mRNA

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Why in News?

Recently, the U.S. Food and Drug Administration (FDA) refused to review Moderna's new mRNA influenza vaccine (mRNA-1010).

- **mRNA –** They are messenger RNA that ***acts as a blueprint for creating proteins essential for body functions.***
  - mRNA copies instructions from Deoxyribonucleic acid (DNA) and serves as a template for cells to produce specific proteins.
- **Temporary Role -** Cells use mRNA to produce the protein and then degrade it once the job is done.
- **Limitation –** Errors in DNA can affect mRNA instructions, potentially causing diseases.
- **mRNA Vaccines –** These vaccines use a copy of mRNA to produce an immune response.
- It encodes a viral protein, usually the spike protein, without exposing individuals to the virus itself.
- **Mechanism –** The mRNA is delivered into immune cells, which produce the protein, triggering an adaptive immune response.
  - It teaches the body to recognise and destroy the virus.
- **Features –** Easy and fast to design with lower production cost.
- Can be updated quickly for emerging viral strains.
- ***Induce both cellular (T Cells) and humoral (B Cells) immunity.***
- Does not alter genomic DNA.
- **Challenges –** Require ultra-cold storage (-90°C to -50°C).
- May cause adverse reactions in individuals prone to autoimmune responses.
- Long-term effects are still unknown.
- **Difference from Traditional Vaccines – Rapid development –** mRNA vaccines can be designed in days to weeks once the viral genetic code is known, unlike traditional vaccines that may take years.
- **Traditional Vaccines –** Introduce viral proteins or a weakened/inactivated virus into the body.
- Stimulate the immune system to recognize and fight the real virus.
- **Viral Vector Vaccines –** Use a harmless virus to deliver DNA coding for a viral protein.

- The body’s cells produce the viral protein, which triggers immunity.
- **mRNA Vaccines –** Deliver mRNA instructions wrapped in lipid molecules for stability.
- Cells use the mRNA to produce the viral protein themselves, stimulating an adaptive immune response.

FDA’s Refusal

- **mRNA-1010** – It is an mRNA-based ***seasonal influenza vaccine targeting seasonal influenza A and B strains.***
- **Core Issue –** Moderna compared the mRNA-1010 vaccine to a standard-dose flu shot.
- **FDA stance –** Adults who are 65 and above require high-dose or adjuvanted vaccines as the preferred standard.
- Using a weaker comparator made the trial “inadequate and not well-controlled” for review.
- **Future Implications – Delayed Access –** While mRNA-1010 has been accepted for review in the EU, Canada, and Australia, its availability in the U.S. is now delayed indefinitely.
- **Combo Vaccine Impact –** This refusal also stalls Moderna's combination flu/COVID-19 vaccine (mRNA-1083).
- **Industry Precedent –** FDA sets a higher bar requiring the strongest available comparator for future vaccines.

Reference

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