

The Drugs, Medical Devices and Cosmetics Bill, 2022

(GS Paper 3, Health)

Context:

- The Union Health Ministry recently published a new draft Bill to **replace the antiquated Drugs and Cosmetics Act, 1940**.

Issues:

- To begin with, although the Ministry has described it as being consistent with the government's move to review obsolete pre-Independence legislation, most of it is a copy of the old law.
- There is nothing new in this Bill regarding drug regulation. And the Bill does nothing to address burning issues thrown up over the last decade since the Ranbaxy scandal.



Govt introduces draft of New Drugs, Medical Devices and Cosmetics Bill, 2022, invites comments

Old Regulatory theory:

- The original Act was enacted when the Indian pharmaceutical industry was in its infancy. At the time, the guiding theory of **this law was based on testing manufactured drugs purchased by drug inspectors** from the open market.
- If a drug failed quality testing, the manufacturer could be jailed. This was not the most efficient system of regulation because it depended entirely on luck or fate – only if a drug inspector picked a certain drug on a certain day and it failed testing would the manufacturer face legal action.
- Much of the world has shifted to a more rigorous system of regulation centered around the compliance of manufacturing units with **good manufacturing practices (GMPs)**. In theory, a drug manufactured in compliance with GMPs is subject to so many checks that it is unlikely that it would fail quality tests once shipped to the market.

Good Manufacturing Practices (GMPs):

- In **1988, India incorporated a system of GMPs** via rules framed by the government rather than Parliament. But even then, the government did not make GMPs the centrepiece of its regulatory strategy.
- In the U.S., the regulator's focus is in ensuring that manufacturing units comply with GMPs. American law presumes that any drug that is manufactured in a facility that **fails to comply with GMPs is 'adulterated'**.

Given this focus on GMP compliance, **U.S. law mandates the publication of reports of inspections conducted by its drug inspectors.**

- Indian law, on the other hand, contains no such criminal penalties for pharmaceutical companies failing to comply with GMPs.
- **At the most, licences may be cancelled**, but since inspection reports are never published, citizens have no idea if drug inspectors are conducting GMP compliance-related inspections.
- There is ample evidence to suggest that such inspections are not carried out. The Bill does nothing to change this system. In fact, it does not mention the phrase GMP even once.

Uneven enforcement:

- The one issue that has come up in every review of the drug regulatory system since 1947 has been the **uneven enforcement of the Drugs and Cosmetics Act** across India.
- This is because, unlike the U.S. which has a single federal agency tasked with enforcing drug regulation across the country, **India has 37 agencies for the same job**: one in each State and Union Territory along with the Central Drugs Standard Control Organisation (CDSCO), which is under the control of the Union Health Ministry.
- State drug controllers are expected to license drug manufacturing and also conduct enforcement actions such as sampling, testing and prosecution for substandard drugs.
- **The CDSCO's role is limited to regulating imports** and to deciding whether new drugs have adequate clinical evidence before they can be sold.
- Over the years, even the CDSCO has started drawing samples for testing and prosecuting erring manufacturers. In addition, the Health Ministry is in charge of laying down rules and regulations and banning drugs which do not have supporting clinical evidence.

Example of Himachal Pradesh:

- A problem with this setup is that States such as Himachal Pradesh, which account for a bulk of pharmaceutical manufacturing on account of a tax holiday, do a poor job in enforcing the Drugs and Cosmetics Act.
- This is not just because of poor state capacity; the fear of scaring away investments by the pharmaceutical industry likely plays a key role in the State's decision to not enforce the law.
- Since India is a single market, drugs manufactured in Himachal Pradesh are sold across the country and even States with relatively more competent drug regulators, such as Tamil Nadu, Karnataka and Gujarat, can do little to stop the flood of these substandard drugs.
- It is only the drug controller in Himachal Pradesh who can cancel manufacturing licences of facilities located in that State.
- This is the reason that the **Mashelkar Committee in 2003 had recommended centralising drug licensing** with the central regulator. The present Bill is silent on the issue.

