THE DRUGS AND COSMETICS ACT, 1940

SUMMARY

The Drugs and Cosmetics Act, 1940 is an Indian law that regulates the import, manufacture, distribution, and sale of drugs and cosmetics. The Act establishes a regulatory framework for the quality control and standardization of drugs and cosmetics, including provisions for the licensing and registration of manufacturers, wholesalers, and retailers. The Act also establishes the Central Drugs Standard Control Organization (CDSCO), which is responsible for implementing and enforcing the provisions of the Act. The Act prescribes penalties for non-compliance, including fines and imprisonment.

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CHAPTER I: INTRODUCTORY

Section 1: Short Title, Extent And Commencement

(1) This Act may be called the Drugs and Cosmetics Act, 1940.

(2) It extends to the whole of India.

(3) It shall come into force at once; but Chapter III shall take effect only from such date6 as the Central Government may, by notification in the Official Gazette, appoint in this behalf, and Chapter IV shall take effect in a particular

State only from such date as the State Government may, by like notification, appoint in this behalf:

Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such date after the commencement of the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), as the Central Government may, by notification in the Official Gazette, appoint in this behalf.

Simplified Act

(1) The name of this law is the Drugs and Cosmetics Act, 1940.

(2) This law applies to all of India.

(3) This law is in effect immediately. However, Chapter III will start on a date that the Central Government decides and announces in an official publication. Similarly, Chapter IV will start in each state on a date decided and announced by that state's government:

But for the state of Jammu and Kashmir, Chapter III will start on a date after the Drugs and Cosmetics (Amendment) Act, 1972 began, which the Central Government will decide and announce in an official publication.

Explanation using Example

Imagine a pharmaceutical company, "HealFast Pharma," wants to launch a new antibiotic in India. Before they can do so, they must ensure compliance with the Drugs and Cosmetics Act, 1940. The Act's name and its applicability across India mean that HealFast Pharma must adhere to the same set of regulations in Mumbai as it would in Kolkata or any other part of the country.

Further, the company must pay attention to the notifications published by the Central Government regarding Chapter III, which deals with the import of drugs and cosmetics. If the Central Government announces a new effective date for certain provisions in Chapter III, HealFast Pharma must adjust its import plans accordingly.

Similarly, if they are operating in a particular state, they must also be aware of any specific dates when Chapter IV, which pertains to the manufacture, sale, and distribution of drugs and cosmetics, comes into effect as notified by the State Government.

Section 2: Application Of Other Laws Not Barred

The provisions of this Act shall be in addition to, and not in derogation of, the Dangerous Drugs Act, 1930 (2 of 1930), and any other law for the time being in force.

Simplified Act

This law adds to the rules of the Dangerous Drugs Act, 1930 and any other existing laws. It doesn't replace or reduce the importance of those other laws.

Explanation using Example

Imagine a pharmaceutical company that manufactures a cough syrup containing a substance regulated under the Dangerous Drugs Act, 1930. While this company must comply with the regulations of the Dangerous Drugs Act for that substance, they must also adhere to the standards and requirements set by The Drugs and Cosmetics Act, 1940 for the overall production, quality, and labeling of the cough syrup. This ensures that there is a comprehensive legal framework governing the safety and efficacy of drugs, without one law undermining the provisions of the other.

Section 3: Definitions

In this Act, unless there is anything repugnant in the subject or context, -

"Ayurvedic, Siddha or Unani drug" includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in, the authoritative books of Ayurvedic, Siddha and Unani Tibb system of medicine, specified in the First Schedule;

"the Board" means -

in relation to Ayurvedic, Siddha or Unani drug, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board constituted under section 33C; and

in relation to any other drug or cosmetic, the Drugs Technical Advisory Board constituted under section 5;

"cosmetic" means any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the human body or any

part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic;

"drug" includes -

all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;

all substances intended for use as components of a drug including empty gelatin capsules; and

such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

"Government Analyst" means -

in relation to Ayurvedic, Siddha or Unani drug, a Government Analyst appointed by the Central Government or a State Government under section 33F; and

in relation to any other drug or cosmetic, a Government Analyst appointed by the Central Government or a State Government under section 20;

"Inspector" means -

in relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State Government under section 33G; and

in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;

"manufacture" in relation to any drug or cosmetic includes any process or part of a process for making, altering, ornamenting, finishing, packing, labeling, breaking up or otherwise treating or adopting any drug or cosmetic with a view to its sale or distribution but does not include the compounding or dispensing of any drug, or the packing of any drug or cosmetic, in the ordinary course of retail business; and "to manufacture" shall be construed accordingly;

"to import", with its grammatical variations and cognate expressions means to bring into India;

"patent or proprietary medicine" means, -

in relation to Ayurvedic, Siddha or Unani Tibb systems of medicine all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurvedic, Siddha or Unani Tibb systems of medicine specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

in relation to any other systems of medicine, a drug which is a remedy or prescription presented in a form ready for internal or external administration of human beings or animals and which is not included in the edition of the Indian Pharmacopoeia for the time being or any other Pharmacopoeia authorised in this behalf by the Central Government after consultation with the Drugs Technical Advisory Board constituted under section 5;

"prescribed" means prescribed by rules made under this Act.

Simplified Act

This section explains some terms used in the Drugs and Cosmetics Act, 1940:

"Ayurvedic, Siddha or Unani drug" refers to any medicine made strictly following traditional Indian medical systems (Ayurveda, Siddha, or Unani) formulas, which is used for diagnosing, treating, or preventing diseases in humans or animals.

"The Board" refers to the group of experts who advise on Ayurvedic, Siddha, or Unani drugs and other drugs or cosmetics. There are two separate boards for these, one for traditional systems and one for others.

"Cosmetic" is anything you apply to your body to clean, beautify, or change its appearance, including parts of cosmetics.

"Drug" includes all medicines and substances used for treating or preventing diseases in humans or animals and can also refer to components of a drug or devices used for medical purposes.

"Government Analyst" is a person appointed by the government to analyze the quality of Ayurvedic, Siddha, or Unani drugs and other drugs or cosmetics.

"Inspector" is a person appointed by the government to check and enforce the law concerning Ayurvedic, Siddha, or Unani drugs and other drugs or cosmetics.

"Manufacture" means making, altering, packaging, or any other process involved in preparing a drug or cosmetic for sale, except for mixing or packaging drugs at a pharmacy.

"To import" means to bring something into India from another country.

"Patent or proprietary medicine" refers to a ready-to-use medicine that follows the recipes from traditional Indian medical books or, for other medicines, is not listed in official medicinal texts but is approved by the government.

"Prescribed" means set out by the rules of this Act.

Explanation using Example

Imagine a company in India that produces a herbal ointment, claiming it can treat eczema. The ointment is made following traditional Ayurvedic formulas and is intended for external application to the skin. This product would be considered an "Ayurvedic drug" under the Drugs and Cosmetics Act, 1940.

Before the ointment can be sold, the company must ensure it complies with the Act. This means the product must be manufactured exclusively in accordance with the formulae described in the authoritative Ayurvedic texts listed in the First Schedule of the Act. Additionally, the company must abide by the regulations concerning the manufacture, labeling, and sale of such drugs, which may involve seeking approval from the "Board"—in this case, the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board.

If the government suspects the ointment is not in compliance, a "Government Analyst" may test it to ensure its safety and efficacy, and an "Inspector" may visit the manufacturing facility to ensure that the production processes meet the regulatory standards.

Section 3A: Construction Of References To Any Law Not In Force Or Any Functionary Not In Existence In The State Of Jammu And Kashmir

Any reference in this Act to any law which is not in force, or any functionary not in existence, in the State of Jammu and Kashmir, shall, in relation to that State, be construed as a reference to the corresponding law in force, or to the corresponding functionary in existence, in that State.

Simplified Act

Simplified Explanation of Section 3A of The Drugs and Cosmetics Act, 1940

If this law mentions another law that isn't active, or a government official who doesn't exist in the State of Jammu and Kashmir, then, for that State, you should read it as if it's talking about the equivalent law that is active, or the equivalent government official who does exist there.

Explanation using Example

Imagine a pharmaceutical company wants to distribute a new drug in various parts of India, including the State of Jammu and Kashmir. The company is aware that certain central laws might not be in force in Jammu and Kashmir or there may be local functionaries instead of central ones. According to Section 3A of The Drugs and Cosmetics Act, 1940, when the company looks at the requirements for drug approval under this Act, any reference to a law that is not in force in Jammu and Kashmir will be interpreted as referring to the equivalent law that is in force in Jammu and Kashmir. Similarly, if the Act mentions a central authority that does not exist in Jammu and Kashmir, the reference will be understood as the corresponding local authority that performs the same functions in Jammu and Kashmir. This ensures that the company follows the correct legal procedures and engages with the appropriate regulatory bodies specific to Jammu and Kashmir for the distribution of their drug.

Section 4: Presumption As To Poisonous Substances

Any substance specified as poisonous by rule made under Chapter II or Chapter IV or Chapter IVA shall be deemed to be a poisonous substance for the purposes of Chapter III or Chapter IV or Chapter IVA, as the case may be.

Simplified Act

Simple Explanation of Section 4: If a substance is declared poisonous in the rules under Chapter II, IV, or IVA of The Drugs and Cosmetics Act, 1940, it will be officially considered poisonous when applying the rules of Chapter III, IV, or IVA, whichever is relevant.

Explanation using Example

Imagine a pharmaceutical company wants to manufacture a new cough syrup that contains a substance which has been specified as poisonous under the rules of The Drugs and Cosmetics Act. According to Section 4, because the substance is listed as poisonous in the rules, the company must comply with the regulations for handling poisonous substances in the manufacturing, storage, distribution, and sale of the cough syrup as outlined in Chapters III, IV, or IVA of the Act. This might include obtaining special licenses, following strict safety protocols, and ensuring proper labeling to warn consumers of the potential risks.

CHAPTER II: THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE

Section 5: The Drugs Technical Advisory Board

(1) The Central Government shall, as soon as may be, constitute a Board (to be called the Drugs Technical Advisory Board) to advise the Central Government and the State Governments on technical matters arising out of the administration of this Act and to carry out the other functions assigned to it by this Act.

(2) The Board shall consist of the following members, namely:

(i) the Director General of Health Services, ex officio, who shall be the Chairman;

(ii) the Drugs Controller, India, ex officio;

(iii) the Director of the Central Drugs Laboratory, Calcutta, ex officio;

(iv) the Director of the Central Research Institute, Kasauli, ex officio;

(v) the Director of the Indian Veterinary Research Institute, Izatnagar, ex officio;

(vi) the President of the Medical Council of India, ex officio;

(vii) the President of the Pharmacy Council of India, ex officio;

(viii) the Director of the Central Drug Research Institute, Lucknow, ex officio;

(ix) two persons to be nominated by the Central Government from among persons who are in charge of drugs control in the States;

(x) one person, to be elected by the Executive Committee of the Pharmacy Council of India, from among teachers in pharmacy or pharmaceutical chemistry or pharmacognosy on the staff of an Indian university or a college affiliated thereto;

(xi) one person, to be elected by the Executive Committee of the Medical Council of India, from among teachers in medicine or therapeutics on the staff of an Indian university or a college affiliated thereto;

(xii) one person to be nominated by the Central Government from the pharmaceutical industry;

(xiii) one pharmacologist to be elected by the Governing Body of the Indian Council of Medical Research;

(xiv) one person to be elected by the Central Council of the Indian Medical Association;

(xv) one person to be elected by the Council of the Indian Pharmaceutical Association;

(xvi) two persons holding the appointment of Government Analyst under this Act, to be nominated by the Central Government.

(3) The nominated and elected members of the Board shall hold office for three years, but shall be eligible for re-nomination and re-election:

Provided that the person nominated or elected, as the case may be, under clause (ix) or clause (x) or clause (xi) or clause (xvi) of sub-section (2) shall hold office for so long as he holds the appointment of the office by virtue of which he was nominated or elected to the Board.

(4) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and the conduct of all business to be transacted by it.

(5) The Board may constitute sub-committees and may appoint to such sub-committees for such periods, not exceeding three years, as it may decide, or

temporarily for the consideration of particular matters, persons who are not members of the Board.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

Simplified Act

Simplified Explanation:

(1) The Indian government will establish a group called the Drugs Technical Advisory Board. This board will provide advice on technical issues related to the enforcement of the Drugs and Cosmetics Act and perform other duties as outlined by the Act.

(2) The board will include the following people:

The Director General of Health Services (Chairman),

The Drugs Controller of India,

The Director of the Central Drugs Laboratory in Calcutta,

The Director of the Central Research Institute in Kasauli,

The Director of the Indian Veterinary Research Institute in Izatnagar,

The President of the Medical Council of India,

The President of the Pharmacy Council of India,

The Director of the Central Drug Research Institute in Lucknow,

Two people chosen by the government from state drug control officials,

One person elected from pharmacy or pharmaceutical teachers by the Pharmacy Council of India,

One person elected from medicine or therapeutics teachers by the Medical Council of India,

One person from the pharmaceutical industry nominated by the government,

One pharmacologist elected by the Indian Council of Medical Research,

One person elected by the Indian Medical Association,

One person elected by the Indian Pharmaceutical Association,

Two government analysts working under this Act, nominated by the government.

