising, and we look forward to advancing our understanding of the benefits of this therapy to patients at risk."

The RenalGuard System is CE-marked and commercially available in Europe. A pivotal study is underway in the United States to support a planned premarket approval (PMA) filing with the U.S. Food and Drug Administration (FDA) in 2018 for the prevention of CI-AKI. •

Trouble for Sanofi dengue vaccine

The World Health Organization said recently it hopes to review safety data on Sanofi's dengue vaccine this month, while the Philippines ordered an investigation of its now suspended massive immunization program after the French drugmaker said it could actually worsen the disease in some cases.

The safety fears involve possible increased risk to people who had not previously been exposed to the dengue virus prior to vaccination with Dengvaxia.

Sanofi SA (SASY.PA) attempted to allay concerns, saying in a statement that "the vast majority of those vaccinated to date live in high endemic settings and, therefore, will have had a prior dengue infection before vaccination."

Dengvaxia, the first approved Dengue vaccine, had been forecast by Sanofi to eventually bring in nearly $1 billion in annual sales. But even recent more modest analysts' sales forecasts are now looking unattainable given the safety issue and clinical evidence revealing unequal protection against different strains of dengue.

The vaccine so far has been approved in 19 countries and launched in 11, Sanofi said. Most sales have come from the Philippines through its government immunization program involving more than 730,000 children and Brazil, where the state of Parana has seen a three-fold increase in dengue in the past few years.

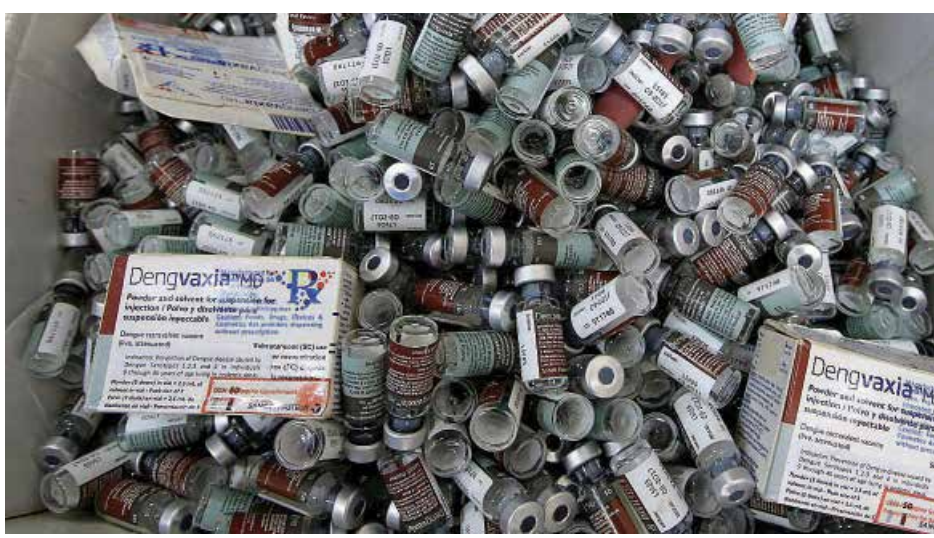
Dengue is a mosquito-borne tropical disease that kills about 20,000 people a year and infects hundreds of millions.

The WHO, which issued a report identifying the vaccine's safety risk in mid-2016, recommended it only be used in people who had prior dengue infection.

Brazil confirmed it already had recommended restricting use of the vaccine to those previously infected with dengue but had not suspended it entirely.

Brazilian health regulator Anvisa, in an emailed statement to Reuters, said it had not received any reports of vaccine recipients dying or falling more severely ill because of the drug. It does not know how many people have received the vaccine in Brazil since its 2015 approval.

Sanofi, whose shares rose 0.4 percent in Paris, explained its "new findings" of increased risk at a news conference in Manila. It did not say why action was not taken when the WHO raised the issue last year.



The Philippines Department of Health halted use of Dengvaxia last week after Sanofi reported it could worsen the disease in some people.

"As far as we know, as far as we are made aware, there are no reported deaths that are related to dengue vaccination," said Ruby Dizon, Medical Director at Sanofi Pasteur Philippines.

A Philippine health official said the deaths of three children who received Dengvaxia, reported by a non-government organization, were not related to the vaccine.

Nearly 734,000 children aged 9 and over in the Philippines have received one dose of the vaccine as part of a program that cost 3.5 billion pesos ($69.54 million).

Sanofi said it had not seen any evidence of increased incidence of severe dengue in vaccinated individuals in the real world experience with the vaccine. The drugmaker said the long-term safety evaluation of Dengvaxia showed significantly fewer hospitalizations due to dengue in vaccinated people over 9 years old compared with those who had not been vaccinated.

Singapore's Health Sciences Authority said that was working with Sanofi to strengthen risk warnings on the drug's packaging.

Sanofi spent 20 years developing the world's first dengue vaccine at a cost of around 1.5 billion euros ($1.78 billion).

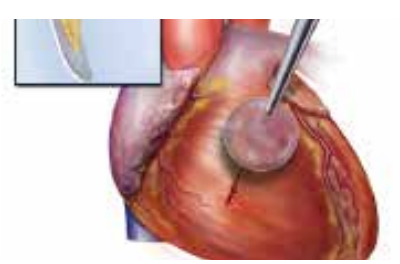
In addition to Brazil, the Philippines and Singapore, Dengvaxia is being sold in Mexico, Indonesia, Thailand, Paraguay, Peru, Costa Rica, El Salvador and Guatemala.

Health officials in Mexico, the first country to approve the vaccine in 2015, and in Peru had no immediate comment. Paraguay's health officials said Dengvaxia is not widely used due to cost but that they have not received reports of problems from doctors who provide the vaccine. ●

Breathing trouble may follow preemies to adulthood

People who were born prematurely may have smaller-than-normal airways in adulthood, which can cause respiratory problems, researchers say. Premature birth is associated with poorer heart and lung function, but the reasons why have not been fully understood. In a new study, investigators compared adults who were born eight weeks or more early with people who were born at full-term. Both groups were the same age and height. The researchers used lung function tests to calculate the airway size of each study participant, and concluded that airway size in the premature group was smaller than in the full-term group.

New 'Patch' may repair damaged hearts



A patch that might one day help repair heart attack damage has been developed by researchers. The patch, which consists of fully functioning artificial human heart muscle, is large enough to cover damage typically caused by a heart attack, according to biomedical engineers at Duke University. The Duke team described the development, which was tested in rodents, as a significant advance in efforts to repair dead heart muscle.

Is low-dose Aspirin right for you after Surgery?

Each year, millions of American heart patients go "under the knife" for various kinds of surgery. Often they're told to take a low-dose aspirin, to help lower their

odds for a post-op blood clot. But does that practice reduce the risk of additional heart problems? A new study says yes. Giving low-dose aspirin after surgeries unrelated to heart problems -- things like knee replacements, cancer surgeries or a myriad of other operations -- reduces the risk of heart attack and death in people who've previously had artery-opening angioplasty. The new study was led by Dr. P.J. Devereaux, of McMaster University in London, Ontario, Canada.

