Clinical Studies-
Role of Regulators, FBOs and CROs

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- **Clinical studies play a crucial role in ensuring the safety and efficacy of new drugs and food products.**
- **The successful conduct of these trials is a collaborative effort involving regulatory agencies, food business operators (FBOs), and contract research organizations (CROs).**

- **Clinical trials in drugs are governed by strict regulations to ensure patient safety and the efficacy of the products.**
- **Regulatory agencies, such as the Food and Drug Administration (FDA) in the United States and the Central Drugs Standard Control Organization (CDSCO) in India, play a vital role in setting guidelines and monitoring clinical trials.**
  - **These agencies are responsible for approving clinical trial protocols, ensuring adherence to good clinical practice (GCP) guidelines, and evaluating trial results.**
  - **They review and approve trial protocols, monitor study conduct, and evaluate the safety and efficacy of investigational products.**

- **Food business operators (FBOs) are responsible for complying with regulatory requirements and ensuring that their products are safe and of high quality.**
- **FBOs, including pharmaceutical and food companies, are responsible for developing and testing new products in accordance with regulatory requirements.**
- **This is particularly relevant for functional foods and nutraceuticals, which may have therapeutic benefits similar to drugs.**
- **They collaborate with CROs to design, implement, and manage clinical studies, leveraging the specialized expertise of CROs in areas such as data management, statistical analysis, and regulatory compliance.**

- **Contract research organizations (CROs) provide essential support and expertise in conducting clinical trials, helping FBOs and pharmaceutical companies navigate complex regulatory landscapes.**
- **CROs offer various services, including trial design, patient recruitment, data management, and statistical analysis.**
- **The use of CROs can improve efficiency and reduce costs for companies conducting clinical trials.**

Present Status of Clinical Trials in Drugs and its Proposed Similarities for Food

- **In recent years, there has been a shift towards a more streamlined and efficient approach to conducting clinical trials, facilitated by the adoption of new technologies, such as electronic data capture and remote monitoring.**
- **The food industry is progressively adopting similar approaches in response to the increasing demand for evidence-based functional foods and nutraceuticals.**