(3) Members who are nominated or elected will serve for three years and can be nominated or elected again. However, those nominated or elected for certain positions will serve as long as they hold their current job.

(4) The board can create its own rules for meetings and business, but it needs the government's approval first.

(5) The board can form smaller groups and can include people who are not board members for up to three years or for specific issues.

(6) The board can still function even if some positions are vacant.

(7) The government will appoint a Secretary for the board and provide the necessary staff.

Explanation using Example

Imagine a pharmaceutical company has developed a new drug and is seeking approval for its sale in India. Before the drug can be approved, it must be reviewed for safety, efficacy, and quality. The Drugs Technical Advisory Board (DTAB), as constituted under Section 5 of the Drugs and Cosmetics Act, 1940, plays a crucial role in this process.

In this scenario, the DTAB would be called upon to provide technical advice to the Central Government regarding the new drug. The Board, with members like the Director General of Health Services and the Drugs Controller of India, among others, would evaluate the data submitted by the pharmaceutical company. They might also set up a sub-committee with experts to closely examine specific technical aspects of the drug.

Once the DTAB has reviewed the drug and provided its recommendations, the Central Government can make an informed decision on whether to approve the drug for the Indian market, ensuring that the drug is safe for public consumption and meets all regulatory requirements.

Section 6: The Central Drugs Laboratory

(1) The Central Government shall, as soon as may be, establish a Central Drugs Laboratory under the control of a Director to be appointed by the Central Government, to carry out the functions entrusted to it by this Act or any rules made under this Chapter : Provided that, if the Central Government so prescribes, the functions of the Central Drugs Laboratory in respect of any drug or class of drugs or cosmetic or class of cosmetics shall be carried out at the Central Research Institute, Kasauli, or at any other prescribed Laboratory and the functions of the Director of the Central Drugs Laboratory in respect of such drug or class of drugs or such cosmetic or class of cosmetics shall be exercised by the Director of that Institute or of that other Laboratory, as the case may be.

(2) The Central Government may, after consultation with the Board, make rules prescribing

(a) the functions of the Central Drugs Laboratory;

(d) the procedure for the submission to the said Laboratory under Chapter IV or Chapter IVA of samples of drugs or cosmetics for analysis or test, the forms of the Laboratory's reports thereon and the fees payable in respect of such reports;

(e) such other matters as may be necessary or expedient to enable the said Laboratory to carry out its functions;

(f) the matters necessary to be prescribed for the purposes of the proviso to sub-section (1).

Simplified Act

Simplified Explanation of Section 6 of The Drugs and Cosmetics Act, 1940

1. Setting Up the Central Drugs Laboratory: The Indian government must create a main laboratory called the Central Drugs Laboratory. This lab will be managed by a Director appointed by the government. The lab's job is to perform tasks given to it by this law or any rules made under this section. However, the government can decide that certain drugs or cosmetics can be tested at the Central Research Institute in Kasauli or any other designated lab instead. In such cases, the Director of those institutes or labs will take over the responsibilities of the Director of the Central Drugs Laboratory for those particular products.

2. Government Rules for the Laboratory: The government can make rules for the Central Drugs Laboratory after discussing with the Board. These rules can include:

What the lab is supposed to do.

How to send drug or cosmetic samples to the lab for testing, how the lab will report the results, and the charges for these reports.

Any other details that will help the lab do its job.

Specific details needed because of the special provision in the first point above.

Explanation using Example

Imagine a pharmaceutical company, "HealthPlus Pharma," has developed a new antibiotic. Before they can market this antibiotic in India, they must ensure it complies with the standards set by the Drugs and Cosmetics Act, 1940. As per Section 6 of the Act, HealthPlus Pharma sends a sample of the new antibiotic to the Central Drugs Laboratory (CDL) for analysis and testing.

The CDL, established by the Central Government, is responsible for analyzing the sample to ensure it meets the necessary quality and safety standards. The Director of the CDL, appointed by the government, oversees the testing process. After thorough analysis, the CDL provides a report on the antibiotic, which HealthPlus Pharma must review. If the report indicates that the antibiotic conforms to the prescribed standards, HealthPlus Pharma can proceed with the process of obtaining approval for its new antibiotic. If not, they must make the necessary adjustments to meet the required criteria.

In this scenario, Section 6 of the Drugs and Cosmetics Act, 1940, ensures that all drugs, including the new antibiotic from HealthPlus Pharma, are rigorously tested for safety and efficacy before they are available to the public, thereby safeguarding public health.

Section 7: The Drugs Consultative Committee

(1) The Central Government may constitute an advisory committee to be called "the Drugs Consultative Committee" to advise the Central Government, the State Governments and the Drugs Technical Advisory Board on any matter tending to secure uniformity throughout India in the administration of this Act.

(2) The Drugs Consultative Committee shall consist of two representatives of the Central Government to be nominated by that Government and one representative of each State Government to be nominated by the State Government concerned.

(3) The Drugs Consultative Committee shall meet when required to do so by the Central Government and shall have power to regulate its own procedure.

Simplified Act

(1) The government of India can set up a group called "the Drugs Consultative Committee." This group's job is to give advice to both the national (Central) and regional (State) governments, as well as to the Drugs Technical Advisory Board, to help make sure the rules of the Drugs and Cosmetics Act are followed the same way all over the country.

(2) This committee will have two members from the national government chosen by that government, and each regional government will choose one member to represent them.

(3) The Drugs Consultative Committee will meet whenever the national government says it's necessary. The committee can also decide how it wants to run its meetings.

Explanation using Example

Imagine a pharmaceutical company in India has developed a new drug and is seeking approval for its nationwide distribution. The Central Government, aiming to ensure that the drug meets safety standards across all states, decides to consult with the Drugs Consultative Committee (DCC) as per Section 7 of The Drugs and Cosmetics Act, 1940.

In this scenario, the DCC, comprising representatives from the Central and State Governments, convenes to review the drug's compliance with safety regulations. Their role is to provide advice that helps maintain uniform drug administration standards across India. After thorough deliberation, the DCC offers recommendations to the Central and State Governments, which could include additional testing requirements or specific labeling guidelines to ensure consumer safety.

Section 7A: Sections 5 And 7 Not To Apply To Ayurvedic, Siddha Or Unani Drugs

Nothing contained in sections 5 and 7 shall apply to Ayurvedic, Siddha or Unani drugs.

Simplified Act

Explanation of Section 7A - Exemption for Traditional Medicines

The rules in sections 5 and 7 of this law do not apply to traditional Indian medicines, which include Ayurvedic, Siddha, and Unani treatments.

Explanation using Example

Imagine a local manufacturer in India produces a traditional Ayurvedic cough syrup using herbs and natural ingredients. According to Section 7A of The Drugs and Cosmetics Act, 1940, the manufacturer is not required to follow the provisions mentioned in sections 5 and 7 of the same act, which pertain to the standards of quality and misbranded drugs, respectively. This means that while the manufacturer must ensure the safety and efficacy of the Ayurvedic cough syrup, they are not bound by the specific quality standards and labeling requirements set for allopathic drugs under those sections.

CHAPTER III: IMPORT OF DRUGS AND COSMETICS

Section 8: Standards Of Quality

(1) For the purposes of this Chapter, the expression "standard quality" means -

(a) in relation to a drug, that the drug complies with the standard set out in the Second Schedule, and

(b) in relation to a cosmetic, that the cosmetic complies with such standard as may be prescribed.

(2) The Central Government, after consultation with the Board and after giving by notification in the Official Gazette not less than three months' notice of its intention so to do, may by a like notification add to or otherwise amend the Second Schedule, for the purposes of this Chapter, and thereupon the Second Schedule shall be deemed to be amended accordingly.

Simplified Act

Simplified Explanation of Quality Standards

What "standard quality" means:

(a) For a medicine, it must meet the quality requirements listed in a specific part of the law (the Second Schedule).

(b) For a beauty product, it must meet quality standards that the government will specify.

How the quality requirements can change:

The government can update the quality requirements for medicines after discussing with a special board and letting the public know about this intention at least three months in advance through an official announcement. Once announced, the changes are considered part of the law.

Explanation using Example

Imagine a pharmaceutical company, "HealthPlus Pharma," wants to introduce a new antibiotic to the market. Before they can sell the drug, they must ensure it meets the "standard quality" as defined by the Drugs and Cosmetics Act, 1940. Specifically, under Section 8:

The antibiotic must comply with the standards set out in the Second Schedule of the Act, which includes requirements for purity, strength, and labeling.

HealthPlus Pharma conducts rigorous testing and ensures the antibiotic meets these criteria. If the Central Government, after consulting with the appropriate board, decides to update the standards in the Second Schedule, HealthPlus Pharma would need to comply with the new standards for their antibiotic to maintain its status as being of "standard quality."

Section 9: Misbranded Drugs

For the purposes of this Chapter, a drug shall be deemed to be misbranded -

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is;

(b) if it is not labelled in the prescribed manner;

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Simplified Act

Understanding Misbranded Drugs

A drug is considered "misbranded" (which means it's labeled or presented in a misleading way) in the following situations:

(a) If it's been colored, coated, powdered, or polished to hide damage or to make it look like it has more health benefits than it actually does;

(b) If it doesn't have the proper labeling as required by the law;

(c) If the label, container, or anything that comes with the drug has any claims or information that are not true or are misleading in any way.

Explanation using Example

Imagine a company named "HealthPlus" manufactures a pain relief cream called "FastRelief." The cream's actual efficacy is similar to other products on the market. However, HealthPlus decides to add a shiny gold coating to the packaging and includes a label that states "New Improved Formula with Double Effectiveness." Upon investigation, it is found that there is no change in the formula, and the product's effectiveness is unchanged. This would be a case of misbranding under Section 9(a) of The Drugs and Cosmetics Act, 1940, because the product is made to appear of greater therapeutic value than it really is through deceptive packaging.

Section 9A: Adulterated Drugs

For the purposes of this Chapter, a drug shall be deemed to be adulterated,

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance;

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health;

(c) if its container is composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed;

(e) if it contains any harmful or toxic substance which may render it injurious to health;

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

Simplified Act

What counts as an adulterated drug? A drug is considered "adulterated" if:

(a) it includes any dirty or rotten parts;

(b) it was made or packaged in dirty conditions that could have contaminated it or made it harmful;

(c) its packaging contains any harmful materials that could affect your health;

(d) it uses colors not approved by regulations just to make it look a certain way;

(e) it has any dangerous substances that could be harmful to your health;

(f) something has been added to it that lowers its quality or effectiveness.

Explanation using Example

Imagine a pharmaceutical company, "HealthPlus Pharma," that manufactures a cough syrup. A batch of this syrup was found to contain a small amount of a toxic chemical that somehow got mixed during the production process. This chemical is not harmful in very tiny amounts but can be dangerous if consumed in larger quantities.

Upon investigation, it was discovered that the storage tanks were not cleaned properly and the toxic chemical residue from a previously manufactured product was not entirely removed. This residue mixed with the cough syrup, thus falling under Section 9A of The Drugs and Cosmetics Act, 1940, specifically clause (b), as the syrup was packed under insanitary conditions leading to contamination, and clause (e), as it contains a harmful substance that may render it injurious to health.

As a result, the batch is deemed adulterated and must be removed from the market to ensure public safety. HealthPlus Pharma may face legal consequences for this violation of the Act.

Section 9B: Spurious Drugs

For the purposes of this Chapter, a drug shall be deemed to be spurious:

(a) if it is imported under a name which belongs to another drug;

(b) if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug;

(c) if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist;

(d) if it has been substituted wholly or in part by another drug or substance;

(e) if it purports to be the product of a manufacturer of whom it is not truly a product.

Simplified Act

What counts as a fake drug?

A drug is considered fake if it meets any of the following criteria:

(a) It's brought into the country with a name that actually belongs to a different drug.

(b) It's made to look like or replace another drug, or it's so similar that it could trick someone. Also, if it has the name of another drug on it or its packaging, unless it's clearly labeled to show what it really is and that it's not the same as the other drug.

(c) The label or container says it's made by a person or company that doesn't really exist or is made up.

(d) It's been completely or partly replaced with a different drug or substance.

(e) It claims to be made by a manufacturer who didn't actually make it.

Explanation using Example

Imagine a situation where a local pharmacy receives a shipment of medication labeled as a well-known brand of ibuprofen, a common pain reliever. However, upon closer inspection, it's discovered that the tablets inside the bottles do not match the appearance of the genuine product. The medication was imported under the brand name but is actually a different, lower-quality drug designed to imitate the legitimate product. This is a clear violation of Section 9B(a) of The Drugs and Cosmetics Act, 1940, as the drug was imported under a name that belongs to another drug. The authorities would investigate the source of these spurious drugs to ensure public safety and take appropriate legal action against the responsible parties.

Section 9C: Misbranded Cosmetics

For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded -

(a) if it contains a colour which is not prescribed;

(b) if it is not labelled in the prescribed manner;

(c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Simplified Act

Understanding Misbranded Cosmetics

A cosmetic product is considered "misbranded" if it meets any of the following conditions:

(a) It has a color additive that is not approved or allowed by the regulations;

(b) The packaging does not have the correct labeling as required by the regulations;

(c) Any written, printed, or graphic material on the label, packaging, or that comes with the cosmetic is untrue or could mislead a person in any way.