Swings in Blood Pressure can pose long-term dangers

Everyone knows that sustained high blood pressure does not favor for your heart or life span. But new research suggests that up-and-down shifts in blood pressure may be equally hazardous to your health. "The takeaway from the study is, if you allow your blood pressure to be uncontrolled for any period of time, or notice big changes in your blood pressure between doctor visits, you increase your risk of stroke, heart attack, kidney or heart failure or even death," said study author Dr. Brian Clements. He's an internal medicine specialist at Intermountain Medical Center Heart Institute in Salt Lake City. One cardiologist who reviewed the findings wasn't surprised. "Swings in blood pressure cause more stress to the arteries of the heart and brain than a consistent blood pressure," said Dr. Satjit Bhusri, of Lenox Hill Hospital in New York City. He said the study supports the notion that high blood pressure medications should be taken continuously, not just when pressure seems to spike. "All too often patients take their blood pressure medications 'as needed,' "Bhusri said. "It is up to their doctor to reinforce that blood pressure medications are not 'as needed' meds, and that in fact the 'as needed' use of such meds can cause more harm than not taking them at all."

Tree cover linked to fewer asthma cases in polluted urban neighborhoods

People living in polluted urban areas are far less likely to be admitted to hospital with asthma when there are lots of trees in their neighborhood, a recent study has found. The study into the impact of urban greenery on asthma suggests that respiratory health can be improved by the expansion of tree cover in very polluted urban neighborhoods. The study, published in the journal Environment International, looked at more than 650,000 serious asthma attacks over a 15 year period.

Can aspirin stop Liver Cancer in Hepatitis B patients?

Daily aspirin may reduce the risk of liver cancer for people with hepatitis B infection, a new study suggests. Hepatitis B virus attacks the liver and can cause cirrhosis and liver cancer. Previous research suggests daily low-dose aspirin therapy may prevent cancer, but there is little clinical evidence on whether regular aspirin use can prevent liver cancer in people with hepatitis B. Researchers from Taiwan analyzed data from close to 205,000 patients with chronic hepatitis B. They found that those on daily aspirin were much less likely to develop liver cancer over five years than those who did not take aspirin. It's important to note, however, that the study only found these associations, but did not establish a cause-and-effect link.

Researchers reduce over-prescription of antibiotics by using computer alerts to inform doctors

Physicians in USA, reduced the odds of prescribing an antibiotic for sinusitis by 22 percent using computer alerts to inform doctors when antibiotics may not be the best course of treatment. The research was published in the American Journal of Managed Care. The work is a continuation of research to better understand what drives over-prescription of antibiotics and determine best approaches to improving physician prescribing practices, said study.

A faster test for antibiotics against UTIs?

Urinary tract infections (UTIs) plague millions of Americans each year. Now, researchers say they've developed a test that can tell in minutes whether or not a particular antibiotic can clear up the problem. The issue is an important one, doctors say, since many of the bacteria behind UTIs have grown resistant to certain antibiotics. And, left untreated, these infections can have serious effects, especially in the frail and elderly. "We live in an era of multidrug-resistant bacteria, so-called 'superbugs' that can cause life-threatening infections," said infectious disease specialist Dr. Sunil Sood, who reviewed the new study. "Modern molecular techniques to distinguish bacteria that are resistant from those that are susceptible to common antibiotics could be lifesaving," said Sood. He is chair of pediatrics at Northwell Health's Southside Hospital in Bay Shore, N.Y. According to the study authors, current urine tests can rapidly spot a UTI, but it can still take days for the exact germs – and the proper antibiotic to use against them -- to be identified. In the new study, researchers led by Nathan Schoepp, of the California Institute of Technology, developed a new way of analyzing germs in urine samples. Instead of isolating germs and waiting for them to grow, the researchers used a "DNA amplification" technique to analyze the bacteria's genome, or "genetic blueprint." The investigators tested the new screen out on 51 urine samples containing either antibiotic-resistant or antibiotic-susceptible strains of bacteria.

Pharmacovigilance training at your fingertips

Anna Hogorlus
Senior Specialist
Education and Training, UMC

With the launch of its own distance learning platform, UMC now offers an even more diverse range of education and training to meet the needs of pharmacovigilance professionals. The first online course on signal detection and causality assessment is now freely available and open for registration.

THERE IS A GREAT NEED for training in pharmacovigilance and for many years UMC has taken a variety of approaches to support pharmacovigilance professionals around the world. The popular annual course in Uppsala will be held for the twentieth time in 2018 and UMC staff travel regularly to member countries of the WHO Programme for International Drug Monitoring, to engage in training activities and conferences on site.

"Our microlearning approach makes training accessible even to people with very busy schedules. Now anyone can learn pharmacovigilance!"

To complement such face-to-face training, UMC has launched a distance learning platform to reach out to even more people than before. The first online course deals with signal detection and causality assessment, topics frequently requested by pharmacovigilance centre staff. The course was developed using the microlearning approach, which offers bite-sized 'nuggets' of information that can be easily absorbed and revisited. The course is divided into modules, which are subdivided into lessons. Each lesson is concise and related to a clear learning objective. Transcripts are available to help those who may find the spoken English difficult to follow, and they can also be used to review the contents quickly without having to replay the video. By taking a test at the end of each module, students can check whether they understood the material and keep track of their progress. The first four course modules were launched in October, while a fifth module will be released in 2018.

THE ADVANTAGE of the online course is its flexibility – it can be studied anytime, anywhere and at any pace. "Distance learning is perfect for anyone who may not be able to travel to a training session," says Johan Ellenius, Team Manager in UMC's Research Department. "Our microlearning approach makes training accessible even to people with very busy schedules. Now anyone can learn pharmacovigilance!"

The material is entirely free, so all the students need a computer, a tablet or a mobile phone connected to the internet. The platform will be of special value to pharmacovigilance professionals who are unable to attend UMC's live training, but it can also be used to brush up on specific topics after attending a live event. An added benefit of the distance learning approach is that by reducing travelling, it will save time, money and the environment.

So far, audience response has exceeded expectations – over 1,500 people signed up for the course within a month of its launch, and numbers are increasing steadily. The project is in its pilot phase now and its usability, relevance and impact will be evaluated to decide if more courses should be added. For that, UMC relies on your participation and valuable feedback. If you know somebody who would be interested in helping us by undertaking the course, do spread the word. We hope that many pharmacovigilance professionals will complete the course and give us their feedback. The lessons were designed with pharmacovigilance centre staff in mind, especially new signal assessors, but they are freely available to anyone with an interest in the topic. •

Source: Uppsala Monitoring Centre

Focus on 2018 FIP World Congress of Pharmacy & Pharmaceutical Sciences

Transforming outcomes: How pharmacy can play its part
Ahead of the 2018 FIP World Congress of Pharmacy and Pharmaceutical Sciences in Glasgow, Scotland, Harriet Pike speaks to some of the key players behind the congress programme to find out what's in store.

Wherever you practise, patients' needs are changing. Advances in science and technology mean that individualised treatments can offer better outcomes than a "one-size-fits-all" approach. But there are challenges: new technologies often come with a hefty price tag, adding to the huge financial pressures already faced by health systems; practitioners are increasingly expected to emerge from their professional silos to collaborate for the benefit of patients; and the health workforce is not always a predictable resource.

The International Pharmaceutical Federation (FIP) wants pharmacists to be part of the solution. "It is the responsibility of each of us to transform and advance the profession to improve the health of our patients and nations," says Lars-Åke Söderlund, head of national customers and new businesses at Apoteket AB, Sweden, and a member of the 2018 *World Congress of Pharmacy and Pharmaceutical Sciences* programme committee.

Linda Hakes, a pharmaceutical scientist, who also sits on the programme committee, agrees that pharmacists can play a central role in transforming healthcare. "The role of pharmacists is often undervalued and yet, when healthcare budgets around the world are being squeezed, pharmacists can help to make care more efficient, effective and accessible," she says.