Issue of transparency:

- Drug regulation by its very nature vests vast discretionary powers in unelected bureaucrats to take decisions such as approving a new drug or a new manufacturing facility, both of which can have huge implications for public health and profits of the pharmaceutical industry.
- These decisions are often based on scientific data, inspections, reports, etc. In such circumstances, the only safeguard to ensure **bureaucratic accountability is transparency**.
- As citizens, we should not be required to run after the regulator begging for information under the Right to Information Act, 2005. Rather, **the law should be written in a way to guarantee proactive disclosure** of all crucial documentation related to regulatory decisions.
- If a new drug is being approved, the regulator should be required to disclose all the data, including clinical trial data. Every time a drug is tested in a government laboratory, **the test report should be published on a publicly accessible database**.
- Each inspection for GMP compliance should conclude with an inspection report accessible to the general public. This is the only way to ensure accountability and build public confidence in the regulator.
- The **new law is silent on this critical issue of transparency** because it is structured largely on the basis of the original colonial-era legislation. The government must consider rewriting this law in a way that guarantees transparency by design.

Way Forward:

- Modern regulation delegates an incredible amount of power to unelected bureaucrats and technocrats. From a perspective of efficiency, such delegation is required, but from the perspective of accountability, it leads to a democratic deficit.
- This is why a modern regulatory system should be designed in a manner that guarantees citizens a right to participate in decision making. **Making information available to citizens** is only the first step in this process.
- The next step is to **create legal pathways**, such as public hearings or citizen's petitions which will enable citizens to participate in the regulatory process and register their objections.
- Since the present reform process is still in the early days, nobody will fault the Health Minister for junking this draft Bill and appointing a new committee of external experts to draft a Bill reflecting the democratic character of an India celebrating its 75th year of independence.

Tunnel vision that is endangering India's history

(GS Paper I, Culture)

Context:

- The Government has announced that a Bill will be introduced in the monsoon session to modify a law dealing with ancient monuments.
- The Bill will "provide more teeth to the Archaeological Survey of India".
- This move will align the Bill with the new bronze statue, which has a more aggressive expression than an ancient Ashokan sculpture from Sarnath (Uttar Pradesh) from which its form is derived.



Section 20 of AMASR Act:

- **Section 20 of the Ancient Monuments and Archaeological Sites and Remains (AMASR) Act of 1958**, last amended in 2010, **prohibits construction within a 100 metre radius** of all Archaeological Survey of India (ASI)-protected monuments and regulates activities within another 300 metre radius.
- The new Bill proposes to revise this section. Henceforth, expert committees will decide on the extent of the prohibited and regulated areas around each monument and activities permitted herein.

Sites under ASI:

- **The ASI protects around 3,700 archaeological sites and ancient monuments.**
- Taken together, they **mark milestones in India's history:** the emergence of well-planned cities, the rise of empires inspired by egalitarian ideals, the development and dispersion of Buddhism along trade routes, the flourishing of temple cultures, the establishment of Sultanate polities, creative and competitive encounters among and between the Mughals and the Rajputs, the ascendancy of the British Raj, and a largely non-violent movement that overthrew colonial rule.

The larger connections:

- Historically, each monument was integrally connected to the landscape around it. Here are a few examples.
- **Rock-cut sanctuaries from Barabar (Bihar) to Ajanta (Maharashtra) and from Masrur (Himachal Pradesh) to Guntupalli (Andhra Pradesh)** were physically connected to outcrops and canyons. **Pattadakal's temples (Karnataka)** were symbolically linked to the **Malaprabha River** that flowed past them.
- **Viramgam's Munsar Talav (Gujarat)** was the centrepiece of a landscape consisting of interlocking ponds, sluice gates, decanting wells, irrigation canals, and farmlands.
- **Lucknow's imambaras** were tied to markets, palaces, processional roads, and gardens.