Explanation using Example

Imagine a company named "Glow & Shine" that manufactures a face cream called "Radiant Youth." Upon inspection, it is found that the cream contains a blue dye that is not on the list of approved color additives as per the regulations. Additionally, the cream's label lacks the mandatory manufacturing date and list of ingredients. Furthermore, the packaging claims that the product can "reverse aging," which is scientifically unsubstantiated and therefore misleading.

In this scenario, "Radiant Youth" face cream would be considered misbranded under Section 9C of The Drugs and Cosmetics Act, 1940 for the following reasons:

The cream contains a non-prescribed colour, violating clause (a).

The labeling does not include all the required information, violating clause (b).

The claim of reversing aging is false and misleading, violating clause (c).

As a result, "Glow & Shine" could face regulatory actions, including the removal of the product from the market and potential penalties.

Section 9D: Spurious Cosmetics

For the purposes of this Chapter, a cosmetic shall be deemed to be spurious:

(a) if it is imported under a name which belongs to another cosmetic;

(b) if it is an imitation of, or is a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic;

(c) if the label, or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist;

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.

Simplified Act

Understanding Spurious Cosmetics

In simple terms, a cosmetic is considered fake or counterfeit if:

(a) It is brought into the country using the name of a different cosmetic product.

(b) It copies or tries to replace another cosmetic product, or looks so similar that it could confuse people. It's also fake if it uses the name of another cosmetic on its packaging, unless it's clearly marked to show what it really is and that it's not the same as the other product.

(c) The name on the label or the packaging claims to be from a manufacturer that doesn't exist or is made up.

(d) It claims to be made by a real manufacturer, but it's not actually made by them.

Explanation using Example

Imagine a situation where a local beauty store is importing a face cream that is packaged and labeled very similarly to a well-known international brand. The store advertises and sells the cream under the famous brand's name, but the product is actually manufactured by an unknown company and does not contain the same ingredients or quality. This face cream would be considered a spurious cosmetic under Section 9D of The Drugs and Cosmetics Act, 1940, because it:

Imitates another cosmetic, deceiving customers into thinking it is the genuine brand (clause b);

Does not clearly reveal its true character and its lack of identity with the genuine brand (clause b);

Purports to be the product of a well-known manufacturer when it is not (clause d).

Consequently, the authorities could take legal action against the store for dealing in spurious cosmetics.

Section 10: Prohibition Of Import Of Certain Drugs Or Cosmetics

From such date as may be fixed by the Central Government by notification in the Official Gazette in this behalf, no person shall import:

(a) any drug or cosmetic which is not of standard quality;

(b) any misbranded drug or misbranded or spurious cosmetics;

(bb) any adulterated or spurious drug;

(c) any drug or cosmetic for the import of which a licence is prescribed, otherwise than under, in accordance with, such licence;

(d) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

(e) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(ee) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(f) any drug or cosmetic the import of which is prohibited by rule made under this Chapter:

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

Simplified Act

Starting on a date set by the Central Government, which will be announced, you are not allowed to bring into the country:

(a) any medicine or beauty product that does not meet the required quality standards;

(b) any medicine that is wrongly labeled or beauty products that are falsely labeled or fake;

(bb) any medicine that is tainted or fake;

(c) any medicine or beauty product that you need a special license to import, unless you have that license and follow its rules;

(d) any medicine with a brand or patent that doesn't show the exact formula or list of active ingredients and their amounts on the label or container;

(e) any medicine that claims to treat or relieve any disease or condition, or to have any other effect that is not allowed;

(ee) any beauty product that has something in it that could make it unsafe or harmful when used as directed or suggested;

(f) any medicine or beauty product that you are not allowed to bring into the country according to the rules of this law.

However, this rule does not apply to bringing in small amounts of any medicine for testing, research or personal use, as long as certain conditions are met:

Also, the Central Government can allow, with advice from the Board and announced in an official notice, the import of any medicine or type of medicine even if it doesn't meet the quality standards, as long as certain conditions are followed.

Explanation using Example

Imagine a company, "HealthFirst Imports," plans to import a batch of a new skin cream, "GlowRight," from a manufacturer in France to India. Before importing, they must ensure that GlowRight complies with the Drugs and Cosmetics Act, 1940, specifically Section 10. Here's how the Act applies:

HealthFirst must verify that GlowRight is of standard quality and not adulterated, ensuring it meets the quality requirements set by Indian authorities.

The cream should not be misbranded, meaning it must be labeled correctly with accurate information about its purpose and contents.

If a licence is required for the import of cosmetics, HealthFirst must obtain this licence and import GlowRight in accordance with its conditions.

The packaging of GlowRight must display the true formula or list of active ingredients along with their quantities, as this is a requirement for patented medicines or proprietary cosmetics.

HealthFirst must ensure that GlowRight doesn't claim to cure or mitigate diseases or ailments unless such claims are allowed by Indian regulations.

The cream should not contain any ingredient that may make it unsafe or harmful when used as directed.

Finally, HealthFirst must check if there are any rules that specifically prohibit the import of GlowRight or similar cosmetics.

If HealthFirst wants to import small quantities of GlowRight for testing or personal use, they may do so under certain conditions. Additionally, the Central Government has the power to permit the import of non-standard quality drugs or cosmetics under specific circumstances after consulting with the appropriate board.

Section 10A: Power Of Central Government To Prohibit Import Of Drugs And Cosmetics In Public Interest

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, prohibit the import of such drug or cosmetic.

Simplified Act

Simplified Explanation of Section 10A - Power to Ban Import of Drugs and Cosmetics for Public Safety

If the Central Government believes that a drug or cosmetic could be harmful to people or animals, or if the drug doesn't do what it claims to do, or has ingredients in amounts that aren't medically necessary, it can act in the public's interest. The Government has the power to officially announce a ban on bringing such drug or cosmetic into the country.

Explanation using Example

Imagine a scenario where a new drug for treating a common cold, named "ColdNoMore," is introduced in the international market by a pharmaceutical

company. The drug claims to reduce symptoms in half the time than existing medications. However, after some months, reports from other countries start surfacing that "ColdNoMore" has led to severe allergic reactions in a significant number of patients, and in some cases, it has caused more harm than benefit due to its high concentration of a particular active ingredient.

In response to these reports, the Central Government of India begins an investigation and reviews the clinical data. The investigation reveals that the therapeutic claims made by the drug are exaggerated and the risks outweigh the benefits for Indian consumers. Concerned about the health and safety of its citizens, the Central Government decides to act in the public interest.

Using the powers granted under Section 10A of The Drugs and Cosmetics Act, 1940, the government issues a notification in the Official Gazette to prohibit the import of "ColdNoMore" into India, thereby preventing its distribution and sale within the country. This action is taken to protect the public from the potential risks associated with the drug.

Section 11: Application Of Law Relating To Sea Customs And Powers Of Customs Officers

(1) The law for the time being in force relating to sea customs and to goods, the import of which is prohibited by section 18 of the Sea Customs Act, 1878(18 of 1878) shall, subject to the provisions of section 13 of this Act, apply in respect of drugs and cosmetics the import of which is prohibited under this Chapter and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a Commissioner of Custom and other officers of Customs, shall have the same powers in respect of such drugs and cosmetics as they have for the time being in respect of such goods as aforesaid.

(2) Without prejudice to the provisions of sub-section (1), the Commissioner of Customs or any officer of the Government authorised by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug or cosmetic the import of which is prohibited under this Chapter and shall forthwith report such detention to the Drugs Controller, India and, if necessary, forward the package or sample of any suspected drug or cosmetic found therein to the Central Drugs Laboratory.

Simplified Act

Simplified Explanation of Section 11 of The Drugs and Cosmetics Act, 1940

Part 1: The current laws that manage sea customs and banned imports will also apply to drugs and cosmetics that are not allowed to be imported, as long as they don't conflict with a specific section (section 13) of this Act. Customs officers have the same authority to deal with these drugs and cosmetics as they do with other prohibited goods.

Part 2: In addition to what's mentioned above, the Commissioner of Customs or any government officer authorized by the Central Government can hold any imported package they think might contain drugs or cosmetics that are not allowed to be imported. They must tell the Drugs Controller of India about this right away and might need to send the package or a sample of the suspected item to the Central Drugs Laboratory for testing.

Explanation using Example

Imagine a shipment of beauty creams arrives at a port in India. The customs officer, while inspecting the cargo, suspects that the creams may contain ingredients not approved by Indian regulations, potentially making their import prohibited under The Drugs and Cosmetics Act, 1940. According to Section 11(1), the customs officer can apply the same laws that govern prohibited sea customs goods to this shipment of beauty creams.

Acting under Section 11(2), the customs officer detains the shipment and informs the Drugs Controller, India, of the detention. The officer also sends a sample of the beauty cream to the Central Drugs Laboratory to verify whether the ingredients meet the legal standards for import. If the laboratory confirms that the ingredients are indeed prohibited, the entire shipment may be seized and prevented from entering the Indian market.

Section 12: Power Of Central Government To Make Rules

(1) The Central Government may, after consultation with or on the recommendation of the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter: Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any

suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may

(a) specify the drugs or classes of drugs or cosmetics or classes of cosmetics for the import of which a licence is required, and prescribe the form and conditions of such licences, the authority empowered to issue the same, the fees payable therefor and provide for the cancellation, or suspension of such licence in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which the licence is issued is not complied with;

(b) prescribe the methods of test or analysis to be employed in determining whether a drug or cosmetic is of standard quality;

(c) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

(cc) prescribe under clause (d) of section 9A the colour or colours which a drug may bear or contain for purposes of colouring;

(d) specify the diseases or ailments which an imported drug may not purport or claim to prevent, cure or mitigate and such other effects which such drug may not purport or claim to have;

(e) prescribe the conditions subject to which small quantities of drugs, the import of which is otherwise prohibited under this Chapter, may be imported for the purpose of examination, test or analysis or for personal use;

(f) prescribe the places at which drugs or cosmetics may be imported, and prohibit their import at any other place;

(g) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the label or container of any specified imported drug or class of such drug, and prohibit the import of the said drug or class of drug after the expiry of a specified period from the date of manufacture;

(h) regulate the submission by importers, and the securing, of samples of drugs or cosmetics for examination, test or analysis by the Central Drugs Laboratory, and prescribe the fees, if any, payable for such examination, test or analysis;

(i) prescribe the evidence to be supplied, whether by accompanying documents or otherwise, of the quality of drugs or cosmetics sought to be imported, the

procedure of officers of Customs in dealing with such evidence, and the manner of storage at places of import of drugs or cosmetics detained pending admission;

(j) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter and the rules made thereunder of drugs or cosmetics imported for the purpose only of transport through, and export from, India;

(k) prescribe the conditions to be observed in the packing in bottles, packages or other containers, of imported drugs or cosmetics including the use of packing material which comes into direct contact with the drugs;

(l) regulate the mode of labelling drugs or cosmetics imported for sale in packages, and prescribe the matters which shall or shall not be included in such labels;

(m) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any imported drug, prohibit the import of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(n) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the label or wrapper of any imported, patent or proprietary medicine containing such drug;

(o) provide for the exemption, conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder of any specified drug or class of drugs or cosmetics or class of cosmetics.

Simplified Act

The Indian Central Government has the authority to create rules related to the importation of drugs and cosmetics. They usually do this after discussing with a specialized board and announcing their intentions publicly. However, if there's an urgent situation, they can make rules without initial discussion, but must consult the board within six months.

These rules can include:

(a) Defining which drugs or cosmetics need a license to be imported, setting the license conditions, who can issue them, the cost, and how they can be canceled or suspended if rules are broken;

(b) Outlining how to test drugs and cosmetics to make sure they meet quality standards;

(c) Establishing how to measure the strength of biological and complex chemical compounds;

(cc) Deciding what colors can be added to drugs;

(d) Stating which diseases or conditions drugs cannot claim to treat or prevent;

(e) Allowing small amounts of otherwise banned drugs to be imported for testing or personal use;

(f) Naming specific places where drugs and cosmetics can be imported and banning import from other places;

(g) Requiring labels to show when a drug was made and when it expires, and banning import of drugs past a certain time after they were made;

(h) Managing how importers provide samples for testing, and setting any related fees;

(i) Detailing what proof of quality is needed for imported drugs or cosmetics, how customs officers should handle it, and how to store these items while they're being checked;

(j) Giving certain drugs or cosmetics a pass from some rules if they're just passing through India for export;

(k) Setting rules for how drugs or cosmetics should be packaged, including what materials can touch the drugs;

(l) Controlling how imported drugs or cosmetics should be labeled and what information must or must not be included;

(m) Limiting the amount of any poisonous substance in drugs, banning drugs that exceed this limit, and defining what substances are poisonous;

(n) Requiring the scientific name of a drug to be shown on the label of any medicine that contains it;

(o) Allowing certain drugs or cosmetics to be exempt from some rules under specific conditions.