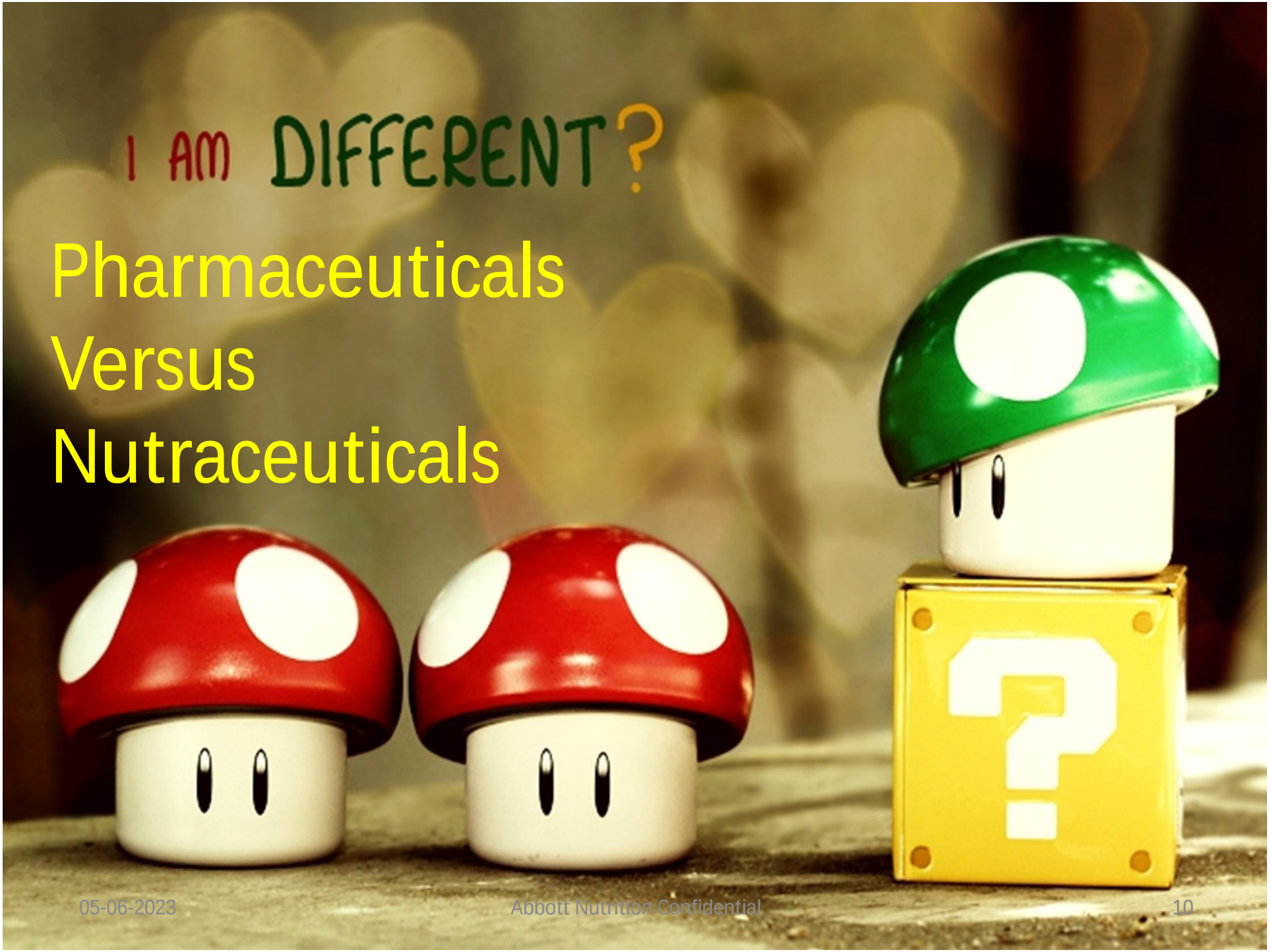
Present Status of Clinical Trials in Drugs and its Proposed Similarities for Food (Contd...)

- **The current landscape of drug clinical trials is characterized by a growing emphasis on personalized medicine, increasing complexity of study designs, and a shift towards decentralized trials.**
- **Similar trends are emerging in food clinical trials, as the concept of personalized nutrition gains attraction.**
- **As with drug trials, the focus in food trials is shifting towards understanding the unique nutritional needs of individuals and developing products that cater to these requirements.**

Present Status of Clinical Trials in Drugs and its Proposed Similarities for Food (Contd...)

- Recent advances in genomics, proteomics, and metabolomics have facilitated the development of targeted therapies tailored to individual patients, resulting in improved outcomes and reduced side effects.
- As with drug trials, the focus in food trials is shifting towards understanding the unique nutritional needs of individuals and developing products that cater to these requirements.
- Similarly, shift to the concept of personalized nutrition gains necessitates the development of robust methodologies, biomarkers, and endpoints for evaluating the safety and efficacy of novel food products.