British intervention:

- After 1857, colonial authorities reorganised cities by widening streets and demolishing dwellings around certain majestic older buildings so that they could properly survey the populace.
- In their effort to reposition architectural fragments of India's past as Britain's patrimony, colonial administrators placed select buildings on cushions of emerald grass.
- On occasion, they also **dismantled and removed edifices and sculptural ensembles** that they felt were inconsistent with the forms and functions of buildings that most interested them.

Serving diverse needs:

- Over the past 75 years, grounds around ASI-protected sites have served diverse needs. In Delhi, the grounds of the Purana Quila and other iconic buildings quickly transformed into campsites for tens of thousands of individuals arriving from newly-formed Pakistan.
- As these refugees resettled in various neighbourhoods and cities, these grounds emerged as public spaces for exercise, prayer meetings, protests, and more.
- With the progressive transformation of the capital into a concrete jungle, the green edges around Delhi's protected monuments became havens for migratory birds, small mammals, and host of reptiles and amphibians.

Threats to monuments:

- Rezoning land around ASI-protected monuments into industrial, commercial, or even residential plots will thus **deprive human and animal communities of much-needed commons.** Moreover, permitting construction work risks weakening the foundations of centuries-old edifices. The chances of inadvertent damage are also higher.
- **A hastily grounded electric pole might hit a monument's finial,** leading it to fall to the ground. Sacks of cement stacked against a frescoed wall can irreversibly abrade its surface.
- As is well known, many monuments in India are already threatened by anthropogenic forces. **Domestic waste and greywater regularly seep** into the subterranean sixth-century sanctuary at Jogeshwari in Mumbai. **Air and water pollution continue to turn the white marble of the Taj Mahal yellow and green,** and so on.

Archaeological impact assessments:

- For a well-trained historian, the earth around an archaeological site or ancient monument is like a text. If construction machines disturb it, then artefacts long buried in layers of soil risk being broken and their contexts destroyed.
- In recent years, the **Government has built new highways, metro-rail systems, and industrial parks** without methodical archaeological impact assessments. These projects have led to the shattering of an untold number of historical artefacts and the casual collection of many others.

Preserving composite tangible heritage:

- Conservation architect Ritish Nanda's team at Humayun's Tomb in Delhi has conserved a dazzling edifice and provided meaningful employment to an entire basti.
- In Bhubaneswar, the Odisha government has formulated a scheme to protect a cluster of ancient temples, tanks, and ponds to nurture a sense of regional identity, restore habitats, and bring in visitors in a methodical way.
- At the ancient city of Nagaur, Rajasthan, local artisans and multidisciplinary teams led by conservation architect Minakshi Jain have worked together to conserve a citadel, reopen ancient gates, plant trees, and promote a lively bazaar outside its main entrance, ultimately giving a new lease of life to a medieval complex and strengthening social fabrics.

Way Forward:

- It is unclear whether the new Bill will empower the ASI. Various laws and statutory bodies, such as the National Monuments Authority (under the Ministry of Culture), are already in place to help the ASI to fulfil its mandate.
- It is the time to ask for new, well-planned archaeological excavations to be undertaken at Sarnath and beyond, new partnerships to be formed with academic institutions committed to the rigorous study of India's past, and new accessible articulations of why studying history is important today.
- Such efforts will safeguard and promote our heritage in the years to come.

Prioritising development of NE India via six pillars of connectivity

(GS Paper 3, Infrastructure)

Contexts:

- For decades, states in North East region (NER) had suffered, because of "the tyranny of distance" syndrome. The region was not only cut off from the rest of nation geographically, but also at an emotional and psychological levels.
- Most of these stemmed from the lack of empathy and understanding on the part of former governments towards the unique socio-cultural, aspirational and developmental challenges and needs of the North East region.
- However, all that changed after current Government declared the development of NE Indian states as one of key priority areas for his government.