Explanation using Example

Imagine a pharmaceutical company, "HealthFirst Pharma," wants to import a new drug called "Zyrelief" into India for the treatment of migraines. Before they can do so, they need to obtain an import license as per the Drugs and Cosmetics Act, 1940, specifically under Section 12.

Under the rules framed by the Central Government after consultation with the Drugs Technical Advisory Board (DTAB), "HealthFirst Pharma" must submit an application in the prescribed form. The application includes details about the drug, such as its composition, intended use, and method of analysis to ensure it is of standard quality.

The Central Government has specified that migraine medication requires a specific method of test or analysis, as per Section 12(2)(b). "HealthFirst Pharma" must demonstrate that "Zyrelief" passes these tests to confirm it meets the quality standards.

Furthermore, the packaging of "Zyrelief" must clearly state the date of manufacture and the date of expiry of potency, as required under Section 12(2)(g). The company must also ensure that the drug does not claim to cure diseases or ailments which are not approved by the authorities, complying with Section 12(2)(d).

"HealthFirst Pharma" must also adhere to the rules regarding the labeling of the drug, ensuring the accepted scientific name is displayed prominently, as per Section 12(2)(n).

Once "HealthFirst Pharma" complies with all the rules and pays the necessary fees, the authority empowered to issue licenses may grant them a license to import "Zyrelief." If they fail to comply with any condition, their license could be suspended or canceled under Section 12(2)(a).

Section 13: Offences

(1) Whoever himself or by any other person on his behalf imports,

(a) any drug deemed to be adulterated under section 9A or deemed to be a spurious drug under section 9B or any spurious cosmetic referred to in section 9D or any cosmetic of the nature referred to in clause (ee) of section 10 shall be punishable with imprisonment for a term which may extend to three years and a fine which may extend to five thousand rupees;

(b) any drug or cosmetic other than a drug or cosmetic referred to in clause (a), the import of which is prohibited under section 10, or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months, or with fine which may extend to five hundred rupees, or with both;

(c) any drug or cosmetic in contravention of the provisions of any notification issued under section 10A, shall be punishable with imprisonment for a term which may extend to three years, or with fine which may extend to five thousand rupees, or with both.

(2) Whoever having been convicted of an offence

(a) under clause (a) or clause (c) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to five years, or with fine which may extend to ten thousand rupees, or with both;

(b) under clause (b) of sub-section (1), is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to one year, or with fine which may extend to one thousand rupees, or with both.

(3) The punishment provided by this section shall be in addition to any penalty to which the offender may be liable under the provisions of section 11.

Simplified Act

Simplified Explanation of Section 13 Offences:

(1) If a person imports any of the following, they can be punished:

(a) A drug or cosmetic that is fake or harmful, they could go to jail for up to three years and/or be fined up to 5,000 rupees.

(b) A drug or cosmetic that is not allowed to be imported, they could face jail time of up to six months and/or a fine of up to 500 rupees.

(c) A drug or cosmetic that goes against specific government rules, they could be jailed for up to three years and/or fined up to 5,000 rupees.

(2) If a person has already been punished for one of these crimes and does it again:

(a) For repeating the offenses mentioned in parts (a) or (c) of the first point, they could be jailed for up to five years and/or fined up to 10,000 rupees.

(b) For repeating the offense mentioned in part (b) of the first point, they could be jailed for up to one year and/or fined up to 1,000 rupees.

(3) These punishments are in addition to any other penalties that the law says the person might have to face.

Explanation using Example

Imagine a company named "HealthFirst Pharma" decides to import a new skin cream called "GlowMax" into the country. The cream is marketed as containing a revolutionary vitamin complex. However, upon inspection by the health authorities, it is found that "GlowMax" contains a prohibited substance that can cause severe allergic reactions, which was not declared on the product's label. This substance is also banned under a notification issued under section 10A of The Drugs and Cosmetics Act, 1940.

In this scenario, HealthFirst Pharma has violated Section 13 of the Act by importing a cosmetic that contravenes the provisions of a notification issued under section 10A. As a result, the company could face a punishment of imprisonment for up to three years or a fine of up to five thousand rupees, or both, for their first offense.

If HealthFirst Pharma had previously been convicted for a similar offense and is again found guilty, the punishment would be more severe. They could face imprisonment for up to five years and a fine of up to ten thousand rupees, as per the provisions for repeat offenders under Section 13(2)(a).

Section 14: Confiscation

Where any offence punishable under section 13 has been committed, the consignment of the drugs or cosmetics in respect of which the offence has been committed shall be liable to confiscation.

Simplified Act

If someone breaks the law as described in section 13 of The Drugs and Cosmetics Act, 1940, the drugs or cosmetics involved in that crime can be seized by the authorities.

Explanation using Example

Imagine a pharmaceutical company imports a large consignment of a new drug into the country without obtaining the necessary permissions from the drug control authorities, which is required by law. This action is an offence under section 13 of The Drugs and Cosmetics Act, 1940. As a result, the entire consignment of the imported drug can be seized and confiscated by the authorities as per the application of Section 14 of the Act. The company would not only face penalties for the offence but also lose the entire consignment of drugs due to the confiscation.

Section 15: Jurisdiction

No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under section 13.

Simplified Act

Only a higher-level court with a Metropolitan Magistrate or a Judicial Magistrate of the first class can handle cases related to crimes mentioned in section 13 of this law.

Explanation using Example

Imagine a local cosmetic shop owner is found selling a face cream that has been adulterated with a harmful chemical, which is not allowed under the regulations. A consumer files a complaint, and the shop owner is charged with an offence under section 13 of The Drugs and Cosmetics Act, 1940. According to section 15 of the Act, the shop owner's trial cannot be conducted by a court that is lower in authority than a Metropolitan Magistrate or a Judicial Magistrate of the first class. Therefore, the case will be heard and decided by a court that is presided over by at least a Metropolitan Magistrate or a Judicial Magistrate of the first class, ensuring that a magistrate with the requisite authority and experience handles the matter.

CHAPTER IV: MANUFACTURE SALE AND DISTRIBUTSION OF DRUGS AND COSMETICS

Section 16: Standards Of Quality

(1) This Act may be called the Drugs and Cosmetics Act, 1940.

(2) It extends to the whole of India.

(3) It shall come into force at once; but Chapter III shall take effect only from such dates the Central Government may, by notification in the Official Gazette, appoint in this behalf, and Chapter IV shall take effect in a particular State only from such dates the State Government may, by like notification, appoint in this behalf:

Provided that in relation to the State of Jammu and Kashmir, Chapter III shall take effect only from such dateafter the commencement of the Drugs and Cosmetics (Amendment) Act, 1972 (19 of 1972), as the Central Government may, by notification in the Official Gazette, appoint in this behalf.

Simplified Act

(1) The official name of this law is the Drugs and Cosmetics Act, 1940.

(2) The law applies to the entire country of India.

(3) The law is effective immediately. However, Chapter III will start to apply only when the Central Government decides and announces a specific date(s). Similarly, Chapter IV will start to apply in each state on the date(s) decided and announced by that state's government.

However, for the state of Jammu and Kashmir, Chapter III will begin to apply only after a specific date that follows the start of the Drugs and Cosmetics (Amendment) Act, 1972. This date will also be announced by the Central Government.

Explanation using Example

Imagine a pharmaceutical company, "HealthPlus Pharma," wants to launch a new drug in India. Before they can do so, they need to ensure that they comply with the Drugs and Cosmetics Act, 1940. As per Section 16(1), this Act is the governing law for drugs and cosmetics in India. According to Section 16(2), HealthPlus Pharma must adhere to this Act across the entire country, as it extends to all of India.

Furthermore, Section 16(3) indicates that while most of the Act is already in force, specific chapters become effective on dates set by the government. For instance, HealthPlus Pharma must stay updated with notifications in the Official Gazette because Chapter III, which pertains to the import of drugs and

cosmetics, will only be applicable from the date the Central Government specifies. Similarly, for the provisions in Chapter IV, which deal with the manufacture, sale, and distribution of drugs and cosmetics, to be applicable in their state, they must wait for the State Government's notification.

In the case of Jammu and Kashmir, there is an additional provision due to the amendment in 1972, which means HealthPlus Pharma would have to look out for a specific commencement date for Chapter III in that state, as notified by the Central Government post-1972.

Section 17: Misbranded Drugs

For the purposes of this Chapter, a drug shall be deemed to be misbranded, -

(a) if it is so coloured, coated, powdered or polished that damage is concealed or if it is made to appear of better or greater therapeutic value than it really is;

(b) if it is not labelled in the prescribed manner;

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Simplified Act

What Does "Misbranded Drugs" Mean?

A drug is considered "misbranded" if:

(a) It has been altered in color, coating, powdering, or polishing to hide damage or make it seem more effective for treatment than it actually is;

(b) It doesn't have the proper labeling as required by law;

(c) The label, container, or any accompanying material has any false or misleading claims or information about the drug.

Explanation using Example

Imagine a pharmaceutical company named "HealFast Pharma" produces a pain relief medication called "PainAway." The company uses a special coating on the tablets that makes them look shiny and more effective. Additionally, they label the product as having "advanced pain-relief properties" without any scientific

evidence to support this claim. They also fail to include required information on the label, such as side effects and expiration date.

Under Section 17 of The Drugs and Cosmetics Act, 1940, "PainAway" would be considered misbranded because:

The coating is misleading consumers to believe the drug has better therapeutic value.

The label does not follow the prescribed manner of labeling, lacking important information.

The label makes a false claim about the drug's effectiveness, which is misleading.

As a result, HealFast Pharma could face legal actions for selling a misbranded drug.

Section 17A: Adulterated Drugs

For the purposes of this Chapter, a drug shall be deemed to be adulterated, -

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance;

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health;

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed;

(e) if it contains any harmful or toxic substance which may render it injurious to health;

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

Simplified Act

Simple Explanation of Adulterated Drugs

A drug is considered to be "adulterated" (contaminated and not safe) if it meets any of the following conditions:

(a) It contains any dirty, rotten, or decaying material.

(b) It was made, packaged, or stored in dirty conditions that could have made it contaminated or harmful.

(c) The container of the drug includes poisonous materials that could harm your health.

(d) It has added colors that are not approved for use in drugs.

(e) It has dangerous or poisonous substances that could be harmful to health.

(f) Something has been mixed with it that lowers its quality or strength.

Explanation using Example

Imagine a pharmaceutical company, 'HealthPlus Inc.', that manufactures a cough syrup. During a routine inspection, a batch of this syrup is found to be stored in a warehouse with a leaking roof, leading to water seepage into the syrup bottles. This has caused some of the bottles to contain a diluted syrup, which not only reduces the efficacy of the medicine but also introduces harmful bacteria, making it potentially dangerous for consumption.

Under Section 17A of The Drugs and Cosmetics Act, 1940, this batch of cough syrup would be deemed adulterated because:

It has been stored under insanitary conditions that allowed the medicine to be contaminated (clause b).

The contamination may have rendered the syrup injurious to health (clause e).

The quality and strength of the syrup have been reduced due to the dilution (clause f).

As a result, HealthPlus Inc. may be subject to legal action, and the adulterated batch would likely be recalled and destroyed to protect public health.

Section 17B: Spurious Drugs

For the purposes of this Chapter, a drug shall be deemed to be spurious, -

if it is manufactured under a name which belongs to another drug; or

if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

if it has been substituted wholly or in part by another drug or substance; or

if it purports to be the product of a manufacturer of whom it is not truly a product.

Simplified Act

Simple Explanation of Spurious Drugs

A drug is considered fake or counterfeit in the following situations:

It is made using the name of a drug that belongs to a different product.

It copies or replaces another drug, or looks so similar that it could confuse people, and it doesn't have clear markings to show its real nature and that it's different from the other drug.

The label or container lists a manufacturer that doesn't really exist or is made up.

It has been partially or completely replaced with a different drug or substance.

It claims to be made by a manufacturer who actually didn't make it.

Explanation using Example

Imagine a scenario where a local pharmacy is selling a medication named 'PainRelief', which is packaged to look nearly identical to a well-known painkiller 'PainAway'. The tablets inside the 'PainRelief' bottle are also made to closely resemble 'PainAway' tablets. This causes customers to mistakenly buy 'PainRelief' thinking it is 'PainAway'. According to Section 17B of The Drugs and Cosmetics Act, 1940, 'PainRelief' would be considered a spurious drug because it resembles 'PainAway' in a manner likely to deceive customers.

Section 17C: Misbranded Cosmetics

For the purposes of this Chapter, a cosmetic shall be deemed to be misbranded, -

(a) if it contains a colour which is not prescribed; or

(b) if it is not labelled in the prescribed manner; or

(c) if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular.

Simplified Act

What is a Misbranded Cosmetic?

A cosmetic is considered misbranded if:

(a) It has a color added to it that is not allowed by the rules;

(b) It doesn't have the correct label as required by the rules; or

(c) The label, container, or anything that comes with the cosmetic has information that is untrue or can mislead someone.

Explanation using Example

Imagine a company named "GlowPure" produces a face cream and includes a non-approved green dye to enhance the product's appearance. According to Section 17C(a) of The Drugs and Cosmetics Act, 1940, this face cream would be considered misbranded because it contains a color that is not prescribed.

