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Guidelines for Evaluation of Nanopharmaceuticals in India

Recently, the Government of India released “**Guidelines for Evaluation of Nanopharmaceuticals in India**”.

- There are no internationally accepted uniform guidelines for nano-pharmaceuticals. The usual consensus for evaluation of quality, safety and efficacy of nanotechnology-based products is to have a case-to-case approach.
- It takes into account the physical, chemical and biological characteristics of the nano-material used and the product, route of administration, the indication for which the product is intended to be used and other related aspects.

Nanopharmaceuticals

- Nanopharmaceuticals is defined as a pharmaceutical preparation containing **nanomaterials** intended for internal use or external application on a human for the purpose of therapeutics, diagnostics and health benefits.
- **Nanomaterial** is defined as material having a **particle size in the range of 1 to 100 nm** in at least **one dimension**.
- Nano-formulations are not entirely new drugs but medicines that have better quality because of the technology-led delivery mechanisms that are used to make its administration in the body more effective.

Nanopharmaceuticals Guidelines

- These guidelines have been developed in line with the provisions of **Schedule Y of Drugs and Cosmetics Rules, 1945** as well as **Second Schedule of the New Drugs and Clinical Trials Rules, 2019** with specific requirements for nanopharmaceuticals.

- The guidelines include,
 - The nano-size range **should be declared** in the **product specification**.
The particles should be within the claimed **nano-size range in all given testing conditions**.
 - The **detailed methods** of the manufacturing process and the **impact** of nanomaterial waste disposal on the **environment** should also be declared.
 - The **added advantage and possible disadvantage of nanopharmaceuticals** in comparison to conventional/traditional drug/API should be clearly stated on the products.
 - Though Nanocarrier based targeted drug delivery and nanoformulations have higher efficacy, lower toxicity and are safer than the conventional drugs.
 - A **Nanocarrier** is a nanomaterial being used as a transport module for another substance like a drug.
 - The **stability testing for Nanoformulations** should focus on functionality, integrity, size range of nanopharmaceuticals.
 - It will cover nanopharmaceuticals in the form of **finished formulation as well as Active Pharmaceutical Ingredient (API)** of a new molecule or an **already approved molecule with altered nanoscale** dimensions, properties.
It also covers the **phenomenon associated with the application of nanotechnology** intended to be used for treatment, in vivo diagnosis, mitigation, cure or prevention of diseases and disorders in humans.

Advantages of Guidelines

- The **regulatory system for Nanoformulations is expected to be strengthened** as the result of released guidelines.
Indian researchers and industry would be facilitated to undertake research in nanopharmaceuticals product development and commercialization.
- The guidelines will pave the way for significant benefits through such cutting edge technology and contribute to the mission of **“Affordable Health Care for All”**.