Funding commitments:

- **54 Ministries/Departments under the Central government** are today required to spend **at least 10 per cent of their budget in the North Eastern Region.**
- In 2014-15 the yearly budget allocation for the development of NE states was Rs 24,819.18 crores, in 2021-22 it rose to **70,874.32 crores, marking an increase of over 285%** in the past eight years alone.
- The government has not only outlined a development vision for the North East, but has also **provided adequate financial resources towards realising this vision.** In the past eight years, government has allocated over Rs 336,640.97 crores for the development of NE Region, which is tremendously helping boost the regional economy and connectivity.

The six pillars of connectivity:

- **For decades, infrastructure development in NE** had been marked by **repeated delays, abysmally poor quality of work, and institutional corruption**, and the lack of proper infrastructure had remained one of them.

Air connectivity:

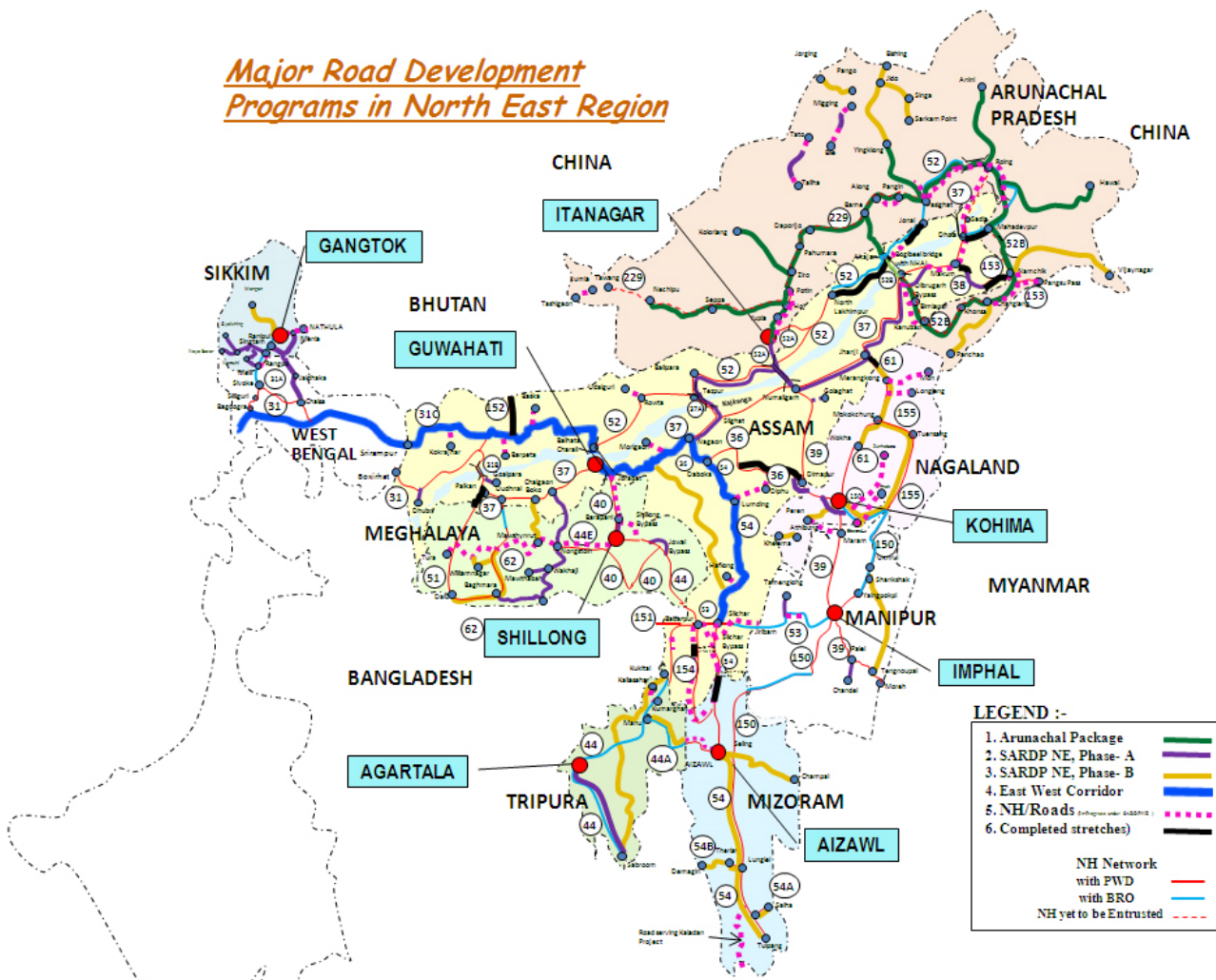
- The development of the North East region is of strategic importance and country is bound to grow only when all regions are performing at their best. With this in mind, the government worked persistently towards improving air connectivity and developing aviation infrastructure in the region, through the '**Ude Desh Ka Aam Nagrik**' (UDAN) scheme.
- From the financial years 2016-17 to 2021-22 a total of **28 air connectivity projects** have been completed in the region at a cost of Rs 979.07 crore, and 15 more projects worth Rs 2212.30 crores are currently under the process of completion.
- This is helping **boost regional connectivity and tourism sector** in the region.