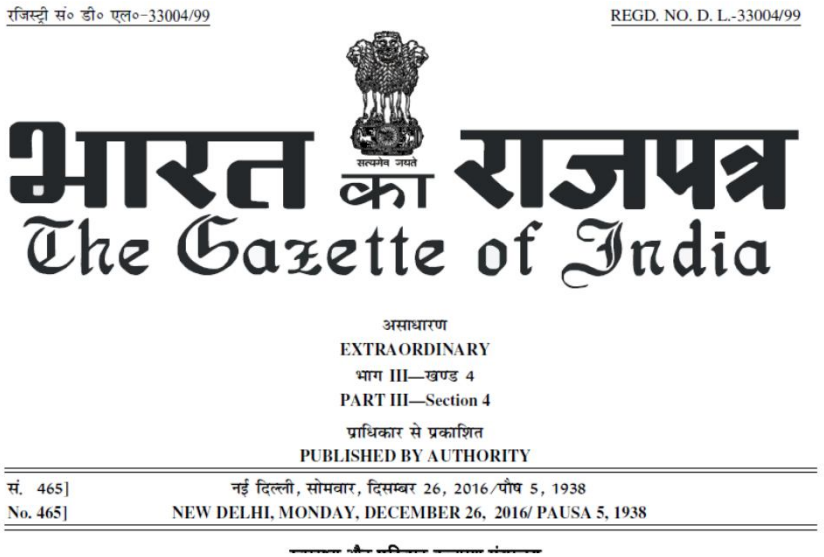
Clinical Trials in Nutraceuticals



Pharmaceuticals Versus Nutraceuticals

Related Regulations….

No. 1-4/ Nutraceutical/ FSSAI-2013.-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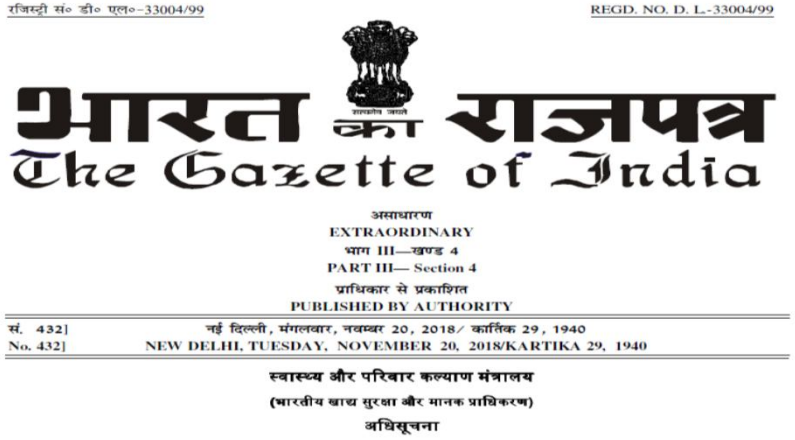
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(भारतीय खाद्य सुरक्षा और मानक प्राधिकरण)
अधिसूचना

F. No. 1-94/FSSAI/SP(Claims and Advertisements)/2017.–

Need for clinical Data

(d) the use of word "shown" as depicted in the example below when a single human intervention study shows significant benefit:

"Product <Name of the Product> is 'shown' to be helping in <keeping your heart healthy> or <heart healthy>:

(e) the use of word "Proven" as depicted in the example below when more than one human intervention studies or epidemiological evidence on Indian population have been provided with concurrent validity:

"Product <Name of the Product> is 'proven' <to make you lose weight>:

(4) Where a claimed benefit is attributed directly to the product or used on labels, advertisements or any other means as a mode of communication to the consumer, it shall be based on statistically significant results from appropriate scientific research study(s), OR a well designed, randomized double blind (Unless technically not feasible) clinical study(s), conducted by OR under guidance of established research institutions, in line with the principles of GCP (Good Clinical Practices) and Peer Reviewed OR published in a Peer reviewed reputed scientific journal with an impact factor of not less than 1 at the time of submission of paper.