Section 17D: Spurious Cosmetics

For the purposes of this Chapter, a cosmetic shall be deemed to be spurious:

(a) if it is manufactured under a name which belongs to another cosmetic;

(b) if it is an imitation of, or a substitute for, another cosmetic or resembles another cosmetic in a manner likely to deceive or bears upon it or upon its label or container the name of another cosmetic unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other cosmetic;

(c) if the label or container bears the name of an individual or a company purporting to be the manufacturer of the cosmetic which individual or company is fictitious or does not exist;

(d) if it purports to be the product of a manufacturer of whom it is not truly a product.

Simplified Act

What are Spurious Cosmetics? - In simple terms, a cosmetic is considered fake or counterfeit if:

(a) It is sold under the name of a cosmetic that belongs to someone else.

(b) It copies or tries to replace another cosmetic, or looks so similar to another product that it could trick people. This also applies if it uses the name of another cosmetic on its packaging, unless it's clearly marked to show what it really is and that it's not the same as the other product.

(c) The name on the label or container claims it's made by a person or company that doesn't actually exist or is made up.

(d) It claims to be made by a real manufacturer, but in reality, it's not made by them at all.

Explanation using Example

Imagine a company named "GlowBeauty" that produces a popular face cream called "GlowRadiant". Another company produces a face cream and labels it as "GlowRadiance", which is very similar in packaging and appearance to "GlowRadiant". This could deceive customers into thinking they are buying the original "GlowBeauty's GlowRadiant" cream. According to Section 17D of the Drugs and Cosmetics Act, 1940, the "GlowRadiance" cream would be considered a spurious cosmetic because it resembles another cosmetic in a manner likely to deceive (clause b). If legal action is taken, the company producing "GlowRadiance" could face penalties under this Act for manufacturing and selling a spurious cosmetic.

Section 17E: Adulterated Cosmetics

For the purposes of this Chapter, a cosmetic shall be deemed to be adulterated:

(a) if it consists in whole or in part, of any filthy, putrid or decomposed substance;

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health;

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed;

(e) if it contains any harmful or toxic substance which may render it injurious to health;

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

Simplified Act

Simple Explanation of Adulterated Cosmetics

A cosmetic product is considered to be "adulterated" (contaminated and not safe to use) if it meets any of the following conditions:

(a) It contains any dirty, rotten, or spoiled substance.

(b) It was made, packed, or kept in dirty conditions, which could have caused it to become contaminated or harmful.

(c) The container of the cosmetic includes any toxic material that could harm a person's health.

(d) It uses a color for its appearance that is not approved by the regulations.

(e) It has a dangerous or poisonous ingredient that could be harmful to health.

(f) It has been mixed with something else that makes it less effective or of lower quality.

Explanation using Example

Imagine a consumer purchases a lipstick from a local store. After using the lipstick, she experiences severe allergic reactions. Upon investigation, it's discovered that the lipstick contained a high level of lead, a toxic substance not

suitable for cosmetic products. This scenario demonstrates the application of Section 17E of The Drugs and Cosmetics Act, 1940, specifically under clauses (e) and (f), where the lipstick is considered adulterated because it contains a harmful substance (lead) that rendered it injurious to health and reduced its quality or strength.

Section 18: Prohibition Of Manufacture And Sale Of Certain Drugs And Cosmetics

From such date as may be fixed by the State Government by notification in the Official Gazette in this behalf, no person shall himself or by any other person on his behalf:

manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute

any drug which is not of a standard quality, or is misbranded, adulterated or spurious;

any cosmetic which is not of a standard quality or is misbranded, adulterated or spurious;

any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it together with the quantities thereof;

any drug which by means of any statement design or device accompanying it or by any other means, purports or claims to prevent, cure or mitigate any such disease or ailment, or to have any such other effect as may be prescribed;

any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

any drug or cosmetic in contravention of any of the provisions of this Chapter or any rule made thereunder;

sell or stock or exhibit or offer for sale, or distribute any drug or cosmetic which has been imported or manufactured in contravention of any of the provisions of this Act or any rule made thereunder;

manufacture for sale or for distribution, or sell, or stock or exhibit or offer for sale, or distribute any drug or cosmetic, except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter:

Provided that nothing in this section shall apply to the manufacture, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis:

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the manufacture for sale or for distribution, sale, stocking or exhibiting or offering for sale or distribution of any drug or class of drugs not being of standard quality.

Simplified Act

Starting on a date set by the State Government and announced in the Official Gazette, no person is allowed to do the following, either themselves or through someone else:

Make, sell, hold in stock, show, or offer to sell or give away:

any medicine that doesn't meet quality standards, is falsely labeled, tampered with, or fake;

any beauty product that doesn't meet quality standards, is falsely labeled, tampered with, or fake;

any patented or exclusive medicine unless it clearly shows the exact formula or list of active ingredients and their amounts on the label or container;

any medicine that claims to prevent, treat, or lessen any disease or condition, or claims to have any other effects that are set by law, without proper justification;

any beauty product with an ingredient that could make it unsafe or harmful when used as directed or suggested;

any medicine or beauty product that goes against the rules of this chapter or any related laws;

Sell, hold in stock, show, or offer to sell or give away any medicine or beauty product that was imported or made in violation of this Act or its rules;

Make, sell, hold in stock, show, or offer to sell or give away any medicine or beauty product without following the conditions of a license given for that purpose under this chapter:

However, this section doesn't apply to making small amounts of a drug for testing or analysis, as long as certain conditions are met;

Also, the Central Government can allow, after talking with the Board and announcing it in the Official Gazette, the making for sale or distribution, selling, stocking, showing, or offering for sale or distribution of any medicine or class of medicines that are not up to standard quality, as long as certain conditions are met.

Explanation using Example

Imagine a local pharmacy in your neighborhood. According to Section 18 of The Drugs and Cosmetics Act, 1940, this pharmacy is not allowed to:

Manufacture, sell, or stock any medicines that are of substandard quality, mislabeled, or counterfeit.

Offer for sale any cosmetics that are harmful or not up to the required safety standards.

Display or sell any patent medicine without listing its active ingredients and their amounts on the packaging.

Promote drugs with false claims, like suggesting they can cure diseases when they cannot.

Handle any drugs or cosmetics in a way that violates the rules set out in this Act or the rules made under it.

Engage in any sale or distribution of drugs or cosmetics without a proper license.

For instance, if the pharmacy tried to sell a batch of cough syrup that was found to be adulterated, they would be violating the Act. Similarly, if they imported a skin cream that was manufactured without following the prescribed safety standards, they would also be in breach of the Act.

Section 18A: Disclosure Of The Name Of The Manufacturer, Etc

Every person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the drug or cosmetic.

Simplified Act

Simplified Explanation of Section 18A of The Drugs and Cosmetics Act, 1940:

If you sell or distribute drugs or cosmetics but you didn't make them yourself, and you're not the official distributor, you have to tell the Inspector who you got them from. This includes giving the Inspector the name, address, and other details about the original manufacturer when asked.

Explanation using Example

Imagine a scenario where a local pharmacy is selling a particular brand of cough syrup. A customer has reported an adverse reaction after using this syrup, and the authorities are investigating the source of the product to ensure it complies with safety standards. An Inspector from the drug regulatory authority visits the pharmacy and asks the pharmacist where they sourced the cough syrup from. Under Section 18A of The Drugs and Cosmetics Act, 1940, the pharmacist is legally obligated to provide the Inspector with the name, address, and other relevant details of the supplier or wholesaler from whom they purchased the cough syrup. This information helps the authorities trace the distribution chain and ensure that all parties comply with the legal standards for drug safety.

Section 18B: Maintenance Of Records And Furnishing Of Information

Every person holding a licence under clause (c) of section 18 shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

Simplified Act

Simplified Explanation of Section 18B - Record-Keeping and Providing Information

Anyone with a license under section 18, clause (c), must keep specific records and documents as required by law. They must also provide information to any official or agency that needs it to enforce this law.

Explanation using Example

Imagine a pharmaceutical company, 'MediHealth Inc.', which holds a license to manufacture drugs under clause (c) of section 18 of The Drugs and Cosmetics Act, 1940. As per Section 18B, the company is required to maintain detailed records of their drug manufacturing processes, including raw material procurement, batch production records, quality control reports, and distribution logs. One day, a drug inspector visits MediHealth Inc. to ensure compliance with the Act. The inspector requests to see the records to verify that the drugs are being produced in accordance with the prescribed standards. MediHealth Inc. complies by providing the inspector with the required information, thus demonstrating their adherence to Section 18B.

Section 19: Pleas

(1) Save as hereinafter provided in this section, it shall be no defence in a prosecution under this Chapter to prove merely that the accused was ignorant of the nature, substance or quality of the drug or cosmetic in respect of which the offence has been committed or of the circumstances of its manufacture or import, or that a purchaser, having bought only for the purpose of test or analysis, has not been prejudiced by the sale.

(2) For the purposes of section 18 a drug shall not be deemed to be misbranded or adulterated or spurious or to be below standard quality nor shall a cosmetic be deemed to be misbranded or to be below standard quality only by reason of the fact that -

(a) there has been added thereto some innocuous substance or ingredient because the same is required for the manufacture or preparation of the drug or cosmetic as an article of commerce in a state fit for carriage or consumption, and not to increase the bulk, weight or measure of the drug or cosmetic or to conceal its inferior quality or other defects; or

(b) in the process of manufacture, preparation or conveyance some extraneous substance has unavoidably become intermixed with it: provided that this clause shall not apply in relation to any sale or distribution of the drug or

cosmetic occurring after the vendor or distributor became aware of such intermixture.

(3) A person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, shall not be liable for a contravention of section 18 if he proves -

(a) that he acquired the drug or cosmetic from a duly licensed manufacturer, distributor or dealer thereof;

(b) that he did not know and could not, with reasonable diligence, have ascertained that the drug or cosmetic in any way contravened the provisions of that section; and

(c) that the drug or cosmetic, while in his possession, was properly stored and remained in the same state as when he acquired it.

Simplified Act

Simplified Explanation of The Drugs and Cosmetics Act, 1940 - Section 19

(1) In a court case about breaking drug or cosmetic laws, you can't defend yourself by just saying you didn't know what was in the product, how it was made, or how it was brought into the country. It also doesn't matter if the buyer was only testing the product and wasn't harmed by buying it.

(2) A drug or cosmetic won't be considered wrongly labeled, tainted, fake, or below the required quality if:

(a) A harmless substance was added to it because it's needed to make or prepare the product for sale or use, as long as it's not to make the product seem heavier, larger, or hide that it's bad quality or has faults.

(b) Something got mixed in with it by accident during making, preparing, or moving it. But, this doesn't count if the seller or person giving it out knew about the mix-up when they sold or gave out the product.

(3) If you're not the maker of the drug or cosmetic, or their distribution agent, you won't be held responsible for breaking the law if you can show:

(a) You got the product from a licensed maker, distributor, or seller.

(b) You didn't know, and couldn't have found out even if you tried, that the product broke any laws.

(c) You kept the product stored properly and it stayed in the same condition as when you first got it.

Explanation using Example

Imagine a pharmacy owner, Mr. Gupta, sells a cough syrup to a customer. Later, it's discovered that the syrup is adulterated and does not meet the quality standards set by the law. A legal action is initiated against Mr. Gupta under The Drugs and Cosmetics Act, 1940.

Mr. Gupta cannot claim ignorance about the syrup's quality as a defense, according to Section 19(1). However, if he can prove that the adulteration was due to an innocuous substance added for legitimate reasons, as per Section 19(2)(a), or a substance unavoidably intermixed during manufacturing as per Section 19(2)(b), he might not be held liable, provided he wasn't aware of the intermixture at the time of sale.

Additionally, if Mr. Gupta can demonstrate that he purchased the syrup from a licensed source, was unaware of the adulteration, and maintained the syrup properly as per Section 19(3), he may not be found guilty of the contravention of Section 18.

Section 20: Government Analysts

The State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas in the State and in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

The Central Government may also, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts in respect of such drugs or classes of drugs or such cosmetics or classes of cosmetics as may be specified in the notification.

Notwithstanding anything contained in sub-section (1) or sub-section (2), neither the Central Government nor a State Government shall appoint as a Government Analyst any official not serving under it without the previous consent of the Government under which he is serving.

No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be a Government Analyst under sub-section (1) or sub-section (2) of this section.

Simplified Act

Simplified Explanation of Government Analysts Appointment

The State Government has the authority to appoint qualified individuals as Government Analysts. These analysts are designated for specific regions within the state and are tasked with analyzing certain drugs or cosmetics as announced in official government publications.

Similarly, the Central Government can appoint qualified individuals as Government Analysts for certain drugs or cosmetics, and these appointments are also announced in official government publications.

However, neither the Central nor State Governments can appoint someone as a Government Analyst if that person is already working for a different government, unless they have permission from that person's current employer.

Additionally, anyone with a financial interest in the drug or cosmetic industry, such as those involved in importing, manufacturing, or selling these products, cannot be appointed as a Government Analyst.

Explanation using Example

Imagine a scenario where the government of a state in India is concerned about the quality of drugs being sold in its region. To ensure that all drugs meet the necessary standards, the state government decides to appoint a Government Analyst as per Section 20 of The Drugs and Cosmetics Act, 1940.

