Current Regulatory Requirements for Conducting Clinical Trials in India

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Lecture – 03
Drug Regulatory Authorities

Hello friends, welcome back to lecture 3. This lecture is regarding Drug Regulatory Authorities of different countries of India and their functions.

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So, the learning objective of this lecture, you would be able to understand more about the national regulatory authority of India, its structure, its composition, functions of CDSCO and state licensing authority. Different ministries approval for the approval of this in drugs, then you will get familiar with some of the regulatory authorities which are important globally and also you will be able to understand the objective of these regulatory authorities. So, let us start with the different regulatories.

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See the in global map we can see the Canada is having its regulatory authority as a Health Canada, then UK is having an MHRA and in India it is a CDSCO, that is the Central Drugs Standard Control Organisation. If you see in the Australia it is a TGA, then for Japan it is a PMDA and for ANVISA it is a Brazil. Let us see some other major and important regulatory authorities also. So, the India as I have said it is a Central Drugs Standard Control Organisation: CDSCO.

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And at the state level it is either Food and Drug Administration or the Control Authority, in the European Union it is a European Medical Agency, in the UK it is MHRA that is a Medicines and Healthcare products Regulatory Agency. USA it is the most important and it is USFDA that is US Food and Drug Administration, then Australia is what we are saying it is TGA that is Therapeutic Goods Administration.

Then New Zealand it is a MEDSAFE that is Medicines and Medical Devices Safety, South Africa it is Medicines Council Control: MCC, for the Japan it is a PMDA that is Pharmaceuticals and Medical Device Agency. They control both medical device and the drug Switzerland it is a Swissmedic.

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For the Brazil it is a ANVISA that is Agencia Nacional de Vigilancia Sanitaria, Mexico it is COFEPRIS is a Comision Federal par la Proteccion contra Riesgos Sanitarios; Federal Commission for the Protection against Sanitary Risk.

For the Chile country it is a ISP that is Instituto de Salud Publica de Chile, for the Columbia it is INVIMA; INVIMA that is Instituto Nacional de Vigilancia de Medicamentos Alimentos Carrera. For the Argentina it is ANMAT A N M A T which is a Argentine National Administration of Drugs, Food and Medical Technology, for the France it is Agence Francaise de Securite Sanitaire des Produits de Sante, for the Germany it is Federal Institute for Drugs and Medical Devices. Let us see the objective of NRA.

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The objective of every National Regulatory Authority is to ensure the safety, quality and efficacy of the drug available in the market. The regulatory system for medicines must continue to ensure that medicines available in the market are having highest possible level of confidence in their overall safety and quality of the drug and its efficacy. The current system of contemporary medicines allow consumer to have faith in quality, safety and efficacy of medicines. Let us see the different ministries and departments involved in the drug regulatory processes.

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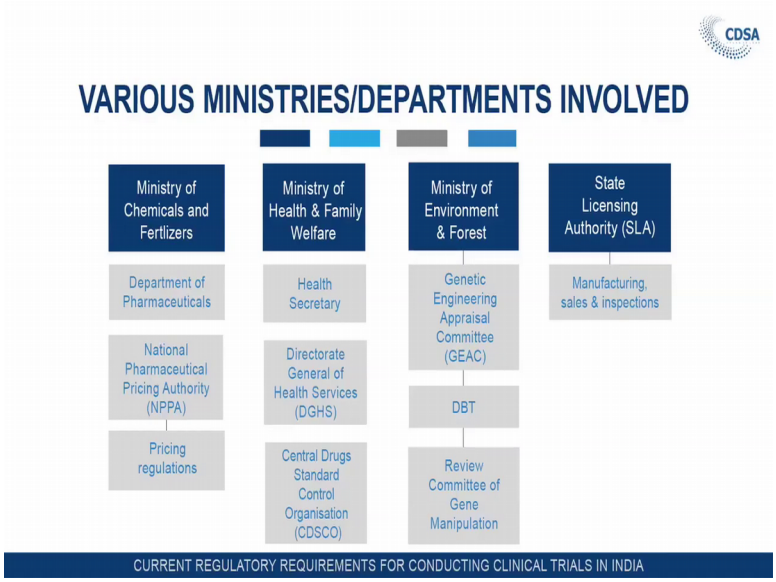

So, there are many of the ministries like ministry of chemical and fertilizer is having the department of pharmaceuticals under the department of pharmaceuticals, these is a department of NPPA that is National Pharmaceutical Pricing Authority. And this department and this department are mainly involved for the pricing of the drug available in India.