Transforming outcomes is the theme of the FIP congress to be held in Glasgow, Scotland, from 2 to 6 September 2018; a theme that will serve as a reminder to participants that their focus should always be on patients. Participants can expect to learn about new scientific developments and new models of pharmacy practice in sessions ranging from "Breakthroughs in pharmaceutical nanotechnology for oral delivery of anticancer drugs" to "Expanding the role of pharmacists in primary healthcare through collaborative non-dispensing services". Sessions will also focus on innovations in education and collaborative working with other professions, for example, in the session "Interprofessional education: Transforming outcomes for the 21st century".

Pharmacy: the gateway to care

The congress programme evolves around three key issues relating to the transformation of healthcare: people — the patients and workforce; systems — how healthcare is organised and financed; and medicines and technologies. All lie at the heart of the challenges facing today's healthcare systems all over the world. By bringing pharmacists and pharmaceutical scientists from around the world together, the congress highlights ways in which pharmacy can transform patient outcomes.

Advocacy in action: power to transform outcomes

Positive changes are happening in the pharmacy profession globally, but not at the rate that pharmacists want or that are needed to improve patient safety and optimise the outcomes of therapy. Dominique Jordan, chairman of FIP's Board of Pharmaceutical Practice, says that pharmacists' ability to influence policymakers and regulators is key to getting recognition within health systems, both for the value that pharmacists bring to patients and for new extended roles. This influence is also critical if pharmacists are to be paid appropriately for new services. A presentation on political advocacy will explore how advocacy can be used to drive transformation.

"Pharmacists have to prove their added-value in the health system," says Mr Jordan, who will present case studies on successful approaches to change as part of the session.

Mike Rouse, assistant executive director at the US Accreditation Council for Pharmacy Education, will join the advocacy session as a speaker. He agrees that pharmacists need to demonstrate their worth and says there is plenty of evidence of the value and impact that pharmacists can have in health systems.

Inspire and be inspired

The FIP congress is a catalyst that allows pharmacists from around the world to reach consensus on topics such as medicines shortages, antimicrobial resistance and responses to natural and man-made disasters. International groups have produced recommendations that form the basis for discussions with the World Health Organization, governments and other stakeholders. ●

Source: FIP

International Meeting on Traditional & Alternative Medicine

"International Meeting on Traditional & Alternative Medicine" scheduled on July 23-24, 2018 Osaka Japan. Traditional Medicine congress is organized with the theme "Exploring New Horizons in Traditional & Alternative Medicine".

Traditional Medicine 2018 invites participants, moderators, and exhibitors from everywhere throughout the world to Osaka, Japan

Why to Attend:

Traditional Medicine main slogan is to address the challenges in making a safer, sustainable and affordable system for medication and health through consolidating the underpinning Alternative Medicine research platforms. Researcher and Expertise who's in these subjects need in-depth understanding. It's important to share knowledge with others due to newly generated problem. For that they need a platform to share their knowledge. We could say we create a golden opportunity for those to people expose their knowledge through this conference.

In addition to attending the Traditional Medicine Conference, we invite you to experience Osaka, the beautiful and famous city in Japan, which attracts people from around the world.

Target Audience:

Medical Practitioners, Ayurveda Practitioners, Homeopathy Practitioners, Acupuncturists, Herbal Medicine, Acupuncture Practitioners, Traditional Medicine Practitioners, Naturopathic Physicians, Natural therapists, Business/Practice Managers, Associations, Societies and Universities

Conference Highlights:

- Clinical Research on Traditional and Alternative Medicine
- Natural Products Development
- Molecular Biology, Biotechnology and Nanotechnology of Medicinal Plants
- Pharmacognosy and Phytochemistry of Medicinal Plants
- Ethnomedicine and Traditional Medicine
- Complementary and Alternative Medicine (CAM)
- Ethnobiology and Ethnobotany
- Ethnomedicine
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HISTORY MAKER

Sir Alexander Fleming

In 1928, Sir Alexander Fleming observed that colonies of the bacterium Staphylococcus aureus could be destroyed by the mold Penicillium notatum, proving that there was an antibacterial agent there in principle. This principle later lead to medicines that could kill certain types of disease-causing bacteria inside the body. At the time, however, the importance of Alexander Fleming's discovery was not known. Use of penicillin did not begin until the 1940s when Howard Florey and Ernst Chain isolated the active ingredient and developed a powdery form of the medicine. He was born August 6, 1881 in Darvel, Scotland and died on March 11, 1955 in London, England.

Dr. Muriel Petioni

Also known as the "matron of Harlem health," Dr. Petioni, a graduate of Howard University Medical School in 1937, was known for her commitment to women's issues, health care for the underserved, community medicine, and social justice. In 1974, she founded the Susan Smith McKinney Steward Medical Society for Women, a professional association for African American women physicians in the greater New York area. She also developed a mentorship program with the Coalition of 100 Black Women that guided young African American women into careers in science and medicine. In 1976, she founded the Medical Women of the National Medical Association.

ivacaftor + lumacaftor (Orkambi) and cystic fibrosis

A harm-benefit balance that requires further investigation

Judgement Reserved

In two double-blind randomised trials in cystic fibrosis patients with the F508del mutation in both alleles of the CFTR gene, the ivacaftor + lumacaftor combination reduced the frequency of pulmonary exacerbations requiring intravenous antibiotic therapy or hospitalization over a six-month period. However, after two years, this effect appeared less marked. The combination's effect on lung function is weak and possibly not sustained. In terms of adverse effects, this combination exposes patients to many drug interactions, as well as respiratory and hepatobiliary disorders that require additional long-term evaluation.

Compare before deciding

Cystic fibrosis is a severe genetic disorder that causes lung dysfunction, often accompanied by exocrine pancreatic insufficiency resulting in intestinal malabsorption and growth failure (see "Compare before deciding" p. 285). The commonest mutation is the class II mutation F508del, which impairs processing of the CFTR (cystic fibrosis transmembrane conductance regulator) protein and its transport to the cell surface. The CFTR protein plays a role in transmembrane ion transport at the chloride channel level. In France, about 40% of patients with the F508del mutation are homozygotes, i.e. the mutation is present in both alleles of the CFTR gene.

There is no known cure for cystic fibrosis as of mid-2017. Ivacaftor is described as a selective "potentiator" of CFTR protein. It is thought to act by increasing the probability of chloride channel opening, through a poorly elucidated mechanism. In 2012, it was authorised in the European Union for patients with the class III mutation G551D, which affects about 5% of patients. It is now also authorised for use in cystic fibrosis patients with other class III or IV mutations.

In patients who are homozygous for the F508del mutation, a placebo-controlled trial of ivacaftor found no improvement in the frequency of pulmonary exacerbations, eight gain, quality of life or even the forced expiratory volume in one second (FEV1).

What's New?

Lumacaftoris described as a CFTR protein "corrector". It acts directly on the defective protein through a poorly understood mechanism, improving its maturation and transport to the cell surface.

A fixed-dose combination, containing 125 mg of invocator and 200 mg of lumacaftor in a single tablet (Orkambio, Vertex), has been authorised in the European Union for use in cystic fibrosis patients aged 12 years and older who have the F508del mutation in both alleles of the CFTR gene.

The ivacaftor + Iumacaftor combination is claimed to increase the quantity of CFTR protein at the cell surface and then to increase chloride ion transport through the action of ivacaftor.

In these patients, does adding ivacaftor and lumacaftor to standard treatments prevent or reduce the manifestations and complications of cystic fibrosis, or increase survival? And what are its adverse effects?

In the short term, fewer severe pulmonary exacerbations.

