PHARMA BUREAU
HEALTH. SAFETY. QUALITY. INTEGRITY

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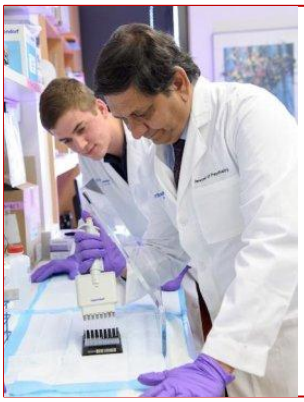
Newsletter

Depressed with a chronic disease? Many find antidepressants are not working



Dr. Madhukar Trivedi (front) is senior author of a JAMA study that adds to evidence that commonly prescribed antidepressants aren't effective in people battling both depression and a chronic medical disease. The findings raise a critical question of whether doctors should enact widespread changes in how they treat millions of depressed Americans.

Scientists are finding more evidence that commonly prescribed antidepressants aren't effective in people battling both depression and a chronic medical disease, raising a critical question of whether doctors should enact widespread changes in how they treat millions of depressed Americans.

A new study published in the Journal of the American Medical Association found depressed patients with chronic kidney disease did not benefit from a common antidepressant. The finding follows other research that indicates traditional antidepressants are also ineffective in depressed people with chronic conditions such as asthma and congestive heart failure.

Experts with the O'Donnell Brain Institute say enough evidence now exists to prompt immediate change in how doctors approach depression cases in conjunction with chronic medical diseases.

"There is little justification in prescribing an antidepressant that will not work and will only cause side effects," says Dr. Madhukar Trivedi, senior author of the JAMA study and director of the Center for Depression Research and Clinical Care, part of the Peter O'Donnell Jr. Brain Institute at UT Southwestern Medical Center. "We should go back to the drawing board to understand the brain changes involved in these subtypes of depression."

Nearly half of Americans live with a chronic medical condition, ranging from cancer and dementia to arthritis and asthma, according to the Centers for Disease Control and Prevention. Many of these people also have major depression, including more than half of Parkinson's patients, 41 percent of cancer patients, and more than a quarter of those with diabetes.
Doctors and patients should take these statistics into account when treating cases of major depression, says Dr. Trivedi, Professor of Psychiatry and holder of the Betty Jo Hay Distinguished Chair in Mental Health and the Julie K. Hersh Chair for Depression Research and Clinical Care.
He says both sides should understand that standard antidepressants may not work and be prepared to try alternatives if routine monitoring of symptoms and side effects show another strategy is needed.

Dr. Trivedi, who led the Star*D studies that established widely accepted treatment guidelines for depressed patients, has recently made progress on developing a blood test to determine in advance which antidepressants are more likely to work for important subgroups of patients. He also notes a range of other therapies that have proven effective for patients who don't respond to initial treatments. These include ketamine, electroconvulsive therapy, neuromodulation with magnetic stimulation, psychotherapy, and exercise.

[Source: Science Daily]

Why developing countries must improve primary care

The changing burden of disease requires a better approach to keeping people healthy

IN POOR countries people are living longer and healthier lives than ever. Since 2000 child mortality has fallen by almost half. The rate of new HIV/AIDS infections has dropped by 40%. About 7m deaths from malaria have been prevented.

Yet there is much more to be done. By one measure, the World Health Organisation reckons about 400m people still have no access to primary care—the basic form of medicine that should be at the forefront of any well-run health system. The real figure is probably much higher. And even for those fortunate enough to see a general practitioner, or more usually a semi-trained medic or quack, treatment is often dire.

The poor state of primary care will matter even more as the burden of disease in poor countries comes to resemble that in rich ones, shifting from infectious diseases to chronic conditions. By 2020 non-communicable diseases will account for about 70% of deaths in developing countries. But the majority of people with high blood pressure, diabetes or depression do not get effective treatment—and may not even know they have a problem. They deserve better.