The another ministry that is ministry of health and family welfare, the head is a health secretary and having subordinate office DGHS Directorate General of Health Services under that CDSCO is mainly responsible for giving the approval of new drug, giving the approval of clinical trials and giving the permission for import and manufacturing. We will see the functions in detail in our subsequent slides.

Then the ministry of environment and forest; so, under these ministry there is a department like GEAC that is Genetically Engineered Appraisal Committee. This committee is mainly responsible for review and application of activity involving large scale of genetically engineered organism which are used for the R and D purposes. Then the department of biotechnology is under the ministry of science and technology is having RCGM that is Review Committee of Gene Manipulation. And this department is mainly responsible for authorising import and exports of the bio-similar drugs.

This department is also responsible for review or the preclinical data and it gives the recommendation whether to conduct the clinical trial or not. State licensing authority as we have seen every state is having different laboratories and every state is having its own; food and drug administration sometimes called as drug control authority also. They are having the different functions like giving the manufacturing permission, giving the cell licences we will see this in detail in our subsequent slide.

So, what is Indian NRA and what is its composition? So, this is the Indian NRA that is National Regulatory Authority of India we call it as a Central Drugs Standard Control Organisation that is CDSCO. Let us see the composition and structure in detail for the CDSCO.

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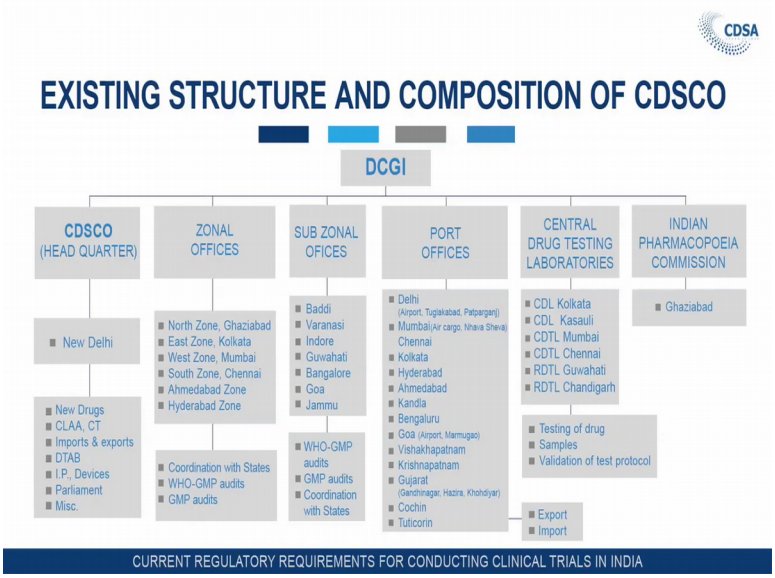

As shown in the picture the CDSCO is having its office that is headquarter at New Delhi and it is interested with the different types of function. It is headed by the DCGI we have seen it and the main function is to give the approval for the clinical trial, for the import, for the export purpose, for the DTAB product and for the LVP and some special biological products approval that is vaccine, sero diagnostic and other product like medical devices.

Zonal offices the CDSCO is having around 30 zonal and sub zonal offices and this offices are at north zone the offices at Ghaziabad, for the east zone the office is at Kolkata, for the west zone the office is at Mumbai and for the south zone it is at Chennai, Ahmadabad for it is zonal office and Hyderabad it is also zonal office for the south region. To assist this zonal offices and for the convenience of the customer and to keep more vision in directly on the drugs there are some sub zonal offices.