Clinical evaluation of the ivacaftor+ lumacaftor combination is based on two double-blind randomised placebo-controlled trials, with identical protocols, in a total of 832 adults and 290 adolescents with cystic fibrosis (3-5). All patients were homozygous for the F508del CFTR mutation. Their average FEV1 was 60% of the predicted value, and was less than 40% of the predicted value in 7Y" of cases.

The patients, were randomly assigned to receive one of the following study treatments for six months, in addition to their usual therapy: ivacaftor 500 mg + lumacaftor 600 mg per day, ivacaftor 500 mg + lumacaftor 800 mg per day (the dose for which marketing authorisation has been granted), or placebo. In this review, we will only discuss the results obtained with the authorised daily dose.

In both trials, compared with the placebo groups, ivacaftor + lumacaftor therapy was associated with a statistically significant reduction in the number of pulmonary exacerbations requiring intravenous antibiotics over the 6-month trial period: about 32 exacerbations versus 62 to 87 with placebo. In other words, it would be necessary to treat 3 patients for 1 year to prevent 1 exacerbation. This was also the case for exacerbations requiring hospitalisation. After six months of treatment,

there was no statistically significant decrease in the impact of respiratory disorders on quality of life in the ivacaftor + lumacaftor groups (evaluated using a questionnaire specific for cystic fibrosis, CFQ-R).

A statistically significant increase in body mass index (BMI) was found with ivacaftor + lumacaftor compared with placebo in one trial, but not in the other. This increase in BMl was statistically significant in a pooled analysis of the two trials, with a magnitude of about 0.25 kg/m2 (3,4). The mean absolute change in FEV1 (primary endpoint) after 6 months was small in both trials: about +3 percentage points compared with placebo (statistically significant in each trial).

In the trial in 215 patients who continued treatment with ivacaftor+ lumacaftorlor an additional 2 years, but without a comparator group, the annual frequency of exacerbations increased slightly compared with the first six months of the trial, and the average FEV1 fell to a value similar to that seen at the start of the trial. The BMI increased by about 1 kg/m2 compared with the start of the trial, but since there was no comparator group, it is impossible to determine whether the drugs contributed to this finding.

More respiratory disorders

The main known adverse effects of ivacaftor are: upper respiratory tract infections; headache, dizziness and ear disorders; lens opacity; and possibly liver disorders.

In the two pivotal trials of ivacaftor+ lumacaftor, treatment discontinuations due to an adverse event (mainly respiratory disorders) were slightly more frequent in the ivacaftor + Iumacaftor groups: reported in 4.2% of patients versus 1.60/" in the placebo groups (3,6). No patients died during these trials.

Respiratory adverse events were more frequent in the ivacaftor + lumacaftorgroups: reported in 26% of patients versus 17% in the placebo groups. The commonest were dyspnoea (14% versus g%) and other respiratory difficulties such as chest tightness, bronchospasm or wheezing g (10%versus 6%). These events were mainly observed in the early stages of treatment. Upper respiratory tract infections were more frequent in the ivacaftor + lumacaftor groups: 8olo, versus 5% in the placebo groups.

Rash was reported more frequently in the ivacaftor + lumacaftor groups: in 6% of patients, versus 2% in the placebo groups.

Beware of liver injury

Seven patients in the ivacaftor + lumacaftor groups had a severe hepatic adverse event with elevated transaminases, associated in three cases with elevated bilirubin and with hepatobiliary disorders, including two cases of cholestatic hepatitis and one case of hepatic encephalopathy. The fact that hepatic disorders are frequent in patients with cystic fibrosis makes these findings difficult to interpret.

Muscle disorders. Dose-dependent creatine phosphokinase (CK) elevations were measured in the ivacaftor+ lumacaftor groups during trials: in about 4Yo of patients in the lumacaftor 600 mg groups and 77io in the lumacaftor 800 mg groups (leading to drug discontinuation in 4 patients), versus 5% in the placebo group (with no treatment discontinuation). According to the public assessment report by the European Medicines Agency (EMA), the mechanism underlying this effect is not known.

During clinical development, a case of rhabdomyolysis with CK elevation was reported in a healthy volunteer who received the ivacaftor + lumacaftor combination.

No cases of cataracts were reported during trials.

Numerous drug interactions, in particular with hormonal contraceptives

Lumacaftor is weakly metabolised in the liver. It is an inducer and inhibitor of various cytochrome p450 isoenzymes. It is primarily a potent inducer of Cyp3A4. Lumacaftoris therefore likely to have numerous pharmacokinetic interactions with substrates of this isoenzyme, such as hormonal contraceptives, and may reduce their efficacy. Ivacaftor also has a very high potential for drug interactions.

Lumacaftor reduces exposure lo ivacaftor, which is why 250 mg of ivacaftor is taken at each administration when combined with lumacaftor, ratherthan the 150 mg dose when ivacaftor is used alone.

Best avoided during pregnancy

No abnormalities of fetal development or reproductive toxicity were reported in animal studies of lumacaftor. Ivacaftor affected fertility at doses higher than those used in humans. The ivacaftor + Iumacaftor combination is best avoided during pregnancy, due to the limited data available on pregnant women.

In Practice

In patients aged 12 years and older with the F508del mutation in both alleles of the CFTR gene, the fixed dose combination ivacaftor+ lumacaftor reduced the frequency of exacerbations requiring intravenous antibiotic therapy or hospitalisation, over a period of six months. This effect appeared to decline thereafter, despite continued treatment. Given that its efficacy on other clinical outcomes has not been established, that its effect on disease progression in the long term is unknown, and that it appears to provoke respiratory and hepatobiliary disorders, this combination requires further evaluation in clinical trials. ●

Source: Prescrire

GLOSSARY OF TERMS

Chronic Obstructive Pulmonary Disease

Alpha-1 antitrypsin (AAT): (also called alpha antiproteinase or AAP) A protective material produced in the liver and transported to the lungs to help combat inflammation — Deficiency states occur as the result of hereditary defects.

Atelectasis: partial or complete collapse of the lung, usually due to a blockage of the air passages with fluid, mucus, or infection — Symptoms include dry cough, chest pain, and mild shortness of breath.

BIPAP (bi-level positive airway pressure) machine: a breathing machine that uses two pressure levels (inspiratory and expiratory) to provide breathing assistance — This machine is often used for patients with sleep apnea or respiratory failure.

Bronchospasm: the sudden tightening of the bands of muscle that surround the airways, causing the airways to become narrower — Bronchospasm might result in wheezing.

CPAP (continuous positive airway pressure) machine: A breathing machine that provides pressure to keep the upper airways open during breathing — This machine is often used for patients with obstructive sleep apnea.

CPR (cardiopulmonary resuscitation): a first-aid method to restore breathing and heart action through mouth-to-mouth breathing and chest compression.

EzPAP: a small, hand-held device that helps to keep the airways open and prevent the lungs from collapsing (See mucus clearing device.)

Flutter valve: a small, hand-held device used to loosen mucus through vibration (See mucus clearing device.)

Incentive spirometer: a device that encourages deep inspiration to expand the lungs and improve cough effectiveness Indication: reason to use.

Intubation: placing a tube in the trachea (wind pipe) to enable artificial breathing — This can be a life-saving procedure.

Nasal spray: medication used to prevent nasal allergy symptoms — This is available by prescription or over-the-counter in decongestant, cortico-steroid, or salt-water solution form.

Nebulizer: a machine that changes liquid medicine into fine droplets (in aerosol or mist form) that are inhaled through a mouthpiece or mask — Nebulizers can be used to deliver bronchodilator (airway-opening) medications such as Albuterol and Atrovent. A nebulizer might be used instead of a metered dose inhaler (MDI). It is powered by a compressed air machine and usually plugs into an electrical outlet.