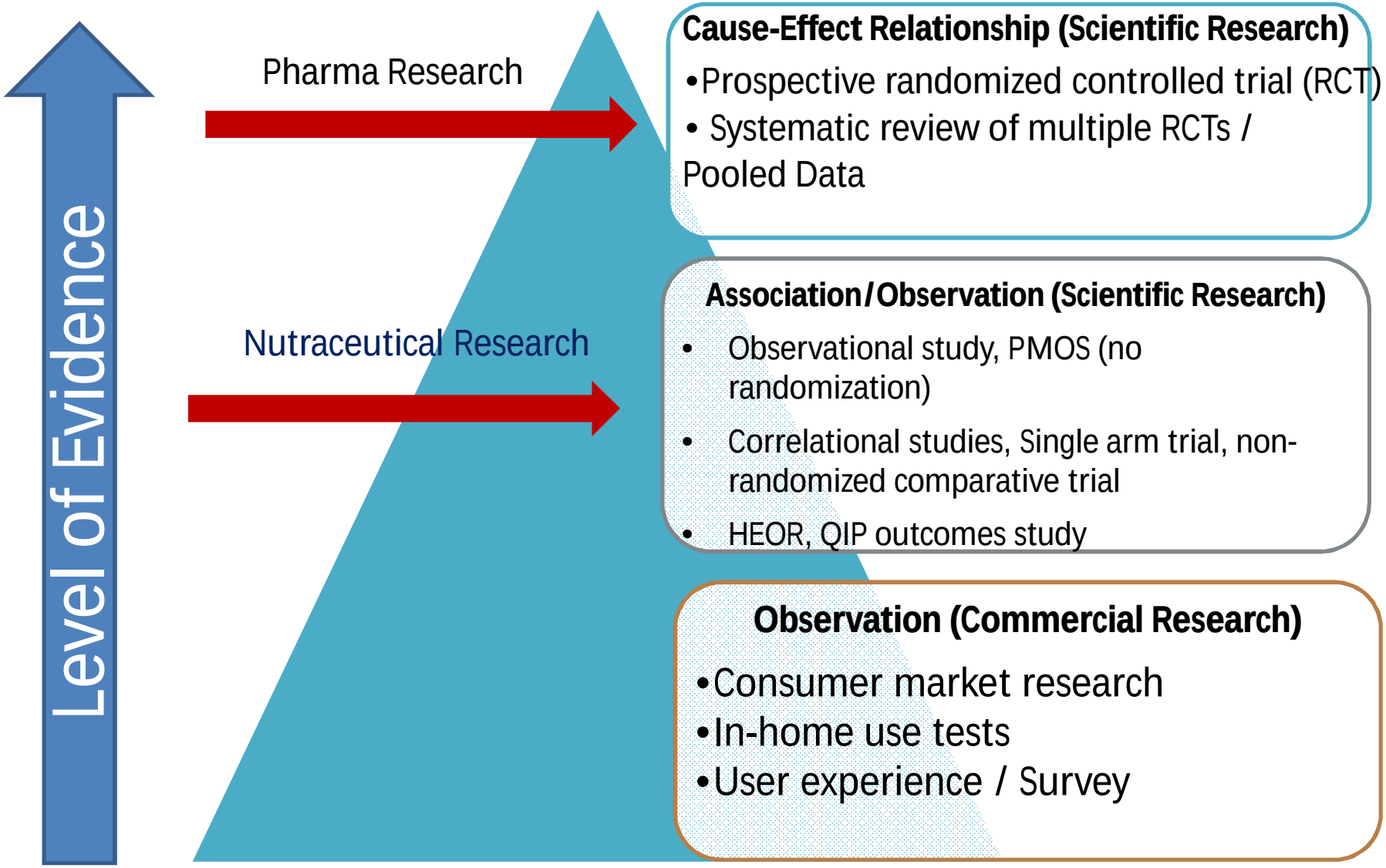
Claims versus Indications

- Claims – Nutritional claims, Health claims (ingredient function, enhanced function, health maintenance, disease risk reduction, immunity claim, anti ageing), product led claims.
- Indication – disease or health condition in which drug is indicated

Nutraceutical product is designed for multiple claims against drug is indicated in one indication.

Types of studies & Clinical Phase

Type of Studies



Needs of various studies

- Social studies – impact of various dietary pattern on various chronic diseases, nutritional pattern, fortification and its impact, nutritional impact on health indices
- Product led studies – Interventional studies, nutritional intervention and health outcomes, HEOR, impact of nutritional protocols, novel ingredients etc.