So, these are the sub zonal offices at Baddi, Varanasi, Indore, Guwahati, Bangalore, Goa and Jammu. To regulate the import and export the offices are also established at the port offices. These are some of the port offices, we are having the office at Delhi airport then Tughlakabad, Patparganj these all the port offices. Delhi airport mainly responsible for the import export of the drug, cosmetic and medical devices, then Mumbai for the west zone it is at air cargo Nhava Sheva, then for the Chennai it is at Chennai and Kolkata these are also having the port offices.

Hyderabad, Ahmadabad, Bengaluru and at Goa also we are having the port offices, Visakhapatnam, Krishnapatnam these are newly created port offices. Gujarat at three places we are having the port offices then Cochin and Tuticorin also we are having the port offices. We have seen the different testing laboratories that is central drug testing laboratories which are at Kolkata, Kasauli Mumbai and central drug testing laboratory is at Mumbai, Chennai. RDTL that is Regional Drug Testing Laboratory at Guwahati and Chandigarh.

These laboratories are mainly involved in testing of drug the samples send by the inspectors and validation of test protocol. One more laboratory that is Indian pharmacopoeia commission it is at Ghaziabad. Let us see the other that is Drug and Cosmetic Act and Rules there under and we will see subsequently the functions of CDSCO and concerned SLA. So, first the Drug and Cosmetic Act and why it is exercised at two level; that is state level and at the central level.

So, I would like to say that the act is in the concurrent list of 7th schedule of Indian constitution and what are the atoms in the concurrent list that has to be exercise at two levels that is at the central level and at the state level. Hence, the act is exercised at two level that is central and the state.

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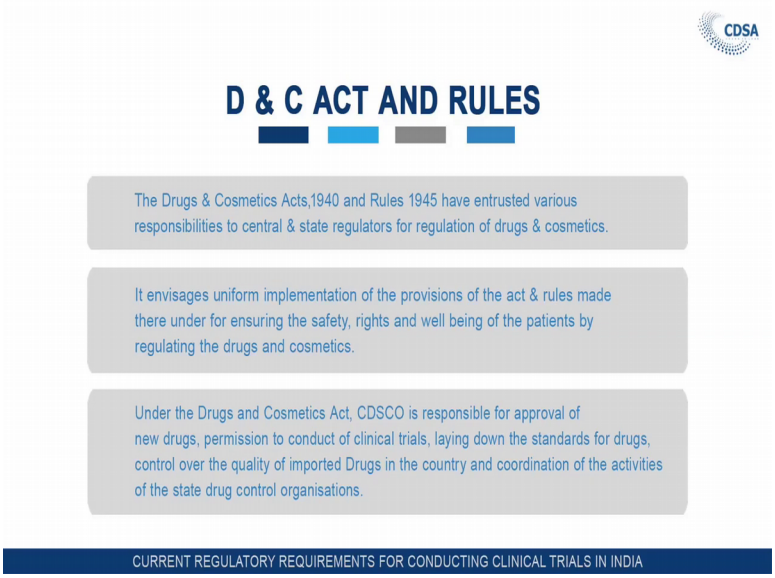

The Drug and Cosmetic Act 1940 and the Rules 1945 have interested various responsibilities to central and state being in the concurrent list. It envisage there is

uniform implementation of provision of the act and rules made there under for ensuring the safety, quality and well being of the patients by a regulating drug and cosmetic and clinical trials.

Under this act CDSCO is mainly responsible for giving the permission for conduct of clinical trials, then for the permission of new drugs subsequent new drug, global clinical trials. It is also responsible for laying down the standards of drug and control over the quality of imported drugs in the country and this can be done in coordination with the state offices. Let us see in detail: what are the functions of CDSCO.