Primary health care is not flashy, but it works. It is the central nervous system of a country's medical services—monitoring the general health of communities, treating chronic conditions and providing day-to-day relief. It can ensure that an infectious disease does not become an epidemic. Before the Ebola outbreak of 2014, nearly half of Liberians could not afford primary care and the deadly virus spread quickly. In parts of west Africa with better primary care, it was more easily contained.

Neglect of primary care is often the unintended result of good intentions. International aid-givers have concentrated much of their effort on cutting the rates of individual infectious diseases, partly because success at treating them is easier to measure. Governments in many developing countries, meanwhile, have ploughed scarce money into visible—and expensive—hospitals in big cities. Between 2002 and 2013 the number of larger hospitals in China nearly doubled, whereas the tally of primary-care providers shrank by 6%. China now has more hospital beds per person than America.

Such lopsidedness is wasteful. Primary care can deal with the vast majority of medical consultations. Expanding primary care tends to bring marked improvements. Brazil's "Family Health Programme", which costs barely $50 a person and covers roughly half the population, has cut infant mortality and needless hospitalisation. Rwanda, Sri Lanka and Thailand have had similar success. Costa Rica spends far less than the global average on health, but has the highest life expectancy in the Americas after Canada and Chile, thanks to its impressive primary care.

There are plenty of good examples to follow. The first step should be to train those already providing care, who are often private practitioners, ranging from drug dispensers to dubious healers. Some medical bodies would like to see care-providers without formal medical qualifications banned, but the evidence is that even short training courses can greatly improve their diagnoses. In South Africa a scheme called the Practical Approach to Care Kit (PACK) uses checklists to train health workers without medical degrees to diagnose 40 common symptoms and treat 20 chronic conditions.

A second step is to make better use of technology. In Delhi's 158 mohalla(community) clinics, the first of which opened in 2015, a testing-kit costing $640 can run 33 common medical tests. Rwanda is trying out a telemedicine scheme to make it easier for patients in rural areas to speak to a doctor. DHIS 2, a free, open-source system for collecting and sharing health data, is used in 47 countries.

A third important change is to design better incentives. Even when clinicians know how to deal with patients properly, they may not do so. Sometimes pressure from patients leads them to overprescribe antibiotics. The problem is made worse when doctors profit from the drugs they prescribe or the tests they order. Better to follow Rwanda, where health workers are rewarded for following clinical guidelines, not for the prescriptions they issue.

In much of the rich world, ageing populations and new technology are leading policymakers to rethink their health services. Many have belatedly realised that, for chronic conditions, there are better and cheaper alternatives to hospitals. Poorer countries have a chance to anticipate these changes. They should seize it.

[Source: The Economist]

November 14:

World Diabetes Day

What is Diabetes?

Diabetes is a number of diseases that involve problems with the hormone insulin. Normally, the pancreas (an organ behind the stomach) releases insulin to help your body store and use the sugar and fat from the food you eat. Diabetes can occur when the pancreas produces very little or no insulin, or when the body does not respond appropriately to insulin. As yet, there is no cure. People with diabetes need to manage their disease to stay healthy. Following are its two main types:

Type 1	Type 2
where the body's immune system attacks and destroys the cells that produce insulin	where the body doesn't produce enough insulin, or the body's cells don't react to insulin

Nutrition

How much sugar a food contains?