Rail connectivity:

- Since 2014, the government has embarked on an ambitious project to **connect all the states in NE region with the national rail grid.**
- Towards this, government **sanctioned 19 projects for a total length of 1,909 kilometres**, with a budget allocation of Rs 77,930 crores, which are at different stages of implementation – planning, approval, execution.
- Up to March 2022, a total of 409-kilometre-length has been commissioned at an expenditure of Rs 30,312 crores.
- These include, 14 New Line Projects of 361-kilometre-length at an expenditure of Rs 27,458 crore; and five Doubling/Multitracking Projects covering a length of 48 kilometre at an expenditure of Rs 2,854 crore.

Road connectivity:

- There was a time when a four-lane highway connecting states in the North East region was unimaginable. However, in recent years, government has completed major highway development projects keeping in view the “Look and Act East” policy.
- A total of 3,099.50-kilometre road at a cost of Rs 15,570.44 crore have been constructed since 2014, and projects connecting 4,016.48 km costing Rs 58,385 crore are currently ongoing in the region.
- The major ongoing Capital Road Connectivity projects in NER include an alternate two-lane highway from Bagrakote to Pakyong (NH-717A) (152 km) in the Sikkim-Kalimpong-Darjeeling region, four laning of Imphal – Moreh section of NH-39 (20 km) and 2-laning of 75.4 km in Manipur; the 4 Laning of Dimapur- Kohima Road (62.9 km) in Nagaland; 4 laning of Nagaon bypass to Holongi (167 km) in Arunachal Pradesh; and 2 laning of Aizawl – Tuipang NH-54 (351 km) in Mizoram.
- All these roads when completed will help provide tremendous boost to regional and national connectivity of NE states to the rest of India.



Power connectivity:

- Since 2014, the Ministry of Power has undertaken many hydro/thermal power generation projects, developed and modernized transmission and distribution networks.
- The Power Grid Corporation of India Ltd. (PGCIL) is executing two major Intra State power transmission and distribution schemes viz.
 - a) North Eastern Region Power System Improvement Project (NERPSIP) for the six states of Assam, Manipur, Meghalaya, Mizoram, Tripura and Nagaland at an estimated cost of Rs 6,700 crore; and
 - b) Comprehensive Scheme for Strengthening of Transmission and Distribution System in Arunachal Pradesh and Sikkim sanctioned at an estimated cost of Rs 9,129.32 crore.

Telecom connectivity:

- Telecom connectivity or lack of it has been a major issue in the entire North East region.
- To address this the Department of Telecommunications has undertaken several projects in the North Eastern States for strengthening telecom connectivity in the region **Bharat Net and Wi-Fi Connectivity for Village Panchayats** in North Eastern Region.
- A total of 1,358 towers covering 1,246 villages have been installed and are providing services in the region.