In this example, the State Government issues a notification in the local Official Gazette, stating the appointment of Dr. Sharma, a qualified individual with a Ph.D. in pharmaceutical sciences, as the Government Analyst for the northern region of the state. Dr. Sharma's responsibilities include analyzing drug samples collected from various pharmacies and manufacturers within the specified area to ensure they are safe and meet the quality standards set by the law.

Dr. Sharma, in his capacity as the Government Analyst, does not have any financial interest in the drug manufacturing or sale businesses to avoid any conflict of interest as mandated by the Act. His analyses and reports are crucial

for the state to take action against those who might be selling substandard or counterfeit drugs.

Section 21: Inspectors

The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

The powers which may be exercised by an Inspector and the duties which may be performed by him, the drugs or classes of drugs or cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed shall be such as may be prescribed.

No person who has any financial interest in the import, manufacture or sale of drugs or cosmetics shall be appointed to be an Inspector under this section.

Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860), and shall be officially subordinate to such authority having the prescribed qualifications, as the Government appointing him may specify in this behalf.

Simplified Act

Understanding Inspectors under The Drugs and Cosmetics Act, 1940

The governments of India, both central and state, can appoint inspectors. These inspectors must have certain qualifications and will be responsible for specific areas.

Inspectors have specific powers and duties when it comes to drugs and cosmetics. These include which items they can inspect and under what conditions they can operate. The exact details of their powers and duties are set out in the rules.

If someone has a financial interest in the drug or cosmetic business, like if they make money from producing or selling these items, they cannot be an inspector.

Inspectors are considered public servants, which means they have legal responsibilities and protections. They report to an authority that the government decides.

Explanation using Example

Imagine a local pharmaceutical company that manufactures and sells generic drugs. The State Government, concerned about the quality of drugs being distributed to the public, decides to enforce regulations under The Drugs and Cosmetics Act, 1940. To ensure compliance, the government appoints qualified inspectors.

One of these inspectors, with a degree in pharmacy and no financial ties to any drug companies, is assigned to monitor manufacturing facilities in a particular area. The inspector is granted the power to enter the pharmaceutical company's premises, inspect the facilities, take samples of the drugs for testing, and ensure that all manufacturing processes comply with the prescribed standards.

If the inspector finds that the company is not adhering to the regulations, such as using substandard ingredients or unapproved methods, they can take action which might include recommending the suspension of the company's manufacturing license. The inspector's role is crucial in safeguarding public health by ensuring that only safe and effective drugs are available in the market.

Section 22: Powers Of Inspectors

(1) Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed, -

inspect, -

any premises wherein any drug or cosmetic is being manufactured and the means employed for standardising and testing the drug or cosmetic;

any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;

take samples of any drug or cosmetic, -

which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;

at all reasonable times, with such assistance, if any, as he considers necessary, -

search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or

enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or

stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed, and order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being, committed, not to dispose of any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been, or is being, committed or which may be employed for the commission of such offence;

examine any record, register, document or any other material object found with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (c), and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder;

require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;

exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made thereunder.

(2) The provisions of the Code of Criminal Procedure, 1973 (2 of 1974) shall, so far as may be, apply to any search or seizure under this Chapter as they apply to any search or seizure made under the authority of a warrant issued under section 94 of the said Code.

(2A) Every record, register or other document seized under clause (cc) or produced under clause (cca) shall be returned to the person, from whom they were seized or who produce the same, within a period of twenty days of the date of such seizure or production, as the case may be, after copies thereof or extracts therefrom certified by that person, in such manner as may be prescribed, have been taken.

(3) If any person wilfully obstructs an Inspector in the exercise of the powers conferred upon him by or under this Chapter or refuses to produce any record, register or other document when so required under clause (cca) of sub-section (1), he shall be punishable with imprisonment which may extend to three years, or with fine, or with both.

Simplified Act

Simplified Explanation of Inspectors' Powers under The Drugs and Cosmetics Act, 1940, Section 22

An inspector has the authority to:

Check manufacturing and sales locations for drugs and cosmetics, including their standardization and testing processes.

Collect samples of drugs or cosmetics from places where they are made or sold, or from people delivering them.

Search any person, place, or vehicle if there's a belief that a drug or cosmetic-related crime is happening. They can also seize any related drugs, cosmetics, or items used in the crime.

Look at and take any documents or objects that might show evidence of a crime involving drugs or cosmetics.

Ask anyone to show documents related to the making, selling, or distribution of drugs or cosmetics if a crime is suspected.

Perform any other necessary actions to enforce this law or its rules.

When an inspector conducts a search or seizure, the same rules apply as if it were a police search under the Code of Criminal Procedure, 1973.

If an inspector takes any documents, they must return them within 20 days after making certified copies or extracts.

Anyone who deliberately hinders an inspector's work or doesn't provide requested documents can face up to three years in jail, a fine, or both.

Explanation using Example

An example application of Section 22 of The Drugs and Cosmetics Act, 1940, could be as follows:

An Inspector appointed under the Act receives information that a local pharmacy may be selling drugs that are not stored at the required temperatures, potentially affecting their efficacy. Acting under Section 22(1)(a)(ii), the Inspector visits the pharmacy to inspect the premises and the conditions in which the drugs are being stocked.

During the inspection, the Inspector, utilizing the powers granted by Section 22(1)(b)(i), takes samples of the drugs that are supposed to be kept refrigerated. These samples are then sent to a laboratory for testing to ensure they meet the necessary standards.

While at the premises, the Inspector also exercises the power under Section 22(1)(e), requiring the pharmacist to produce records and registers related to the drugs' storage conditions to verify compliance with the Act.

If the Inspector finds that the pharmacy is not adhering to the legal requirements, they may, under Section 22(1)(c)(iii), seize the stock of the drugs that are improperly stored and initiate further legal action against the pharmacy.

Should the pharmacist obstruct the Inspector's investigation or refuse to produce the required documents, they may face penalties as outlined in Section 22(3) of the Act.

Section 23: Procedure Of Inspectors

(1) Where an Inspector takes any sample of a drug or cosmetic under this Chapter, he shall tender the fair price thereof and may require a written acknowledgment therefor.

(2) Where the price tendered under sub-section (1) is refused, or where the Inspector seizes the stock of any drug or cosmetic under clause (c) of section 22, he shall tender a receipt therefor in the prescribed form.

(3) Where an Inspector takes a sample of a drug or cosmetic for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he wilfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked:
Provided that where the sample is taken from premises whereon the drug or cosmetic is being manufactured, it shall be necessary to divide the sample into three portions only:
Provided further that where the drug or cosmetic is made up in containers of small volume, instead of dividing a sample as aforesaid, the Inspector may, and if the drug or cosmetic be such that it is likely to deteriorate or be otherwise damaged by exposure shall, take three or four, as the case may be, of the said containers after suitably marking the same and, where necessary, sealing them.

(4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:

one portion or container he shall forthwith send to the Government Analyst for test or analysis;

the second, he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug or cosmetic;

the third, where taken, he shall send to the person, if any, whose name, address and other particulars have been disclosed under section 18A.

(5) Where an Inspector takes any action under clause (c) of section 22,

he shall use all despatch in ascertaining whether or not the drug or cosmetic contravenes any of the provisions of section 18 and, if it is ascertained that the drug or cosmetic does not so contravene, forthwith revoke the order passed

under the said clause or, as the case may be, take such action as may be necessary for the return of the stock seized;

if he seizes the stock of the drug or cosmetic he shall as soon as may be inform a Judicial Magistrate and take his orders as to the custody thereof;

without prejudice to the institution of any prosecution, if the alleged contravention be such that the defect may be remedied by the possessor of the drug or cosmetic he shall, on being satisfied that the defect has been so remedied, forthwith revoke his order under the said clause.

(6) Where an Inspector seizes any record, register, document or any other material object under clause (cc) of sub-section (1) of section 22, he shall, as soon as may be, inform a Judicial Magistrate and take his orders as to the custody thereof.

Simplified Act

Simplified Explanation of Section 23 of The Drugs and Cosmetics Act, 1940

(1) When an Inspector collects a sample of a drug or cosmetic for inspection, they must pay for it and can ask for a written confirmation of payment.

(2) If the payment is not accepted, or if the Inspector has to confiscate the drug or cosmetic, they must provide a formal receipt.

(3) If an Inspector takes a sample to test or analyze it, they must tell the person giving the sample and do the following in front of them (unless the person chooses not to be there):

Divide the sample into four equal parts.

Seal and label each part securely.

Allow the person to add their own seal and label.

However, if the sample is from a manufacturing site, only three parts are needed. If the drug or cosmetic is in small packages and might be damaged if opened, the Inspector can take three or four whole packages instead of dividing them.

(4) The Inspector will give one part of the divided sample or one package back to the person and deal with the rest as follows:

Send one part or package for testing or analysis.

Keep the second part or package for any legal actions that might be taken.

Send the third part or package to the person whose details are on the product, if available.

(5) When an Inspector acts under certain powers to check if a drug or cosmetic violates the law, they must:

Quickly determine if the product violates any rules and if not, cancel any orders made under those powers or return the seized items.

Inform a magistrate about the seizure and follow their orders for keeping the seized items.

If the problem with the product can be fixed, and it is fixed, then the Inspector should cancel their previous order.

(6) If an Inspector seizes any documents or other items under their powers, they must inform a magistrate and get orders on how to keep them.

Explanation using Example

Imagine a local pharmacy where an Inspector from the Drug Control Department visits to check compliance with the Drugs and Cosmetics Act. The Inspector decides to test a batch of medication that has recently been delivered to the pharmacy to ensure it meets safety standards.

The Inspector informs the pharmacist of his intention to take samples for testing. He then proceeds to take a sample of the medication and offers to pay the fair price for the sample taken, as per subsection (1) of Section 23. The pharmacist accepts the payment and provides a written acknowledgment of the transaction.

In accordance with subsection (3), the Inspector, in the presence of the pharmacist, divides the medication into four portions. Each portion is effectively sealed and suitably marked. The pharmacist is also invited to add his own seal and mark to the samples, ensuring transparency in the process.

Following the procedure outlined in subsection (4), the Inspector hands one portion back to the pharmacist, sends one portion to the Government Analyst for testing, keeps one portion for potential court proceedings, and sends the last portion to the manufacturer or importer if their details are available under section 18A.

If the Inspector had found the batch to be suspicious and potentially in violation of the Act, he might have seized the entire stock under clause (c) of section 22, as mentioned in subsection (5). He would then quickly ascertain if the medication was indeed non-compliant, and if not, he would take steps to return the stock or remedy the situation as required.

Section 24: Persons Bound To Disclose Place Where Drugs Or Cosmetics Are Manufactured Or Kept

Every person for the time being in charge of any premises whereon any drug or cosmetic; is being manufactured or is kept for sale or distribution shall, on being required by an Inspector so to do, be legally bound to disclose to the Inspector the place where the drug or cosmetic is being manufactured or is kept, as the case may be.

Simplified Act

Section 24 Simplified: If you're in charge of a place where drugs or cosmetics are made, or where they're stored for sale or distribution, and an Inspector asks you, you must tell them where exactly the drugs or cosmetics are being made or stored.

Explanation using Example

Imagine a scenario where a local drug inspector visits a pharmacy to conduct a routine check to ensure all drugs and cosmetics are properly licensed and stored. The pharmacy manager is present at the time. The inspector, suspecting that certain medications might not be stored at the location shown to him, invokes Section 24 of The Drugs and Cosmetics Act, 1940, and requests the manager to disclose the actual place where these drugs are being stored. Under this law, the manager is legally obligated to provide the inspector with the accurate information about where the drugs are kept, whether it's in the back room of the pharmacy or at a different storage facility. If the manager refuses to disclose this information, they would be violating the law. This section helps ensure that all drugs and cosmetics are accounted for and that their storage complies with legal requirements.

Section 25: Reports Of Government Analysts

(1) The Government Analyst to whom a sample of any drug or cosmetic has been submitted for test or analysis under sub-section (4) of section 23, shall deliver to the Inspector submitting it a signed report in triplicate in the prescribed form.

(2) The Inspector on receipt thereof shall deliver one copy of the report to the person from whom the sample was taken and another copy to the person, if any, whose name, address and other particulars have been disclosed under section 18A, and shall retain the third copy for use in any prosecution in respect of the sample.

(3) Any document purporting to be a report signed by a Government Analyst under this Chapter shall be evidence of the facts stated therein, and such evidence shall be conclusive unless the person from whom the sample was taken or the person whose name, address and other particulars have been disclosed under section 18A has, within twenty-eight days of the receipt of a copy of the report, notified in writing the Inspector or the Court before which any proceedings in respect of the sample are pending that he intends to adduce evidence in controversion of the report.

(4) Unless the sample has already been tested or analysed in the Central Drugs Laboratory, where a person has under sub-section (3) notified his intention of adducing evidence in controversion of a Government Analyst's report, the Court may, of its own motion or in its discretion at the request either of the complainant or the accused cause the sample of the drug or cosmetic produced before the Magistrate under sub-section (4) of section 23 to be sent for test or analysis to the said Laboratory, which shall make the test or analysis and report in writing signed by or under the authority of, the Director of the Central Drugs Laboratory the result thereof, and such report shall be conclusive evidence of the facts stated therein.