LAW RELATING TO DRUGS & COSMETICS

Vijay Malik

Containing

● Drugs & Cosmetics Act, 1940 ● Drugs & Cosmetics Rules, 1945 ● Drugs (Prices Control) Order, 2013 ● List of Drugs approved during January 2006 to January 2014 ● List of Schedule H1 Drugs ● National Pharmaceuticals Pricing Policy, 2012 ● List of Banned Drugs and Combination of Drugs ● DMR Act, 1954 ● Pharmaceuticals and Patents ● Bio-medical waste Rules ● Guidelines for manufacturers ● Guidelines on Registration of Import of Cosmetics and Important Circulars issued by CDSCO ● Penal Laws and other Allied Acts, Rules, Notifications etc.

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RECENT DEVELOPMENTS

New Drugs & Clinical Trials Rules, 2019 [India]

- What has changed ??

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(स्वास्थ्य और परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 19 मार्च, 2019

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 19th March, 2019

G.S.R.227(E) .— WHEREAS the draft of the New Drugs and Clinical Trials Rules, 2018 was published, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) *vide* notification number G.S.R. 104(E), dated the 1st February, 2018, by the Central Government, after consultation with the Drugs Technical Advisory Board, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

AND WHEREAS, copies of the Official Gazette containing the said notification were made available to the public on the 7th February, 2018;

AND WHEREAS, all objections and suggestions received in response to the said draft notification have been duly considered by the Central Government;

AND WHEREAS, the Hon'ble Supreme Court of India in Writ Petition(s) (Civil) No (s). 33/2012 Swathaya Adhikar Manch, Indore and another Versus Union of India and others with W.P.(C) No. 79/2012 (PIL-W), *inter alia,* observed that new clinical trial rules shall be finalised urgently;

NOW, THEREFORE, in exercise of the powers conferred by section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules, namely:—

