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12th, September, 2022



Today's Topic Covered

1) Samples of 13 medicines made in Himachal have also been found to be failed...Read in Detail

2) Himachal dominates MTB Grey Ghost Challenge cycle rally.....Read in Detail

3) Shimla-Dharamshala city's air clean...Read in detail about Air Quality Index

Topic: Samples of 13 medicines made in Himachal have also been found to be failed

Importance: Himachal HPAS Prelims and Mains

Importance for Prelims: Himachal Current Events (Economic and social development – sustainable development poverty, inclusion, demographics, social sector initiatives, etc.)

Importance for Mains Exam:

- *PAPER-V: GENERAL STUDIES-II: Unit II: Topic: Institutional framework, Policies and Interventions for development in various sectors in India.*

What is the news?

- 45 samples of medicines taken from across the country by the Central Drugs Standard Controller Organization have failed. In this, samples of ***13 medicines made in Himachal have also been found to be failed.*** Samples of 1,330 drugs were taken from across the country in August, out of which only 1,285 have passed.



What are these failed medicines?

- The failed samples also include medicines for diabetes, fever, depression, infection, fungal, acidity, gallstones and gas.
- These also include samples of Paracetamol, a fever medicine from three companies. Two samples each of two companies of Solan district have failed.
- The medicines whose samples have failed in the state include companies from Sirmaur and Solan districts.
- State Drug Controller Navneet Marwah said that notices have been issued to the concerned company operators. The market has been asked to lift the stock. The department itself will also examine the samples in these companies at its level.

What are the major concerns of Indian pharma industry?

- India is the largest provider of generic drugs globally. Indian pharmaceutical sector supplies over 50% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. Globally, India ranks 3rd in terms of pharmaceutical production by volume and 14th by value. The domestic pharmaceutical industry includes a network of 3,000 drug companies and ~10,500 manufacturing units. India enjoys an important position in the global pharmaceuticals sector. The country also has a large pool of scientists and engineers with a potential to steer the industry ahead to greater heights. Presently, over 80% of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome) are supplied by Indian pharmaceutical firms.

In itself India represents a major market for pharma companies with a population of over 1.2 billion yet the country posts an impressive export turnover of over US\$10 billion, spread across 200 countries. However, domestic and international pharmaceutical companies face a number of major problems, including the quality of medicines, the quality of clinical trials and patent protection.



Drug Quality:

- The World Health Organization (WHO) estimates that up to 30 percent of branded medicines sold in developing countries are counterfeit, and this can have profound consequences for patients. For instance, it is estimated that counterfeits of tuberculosis and malaria, largely from India and China, kill some 700,000 people a year! Counterfeiters, like legitimate drug manufacturers, are keen to benefit from manufacturing costs in India that are around 40 per cent cheaper than other markets. As a result, India's counterfeit market has reportedly grown at a rate of about 25 per cent per annum, and represents a significant proportion of the global counterfeit drug market (thought to be worth between \$75 billion and \$200 billion a year).
- In response to the significant concerns raised by importers of Indian pharma products, the Indian Government, WHO, and the partnership for safe medicine (PSM) are putting in place initiatives to combat

counterfeit drug manufacturing, including:

- Enhance the capacity of state governments by providing drug testing laboratories with modern technology and the latest rapid testing equipment.
- Implement serialization, non-clonable packaging and 2D barcode.
- Investing in more 'new drug manufacturer inspectors'.
- The intention being to identify quality and safe medicines from spurious and unsafe medicines in the supply chain, and ensure prompt action against manufacturers and dealers found trading in fake and unsafe medicines.
- In addition to the challenge of counterfeit manufacturers, the legitimate manufacturers that make up India's flourishing pharmaceutical export industry also attract the attention of foreign regulators like the FDA. It is easy to see why India is the largest foreign supplier of drugs to the U.S. and has about 200 FDA-approved drug manufacturing facilities. India produces close to 40% of generic and non-prescription drugs and accounts for 10% of finished doses in the United States. The FDA has highlighted an increasing number of quality issues and last year added seven new inspectors to its Indian office, bringing the total number of employees to 19. Increased FDA surveillance has prevented about 19 drug manufacturing facilities in India from supplying drugs to the United States. With restrictions, including import warnings imposed on the facilities of several multinational life sciences companies.

Clinical trial quality:

- In many ways, India is an ideal location to conduct clinical trials given its diverse supply of patients with diverse treatment needs and access to a large and scientifically competent workforce. This has caused huge

growth in the number of clinical trials however, capacity to regulate trials has not kept pace leading to a number of unethical practices such as; a lack of patient compensation for adverse events; approval of drugs without clinical trials and lapses in informed consent procedures. Again increases in regulatory control by the Indian government, in the form of mandatory trial registration and the creation of numerous committees tasked with overseeing trial approval, trial execution, and ethical treatment of patients, is starting to have a more positive impact. The bad news is that delays in new drug approvals as a result of the new regulatory control regime is forcing some multinational companies to rethink their clinical trial activity in this market.

Patent issues:

- In India, 70 per cent of expenditure on healthcare is out-of-pocket, which has led the government and its judiciary to take steps to promote the use of generic products and prevent prices of lifesaving drugs being set by market forces. This has caused a number of issues for multinational companies, leading some to question the commercial viability of India:
- In April 2013, Novartis lost a six-year legal battle after the Supreme Court ruled that small changes to its leukemia drug Glivec would not get a new patent.
- Recently India upheld a compulsory license of Bayer's cancer drug Nexavar, effectively allowing generics firms to copy the patented drug.
- The Indian patent office has revoked Pfizer Inc.'s local patent for its cancer drug Sutent, delivering yet another setback to multinational drug companies over the contentious issue of intellectual property (IP) rights.
- Roche's patent on Pegasys, a hepatitis C drug, was

denied.