High	Low
22.5g or more of total sugar per 100g	5g or less of total sugar per 100g

Breakfast

- plain porridge
- plain wholewheat cereal biscuits
- plain shredded wholegrain pillows
- try wholemeal or granary bread, which is higher in fibre than white bread

Main Meals

- ready-made soups, stir-in sauces and ready meals can also be higher in sugar
- sweet and sour dishes, sweet chilli dishes and some curry sauces, dressings like salad cream are high in sugar

Snacks

- fruit (fresh, tinned or frozen), unsalted nuts, unsalted rice cakes, oatcakes, or homemade plain popcorn.
- lower-calorie hot instant chocolate drink. get chocolate with coffee and chocolate with malt varieties

Desserts

- To prevent tooth decay, dried fruit is best enjoyed at mealtimes – as part of a dessert
- gradually reduce the amount of sugar in tea or coffee until you can cut it out altogether
- fizzy drinks, fruit juice can be high in sugar

On the birthday of Sir Frederick G. Banting

Frederick Grant Banting was born on November 14, 1891, at Alliston, Ont., Canada. He was the youngest of five children of William Thompson Banting and Margaret Grant. Educated at the Public and High Schools at Alliston, he later went to the University of Toronto to study divinity, but soon transferred to the study of medicine.

Banting had become deeply interested in diabetes. The work of Naunyn, Minkowski, Opie, Schafer, and others had indicated that diabetes was caused by lack of a protein hormone secreted by the islets of Langerhans in the pancreas. To this hormone Schafer had given the name insulin, and it was supposed that insulin controls the metabolism of sugar, so that lack of it results in the accumulation of sugar in the blood and the excretion of the excess of sugar in the urine. The problem, therefore, was how to extract insulin from the pancreas before it had been thus destroyed.

Dr. Charles Best, then a medical student, was appointed as Banting's assistant, and together, Banting and Best started the work which was to lead to the discovery of insulin.

In 1923 he was elected to the Banting and Best Chair of Medical Research, which had been endowed by the Legislature of the Province of Ontario. In the Banting and Best Institute, Banting dealt with the problems of silicosis, cancer, the mechanism of drowning and how to counteract it. During the Second World War he became greatly interested in problems connected with flying (such as blackout).

In addition to his medical degree, Banting also obtained, in 1923, the LL.D. degree (Queens) and the D.Sc. degree (Toronto). Prior to the award of the Nobel Prize in Physiology or Medicine for 1923, which he shared with Macleod, he received the Reeve Prize of the University of Toronto (1922). He was knighted in 1934. As a keen painter, Banting once took part of a painting expedition above the Arctic Circle, sponsored by the Government.

Banting married Marion Robertson in 1924; they had one child, William (b. 1928). This marriage ended in a divorce in 1932, and in 1937 Banting married Henrietta Ball.

When the Second World War broke out, he served as a liaison officer between the British and North American medical services. In February 1941, killed in an air disaster in Newfoundland.

[Source: Nobelprize]

Innovative Products

CE Marking for World's Only Integrated HIV Self-Test from Atomo Diagnostics Gives Access to Safe, Accurate and Reliable Self-Testing

The Atomo HIV Self Test is the world's only integrated self-test device, providing greater convenience, ease-of-use and infield diagnostic performance when compared to other multi-component HIV test kits. Atomo Diagnostics is now actively engaging with commercialisation and distribution partners to make the test widely available in European and other global markets during 2018 via retail, e-commerce and public health channels.

Designed as an at-home self-test, the Atomo HIV Self Test is a rapid, lateral flow in vitro qualitative immunoassay for the detection of antibodies to Human Immunodeficiency Virus Type 1 and Type 2 in human whole blood.

The Atomo HIV Self Test needs only a single drop of blood, obtained from the fingertip using the built-in safety lancet. The test device also incorporates a unique blood collection and delivery system to further simplify the test procedure and eliminate user errors common to other test kits. An accurate result is provided in minutes.

HIV self-testing is increasingly seen as vital if the global health community is to achieve the goals of the 90-90-90 initiative of the Joint United Nations Programme on HIV/AIDS (UNAIDS). The aim of the initiative is to ensure that by 2020 90% of those living with HIV will know their status, 90% of those individuals will be on antiretroviral therapy (ART), and 90% of individuals on ART will be virologically suppressed. To achieve even the first 90% is a major undertaking: UNAIDS estimates that, as of July 2017, only 70% of the 36.7 million people living with HIV knew their status.