Postural drainage: positioning oneself in certain postures to allow gravity to help drain mucus or phlegm from the lungs

Pulmonary function tests (PFTS): a series of tests that measure how well air is moving in and out of the lungs and carrying oxygen to the blood stream

Pulmonary hypertension: a rare lung disorder in which the arteries in the lungs have become narrowed, making it difficult for blood to flow through the vessels

Pulmonologist: a doctor who specializes in caring for people with lung diseases and breathing problems

Relapse: the return of signs and symptoms of an illness after a period of improvement

Respiratory failure: the sudden inability of the lungs to provide normal oxygen delivery or normal carbon dioxide removal

FACTS ON **FINGER TIPS**

PNEUMOCONIOSIS

Pneumoconiosis is any lung disease caused by dust particles that can damage the lungs.

Types of dust that may cause pneumoconiosis include: ● coal dust from drilling into rock when mining ● asbestos fibers, often from insulation or roofing ● cotton dust, usually from textile manufacturing ● silica, often from sand and rock at a foundry ● beryllium, a lightweight metal used in electronics and aerospace industries ● aluminum oxide, cobalt, and talc.

Symptoms

Pneumoconiosis can take a long time to develop, as dust can build up slowly or take many years to cause a reaction in the lungs. A person with pneumoconiosis may no longer work in an environment with dust that has caused the disease.

The key symptoms of pneumoconiosis are: ● difficulty breathing, or shortness of breath ● a cough, which may produce phlegm ● tightness in the chest. ● These symptoms can be similar to those of a cold or chest infection.

Risk factors

There are clear risk factors for pneumoconiosis and a range of jobs that are more likely to bring people into contact with harmful dust.

Some examples of occupations that may bring workers into contact with dust particles that cause pneumoconiosis include: ● plumbers, roofers, and builders who work with asbestos ● coal miners ● textile workers.

Working with dust particles does not mean that a person will develop pneumoconiosis. Many steps can be taken to protect workers.

Diagnosis

Many employers offer a routine check for lung diseases, such as a chest X-ray or breathing test, if employees are exposed to harmful dust in the workplace.

A chest X-ray or CT scan can reveal inflammation, excess fluid, or scarring in the lungs. A test may also be done to check how much oxygen is reaching the blood from the lungs. Sometimes a biopsy may be needed to rule out other diseases.

Treatment

Treatment depends on the type and severity of the pneumonia. Bacterial types of pneumonia are usually treated with antibiotics. ● Viral types of pneumonia are usually treated with rest and plenty of fluids. Antiviral medications can be used in influenza. ● Fungal types of pneumonia are usually treated with antifungal medications.

Prevention

There are two different vaccines to prevent pneumococcal disease, the most common bacterial cause of pneumonia. ● pneumococcal conjugate vaccine, or Prevnar ● pneumococcal polysaccharide vaccine, or Pneumovax.

Prevnar (PCV13) is normally included as part of an infant's routine immunizations.

It is recommended for children under 2 years, adults over 65 years, and those between the ages of 2 and 64 years with certain medical conditions.

Pneumovax (PPSV23) is recommended for children and adults who are at increased risk of developing pneumococcal infections.

Amoxicillin containing products

The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) Japan have announced that the package inserts for amoxicillin preparations have been updated to include the risk of thrombocytopenia as a clinically significant adverse reaction. Amoxicillin is an antibiotic used for the treatment of a number of bacterial infections.

Codeine-containing products

The Therapeutic Goods Administration (TGA) Australia has updated the product information documents for all prescription codeine preparations to include the restriction of use in children and ultra-rapid metabolisers. More specifically, codeine products should no longer be used in children under 12 years of age, or in children aged 12-18 years who have recently undergone surgery to remove their tonsils or adenoids. Codeine should also not be used by breastfeeding mothers or in patients known to be ultra-rapid metabolisers. Most product information for over-the-counter codeine preparations now have warnings not to use them in children aged under12 years.

Fluconazole (non-prescription)

Health Canada has recommended that the product safety information for all non-prescription fluconazole products should be updated to include the potential risk of pregnancy loss and birth defects and state that these products are not recommended for use by women who are trying to become pregnant. Non-prescription (oral, 150 mg) fluconazole products are authorized to treat vaginal yeast infections. Health Canada reviewed the potential risk of unwanted effects in pregnancy, including pregnancy loss (i.e., miscarriage or stillbirth) or birth defects (i.e., major congenital malformations) with non-prescription fluconazole use, in part because a recently published study suggested that such a risk may exist.

Moxifloxacin (oral dosage form)

The MHLW and the PMDA Japan have announced that the package insert for moxifloxacin (Avelox®) has been updated to include the risk of rhabdomyolysis as a clinically significant adverse reaction. Moxifloxacin is an antibiotic used for the treatment of a number of bacterial infections. Two cases associated with rhabdomyolysis have been reported in Japan, of which causal relationship could not be excluded.

Laninamivir

The MHLW and the PMDA have announced that the package insert for laninamivir (Inavir®) has been updated to include the risk of bronchial spasm and dyspnoea as clinically significant adverse reactions. Laninamivir is indicated for treatment and prophylaxis of influenza A and B virus infection. Eight cases associated with bronchial spasm and dyspnoea have been reported in Japan. Of these, a causal relationship could not be excluded in three cases.

Fluindione

The ANSM has encouraged health-care professionals to be cautious when initiating therapy with fluindione due to the risk of allergic reactions, particularly during the first six months of treatment. Fluindione (Préviscan®) is an antivitamin K (AVK) class anticoagulant. It is indicated for atrial fibrillation (heart rhythm disorder), venous thrombosis or pulmonary embolism. A survey carried out by the Regional Centre for Pharmacovigilance in Lyon found that the use of fluindione is more frequently associated with the occurrence of rare but often severe DRESS-type immuno-allergic attacks, in particular renal, hepatic, haematological or dermatological disorders. In France, 82% of patients treated with AVK received fluindione, 13% of warfarin and 5% of acenocoumarol. These data are based on the number of daily defined doses consumed in 2016. Warfarin is the most widely used AVK in the rest of the world.

Ketamine

The ANSM has received reports of serious liver injury potentially related to the repeated and/or prolonged use of high dose ketamine. The ASNM has reminded health-care professionals that good practice recommendations for use of ketamine should be implemented. It is essential to observe the recommended dosages and monitor the liver function closely. Ketamine is indicated as an anaesthetic agent, alone or in combination with other anaesthetics. Ten cases of serious liver injuries, including four cases leading to liver transplantation, have been reported by health-care professionals since 2014. These are cholestatic type cholangitis, which may be linked to the repeated and/or prolonged administration of ketamine.

Lithium

The TGA has reminded health-care professionals to remain vigilant for potential signs of lithium toxicity, particularly in patients with risk factors. Early symptoms of lithium toxicity can occur close to or within the serum therapeutic range. Lithium (Quilonum® and Lithicarb®), is indicated for the treatment of acute mania, hypomania and for the prophylaxis of manic-depressive illness. The risk of lithium toxicity is adequately addressed in the product information for lithium. A patient died in 2013 as a result of lithium toxicity and has prompted this reminder. As of 17 May 2017, the TGA has received 58 reports in which lithium was suspected of causing toxicity. Two of these cases resulted in death. Interactions with other medicines were identified as a contributing factor in 17 cases, and may have played a role in four other cases. Inappropriate dosing was found to be a contributing cause of toxicity in two cases, and may have contributed to a third case.