Water connectivity:

- The 6 March, 2022 marked a historic day when **MV Lal Bahadur Shastri docked at Guwahati's Pandu port** on the southern bank of the Brahmaputra, carrying 200 metric tonnes of food grains for the Food Corporation of India (FCI) from Patna.
- The government is developing **River Brahmaputra from Dhubri (Bangladesh border) to Sadiya (891 km) as National Waterway-2** at a cost of Rs 461 crore in five years (2020-2025).
- **River Barak has been declared as National Waterway-16**, and it connects Silchar, Karimganj and Badarpur in Cachar valley of Assam with Haldia and Kolkata ports through Indo-Bangladesh Protocol (IBP) Route. The facilities created and planned would cost Rs.145 crore in 5 years (2020-2025).
- This will help with faster transportation of goods to and from the national and international markets to the region.

Various Schemes:

- In addition to the six pillars of connectivity, the Ministry of Development of North Eastern Region (MDoNER) is implementing **various schemes** such as the
 - North East Special Infrastructure Development Scheme (SIDS),
 - Non-Lapsable Central Pool of Resources (NLCPR) Scheme,
 - Special Packages of Assam [Bodoland Territorial Council (BTC), Dima Hasao Autonomous Territorial Council (DHATC) and Karbi Anglong Autonomous Territorial Council (KAATC)],
 - Hill Area Development Programme (HADP),
 - Social and Infrastructure Development Fund (SIDF),
 - Schemes of NEC (North Eastern Council) and North East Road Sector Development Scheme (NERSDS), for the development of North Eastern Region.

Australia's mean temperature has risen by roughly 1.4 degrees Celsius, since 1910

(GS Paper 3, Environment)

Why in news?

- **Australia's mean temperature has risen by approximately 1.4 degrees Celsius (°C)**, since 1910, according to the State of the Environment Report, released recently.
- The 2021 State of the Environment Report is a **mandatory assessment conducted every five years**.

Key Highlights:

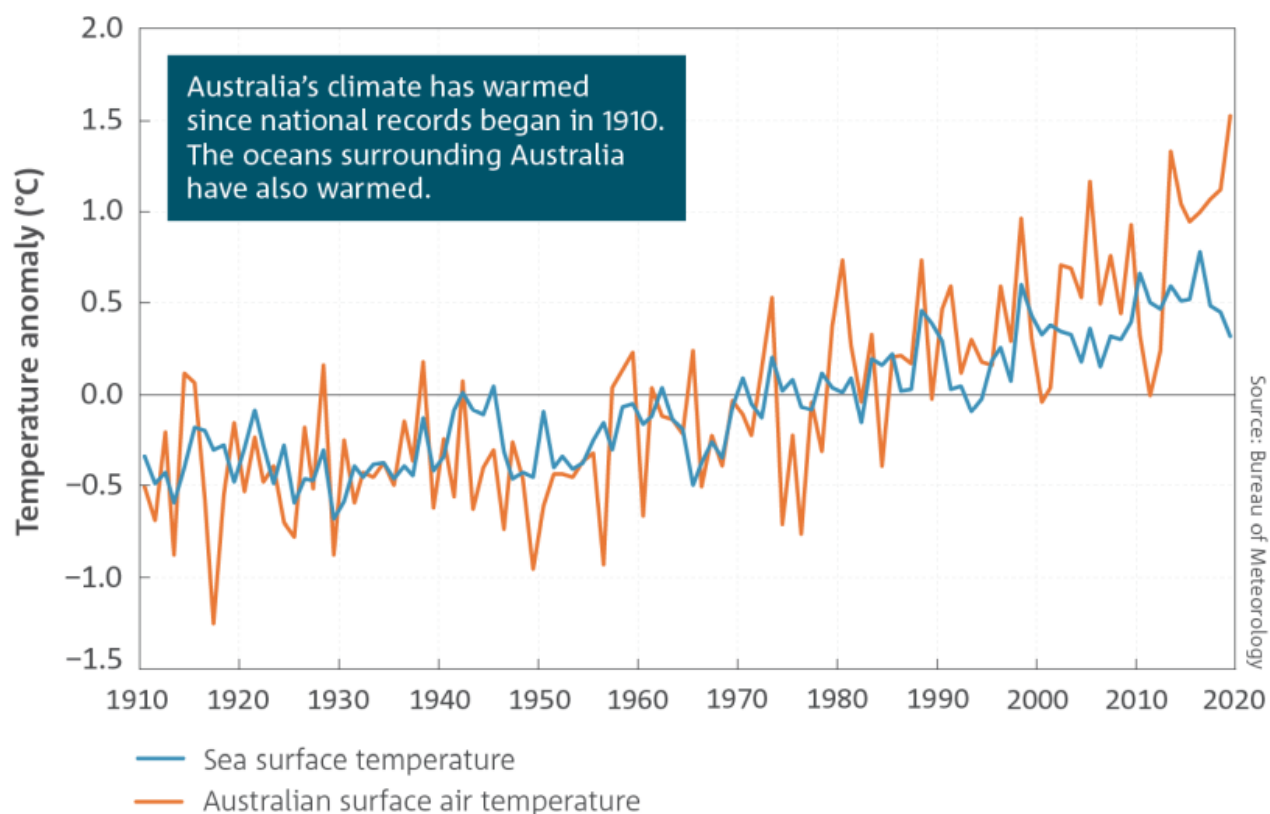
- Some regions are more impacted than others. **Central and eastern interior parts have warmed by more than 2°C**, while north-western Australia and some south-eastern coastal areas have recorded the lowest rise of 0.5-1°C.