News

Presentation by Mr. Rizwan Buttar on 'Barcoding and Serialization'

On invitation by Pharma Bureau, Mr. Rizwan Buttar (Chief Innovative Officer – Zauq Group) gave a presentation highlighting the issues in the implementation of 'Barcoding and Serialization'. He informed the participants of his experience in its implementation for his clients in Punjab and clarified that Product Identification Information and Manufacturing Date, should not be included in 2D data matrix as it contradicts international implementation of Barcodes on pharmaceutical products.

Participants shared that some packaging lines will be online before the deadline but due to impossibly short deadline, they would not be able to print 2D data matrix on all products.

Due to his close coordination with Turkish Ministry of Health, Mr. Buttar stated that in Turkey, a roadmap and detailed implementation guidelines were provided to the pharmaceutical industry.

He presented the implementation of the trace system through the free android app 'Pharma Trax Scanner' that can be downloaded from Google's Play Store. It was developed for the inspectors of the province of Punjab. Barcodes information can be retrieved from the Master Database through this app and genuine drugs identified. Moreover, the whole supply chain can be traced from this app to create value for the companies.

He made a suggestion that to curtail the spread of counterfeit and spurious drugs, government should make it mandatory by law to sell drugs at the pharmacies only after digital scan.

Through his discussions with the DRAP MIS team, he identified various issues that needs to be resolved in the Drug Regulatory Information System (DRIS).

Serialization Partners Launch New Plug-In To Improve Production Efficiency

Commenting on the collaboration, Marco Baietti, commercial director at SEA Vision said: "One of the greatest barriers to serialization compliance is the cost of implementing new systems and processes, and that is why we are focused on helping our customers to achieve wider benefits to help justify the investment.

"Our latest research found that just 44 per cent of companies intend to use the serialization implementation process to achieve wider business benefits. We believe this is a missed opportunity and have made it our mission to help our customers to understand and realise the potential of serialization technology.

The new functionality allows the operator to have a holistic view of the line's efficiency. Using the visual reporting tool, it is possible to analyse the OEE of each line in real-time, during the batch run. In addition, by collecting data from each machine on the line, the plug-in records all rejections and errors, generating a complete audit trail report and assisting compliance requirements.

PepsiCo taps packaging conference attendees for 'active and intelligent' ideas

Packaging serves two primary purposes: to contain and protect food and beverage, and to catch a consumer's eye on the shelf. Premium packaging, if executed and positioned correctly should enable manufacturers to command a higher price point, potentially boosting a brand's top-line performance.

Snacks, candy and gum producers, for example, have debuted various convenience-based packaging innovations — such as resealable pouches, mini packets and car cup holder-sized packages — contributing to a premium perception. Other manufacturers have applied unusual printing techniques, real and imitation texture in package designs, conceptual illustrations and interactive packaging.

According to Nielsen, 63% of consumers say renewable packaging is a key driver in purchase decisions. Sustainability is a key agenda item for PepsiCo as well.

PepsiCo's Gatorade is developing what it calls a first-of-its-kind hydration tracking and personalized sports fuel delivery system featuring formula-specific Gatorade pods and a squeeze bottle with Bluetooth tracking cap, along with a mobile hydration app. On the renewability front, PepsiCo is developing biodegradable bottles made from ingredients like mushrooms and seaweed.

Imports To Fuel India's Active Pharmaceutical Ingredients' Requirements

China has a competitive edge globally in API manufacturing, with exports growing at a compounded annual growth rate of 4.13 percent during 2012-2016. Less stringent environment norms have enabled large-scale production in the country, making it a market leader. However, China's revamped environmental protection law to control pollution may disrupt production in many unorganised API manufacturing units. In such case, import-dependent countries, especially India would be majorly affected.