Obeticholic acid

The US FDA has warned that obeticholic acid (Ocaliva®) is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death. Obeticholic acid is used to treat a rare, chronic liver disease known as primary biliary cholangitis (PBC). The FDA stated that some patients are receiving excessive doses, at a higher than recommended frequency. Obeticholic acid may also be associated with liver injury in some patients with mild disease who are receiving the correct dose. The recommended dosing and monitoring for patients on obeticholic acid are described in the current drug label. The FDA is working with the drug manufacturer, Intercept Pharmaceuticals, to address these safety concerns.

Fluconazole and Fosfluconazole

The MHLW and the PMDA have announced that the package inserts for fluconazole (Diflucan®) and fosfluconazole (Prodif®) have been updated to include the risk of drug-induced hypersensitivity syndrome (DIHS) as a clinically significant adverse reaction. Fluconazole and fosfluconazole (pro-drug of fluconazole) are antifungal medications used for fungal infections with Candida or Cryptococcus. A total of two cases associated with DIHS with fluconazole use have been reported in Japan. Of these, a causal relationship could not be excluded in one of the cases. For fosfluconazole, one case associated with DHIS has been reported. The company core datasheet (CCDS) for fluconazole has also been updated.

Ticagrelor

The MFDS has announced that the label for ticagrelor has been revised to include pulmonary haemorrhage as an adverse reaction. Ticagrelor is used as a platelet aggregation inhibitor. Ticagrelor is administered with aspirin and indicated to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome. At the time of review, the KIDS had received three domestic and six international reports of pulmonary haemorrhage with ticagrelor through KAERS from 1989 to 2015. Reports for ticagrelor and pulmonary haemorrhage were identified to be statistically significant compared to all the other reports from other drugs. This recommendation announced by MFDS was based on a signal analysis evaluation process in KIDS using adverse events reports.

FDA approval of Ozempic (semaglutide) Injection for the treatment of adults with Type 2 Diabetes

Novo Nordisk recently announced that the U.S. Food and Drug Administration (FDA) approved its New Drug Application (NDA) for Ozempic (semaglutide) injection 0.5 mg or 1 mg, a once-weekly glucagon-like peptide (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.1 Ozempic is administered once weekly, on the same day each week, and can be taken any time of the day, with or without meals. The approval of Ozempic is based on the results from a Phase 3a clinical trial program. In people with type 2 diabetes, Ozempic showed clinically meaningful and statistically significant reductions in A1c compared with placebo, sitagliptin and exenatide extended-release.

FDA approves first drug to treat inherited breast cancer

U.S. regulators have approved the first drug aimed at women with advanced breast cancer caused by an inherited flawed gene. The Food and Drug Administration approved AstraZeneca PLC's Lynparza for patients with inherited BRCA gene mutations who have undergone chemotherapy. The drug has been on the market since 2014 for ovarian cancer, and is the first in a new class of medicines called PARP inhibitors to be approved for breast cancer. PARP inhibitors prevent cancer cells from fixing problems in their DNA..

FDA Approves New Continuous Glucose Monitor for Diabetes

The first fingerstick-free blood sugar monitoring system for adults with diabetes has been approved by the United States Food and Drug Administration. The FreeStyle Libre Flash Glucose Monitoring System features a small sensor wire that's placed below the skin's surface and continuously monitors blood sugar (glucose) levels. People with diabetes can wave a mobile reader above the sensor wire to check their glucose levels. The system is approved for use in people with diabetes aged 18 and older. After a 12-hour start-up period, it can be worn for up to 10 days, the FDA said.

Noden Pharma Announces FDA Approval of Tekturna (aliskiren) Oral Pellets for the Treatment of Hypertension in Adults and Children 6 Years of Age and Older

Noden Pharma DAC, a global specialty pharmaceutical company that is focused on acquiring prescription medicines across a broad range of therapeutic areas, announced the approval by the USFDA of Tekturna (aliskiren) Oral Pellets for the treatment of hypertension in adults and children six years of age and older. The new formulation and pediatric indication were approved through the FDA priority review process. The efficacy and safety of Tekturna® for pediatric use was evaluated in an 8-week randomized, double-blind trial in 267 hypertensive patients 6 to 17 years of age, including 208 patients treated for 52 weeks, following the 8-week study.

MEDICAL DEVICES

FDA Approves Stryker's Neuroform Atlas Stent

Stryker Corporation announced that the U.S. Food and Drug Administration has approved the Neuroform Atlas Stent System for marketing under a humanitarian device exemption (HDE). The device is to be utilized in conjunction with neurovascular embolic coils for the treatment of wide neck, intracranial, saccular aneurysms and allows the company to begin US commercialization efforts immediately.

"The hybrid cell stent design of Neuroform Atlas is designed to improve wall apposition, ease of use, deployment accuracy, and catheter re-entry in even the most challenging cases," said Dr. Osama O. Zaidat, Director of the Neuroscience and Stroke Center at Mercy Hospital in Toledo, Ohio, and Co-Principal Investigator of the US Neuroform Atlas investigational trial. "The Atlas design may improve patient care by facilitating the treatment of wide neck aneurysms in tortuous and more complex anatomies."

"The ability to navigate distal anatomy within the brain using the lowest profile delivery on the U.S. market is a significant advantage to physicians," said Dr. Brian Jankowitz, Director of the NeuroEndovascular Fellowship program at the University of Pittsburgh Medical Center and Co-Principal Investigator of the study. "Atlas opens up treatment options for a new segment of patients that would otherwise have been considered too risky to treat."

Mark Paul, President of Stryker's Neurovascular Division, added, "The Neuroform Atlas Stent System is the most recent addition to Stryker's innovative product portfolio, providing a continuum of complete stroke care for patients suffering from cerebrovascular disease. With Neuroform Atlas commercially available in 46 countries, patients around the world are now benefiting from significant advancements in intracranial stents designed specifically for the treatment of wide neck aneurysms. This product is an excellent fit with our mission to make healthcare better."