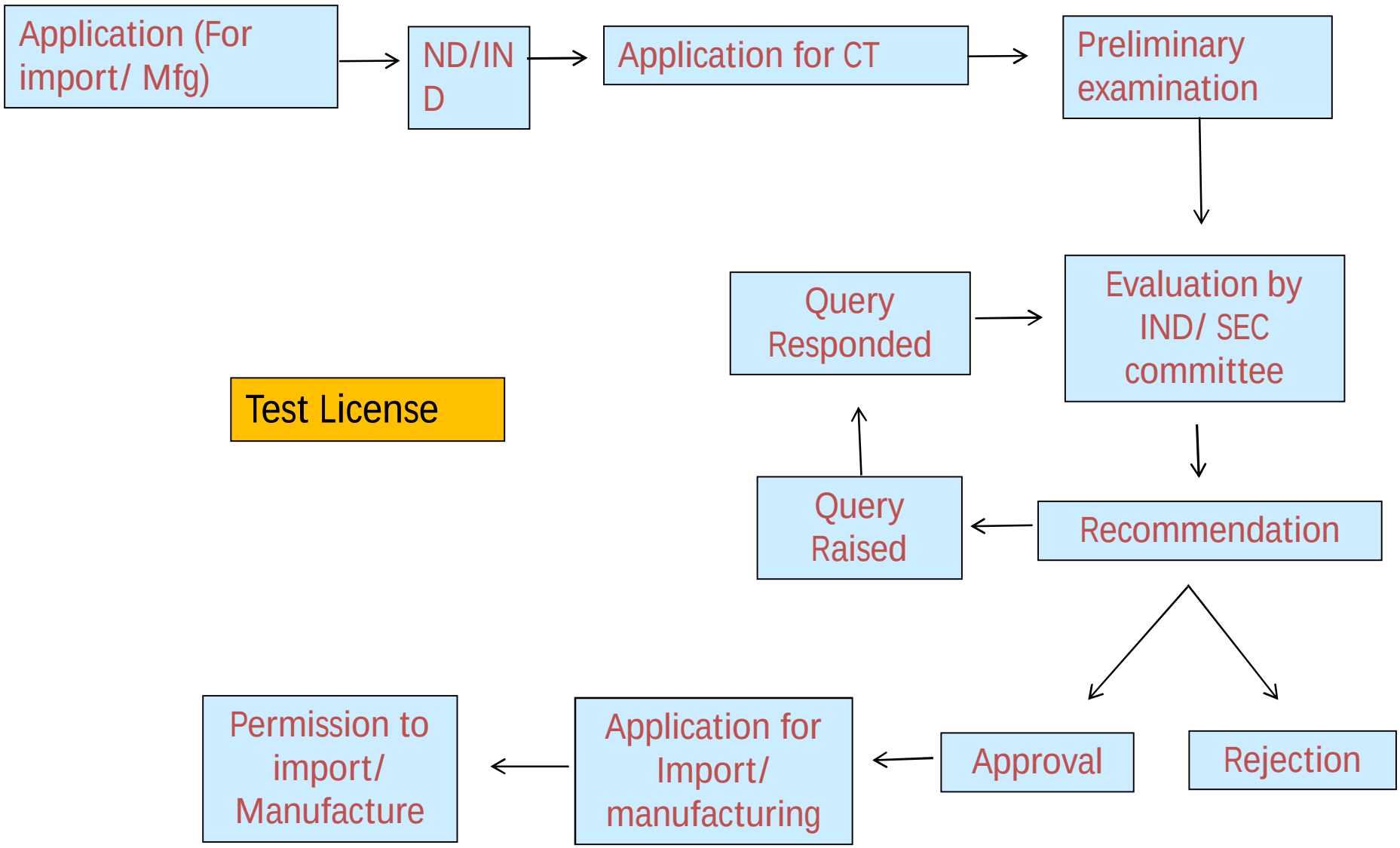
CHAPTER I

PRELIMINARY

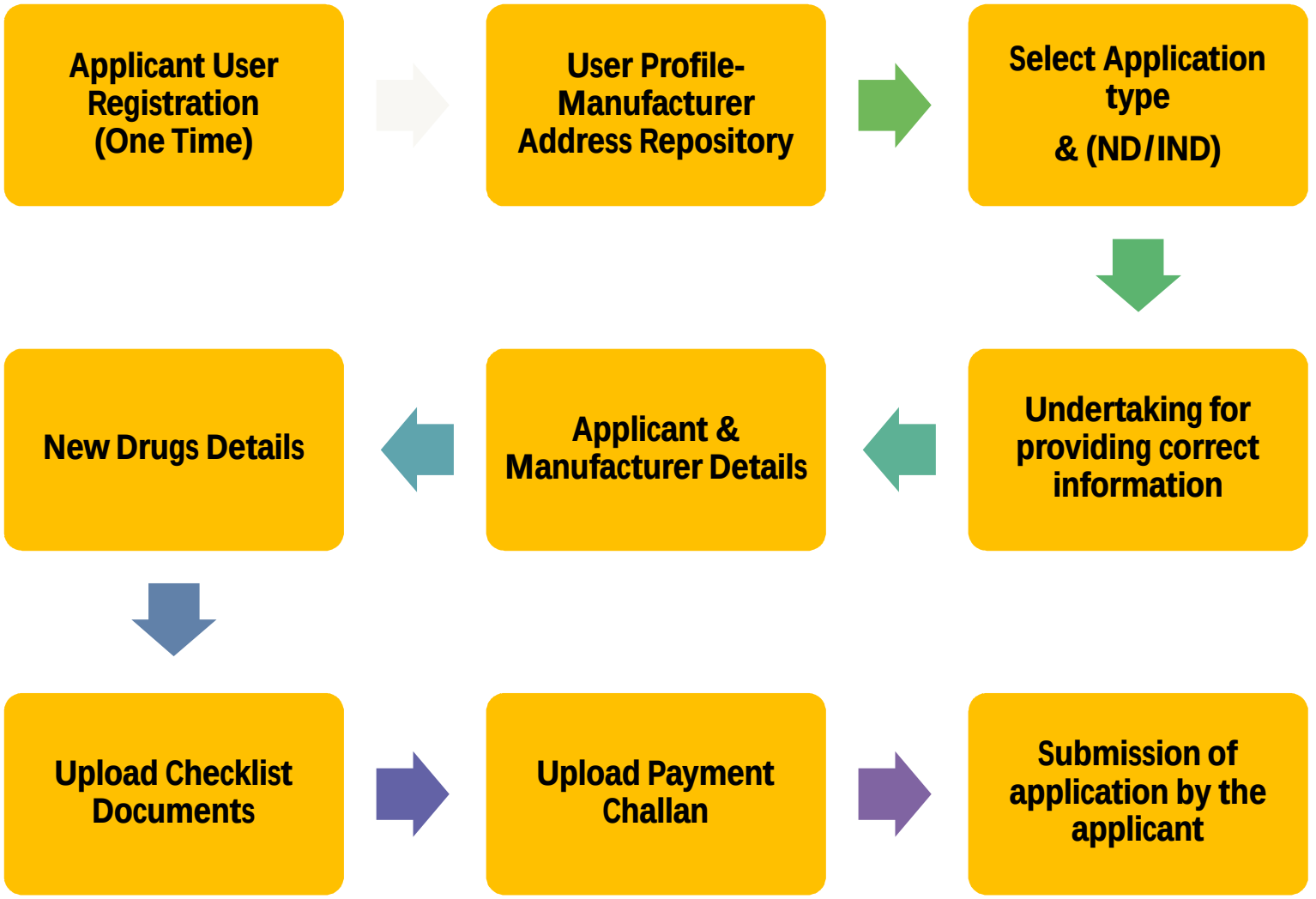
1. Short title, commencement and applicability.— (1) These rules may be called the New Drugs and Clinical Trials Rules, 2019.