Rainfall:

- Australia has witnessed a **10 per cent increase in the intensity of short-duration (hourly) extreme rainfall** events in some regions in recent decades.
- The southwest part of Western Australia saw its average rainfall dropping by 15-20 per cent between 1970 and 2020. **Low rainfall and high evaporation are taking a toll on Australian rivers.** Since 2016, water storage in many had fallen below 10 per cent.

Extreme events:

- Over the last five years, **extreme events such as floods, droughts, wildfires, storms and heatwaves** have affected every part of Australia.
- Australia's fire season has shown an increasing trend since the 1950s. The 2019-2020 bushfire was due to a long preceding dry spell. Further, the heat and particulate matter in the **bushfire smoke plumes have triggered the formation of thunderstorms** in recent years.
- These clouds can generate dangerous and unpredictable fire behaviour, including wind direction changes, cloudbursts and lightning.
- **Invasive plants**, predominantly grasses, are increasing the risk of fire events in some areas of the country.
- The 2019-2020 bushfire event, also had short-term impacts on air quality. Extreme events can have a high impact when subsequent events multiply the effect of initial events.



Sea temperatures:

- Sea temperatures are also on the rise. Since 1900, they have increased by approximately 1.1°C, the report stated.
- Warmer waters expand in response to heat, causing sea levels to rise. **Sea-level rise in Australia is above the global average of 3-3.5 millimetres per year.** The rate of warming is generally slightly higher in eastern Australian waters than in the west.

- The **number of tropical cyclones in the Australian region has declined** since the 1980s. In the ten seasons from 2010-11 to 2019-20, the country recorded an average of 8.9 cyclones per year, about 20 per cent below the 1981–2010 average.

Sea ice formation:

- The report also covered Antarctica, the Southern Ocean and subantarctic islands.
- It stated that patterns in sea ice formation are becoming increasingly unpredictable even as glaciers and ice sheets continue to melt.

Extinction risk:

- Australia has lost more mammal species in the last two centuries than any other.
- In June 2021, more than 1,900 Australian species and ecological communities were known to be threatened and at risk of extinction.
- **As many as 100 species in Australia are listed as extinct or extinct in the Wild.** These include 38 vascular plants, 34 mammals, 10 invertebrates, nine birds, four frogs, three reptiles, one fish and one protist (a single-celled organism).