Clinical Trial of Vaccines: A Legal Perspective

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The outbreak of the coronavirus pandemic has devastated the entire world. "Positive" has become the most "negative" word of the year 2020 and every person has a story of their struggle. While we salute the services of each and every corona-warrior, the pharma companies/governments are making their best efforts to discover the vaccine which is not expected to be released in market until the first half of 2021. With the second wave in sight and governments imposing further lockdowns around the globe, the need for vaccine has become the desperate need of the hour. With more and more companies coming forward to conduct trials and few stepping back in light of side effects and unknown illness, many trials have stopped, and discovery of the vaccine is further prolonged. Hence under the complex legal ecosystem, it becomes all the more important for obtaining approvals for vaccine trials. Some of the important aspects of such regulatory and legal procedures behind the vaccine trails are explained below.

Clinical trials are an arrangement of practices performed to confirm and guarantee the security of a new drug. As defined under Rule 2(j) of the New Drugs and Clinical Trials Rules, 2019 "clinical trial" in relation to a new drug or investigational new drug means any systematic study of such new drug or investigational new drug in human subjects to generate data for discovering or verifying its,-

i. clinical or;
ii. pharmacological including pharmacodynamics, pharmacokinetics or;
iii. adverse effects,

Laws governing the clinical trials in India:

- Drugs and Cosmetics Act – 1940
- Medical Council of India Act – 1956, (as amended in the year 2002)
- Central Council for Indian Medicine Act – 1970
- Guidelines for Exchange of Biological Material (MOH order, 1997)
- Right to Information Act – 2005
- Ethical Guidelines of the Indian Council of Medical Research (2006)
- Indian Good Clinical Practice Guideline (2001)
- New Drugs and Clinical Trial Rules, 2019

Regulatory bodies:

The Central Drugs Standard Control Organisation (CDSCO)

CDSCO is the National Regulatory Authority in India set under the Ministry of Health and Family Welfare, Government of India. Its mission is to safeguard and enhance public health by assuring the safety, efficacy and quality of drugs, cosmetics and medical devices.

Drugs Controller General of India (DCGI)

DCGI is an official of the CDSCO is the ultimate regulatory authority for the approval of clinical trials in the country. Jurisdiction of the office of DCGI, also extends to inspections of trial sites, inspections of sponsors of clinical research and manufacturing facilities in the country, oversight of the Central Drugs Testing Laboratory (Mumbai) and the Regional Drugs Testing Laboratory, heading the Indian Pharmacopeia Commission among various other roles, responsibilities and functions.

Indian Council of Medical Research (ICMR)

ICMR is responsible for the formulation, coordination and promotion of biomedical research in the country. Ministry of Health and Family Welfare and the Department of Health Research, Government of India provides funding to ICMR for carrying out their functions.

The Medical Council of India (MCI) Act states that all clinical trials in India should follow the ICMR guidelines of 2000. Further, Schedule Y along with rules 122A, 122B, 122D, 122DA, 122DAC and 122E of the Medical Council of India Act governs clinical research in the country. There are also 12 appendices, formats for clinical trial protocols, informed consent forms, Ethics Committee (EC) approval templates and format for Serious Adverse Event (SAE) reporting.

An online clinical registry has been initiated by the Indian Council of Medical Research (ICMR) for the registration of any interventional trial to ensure the following goals:

- Transparency and accountability of clinical research
- Internal validity of clinical trials
- To oversee the ethical conduct of clinical trials
- Reporting of results of clinical trials

Stages of clinical trials:

Clinical trials are carried out in four phases. Clinical trials of drugs developed in India must undergo all four phases of trials in India

Phase I or clinical pharmacology trials or "first in man" study

A small number, a minimum of 2 healthy, informed volunteers are identified for each dose under the close supervision of a doctor. The purpose is to identify if the volunteers develop any tolerance and their behaviour to the medicine in the body.

Phase II or exploratory trials

The medicine is administered to a group of approximately 10-12 informed patients in 3 to 4 centers to determine its effect and also to check for any unacceptable side effects.

Phase III or confirmatory trials

The group is between 1000-3000 subjects. If the results are positive, the data is presented to the licensing authorities for a commercial license to market the drug for use by the patient population for the specified and approved indication.

Phase IV trials or post-marketing phase

Phase of surveillance after the medicine is made available to doctors, who start prescribing it. The effects are monitored on thousands of patients to help identify any unforeseen side effects.

Parties involved in the trials

Sponsor: includes a person, a company or an institution or an organization responsible for initiation and management of a clinical trial;

Contract Research Organization: an entity that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis;

Trial Subjects (Volunteers): means a person who is either a patient or a healthy person to whom investigational product is administered for the purposes of a clinical trial.

The trials can be conducted for either Indian (indigenous) or a global drug before the DCGI. Hence application can be classified as:

1. Approval of trials of a global drug (whether new drug or an existing drug whose trails are approved outside India)
2. Approval of trials of an Indian drug (provided that the new drug or investigational new drug as part of discovery or research are discovered in India, research and development of the drug are being done in India and also the drug is proposed to be manufactured and marketed in India).

Compensation for clinical trials

Rule 42 of the New Drugs and Clinical Trial Rules 2019 provides that the independent Committee setup by the DCGI shall examine the cases and make its recommendations for arriving at the cause of death or any serious ailments and the quantum of compensation to be paid to the heirs of the trial subjects (volunteers), in case of clinical trial related death and accordingly, the sponsor or its representative shall be liable to pay the compensation.

Documents required for application for conducting clinical trials

1. Application Form in CT-04 format
2. Details/documents as specified in Second Schedule of the New Drugs and Clinical Trials Rules, 2019
3. Fees prescribed under Sixth Schedule ibid Rs. 3,00,000 for 1st Phase and Rs. 2,00,000 respectively for the remaining phases.

Patents of medicines

The Patents Act 1970 does not recognize the product-based patent for medicines. Only the process i.e., technique of making the medicine is patentable in the country. However, pursuant to becoming a member country to the World Trade Organization (WTO) – TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement in 1995 which prescribed the minimum standards of IP laws to be followed by each of its member nations, India was under a contractual obligation to amend its Patents law to make it compliant with the provisions of the agreement. The first amendment in compliance of the same was made to the Patents (Amendment) Act, 1999 which enabled pipeline protection till product patents are recognized. This was especially important in the pharma sector. The said amendment enabled filing of applications for product patents for drugs with effect from 1st January 1995 as mailbox applications and introduced the grant of Exclusive Marketing Rights (EMRs).

Under the second set of TRIPS obligations, the Patents Act, 1970 was further amended vide Patents (Amendment) Act, 2002 through which a provision of 20 years uniform term of patent for all categories of invention was introduced.

The third set of amendments in the patent law was introduced as the Patents (Amendment) Act, 2005. Under this, product patent regime was introduced in India. Mere discovery of new form, new property or new use of a known substance was made patentable subject to certain conditions, provisions related to pre grant and post grant oppositions were modified and provision for the grant of compulsory license for export of patented pharmaceutical products in certain conditions was introduced.

Therefore, once the vaccine trials pass Stage – 3, it is cleared for patenting and further manufacturing & marketing and so on.

Conclusion

With the New Drugs and Clinical Trials Rules, 2019 in place and few trials being stopped for unknown illness & side effects and many other vaccines currently progressing well, the door is now open for entrepreneurs and pharma companies to grab the opportunity for manufacturing vaccines and make India a global leader in vaccine manufacturing as it has huge manufacturing capabilities and skilled manpower.