(5) The cost of a test or analysis made by the Central Drugs Laboratory under sub-section (4) shall be paid by the complainant or accused as the Court shall direct.

Simplified Act

(1) When a drug or cosmetic is tested by a Government Analyst, they must give three copies of the test report to the Inspector who submitted the sample. The report must be signed and follow a specific format.

(2) The Inspector must then give one copy of the test report to the person from whom the sample was collected, another copy to any person identified under section 18A, and keep the third copy for any legal action related to the sample.

(3) A report from a Government Analyst is considered proof of what it says. This proof is final unless the person who provided the sample or the person named under section 18A challenges it within 28 days by informing the Inspector or the Court that they will present opposing evidence.

(4) If the sample hasn't been tested by the Central Drugs Laboratory and someone challenges the Government Analyst's report, the Court can decide to have the sample tested there. The result from this laboratory is final proof of the test results.

(5) The person who filed the complaint or the accused must pay for the Central Drugs Laboratory test, as the Court decides.

Explanation using Example

Imagine a scenario where a drug inspector visits a pharmacy and collects a sample of a medication suspected of being substandard. The inspector sends the sample to the Government Analyst for testing. According to Section 25(1) of The Drugs and Cosmetics Act, 1940, the Analyst conducts the test and provides a report in triplicate to the inspector.

The inspector then follows Section 25(2) by handing one copy of the test report to the pharmacy owner (from whom the sample was taken) and another copy to the manufacturer if their details were disclosed earlier. The inspector keeps the third copy for potential legal action.

If the report indicates that the drug is indeed substandard, the pharmacy owner, under Section 25(3), has 28 days to challenge the findings by informing the inspector or the court that they intend to present counter-evidence.

If the pharmacy owner disputes the report and notifies their intention to contest, under Section 25(4), the court may decide to send the sample to the Central Drugs Laboratory for a more authoritative analysis. The result from this test is considered conclusive.

Finally, as per Section 25(5), the cost of this additional testing at the Central Drugs Laboratory will be borne by either the complainant or the accused, as the court decides.

Section 26: Purchaser Of Drug Or Cosmetic Enabled To Obtain Test Or Analysis

Any person or any recognised consumer association, whether such person is a member of that association or not, shall, on application in the prescribed manner and on payment of the prescribed fee, be entitled to submit for test or analysis to a Government Analyst any drug or cosmetic purchased by him or it and to receive a report of such test or analysis signed by the Government Analyst.

Explanation - For the purposes of this section and section 32, "recognised consumer association" means a voluntary consumer association registered under the Companies Act, 1956 (1 of 1956) or any other law for the time being in force.

Simplified Act

Any person or officially registered consumer group can ask for a drug or cosmetic they bought to be tested. They must request this in the way the law requires and pay a fee. After the test, they will get a report of the results signed by the Government Analyst.

Note: A "recognised consumer association" is a consumer group that has officially registered under the Companies Act of 1956 or any other current laws.

Explanation using Example

Imagine that Sarah, who suffers from a chronic skin condition, purchases a new cosmetic cream from a local pharmacy. After using the cream, she experiences an adverse reaction and suspects that the product may not comply with the safety standards. As a concerned consumer, Sarah decides to verify the product's compliance with the Drugs and Cosmetics Act, 1940.

Sarah contacts a recognised consumer association, which is registered under the law, and expresses her concerns. The association guides her on how to apply for the test or analysis of the cosmetic cream. Following the prescribed procedure, Sarah pays the necessary fee and submits a sample of the cream to a Government Analyst.

The Government Analyst conducts the required tests and provides Sarah with a detailed report. The report confirms whether the cosmetic cream meets the legal safety standards or if there are any violations of the Drugs and Cosmetics Act. Empowered with this information, Sarah can now decide on the next steps, which might include seeking a remedy or reporting the issue to the authorities.

Section 26A: Powers Of Central Government To Regulate, Restrict Or Prohibit Manufacture, Etc, Of Drug And Cosmetic In Public Interest

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied, that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed or purported to be claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate, restrict or prohibit the manufacture, sale or distribution of such drug or cosmetic.

Simplified Act

Explanation of Government Authority over Drug and Cosmetic Safety

The Central Government has the power to control the production, sale, or distribution of any drug or cosmetic if it believes that the product may be harmful to people or animals. This also applies if a drug is found not to have the health benefits it claims to offer or if it has ingredients in amounts that don't have a health benefit. The government can take these actions if it thinks it's necessary to protect the public. When they decide to do this, they will announce it in an official publication known as the Official Gazette.

Explanation using Example

Imagine a pharmaceutical company, "HealthFirst," has been manufacturing a drug called "PainAway," which is claimed to provide rapid relief from chronic pain. Recent scientific studies, however, have found that the long-term use of PainAway can lead to severe liver damage. The Central Government, upon reviewing these studies and consulting with health experts, becomes satisfied that the continued use of PainAway poses a significant risk to human health.

In response to these findings, the Central Government decides to exercise its powers under Section 26A of The Drugs and Cosmetics Act, 1940. It issues a notification in the Official Gazette to immediately restrict the sale and distribution of PainAway. The notification outlines that the drug can no longer be sold over-the-counter and requires a special prescription under strict medical supervision, to mitigate the risk to public health until further notice or until the drug's formulation is modified to be safe for use.

Section 26B: Powers Of Central Government To Regulate Or Restrict, Manufacture, Etc, Of Drug In Public Interest

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising due to epidemic or natural calamities and that in the public interest, it is necessary or expedient so to do, then, that Government may, by notification in the Official Gazette, regulate or restrict the manufacture, sale or distribution of such drug.

Simplified Act

Simplified Explanation of Section 26B - Government's Power to Control Drug Production During Emergencies

This section says that if the Indian government believes that there is an urgent need for a certain drug because of an epidemic or natural disaster, and it's important for the well-being of the public, then the government has the power to officially announce rules or limits on how that drug is made, sold, or given out to people.

Explanation using Example

Imagine a scenario where a sudden outbreak of a new strain of influenza occurs, leading to a nationwide health emergency. The Central Government, upon recognizing the severity of the epidemic, decides that a specific antiviral drug is crucial for controlling the spread of the disease. To ensure that the drug is available in adequate quantities and is not hoarded or sold at inflated prices, the government invokes Section 26B of The Drugs and Cosmetics Act, 1940.

In this case, the government issues a notification in the Official Gazette, stating that the manufacture, sale, and distribution of this antiviral drug will be

regulated. This could mean setting a price cap, limiting the quantity that can be purchased by individuals, or directing manufacturers to increase production to meet the high demand. The goal is to make sure that the drug is accessible to everyone who needs it during the emergency, and to prevent exploitation of the situation by unscrupulous elements in the market.

Section 27: Penalty For Manufacture, Sale, Etc, Of Drugs In Contravention Of This Chapter

Chapter Whoever, himself or by any other person on his behalf, manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale or distributes, -

any drug deemed to be adulterated under section 17A or spurious under section 17B and which when used by any person for or in the diagnosis, treatment, mitigation, or pre - vention of any disease or disorder is likely to cause his death or is likely to cause such harm on his body as would amount to grevious hurt within the meaning of section 320 of the Indian Penal Code (45 of 1860) solely on account of such drug being adulterated or spurious or not of standard quality, as the case may be, shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and shall also be liable to fine which shall not be less than ten lakh rupees or three times value of the drugs confiscated, whichever is more:

Provided that the fine imposed on and released from, the person convicted under this clause shall be paid, by way of compensation, to the person who had used the adulterated or spurious drugs referred to in this clause:

Provided further that where the use of the adulterated or, spurious drugs referred to in this clause has caused the death of a person who used such drugs, the fine imposed on and realised from, the person convicted under this clause, shall be paid to the relative of the person who had died due to the use of the adulterated or spurious drugs referred to in this clause.

Explanation - For the purposes of the second proviso, the expression "relative" means -

spouse of the deceased person; or

a minor legitimate son, and unmarried legitimate daughter and a widowed mother; or

parent of the minor victim; or

if wholly dependent on the earnings of the deceased person at the time of his death, a son or a daughter who has attained the age of eighteen years; or

any person, if wholly or in part, dependent on the earnings of the deceased person at the time of his death, -

the parent; or

a minor brother or an unmarried sister; or

a widowed daughter - in - law; or

a widowed sister; or

a minor child of a pre - deceased son; or

a minor child of a pre - deceased daughter where no parent of the child is alive; or

the paternal grandparent if no parent of the member is alive;

any drug -

deemed to be adulterated under section 17A but not being a drug referred to in clause (a), or

without a valid licence as required under clause (c) of section 18, shall be punishable with imprisonment for a term which shall not be less than three years but which may extend to five years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than three years and of fine of less than one lakh rupees;

any drug deemed to be spurious under section 17B, but not being a drug referred to in clause (a) shall be punishable with imprisonment for a term which shall not less than seven years but which may extend to imprisonment

for life and with fine which shall not be three lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than seven years but not less than three years and of fine of less than one lakh rupees;

any drug, other than a drug referred to in clause (a) or clause (b) or clause (c), in contravention of any other provision of this Chapter or any rule made thereunder, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to two years and with fine which shall not be less than twenty thousand rupees:

Provided that the Court may, for any adequate and special reasons to be recorded in the judgment, impose a sentence of imprisonment for a term of less than one year.

Simplified Act

Simplified Explanation of Penalties for Illegal Drug Activities

If a person manufactures, sells, or deals with drugs that are either adulterated or fake, and these drugs could cause death or serious injury, they face very strict penalties:

A minimum of 10 years in prison, which could be extended to a life sentence.

A fine of at least 10 lakh rupees or three times the value of the drugs, whichever is higher.

If the drug has caused death, the fine collected will be given to the deceased person's family.

Who gets the compensation?

The spouse, children, parents, or other dependents of the deceased.

If the user was a minor, the parents or other close relatives listed.

For less serious cases involving adulterated drugs or selling without a license:

Imprisonment from 3 to 5 years and a fine of at least 1 lakh rupees or three times the value of the drugs.

The court can reduce the sentence for special reasons.

If the drug is fake but not as dangerous as in the first case:

Imprisonment from 7 years to a life sentence and a fine of at least 3 lakh rupees or three times the value of the drugs.

Again, the court can reduce the sentence for special reasons.

For any other illegal drug activity not covered above:

Imprisonment from 1 to 2 years and a fine of at least 20,000 rupees.

The court can give a lesser sentence if there are special reasons.

Explanation using Example

Imagine a pharmaceutical manufacturer produces a batch of medication that is later found to contain toxic substances, making it adulterated under section 17A of the Drugs and Cosmetics Act, 1940. A patient who takes this medication for a heart condition suffers a severe reaction that causes permanent damage, amounting to grievous hurt as defined by section 320 of the Indian Penal Code.

Upon investigation, it's determined that the manufacturer knowingly used substandard ingredients to cut costs. As a result, under Section 27 of the Drugs and Cosmetics Act, the manufacturer is charged and found guilty of manufacturing and selling an adulterated drug. The court sentences the manufacturer to a minimum of ten years in prison and imposes a fine of ten lakh rupees or three times the value of the drugs confiscated, whichever is higher. Furthermore, the fine collected is directed to be paid as compensation to the patient who suffered harm from using the adulterated drug.

Section 27A: Penalty For Manufacture, Sale, Etc, Of Cosmetics In Contravention Of This Chapter

Whoever himself or by any other person on his behalf manufactures for sale or for distribution, or sells, or stocks or exhibits or offers for sale:

any cosmetic deemed to be spurious under section 17D or adulterated under section 17E shall be punishable with imprisonment for a term which may extend to three years and with fine which shall not be less than fifty thousand

rupees or three times the value of the cosmetics confiscated, whichever is more;

any cosmetic other than a cosmetic referred to in clause (i) in contravention of any provisions of this Chapter or any rule made thereunder shall be punishable with imprisonment for a term which may extend to one year or with fine which may extend to twenty thousand rupees, or with both.

Simplified Act

Penalty for illegal activities related to cosmetics

If a person makes, sells, has in stock for sale, or shows for sale cosmetics illegally:

For fake or contaminated cosmetics (as defined in sections 17D and 17E), the punishment can be up to three years in jail and a fine of at least 50,000 rupees or three times the value of the seized cosmetics, whichever is higher.

For any other cosmetics that break the law or rules of this Chapter, the punishment can be up to one year in jail or a fine up to 20,000 rupees, or both.

Explanation using Example

Imagine a company, "GlowBeauty Cosmetics," has been found manufacturing and selling a line of lipsticks that contain a higher level of heavy metals than is legally permitted, making them adulterated under the law. Upon investigation by regulatory authorities, it is discovered that GlowBeauty Cosmetics knowingly used substandard materials to cut costs. As a result, under Section 27A of The Drugs and Cosmetics Act, 1940, the owner of the company could face imprisonment of up to three years and a minimum fine of fifty thousand rupees or three times the value of the confiscated lipsticks, whichever is higher, for manufacturing and selling adulterated cosmetics.