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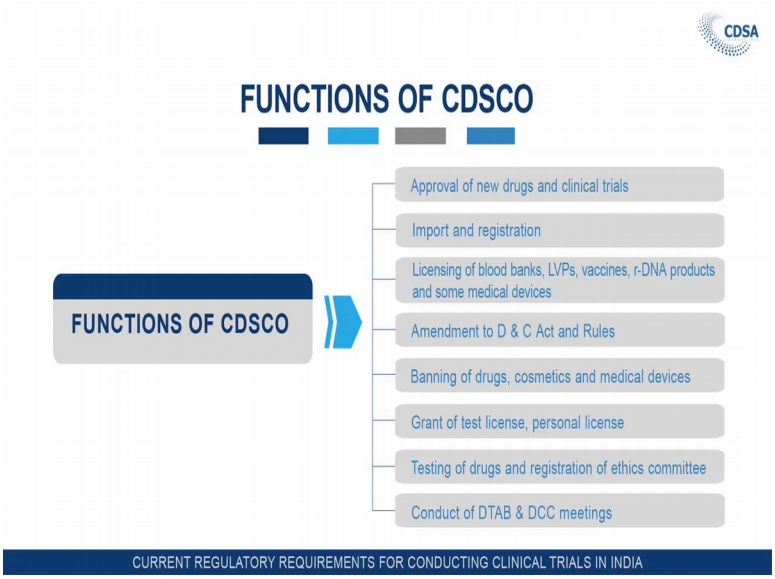

So, the first the function is approval of new drug and it is a clinical trial. So, the firm has firm or applicant has to apply to the CDSCO at head quarter in a specific form we have seen for its a new drug approval and clinical trial. Then import and registration this function has now have become online on Sugam, the applicant has to apply for the input license and for registration certificate into the CDSCO headquarter, then licensing of blood bank, LVPs, vaccine, r-DNA product and some medical devices.

The approval for these new drugs and for LVP, r-DNA it is also what for central CDSCO and at the Delhi headquarter. Then amendment to D and C act and rule is also one of the function of the CDSCO, banning of drug cosmetics and medical device this is also undertaken by CDSCO. Then grant of test license, personal license that is a grant for the

test license before the manufacturing that drug has to be tested or before the import the test license has to be taken that is also given by the CDSCO.

Personal license it is the license that is a for patient required to import some drugs from outside the country, then in that case the personal license can be given by CDSCO. Testing of drug and registration of ethics committee, registration of ethics committee is a mandatory we have seen in the rules. So, the applicant or ethics committee can apply for its registration at the CDSCO headquarter, conduct of DTAB and DCC meeting.

The drug technical advisory board for the technical matters and DCC for ensuring uniform implementation of drug and cosmetic act and this meeting conduct is at CDSCO headquarter.

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Let us see some of the few state licensing authority. So, this is the Food and Drug Administration authority of Maharashtra, then the control department of Karnataka, then Government of Telangana that is Drug Control Authority of the Telangana. We will see in detail what are the functions of the state licensing authorities.

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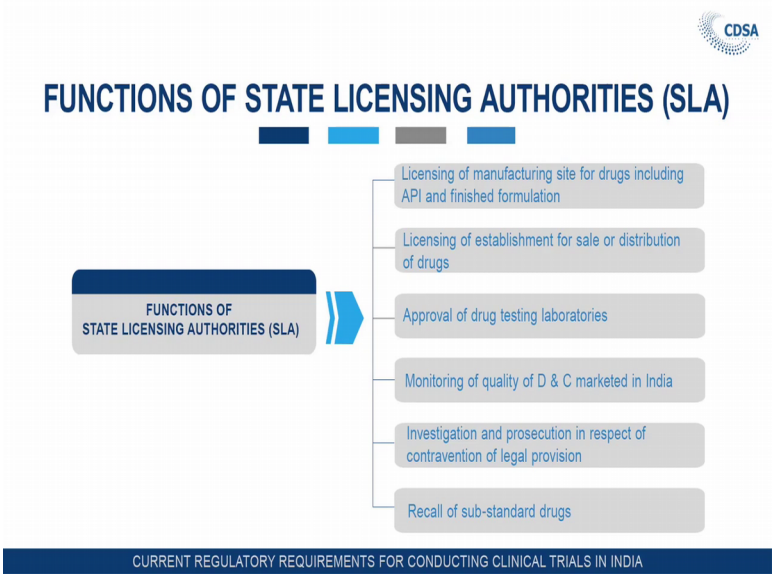

