

# Proposed Structure for Regulation

---

- ❑ Create a **Central Drug Authority of India “CDAI”** (like the US FDA) headed by the DCGI, in place of the CDSCO—with a regulatory mechanism and responsible for all manufacturing, import, export, registration, approval, quality / QA, certification, clinical trials, post-marketing surveillance.
- ❑ New standalone legislation covering drugs and therapeutics for price control instead of using the DPCO.
- ❑ All manufacturing and import licensing with CDAI, State FDAs will inspect factories and grant wholesale/ retail licenses.
- ❑ Define Medical Devices and nutraceuticals specifically under the DCA and provide rules and guidelines for their regulation.
  - ❑ Create a special Medical Devices Division within the CDAI for the above functions to cover all imported and locally made devices.
- ❑ In due course possibly unify the CDAI and NPPA under a single authority.
- ❑ CDAI has been approved by the Cabinet but legislation still pending.