- These challenges, amongst others, have caused pharmaceutical industry growth to slow over the last year (from 16.6 per cent to 9.8 per cent), a trend that both domestic and multinational companies are looking to reverse.
- For this to be achieved companies will need to work closely with the Indian government, regulators and other key stakeholders to establish compliant business practices that are commercially viable.



Some of the solutions include:

- Bolstering internal compliance to keep up with evolving global and domestic regulations concerning quality. This has the potential to drive significant competitive advantage
- Striking a practical balance between underpinning clinical trials with scientifically and ethically correct practices and maintaining the low R&D costs that fueled initial growth in India's pharmaceutical market
- Striking a balance between ensuring affordability of, and access to life saving treatments with securing the future of innovative new medicines globally. Current patent laws have good intentions, however, multinational companies, looking to emerging markets for growth as the price squeeze continue in traditional markets, have been left in a difficult position. Can the developed world continue to foot the bill for innovation? Increasingly,

it seems R&D engines need all the help they can get!

(News Source: Amar Ujala)

Topic: Himachal dominates MTB Grey Ghost Challenge cycle rally.

Importance: Himachal HPAS Prelims and Mains

Importance for Prelims: Himachal Current Events (Economic and social development – sustainable development poverty, inclusion, demographics, social sector initiatives, etc.)

Importance for Mains Exam:

- *PAPER-VI: GENERAL STUDIES-III: Unit III: Topic: Types of tourism: religious, adventure, heritage, Important tourist destinations in Himachal Pradesh.*

What is the news?

- *Himachal dominates MTB Grey Ghost Challenge cycle rally.*

Who organized this?

- *Second MTB Grey Ghost Challenge Cycle Rally organized by cycling association Lahaul-Spiti at Muling Panchayat.*



Winners in different categories:

- Adonis of Manipur has bagged the first position in the ***men's senior category*** of the second MTB Grey Ghost Challenge Cycle Rally organized by cycling association Lahaul-Spiti at Muling Panchayat.
- Himachal's Ashish Sherpa and Shiven finished second and third respectively.

In the men's Under-18 category:

- Assam's Malav Dutta won. Himachal's Pranshu and Krish Gupta bagged the second and third positions respectively.

In the U-14 category:

- Awadh Verma, Aditya Baudh and Anurag Thakur of Himachal bagged the first, second and positions respectively.

(Source: Amar ujala)

Topic: Shimla-Dharamshala city's air clean

Importance: Himachal HPAS Prelims and Mains

Importance for Prelims: Himachal Current Events (General issues on environmental ecology, bio-diversity and Climate Change – that do not require subject specialization and General science)

Importance for Mains Exam:

- *PAPER-VI: GENERAL STUDIES-III: Unit III: Topic: State of environment reports. Environment protection and pollution control Act and rules.*

What is the news?

- After the rains in the state in the monsoon season, the air of two smart cities Shimla and Dharamshala remains the best in the state, while the AQI of Baddi and Kala Amb is moderate. ***The air of Shimla and Dharamshala city is the best.***
- While the AQI in Shimla is 28, it is 23 in Dharamsala.



What is the Air Quality Index?

- The Air Quality Index (AQI) is used for reporting daily air quality. It tells you how clean or polluted your air is, and what associated health effects might be a concern for you. The AQI focuses on health effects you may experience within a few hours or days after breathing polluted air.

How does the AQI work?

- Think of the AQI as a yardstick that runs from 0 to 500. The higher the AQI value, the greater the level of air pollution and the greater the health concern. For example, an AQI value of 50 or below represents good air quality, while an AQI value over 300 represents hazardous air quality.
- For each pollutant an AQI value of 100 generally corresponds to an ambient air concentration that equals the level of the short-term national ambient air quality standard for protection of public health. AQI values at or below 100 are generally thought of as satisfactory.

When AQI values are above 100, air quality is unhealthy: at first for certain sensitive groups of people, then for everyone as AQI values get higher.

- The AQI is divided into six categories. Each category corresponds to a different level of health concern. Each category also has a specific color. The color makes it easy for people to quickly determine whether air quality is reaching unhealthy levels in their communities.

| Daily AQI Color | Levels of Concern | Values of Index | Description of Air Quality |
|-----------------|--------------------------------|-----------------|---|
| Green | Good | 0 to 50 | Air quality is satisfactory, and air pollution poses little or no risk. |
| Yellow | Moderate | 51 to 100 | Air quality is acceptable. However, there may be a risk for some people, particularly those who are unusually sensitive to air pollution. |
| Orange | Unhealthy for Sensitive Groups | 101 to 150 | Members of sensitive groups may experience health effects. The general public is less likely to be affected. |
| Red | Unhealthy | 151 to 200 | Some members of the general public may experience health effects; members of sensitive groups may experience more serious health effects. |
| Purple | Very Unhealthy | 201 to 300 | Health alert: The risk of health effects is increased for everyone. |
| Maroon | Hazardous | 301 and higher | Health warning of emergency conditions: everyone is more likely to be affected. |

Five major pollutants:

Environmental Protection Agency (EPA) establishes an AQI for five major air pollutants regulated by the Clean Air Act. Each of these pollutants has a national air quality standard set by EPA to protect public health:

- 1) Ground-level ozone
- 2) Particle pollution (also known as particulate matter, including PM2.5 and PM10)
- 3) Carbon monoxide
- 4) Sulfur dioxide
- 5) Nitrogen dioxide

(News Source: Divya Himachal)

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