The state licensing authorities are mainly involved in giving the manufacturing licences for drug including API and for the finish formulation. So, the applicant after getting a new drug permissions and approval then for its manufacturing they require to apply in their concerns state licensing authority. After verifying the facility then the state licensing authority, if they will fit they can give the manufacturing license to that particular applicant or particular form.

Licensing of establishment for sale or distribution of a drug; the retail, wholesale these licenses are also given by the concerns state licensing authority after satisfying the norms. Then approval of drug testing laboratory some of the drug testing laboratories are available which are private also. So, approval of these testing laboratories can be given by the state licensing authorities

Monitoring of quality of drug and cosmetic marketed in India. So, for this drug inspector are interested to withdraw the samples and they send the samples to the concerned state laboratory for its a test and analysis. So, this is also the function of state as licensing authority. Investigation and prosecution in respect of contravention of legal provisions; if the drug is found to be sub standards, spurious or misconduct then the inspector and other officers has to launch a prosecution and this has been interested with the state licensing authority.

Also the investigation of these matters is carried out by the state licensing authorities, then recall of sub standard drugs. If the drug has been forwarded for testing and analysis and found it as sub standard and not good for the health of the subject or patients then the recall of that all the drug available in the market is a function of state licensing authorities.

State licensing authority in this regard can issue direction or so, cause notice to the firm to recall all the product. So, this is about the lecture and we will have quick recap what we have understand; the questions for you to check your memory power.

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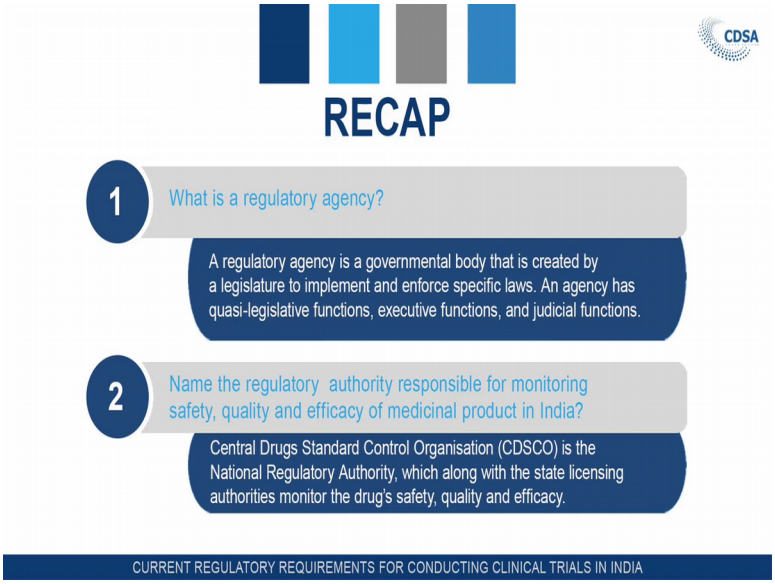

Question first what is a regulatory agency? So, the regulatory agency is a governmental body that is created by a legislature to implement and enforce specific loss for example, drug and cosmetic. An agency has a quasi legislative functions, executive function and judicial functions.

Question 2; which is the regulatory authority responsible for monitoring safety, quality, efficacy of medicinal product in India? CDSCO is the national regulatory body that is NRA which is along with the state drug department monitor drug safety, quality and efficacy.