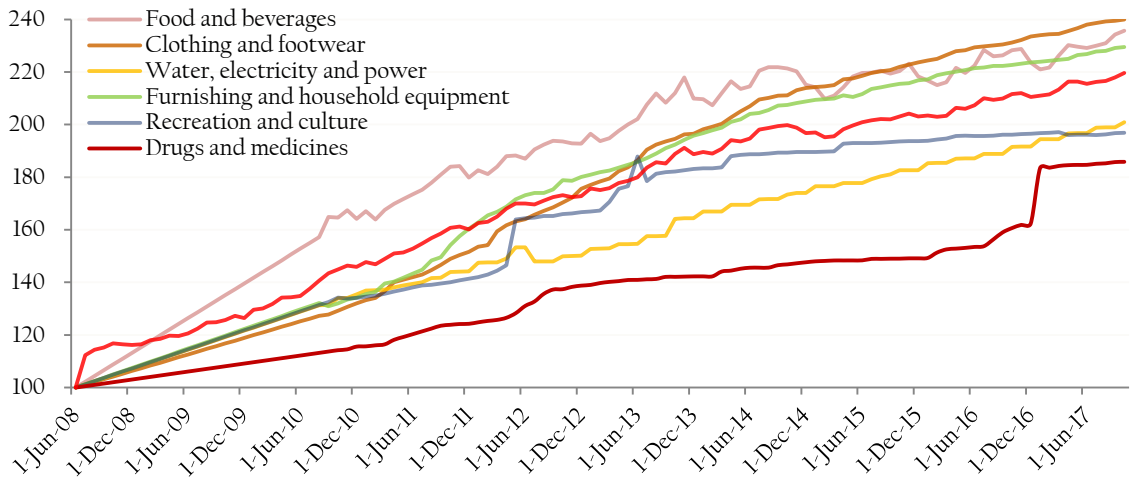
Among the top emerging and developing economies, India is a major importer of bulk drugs from China at 54 percent, followed by Indonesia at 24 percent, Brazil at 12 percent and South Africa at 8 percent.

In India, the initiative to discontinue loan licensing or contract license could have two possible implications: first, the companies would incur capex and set up their own manufacturing units; secondly, there will be backward integration. Also, many CMOs manufacture drugs for different companies under one licence so the integration becomes complicated. Furthermore, most of CMOs fall under the micro small and medium enterprises category, constituting 25 percent of the total market; thus, the implementation of this initiative could have a major negative impact on the market.

Another initiative of prescription of drugs by generics, not by brand will leave the patients at the mercy of the pharmacists as they will be motivated to sell high-margin drugs. Fixed dose combinations and patented drugs can be sold as branded drugs; hence, this may allow companies to modify generics and sell drugs as fixed dose combinations in varying combinations. The agency expects laws enabling pharmacists to substitute the prescribed branded medicines with suitable generics should be introduced to address this issue before the initiative is implemented.

Market Update

Monthly Inflation (Consumer Price Index)



% Increase in CPI vs. Same Month Last Year

From in Sept **3.9** ⇨ To in Oct **3.8**

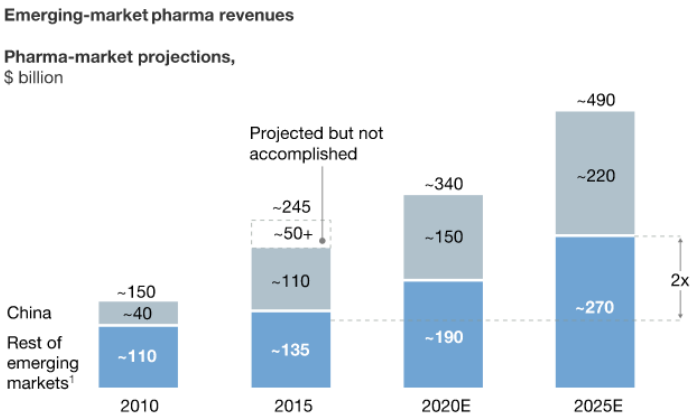
Major increase was due to house rent and education increase of 6.49% and 11.46% respectively, as compared to the previous year. It has a contribution of 25.75% in the Consumer Price Index (CPI). Moreover, price of onions increased by 178.6%.