Source: Chronic Pharmabiz

Brand Name	Generic Name	Manufacturer	Date of Approval	Treatment
Lonhala Magnair	Glycopyrrolate	Sunovion Pharmaceuticals Inc.	December 5, 2017	Chronic Obstructive Pulmonary Disease
Ozempic Injection	Semaglutide	Novo Nordisk	Der 5, 2017	Diabetes Type 2
Ogivri – formerly MYL-1401O	Trastuzumab-dkst	Mylan GmbH	December 1, 2017	Breast Cancer, Stomach Cancer
Sublocade Sustained-Release Injection - formerly RBP-6000	Buprenorphine	Indivior PLC	November 30, 2017	Opioid Use Disorder
Clenpiq Oral Solution	Sodium Picosulfate, Magnesium Oxide, & Anhydrous Citric Acid	Ferring Pharmaceuticals	November 29, 2017	Bowel Preparation
Juluca	Dolutegravir & Rilpivirine	ViiV Healthcare	November 21, 2017	HIV Infection
Hemlibra	Emicizumab-kxwh	Genentech, Inc.	November 16, 2017	Hemophilia A with Inhibitors
Mepsevii	Vestronidase Alfa	Ultragenyx Pharmaceutical, Inc.	November 15, 2017	Mucopolysaccharidosis Type VII
Fasenra Injection	Benralizumab	AstraZeneca	Nov 14, 2017	Asthma
Abilify MyCite formerly Abilify Digital	Aripiprazole	Otsuka Pharmaceutical Co., Ltd	November 13, 2017	Schizophrenia, Bipolar Disorder, Depression
Heplisav-B	Hepatitis B Vaccine, Recombinant Adjuvanted	Dynavax Technologies Corporation	November 10, 2017	Hepatitis B Prophylaxis
Cinvanti Injection	Aprepitant	Heron Therapeutics, Inc.	November 9, 2017	Nausea/Vomiting – Chemotherapy Induced
Prevymis Tablets and Injection	Letermovir	Merck & Co., Inc.	Nov 8, 2017	CMV Prophylax
Vyzulta Ophthalmic Solution - formerly Vesneo	Latanoprostene Bunod	Valeant Pharmaceuticals International, Inc.	November 2, 2017	Glaucoma (Open Angle), Intraocular Hypertensio
CalquenceCapsules	Acalabrutinib	AstraZeneca	Oct 31, 2017	Mantle Cell Lymphoma
Shingrix Injection	Herpes Zoster Subunit Vaccine	GlaxoSmithKline	October 20, 2017	Herpes Zoster – Prophylax
Yescarta Suspension for Intravenous Infusion - formerly KTE-C19	Axicabtagene Ciloleucel	Kite Pharma, Inc.	October 18, 2017	Large B-Cell Lymphoma
Zilretta Sustained-Release Intra-Articular Injection	Triamcinolone Acetonide	Flexion Therapeutics, Inc.	October 6, 2017	Osteoarthritis
Ascor Injection	Ascorbic Acid	McGuff Pharmaceuticals, Inc.	October 2, 2017	Scurvy
Fiasp Injection	Insulin Aspart	Novo Nordisk	September 29, 2017	Diabetes Type 1, Diabetes Type 2
Verzenio Tablets	Abemaciclib	Eli Lilly & Company	Sept 28, 2017	Breast Cancer
Xhance Nasal Spray - formerly OPN-375	Fluticasone Propionate	Optinose US, Inc.	Sept 18, 2017	Nasal Polyps
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

Shafiqur Rahman Zico has recently been promoted as Product Manager, Marketing Strategy Department of NOVO Healthcare and Pharma Ltd. Prior to this, he worked in Nuvista Pharma Ltd. He started his career from NOVO Healthcare and Pharma Ltd. in Quality Assurance Department. He has obtained B.Pharm degree from The University of Asia Pacific and M.Pharm from the State University of Bangladesh.

Salma Islam has recently been promoted as Assistant Manager, Product Development Department of NOVO Healthcare and Pharma Ltd. Prior to this, she worked at Ziska Pharmaceuticals Ltd. as Senior Officer, Product Development Department. She started her career in ALCO Pharma Ltd. She has completed B.Pharm from the University of Science and Technology Chittagong (USTC), M.Pharm from Primasia University, and MPH from AIUB.

Md. Rasheduzzaman has recently been promoted to Senior Executive, PMD in Concord Pharmaceuticals Ltd. He has completed his B. Pharm (Hon's) & MS Pharm Tech. from the University of Asia Pacific. Before joining Concord Pharmaceuticals Ltd. he was in White Horse Pharmaceuticals Ltd.

Shuva Kumar Dey has recently joined as Executive, PMD in Concord Pharmaceuticals Ltd. He has completed his B. Pharm (Hon's) & M. Pharm. from the State University of Bangladesh. Before joining Concord Pharmaceuticals Ltd. he was in Amulet Pharmaceuticals Ltd. He also worked in Sanofi Bangladesh Ltd. as Insulin Associate.

Md. Shoharab Hossain has recently joined as Executive, PMD in Concord Pharmaceuticals Ltd. He has completed his B. Pharm (Hon's) & M. Pharm. from the State University of Bangladesh. Before joining Concord Pharmaceuticals Ltd. he was in Asiatic Laboratories Ltd.

Md. Abu Salman Rana has recently joined as Executive, PMD in Concord Pharmaceuticals Ltd. He has completed his B. Pharm (Hon's) & M. Pharm. from the University Of Development Alternative (UODA). Before joining Concord Pharmaceuticals Ltd. he was in The White Horse Pharmaceuticals Ltd.

Wish to export to Saudi Arabia?

Conditions for Registrations of Companies and their Subsidiaries:

The company's agent shall submit the registration file enclosing the following documents:

1. Authenticated copy of the agency registration certificate at the Saudi Ministry of Commerce.
2. A copy of the license for pharmaceutical wholesale trade.
3. Completed registration application form to be attached.
4. A certificate issued by the health authorities in the country of origin, clearly indicating the following:
   a) That the company is authorized to manufacture pharmaceutical products in the country of origin (Indicate License Number and date).
   b) That the company follows Good Manufacturing Practice.
   c) That the products intended for export to the Kingdom will be identical in their composition as those registered and marketed in the country of origin.
5. A certificate from the company authenticated by the relevant authorities in the country of origin showing in the tabular form, the following information about the company's products:
   a) The trade and/or the generic name of the product.
   b) Composition (active ingredients and their quantities).
   c) Therapeutic category/categories.
   d) Registration number and date in the country of origin.
   e) Date of first marketing in the country of origin.
   f) Names of other countries in which the product is registered and marketed.
6. Research Summary:
   a) Summary of the company's research activity, indicating the products in various research phases, marketed, products discovered or developed by the country.
   b) Copies of the patents and/or recognized international scientific publications which support the validity of data indicated above in 6-a.

7. The following certificate from the parent company authenticated by the relevant authorities should be added in case of applying for registration of subsidiaries.
   a) A certificate specifying its responsibility regarding the quality of products that produced by the subsidiary.
   b) A certificate guaranteeing the subsidiary to be registered technically, financially and legally.

Conditions of product registration and Pricing

Any product from any company registered in compliance with this regulation shall not be registered unless the following documents are attached with the registration application form:

1. Table of contents.
2. Completed registration form should be attached.
3. Full specifications and methods of analysis of the product including stability data and storage conditions.
4. A certificate of analysis for the samples submitted for registration, issued by the company and authenticated from the relevant authorities.
5. A certificate issued by the health authorities indicating the free sale of the product in the country of origin.
6. A certificate issued by the health authorities indicating that the diluents and coloring agents in the product formula are permitted in the country of origin (if the certificate of free sales indicates such information, it will be sufficient).
7. A certificate from the relevant authorities in the country of origin indicating the animal source (specifying the animal), if the product

contains any ingredients of animal origin.

8. Percentage of the alcohol in the finished product, if present, and justifying that percentage.
9. A certificate issued by the health authorities indicating that the enclosed package insert or applicable labeling is the same as that approved and currently used in the country of origin.
10. The package insert should be in Arabic and/or English. The company pledges to add and/or omit any information required for handling the product in the Kingdom and translate the package insert into Arabic Language as determined by the authorities.
11. The product's label.
12. Six samples of the product including samples of the outer carton and container label.
13. An authenticated list of names of the other countries in which the product is registered and currently marketed.
14. Abstracts from independent international scientific reference and publications about the efficacy and safety of the product.
15. Summary of pharmacological, toxicological, and clinical studies as well as post marketing surveillance for products requiring such documents.
16. Studies of bioavailability and bioequivalence.
17. Analytical methods to determine the residues of veterinary products in animal feed.
18. Certificates of prices approved by the relevant authorities the country of origin.
19. Any additional comments or documents, the company wishes to attach.

Regulations:

1. The Exporting Request should be submitted directly by the manufacturer.
2. Each export request should be submitted to the main headquarters of the drug sector.

Requirements:

1. A letter from the manufacturer to Saudi Food & Drug Authority – Drug Sector stating the following:
   a) The name of the exported Products.
   b) The registration number for the registered products.
   c) Quantity, unit and package size.
   d) Batch number.
   e) Total value in Saudi Riyals.
   f) Transportation process.
   g) Exporting port.
   h) The beneficiary and its address.
   i) The Expected date for export.
2. A copy of the invoice issued to the beneficiary.
3. A copy of the Manufacturer license.