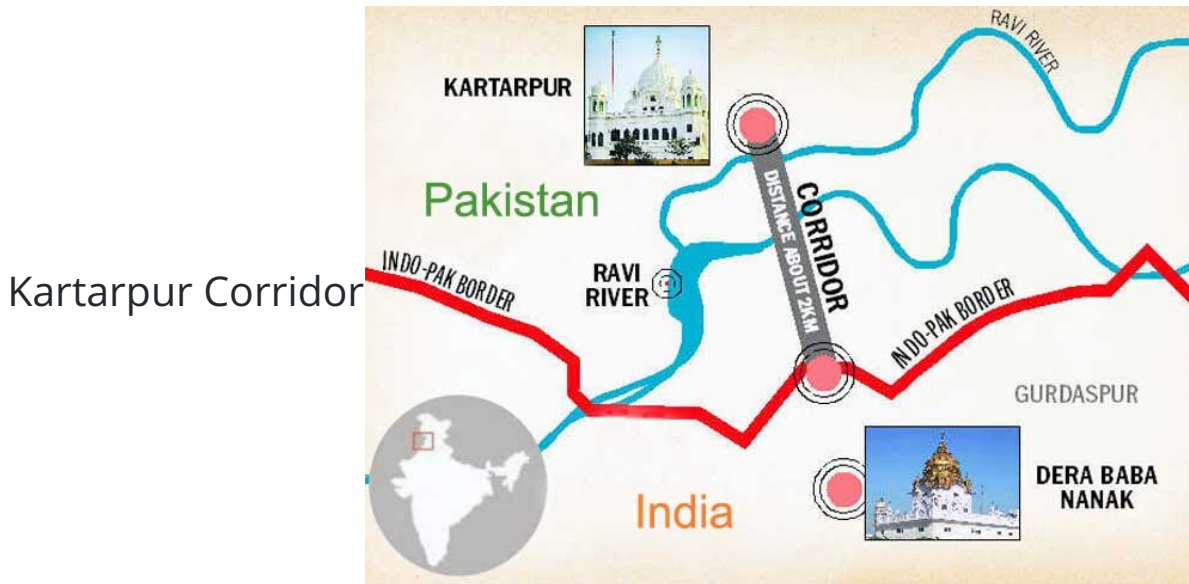
Source: PIB

Kartarpur Corridor

India and Pakistan have signed an **agreement** to operationalise the **Kartarpur corridor**. The agreement is **valid** initially for **five years**.

- Either party can terminate the agreement at any time by giving notice of one month to the other party of its intention to terminate this agreement.

- Also, the pact **could be suspended in case of exigency** or persistent violation of its provisions.
- The **Pakistan** side has agreed to make **sufficient provision for langar** and distribution of prasad in the Gurdwara premises.
- On **Indian side**, all the **required infrastructure**, including the highway and the passenger terminal building are near completion for timely inauguration of the corridor.
 - The **corridor** is expected **to be inaugurated on 9th November 2019**.
 - It would remain open throughout the year.



- The Kartarpur corridor connects the **Darbar Sahib Gurdwara** in Narowal district of **Pakistan** with the **Dera Baba Nanak shrine** in Gurdaspur district in **India's Punjab province**.
- The agreement will facilitate **visa-free movement of Indian pilgrims** who would just need a permit to cross over to Pakistan.
- The corridor was built **to commemorate 550th birth anniversary celebrations of Guru Nanak Dev, founder of Sikhism** on 12th November 2019.

Guru Nanak

- Guru Nanak Dev **Jayanti is observed on the full-moon day in the month of Katak** to celebrate the birth of **Guru Nanak Dev (1469-1539)**.
- He advocated the '**Nirguna**' form of bhakti. He rejected sacrifices, ritual baths, image worship, austerities and the scriptures of both Hindus and Muslims.
- He **set up rules for congregational worship (sangat)** involving collective recitation.
- He appointed one of his disciples, Angad, to succeed him as the preceptor (guru), and this practice was followed for nearly 200 years.

- The **fifth preceptor, Guru Arjan**, compiled Baba Guru Nanak's hymns along with those of his four successors and also other religious poets, like Baba Farid, Ravidas (also known as Raidas) and Kabir, in the **Adi Granth Sahib**.

These hymns, called '**Gurbani**', are composed in many languages.

- Kartarpur gurudwara is the **revered shrine** about 4km across the border where **Guru Nanak Dev spent the last 18 years of his life**.

Source: TH

Odisha's Integrated Irrigation Project for Climate Resilient Agriculture

The Government of India, Government of Odisha and the **World Bank** on 24th October 2019 signed a **\$165 million loan agreement** for the Odisha's Integrated Irrigation Project for Climate Resilient Agriculture.

About Project

- The project aims to **support small landholding farmers** in order to strengthen the resilience of their production systems against adverse climatic conditions by improving access to **climate resilient seed varieties and production technologies**.
- For **increasing the income** of the farmers, the project strives to **diversify** towards more climate-resilient crops and **improve access** to better water management and irrigation services.

The project will also provide **marketing support** to farmers who are able to generate a marketable surplus.

- The project will be implemented in **rural areas** that are **vulnerable to droughts** and are largely **dependent on rainfed agriculture**.

It is expected to benefit about 125,000 smallholder farmer households from 15 districts of Odisha.

- The project also aspires to support the **rehabilitation of 532 water tanks** thereby:
 - Promoting the **productivity improvements** at the farm level,
 - Supporting farmers to reduce the current emphasis on food grains (especially paddy- a water guzzler crop) and **increase the share of high-value and more nutritious products** like fruits and vegetables, and
 - Practising **aquaculture** in rehabilitated tanks so as to help farmers access affordable and quality fingerlings, and disseminate improved aquaculture practices and post-harvest management.

- This project is under the **National Action Plan on Climate Change (NAPCC)** of the government so as to achieve the **sustainable agriculture-related targets** of the SDGs by 2030.