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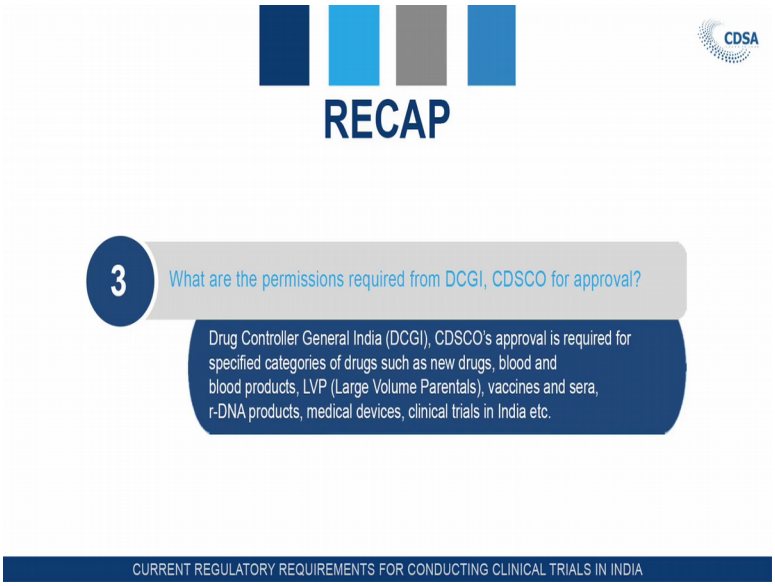

What kind of permission required DCGI or CDSCO for approval? DCGI or CDSCO approval is required for specific category of drugs like a new drug, clinical trial, blood product, LVP medical devices and IVD kits. So, what we have learn let us summarize.

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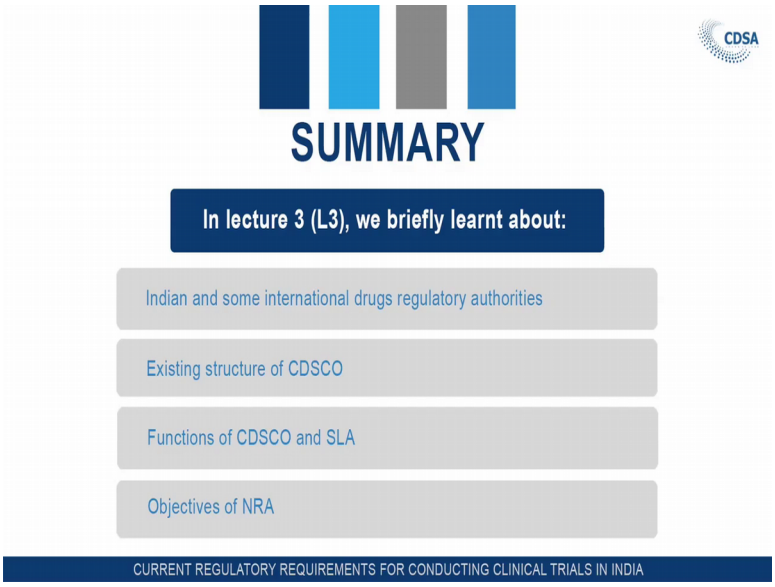

In this session we have learnt about Indian and some international regulatory authorities. Indian drug regulatory authority is a central drug standard control organisation authority. Some other regulatory authorities like USFDA for US and for the Japan it is PMDA, for the UK it is MHRA, for the TGA and the other regulatory authorities like European it is a

EMA and many more we have seen. We have seen the existing structure of CDSCO that is headquarter at Delhi and it is having the subordinate offices; we call zonal offices or sub zonal offices. There are about 13 zonal offices across the country.

Then we have seen the function of CDSCO, it is mainly involved in the approval of the clinical trial, new drug import export and other things. The functions of SLA that is giving the manufacturing licenses, retail licenses, wholesale licenses these are the main functions. Then objective of NRA so, objective of every NRA is to ensure that the safety, efficacy and quality of medicines available in the market. So, we will see some other things in the next subsequent lectures, till then bye bye and.

Thank you.