Re-Exporting:

It is the exporting of products which had been imported to be used in Saudi Arabia, and the request for the re-export should state the reasons and justifications for it.

Regulations:

1. The re-exporting request should be submitted directly by the Agent.
2. Each export request should be submitted to the main headquarters of the drug sector.
3. If the product that is intended to be re-exported is registered in Saudi Arabia, the registration data on the packages must be removed.

Requirements:

1. A letter for product re-exporting from the agent to Saudi Food & Drug Authority – Drug Sector to re-export such products, stating the following:
   a) The name of the re-exported Products.
   b) The registration number for the registered products.
   c) Quantity, unit and package size.
   d) Batch number
   e) Total value in Saudi Riyals.
   f) Transportation process.
   g) Exporting port.
   h) The beneficiary and its address.
   i) The Expected date for export.
   j) Reasons and justifications for re-exporting.

Quiz ON ASTHMA

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

1. *My child was recently diagnosed with asthma. She will not be able to do the things that other kids can and she may not be able to lead an active childhood.*
   ☐ True ☐ False
2. *Asthma has different causes or triggers in different people. Allergies to environmental allergens, such as dust mites or molds, frequently contribute to asthma symptoms.*
   ☐ True ☐ False
3. *Quick-relief or rescue medications for asthma, such as bronchodilators, may be taken on a daily basis to control frequent symptoms.*
   ☐ True ☐ False
4. *Children are more likely to have asthma than are adults. In fact, asthma is the most common long-term childhood disease, according to the Asthma and Allergy Foundation of America. Find out more about this condition by taking the following quiz.*
5. *Asthma is an emotional or psychological illness.*
   ☐ True ☐ False
6. *Asthma flare-ups may cause breathing problems but aren't dangerous.*
   ☐ True ☐ False
7. *Asthma flare-ups usually occur suddenly without warning.*
   ☐ True ☐ False
8. *Asthma can't be cured, but it can be controlled.*
   ☐ True ☐ False
9. *People with asthma have no way to monitor how well their lungs are working.*
   ☐ True ☐ False
10. *Asthma only starts in childhood.*
    ☐ True ☐ False

TITLE	VENUE	SCHEDULE
Arab Health Respiratory Medicine Congress 2018	Dubai , UAE	Jan 31-Feb. 01, 2018
12th World Congress On COPD, Asthma & Respiratory Allergy 2018	Dubai , UAE	February 02-05, 2018
56th Annual Chest Disease Conference	Sun River, USA	February 15-18 2018
International Society For Influenza And Other Respiratory Virus Diseases 2nd International Meeting On Respiratory Pathogens 2018	S'pore City , Singapore	February 07-08, 2018
5th Infectious Diseases Congress	Berlin, Germany	March 01-02, 2018
American Academy of Allergy, Asthma and Immunology Annual Meeting and World Allergy Organization Joint Meeting	Orlando, United States	March 02-05, 2018
International Society for Influenza and other Respiratory Virus Diseases 2nd International Meeting on Respiratory Pathogens 2018	Singapore	March 07-08, 2018
16th European Respiratory Society Lung Science Conference 2018	Estoril , Portugal	March 08-11, 2018
Inhalation & Respiratory Drug Delivery Usa Congress 2018	California , USA	March 12-13, 2018
10th Asia Pacific Global Summit on Healthcare	Singapore	March 12-14, 2018
German Respiratory Society 59th Annual Meeting 2018	Dresden , Germany	March 14-17, 2018
Turkish National Lung Health Congress 2018	Belek, Turkey	March 14-18, 2018
16th International Conference and Exhibition on Pharmaceutics & Novel Drug Delivery Systems	Berlin, Germany	March 19–21, 2018
4th International Conference on Respiratory and Pulmonary Medicine	Bali, Indonesia	March 21-22, 2018
Pakistan Chest Society 2018	Islamabad , Pakistan	March 22-25, 2018
Australia And New Zealand Society Of Respiratory Science And The Thoracic Society Of Australia And New Zealand Annual Meetings 2018	Adelaide, Australia	March 23-27, 2018
7thAustralian Lung Cancer Conference	Sydney Australia	April 05-07 2018
14th International Conference & Exhibition on Nanomedicine & Pharmaceutical Nanotechnology	Amsterdam, Netherlands	April 09–11, 2017
European Lung Cancer Conference 2018	Geneva , Switzerland	April 11-14, 2018
Canadian Respiratory Conference 2018	Vancouver, Canada	April 12-14, 2018
Mayo Clinic Multidisciplinary Update In Pulmonary And Critical Care Medicine 2018	Scottsdale, USA	April 12-15, 2018
17th International Conference on Oral & Maxillofacial Pathology 2018	Las Vegas, USA	April 18–19, 2018
4th International Conference on Antimicrobials, Antibiotics Resistance and Multiple Drug Resistance	LAS VEGAS, USA	April 20-21, 2018
Japanese Respiratory Society 58th Annual Meeting 2018	Osaka , Japan	April 27-29, 2018
Pulmonary And Critical Care Medicine 2018	Cambridge , USA	Apr 29-May 02, 2018
10th Annual European Pharma Congress	Frankfurt, Germany	May 07–09, 2018
3rd Annual Inhalation & Respiratory Drug Delivery Congress 2018	London, UK	May 08-09, 2018
Asthma Congress and Allergy Congress	Singapore, Singapore	May 14-16, 2018
20th International Conference on Allergy, Asthma and Immunology	London, UK	May 14-15, 2018
2nd International Conference and Exhibition on Pharmaceutical Technology and Development		May 14-15, 2018
6th Chronic Obstructive Pulmonary Disease Conference	Tokyo, Japan	May 17-18, 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.*

TITLE	VENUE	SCHEDULE
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	Osaka, 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
Phar-East 2018	Singapore	Feb 28–Mar 02, 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
Pharmaceutica 2018	Berlin, Germany	March 19–21, 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
ISF Kuwait 2018	Mishref, Kuwait	April 03–05, 2018
Kuwait Health 2018	Mishref, Kuwait	April 04–05, 2018
Lab Indonesia 2018	Jakarta, Indonesia	April 04–06, 2018
ECCC 2018	Dubai, UAE	April 05–07, 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
Korea Lab 2018 & Korea Pharma 2018	Seoul, Korea	April 17–19, 2018
Medtec Europe 2018	Seoul, Korea	April 17–19, 2018
Oral Pathology 2018	Las Vegas, USA	April 18–19, 2018
CPhI Japan	Tokyo, Japan	April 18–20, 2018
Exposanita 2018	Bologna, Italy	April 18–20, 2018
UAE International Orthopaedic Congress'18	Dubai, UAE	April 19–21, 2018
IMTEC 2018	Muscat, Oman	April 24–26, 2018
Analitika Expo 2018	Moscow, Russia	April 24–26, 2018
TIHE 2018	Tashkent, Uzbekistan	April 25–27, 2018
HealthGB 2018	Manchester, UK	Apr 30–May 2, 2018

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

FAST FACTS

- The World Health Organization (WHO) estimated that globally around 140 million peoplewerealcoholdependent and another 400 million suffered alcohol related problem.
- The current maternal mortality ratio (MMR) is 196 per 100,000 live births, which were 194 in 2010.
- About 11,956 women are diagnosed with cervical cancer in the country every year and over 6,582 die of the diseases.
- About 6.9 million people are living with diabetes in Bangladesh and it will hit 13.7 million by 2045.