LL.M/OC/PHL/01/001/22

ONE YEAR LL.M DEGREE FIRST SEMESTER EXAMINATION, MARCH 2022

LAW RELATING TO DRUGS AND CLINICAL TRIALS

TIME: 3 HRS **MAX. MARKS 50**

ANSWER ANY FIVE. ALL QUESTIONS CARRY EQUAL MARKS

1. Explain law relating to (i) regulation of manufacturing of drugs (ii) storage of drugs
2. Critically evaluate the role of CDSCO in regulation of pharmaceutical market in India
3. Explain the advancement and governmental intervention in telemedicine in India with special reference to access to health care.
4. "Essential medicines are those that satisfy the priority health care needs of a population" What is the concept of essential drugs? What is the role of NLEM?
5. "Countries have the right to regulate the exercise of the rights granted by the patent in order to fulfil the public good ". Evaluate the significance of compulsory licensing in the context of access to medicine.
6. Explain the law relating to prescription of drugs in connection with rights of patients and duties of physician.
7. Explain the role of ethics committee in regulation of clinical trials in India.
8. Briefly explain the ethical and legal issues relating to clinical trial in India

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