Indian Drugs/Biologics Regulations

Four Essential Elements of Regulations

- There is a **OR** multiple **Regulatory Authority/ies**
- There are **National Laws**
- There are **different entities** to be approved-Drugs, Biologics, Recombinant biologics, Cell-based therapies, Devices etc.
- These entities are at **different levels/stages of development** for approvals-Importation, Pre-clinical, Phase I/II/III or Indigenously developed

Laws on Biologics Regulation in India

Multiple

- The Drugs & Cosmetics Act, 1940
- Schedule Y introduced under Drugs & Cosmetics Act, 1940 in 1988(Amended version, 2005)
- The Environmental Protection Law, 1986
- The Bio-safety Regulations, 1989
- The Patents Law, 1970(The Patents Amendment Act, 2005)

Regulatory Authority/ies

Multiple

- The Drugs Controller General of India (DCGI) under the Ministry of Health & Family Welfare
- The Department of Biotechnology under the Ministry of Science and Technology
- The Ministry of Environment and Forests
- The Controller General of Patents, Designs, Trademarks under the Ministry of Commerce and Industry
- Now proposed National Biotechnology Regulatory Authority

The Drugs & Cosmetics Act, 1940

Schedule Y

Refers to requirements and guidelines to be followed in order to attain permission of:

- Importing

and/or

- Manufacturing New Drugs to market

or

- To undertake clinical trials in India.

Essentials of Schedule Y

- Depends on the status of drug in the country of origin
- Approved Drugs/Biologics-Phase III
- Not Approved Drug-One Phase earlier
- New Discovered Drugs in other countries- Phase I not permitted ; hence Safety data needed
- Trials permitted for drugs of special relevance

Essentials of Bio-safety Laws

- Applicable to all r-DNA products
- Three -tier bio-safety system before clinical trials
    1. IBSC(At the Institute Level)
    2. RCGM(At the D/O Biotechnology level)
    3. GEAC(At the M/O Environment)
- Approval for Human trials given by the DCGI

Drivers of making Laws

- Domestic needs-(Cost-Effective)
- Economic needs- (To capture non-regulated OR semi-regulated markets by making Generics & Bio-similars)
- Political situation-(Adopting Process Patent)
- Providing impetus to technological development (Adopting Process Patent)
- Promoting inventive activities in the country (Adopting Process Patent)
- International obligations on Trade matters (WTO) (Adopting Product Patent)
- Harmonization of International standards for Quality(ICH-GCP)

What is there in Cancer Biologics?

- Cancer Vaccines-Prophylactic (Hep-B, HPV, *H.pylori*)
- Cancer Immuno-modulators(bCG, *M.indicus pranii*)
- Cancer therapeutics(Predominantly Bio-similars)
- Stem Cell therapy-????
- Other cell-based therapies(DC-based)
- Devices????