There are **8 national missions** that form the core of the NAPCC representing the multi-pronged, long term and integrated strategies for achieving key goals in climate change.

Need for Project

- Since 2009, the frequency of droughts in Odisha has increased from 1 in 5 years to 1 in 2 years.
- About 70% of the total cultivated area is prone to droughts as compared to 40% in the 1970s.
- In Odisha, agriculture is also a major source of **Greenhouse Gas (GHG) emissions** and is responsible for about 25% of the GHG emissions in the state.
- Such erratic and extreme weather are responsible for declining yields and falling incomes of the farmers.

Greenhouse Gases (GHG)

- These are the gases that absorb and emit radiant energy within the thermal infrared range.
- **Primary GHGs** are- water vapour, carbon dioxide, **methane**, nitrous oxide, and ozone.
- GHGs create Greenhouse Effect which is the process by which radiation from a planet's atmosphere warms the planet's surface.

Way Forward

The project is intended to be a game-changer for the State by creating a more resilient agricultural sector, enhancing food security, increasing farmers' incomes and reducing the GHG footprint of the sector.

Source: PIB

World Polio Day

World Polio Day was established by **Rotary International** on **24th October** to celebrate the **birth of Jonas Salk**, who developed a **vaccine against poliomyelitis**.

- The establishment of the **Global Polio Eradication Initiative (GPEI) in 1988** reduced polio worldwide by **99%**.

- World Polio Day (2019) marked a milestone in polio eradication as the **independent Global Commission for the Certification of Poliomyelitis Eradication (GCC)** has declared **Wild Polio Virus type 3** to be **globally eradicated**.
It follows the eradication of smallpox and wild poliovirus type 2.

Wild Polio Virus type 3

- There are three individual and immunologically distinct wild poliovirus strains: Wild Polio Virus type 1 (WPV1), Wild Polio Virus type 2 (WPV2) and Wild Polio Virus type 3 (WPV3).
- **Symptomatically**, all three strains are **identical**, in that they cause irreversible paralysis or even death.
- But there are **genetic and virological differences**, which make these three strains three **separate viruses** that must each be eradicated individually.
- WPV2 and WPV3 have been eradicated globally but **WPV1 remains** in circulation in just two countries namely, **Afghanistan and Pakistan**.

Polio

- Polio is a crippling and potentially fatal **viral infectious** disease.
- There is **no cure**, but **can be prevented** through immunization.
- The strategy to eradicate polio is therefore based on preventing infection by immunizing every child until transmission stops.
- There are two types of vaccines to prevent infection.
 - **OPV (Oral Polio Vaccine)**: It is given orally as a birth dose for institutional deliveries, then primary three doses at 6, 10 & 14 weeks and one booster dose at 16-24 months of age.
 - **Injectable Polio Vaccine (IPV)**: It is introduced as an additional dose along with the 3rd dose of DPT under the universal immunization programme (UIP).
- **India** received **polio-free certification** by the **World Health Organisation (WHO)** in 2014.
 - **Eradication of a disease** refers to the complete and permanent worldwide reduction to zero new cases of an infectious disease through deliberate efforts. If a disease has been eradicated, **no further control measures are required**. For eg- **smallpox has been eradicated**.
 - However, **elimination of a disease** refers to **reduction to zero** (or a very low defined target rate) of new cases of an infectious disease in a **defined geographical area**. Elimination requires **continued measures to prevent re-establishment** of disease transmission. **Yaws and Leprosy** have been eliminated from India.

Source: TH

2000 Years Old Trade Centre Unearthed in Andhra Pradesh

Recently, the possible presence of **maritime trade centre** near the banks of the **Swarnamukhi river in Andhra Pradesh** around **2,000 years ago** has been put forward by the Archaeological Survey of India.

Key Findings

- An excavation of the site has unearthed **a huge settlement surrounded by a brick enclosure.**

The size of bricks can be compared to those in the **Satavahana/Ikshvaku period** structures in the Krishna valley.

Thus, the site may date back to the **2nd century to 1st century BCE**

- The excavation of four-armed **2-meter tall sculpture of Vishnu** belonging to the **Pallava period (8th Century CE)**, a series of **broken terracotta pipes** pointing towards a form of drainage make it appears to be a **trade centre.**
- Additionally, the **southern coastal** location and more such evidence of the trade, reinforces the **possibility of the existence of a trade centre** at the excavated site.

Source:TH