- **New Drugs and Clinical Trials Rules, 2019 comprises of**
  - **Chapters - 13**
  - **Rules - 107**
  - **Schedules - 8**
  - **Forms - 28**
- **Definition of**
  - **Academic Clinical Trial**
  - **Bioequivalence Study**
  - **BA/BE study centre**
  - **Biomedical and Health Research**
  - **Good Clinical Practices Guidelines**
  - **Global Clinical Trial**

- **Investigational New Drug**
- **New Chemical entity**
- **New Drug**
- **Orphan Drug**
- **Pharmacovigilance**
- **Phytopharmaceutical drug**
- **Placebo**
- **Post trial access etc**


Application (For import/ Mfg)
ND/IND
Application for CT
Preliminary examination
Evaluation by IND/ SEC committee
Query Responded
Test License
Query Raised
Recommendation
Approval
Rejection
Application for Import/ manufacturing
Permission to import/ Manufacture

Approval process through Online Portal for grant of license for ND/INDs



Ethics committee

Waiver of CT

- If new drug is approved & marketed in countries specified by CLA
- India participates in a GCT & meantime drug is approved in other countries for marketing
- No difference in enzyme/gene involved in metabolism of new drug or any factor affecting PK/PD, safety & efficacy of new drug
- Undertaking to conduct Phase IV study
- Above criteria may be further relaxed where drug is of special relevance to Indian scenario eg: XDR, Hep C, H1N1, Dengue, Malaria
- Data generation requirements is reduced w.r.t. animal tox, reproduction studies, teratogenicity, perinatal studies, carcinogenicity in case the new drug is marketed elsewhere for more than 2 years & there is no adequate published evidence on safety of the drug

Health is a human right and access to healthcare including essential medication is a derived right.

Goal of the National Health Policy (NHP 2017)

- Attainment of the highest possible level of health and wellbeing for all at all ages, through a preventive and promotive health care orientation
- This would be achieved through increasing access, improving quality and lowering the cost of healthcare delivery.

Objective of NHP 2017

- To improve health status through concerted policy action in all sectors and expand preventive, promotive, curative, palliative and rehabilitative services provided through the public health sector with focus on quality.

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THANK YOU

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