% Increase in CPI vs. Previous Month

From in Sept **0.6** ⇨ To in Oct **0.7**

Major increase was due to increase in education (3.66%), house rent (1.34%) and prices of food items such as Tomatoes (31.43%) and Pulse Mash (5.11%) as compared to the previous month. It has a contribution of 26.39% in the Consumer Price Index (CPI).

McKinsey & Company Emerging Markets Update



We believe emerging markets are following a predictable cycle that will likely return them to a positive outlook before long—perhaps as soon as the current wave of launches is complete. In fact, we believe emerging markets could still see a doubling of pharma revenues for the top 20 markets in the next ten years (exhibit). The opportunity remains attractive even if we do not account for China, a large and strategic market for most pharma companies, independent of their strategy in emerging markets.

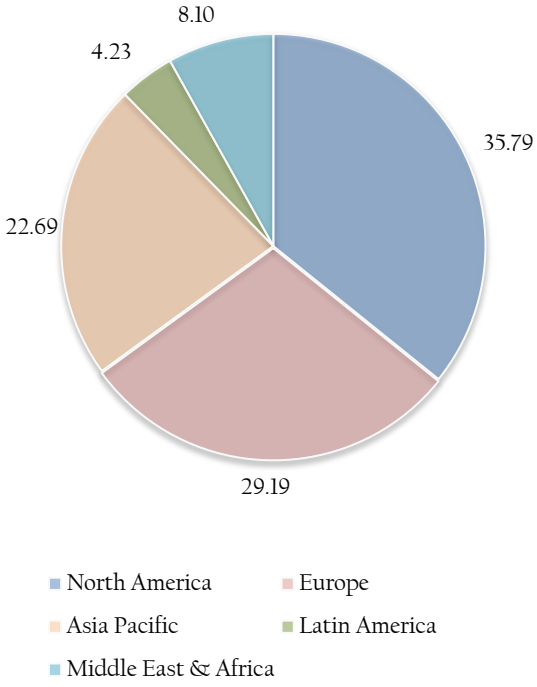
[1]Brazil, India, Russia; Tier 3: Algeria, Argentina, Bangladesh, Chile, Colombia, Egypt, Indonesia, Kazakhstan, Mexico, Nigeria, Pakistan, Philippines, Poland, South Africa, Saudi Arabia, Turkey, Vietnam.

McKinsey&Company | Source: BMI Research (May 2017); IMS Global Use of Medicines

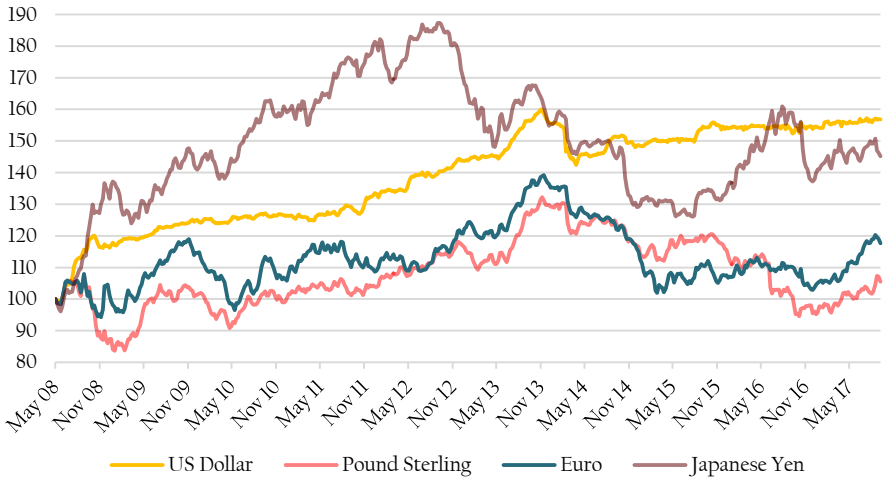
Contract Manufacturing

The market was valued USD 65.10 billion in 2016 and is projected to reach USD 94.38 billion by 2022, at a CAGR of 6.36% during the forecast period, from 2017 to 2022.

The global pharmaceutical contract manufacturing market is segmented, by type, into active pharmaceutical ingredient (API), final dosage formulation (FDF) and secondary. The active pharmaceutical ingredient packaging segment constitutes a major share of the market. The rise in the demand for abbreviated new drug applications (ANDA) and an increase in filing drug master files (DMF) from Indian companies have fueled the growth of the API market. Most of the companies in this industry are increasingly focusing on the development of biological APIs, which is driving this market. Other factors propelling the growth of the API market include stringent government initiatives in the healthcare sector, innovation in biologics and high potency API, and rise in the incidence of cancer and age-related diseases. Captive manufacturers are, currently, leading the API market; however, they are expected to lose the market share to contract manufacturers, by the end of forecast period. This is due to the complex and expensive in-house manufacturing of API and rise in competition from emerging players in this industry [Source: Mordor Intelligence]



Foreign Currencies

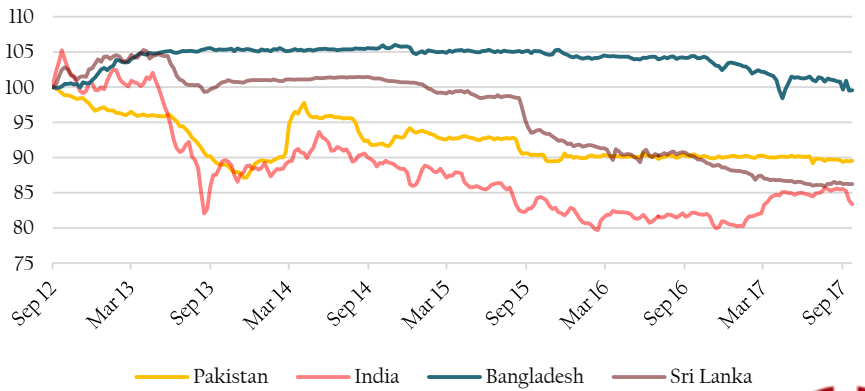


PKR vs. Major Foreign Currencies

PKR has depreciated against USD and GBP in October 2017 by 0.6% and 3.7% respectively and appreciated against Euro and Yen by 1% and 2.7% respectively.

USD vs. Major South Asian Currencies

USD appreciated against Pakistan Rupee (0.2%), Indian Rupee (2.6%), Bangladesh Taka (1.3%) and Sri Lankan Rupee (0.1%)



Questions? We'd love to hear from you

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The Pharma Bureau is a representative body of multinational pharmaceuticals in Pakistan. Part of the Overseas Investors' Chamber of Commerce & Industry, the Pharma Bureau was founded in October, 1988, when a small group of like-minded research based multinational pharmaceutical companies felt the need to have their own separate forum to articulate and resolve the problems and issues confronting overseas investors in the pharmaceutical industry in Pakistan.

Pharma Bureau Mission: Work closely with the relevant Government authorities to tackle and help resolve health industry related issues. Assist member firms in Product Registration Procedures. Protection of Intellectual Property Rights of members by respecting international patent laws. Bring about positive changes in the Health Administration set-ups by encouraging the Government to bring about improvements and changes in the structure and workings of health administrations

Our members: Provide quality drugs to the population at affordable prices without compromising on stringent industry standards. Introduce innovative drugs and medicines in Pakistan to enhance patient welfare and quality of life. Provide refresher courses to doctors on latest health topics / trends and educate them on new medication. Introduce, uphold and promote Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP). Are conscientious and ethical members of society, providing social care and support during national disasters.