Section 28: Penalty For Non-Disclosure Of The Name Of The Manufacturer, Etc

Whoever contravenes the provisions of section 18A or section 24 shall be punishable with imprisonment for a term which may extend to one year, or with a fine which shall not be less than twenty thousand rupees, or with both.

Simplified Act

Simple Explanation of Penalty for Not Sharing Manufacturer Information

If someone breaks the rules in section 18A or section 24 of this law, they can be sent to jail for up to one year, fined at least 20,000 rupees, or both.

Explanation using Example

Imagine a scenario where a pharmacy is selling a drug but refuses to disclose the name and address of the manufacturer when asked by a customer. This act of non-disclosure is a contravention of Section 18A of The Drugs and Cosmetics Act, 1940. Under Section 28, the owner of the pharmacy could face legal consequences for this action, which could include imprisonment up to one year, a fine of at least twenty thousand rupees, or both.

Section 28A: Penalty For Not Keeping Documents, Etc, And For Non-Disclosure Of Information

Whoever without reasonable cause or excuse, contravenes the provisions of section 18B shall be punishable with imprisonment for a term which may extend to one year or with fine which shall not be less than twenty thousand rupees or with both.

Simplified Act

Simple Explanation of Penalty for Not Keeping Required Documents or Not Sharing Information

If someone doesn't have a good reason for not following the rules of section 18B, which probably require keeping certain documents or sharing information, they can be sent to jail for up to one year. They might also have to pay a fine of at least 20,000 rupees. In some cases, they could face both jail time and the fine.

Explanation using Example

Imagine a pharmaceutical company, XYZ Pharma Ltd., which manufactures and distributes various drugs. The company is required by law, under Section 18B of The Drugs and Cosmetics Act, 1940, to maintain records and documents regarding the drugs they manufacture and to disclose necessary information to the authorities when asked.

In a hypothetical scenario, a surprise inspection by the Drug Control Authority finds that XYZ Pharma Ltd. has failed to maintain the required documentation for a new drug they have been selling. Moreover, they have not disclosed complete information about the drug's side effects and clinical trial data when requested by the regulatory body.

As a result, XYZ Pharma Ltd. is charged with contravening the provisions of Section 18B. Under Section 28A, the company could face a penalty that includes imprisonment of responsible individuals for up to one year and/or a minimum fine of twenty thousand rupees, or both, depending on the court's decision.

Section 28B: Penalty For Manufacture, Etc, Of Drugs Or Cosmetics In Contravention Of Section 26A

Whoever himself or by any other person on his behalf manufactures or sells or distributes any drug or cosmetic in contravention of the provisions of any notification issued under section 26A, shall be punishable with imprisonment for a term which may extend to three years and shall also be liable to fine which may extend to five thousand rupees.

Simplified Act

Simple Explanation of Penalty for Illegal Manufacture or Sale of Drugs or Cosmetics

If a person, or someone acting for them, makes, sells, or gives out any drug or cosmetic that goes against the rules set out in a notice under section 26A, they can be sent to jail for up to three years. They can also be fined up to 5,000 rupees.

Explanation using Example

Imagine a pharmaceutical company, "HealthPlus Pharma," that manufactures a cough syrup containing a substance recently banned by a notification under Section 26A due to severe side effects. Despite the ban, HealthPlus Pharma continues to produce and distribute the cough syrup. Upon inspection, authorities discover the violation. As per Section 28B of The Drugs and Cosmetics Act, 1940, the owner of HealthPlus Pharma could face up to three years of imprisonment and a fine up to five thousand rupees for manufacturing

and distributing a drug in contravention of the ban stipulated in the notification under Section 26A.

Section 29: Penalty For Use Of Government Analyst?S Report For Advertising

Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be punishable with fine which may extend to five thousand rupees.

Simplified Act

If someone uses a test report from the Central Drugs Laboratory or a Government Analyst, or even a part of such a report, to advertise a medicine or beauty product, they can be fined up to 5,000 rupees.

Explanation using Example

Imagine a pharmaceutical company, "HealFast Pharma," that has developed a new cough syrup. They receive a positive test report from the Central Drugs Laboratory indicating that the syrup is effective. The marketing team at HealFast Pharma decides to use excerpts from this report in their advertisements. They include statements like "Certified as effective by the Central Drugs Laboratory" on their product packaging and in their commercial campaigns. This action is a direct violation of Section 29 of The Drugs and Cosmetics Act, 1940. As a result, HealFast Pharma could face a penalty and be fined up to five thousand rupees for using the laboratory's report in their advertising materials.

Section 29: Penalty For Use Of Government Analyst?S Report For Advertising

Whoever uses any report of a test or analysis made by the Central Drugs Laboratory or by a Government Analyst, or any extract from such report, for the purpose of advertising any drug or cosmetic, shall be punishable with fine which may extend to five thousand rupees.

Simplified Act

If someone uses a test report from the Central Drugs Laboratory or a Government Analyst, or even a part of such a report, to advertise a medicine or beauty product, they can be fined up to 5,000 rupees.

Explanation using Example

Imagine a pharmaceutical company, "HealFast Pharma," that has developed a new cough syrup. They receive a positive test report from the Central Drugs Laboratory indicating that the syrup is effective. The marketing team at HealFast Pharma decides to use excerpts from this report in their advertisements. They include statements like "Certified as effective by the Central Drugs Laboratory" on their product packaging and in their commercial campaigns. This action is a direct violation of Section 29 of The Drugs and Cosmetics Act, 1940. As a result, HealFast Pharma could face a penalty and be fined up to five thousand rupees for using the laboratory's report in their advertising materials.

Section 30: Penalty For Subsequent Offences

(1) Whoever having been convicted of an offence,

(a) under clause (b) of section 27 is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than seven years but which may extend to ten years and with fine which shall not be less than two lakh rupees:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than seven years and of fine of less than one lakh rupees;

(b) under clause (c) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than ten years but which may extend to imprisonment for life and with fine which shall not be less than three lakh rupees.

(c) under clause (d) of section 27, is again convicted of an offence under that clause shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to four years or with fine which shall not be less than fifty thousand rupee, or with both.

(1A) Whoever, having been convicted of an offence under section 27A is again convicted under that section, shall be punishable with imprisonment for a term which may extend to two years, or with fine which may extend to two thousand rupees, or with both.

(2) Whoever, having been convicted of an offence under section 29 is again convicted of an offence under the same section shall be punishable with imprisonment which may extend to two years, or with fine which shall not be less than ten thousand rupees or with both.

Simplified Act

Explanation of Penalties for Repeat Offenses

If a person is found guilty more than once for the same drug-related crime, the penalties increase as follows:

(a) For a second offense related to certain serious drug violations, the punishment is at least 7 years in prison (which could be up to 10 years) and a fine of at least 2 lakh rupees. However, if the court has a strong reason, it can reduce the sentence to less than 7 years and the fine to less than 1 lakh rupees, but it must explain this decision in the judgment.

(b) For a second offense related to an even more serious drug violation, the punishment is at least 10 years in prison (which could be a life sentence) and a fine of at least 3 lakh rupees.

(c) For a second offense related to a less serious drug violation, the punishment is at least 2 years in prison (which could be up to 4 years), a fine of at least 50 thousand rupees, or both.

Additionally, if someone is convicted a second time for a specific drug trafficking offense, they could face up to 2 years in prison, a fine up to 2 thousand rupees, or both.

Lastly, for a second conviction of another type of drug offense, the punishment could be up to 2 years in prison, a fine of at least 10 thousand rupees, or both.

Explanation using Example

Imagine a pharmaceutical company that was previously found guilty of selling drugs without a valid license, a violation under clause (b) of section 27 of The Drugs and Cosmetics Act, 1940. After paying the required fines and serving a sentence, the company is caught committing the same offence again.

Under Section 30 of the Act, since this is a subsequent offence, the company's owner could now face a harsher punishment. This time, the minimum imprisonment would be seven years, which could extend to ten years, and the fine would not be less than two lakh rupees. However, if the court finds exceptional circumstances, it could reduce the sentence to less than seven years and the fine to less than one lakh rupees, but these reductions must be clearly explained in the court's judgment.

Section 31: Confiscation

(1) Where any person has been convicted under this Chapter for contravening any such provision of this Chapter or any rule made thereunder as may be specified by rule made in this behalf, the stock of the drug or cosmetic in respect of which the contravention has been made shall be liable to confiscation and if such contravention is in respect of:

manufacture of any drug deemed to be misbranded under section 17, adulterated under section 17A or spurious under section 17B; or

manufacture for sale, or for distribution, sale, or stocking, or exhibiting or offering for sale, or distribution of any drug without a valid licence as required under clause (c) of section 18, any implements or machinery used in such manufacture, sale or distribution and any receptacles packages or coverings in which such drug is contained and the animals, vehicles, vessels or other conveyances used in carrying such drug shall also be liable to confiscation.

(2) Without prejudice to the provisions contained in sub-section (1), where the Court is satisfied, on the application of an Inspector or otherwise and after such inquiry as may be necessary that the drug or cosmetic is not of standard quality or is a misbranded, adulterated or spurious drug or misbranded or spurious cosmetic, such drug or, as the case may be, such cosmetic shall be liable to confiscation.

Simplified Act

Simplified Explanation of Section 31 of The Drugs and Cosmetics Act, 1940

(1) If someone is found guilty of breaking the rules in this part of the law, or any specific rules set by the government, the drugs or cosmetics involved in the rule-breaking can be taken away by the authorities. This can happen if the rule-breaking is about:

making a drug that is falsely labeled, contaminated, or fake, as described in sections 17, 17A, or 17B; or

making, selling, distributing, storing, showing, or offering for sale any drug without the proper license required by section 18. In these cases, not only the drug but also any equipment or machines used to make, sell, or distribute it, as well as the containers, packaging, or coverings for the drug, and any animals or vehicles used to transport the drug can also be taken away.

(2) Apart from what's mentioned above, if the court, either on its own or after an Inspector asks for it, believes that the drug or cosmetic is not up to the required quality standards, or is falsely labeled, contaminated, or fake, then that drug or cosmetic can also be taken away after the necessary checks are done.

Explanation using Example

Imagine a local pharmacy where an inspection by a drug inspector reveals that a batch of medication sold there is counterfeit, which is considered a spurious drug under Section 17B of the Drugs and Cosmetics Act, 1940. The owner of the pharmacy is subsequently convicted for selling these spurious drugs. As a result of the conviction, according to Section 31(1)(i) of the Act, not only is the batch of counterfeit medication confiscated, but also the equipment used to sell these drugs and potentially the vehicle used to transport them, if any, may be confiscated as well.

In another scenario, if a consumer complains that a cosmetic product bought from a beauty store caused an adverse reaction, an inspector could investigate and determine that the product is not meeting the standard quality and is, in fact, a misbranded cosmetic. Upon such a finding, and after necessary inquiry, the court, as per Section 31(2), may order the confiscation of the misbranded cosmetic products from the store.

Section 31A: Application Of Provisions To Government Departments

The provisions of this Chapter except those contained in section 31 shall apply in relation to the manufacture, sale or distribution of drugs by any department of Government as they apply in relation to the manufacture, sale or distribution of drugs by any other person.

Simplified Act

Simplified Explanation of Section 31A:

This section means that government departments have to follow the same rules for making, selling, or distributing drugs as any private individual or company, with the exception of the rules mentioned in section 31.

Explanation using Example

Imagine a government hospital that needs to procure a large quantity of a particular vaccine. According to Section 31A of The Drugs and Cosmetics Act, 1940, the hospital's procurement department must adhere to the same standards and regulations that apply to private entities involved in the manufacture, sale, or distribution of drugs. This means that the government hospital cannot bypass quality checks, licensing, or any other regulatory requirements just because it is a government entity. They must ensure the vaccine is safe and effective, just like any private pharmaceutical company would have to do before distributing the drug.

Section 32: Cognizance Of Offences

(1) No prosecution under this Chapter shall be instituted except by -

(a) an Inspector; or

(b) any gazetted officer of the Central Government or a State Government authorised in writing in this behalf by the Central Government or a State Government or by a general or special order made in this behalf by that Government; or

(c) the person aggrieved; or

(d) a recognised consumer association whether such person is a member of that association or not.

(2) Save as otherwise provided in this Act, no court inferior to that of a Court of Session shall try an offence punishable under this Chapter.

(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

Simplified Act

(1) Only certain people can start a legal case under this part of the law:

(a) A government-approved health and safety inspector;

(b) A high-ranking (gazetted) officer from the central or state government, if they have permission in writing;

(c) The person who has been directly affected or harmed;

(d) A consumer association that looks out for buyers' rights, regardless of whether the person affected is a member.

(2) Only a higher-level court, not a lower one, can judge cases about these specific offences.

(3) This part of the law doesn't stop someone from being charged under different laws if their actions also break those laws.

Explanation using Example

Imagine a scenario where a local pharmacy is suspected of selling counterfeit medication. An Inspector of the Drug Control Department conducts an investigation and confirms the violation of the Drugs and Cosmetics Act, 1940. Based on Section 32(1)(a), the Inspector initiates a prosecution against the pharmacy.

In another instance, a consumer who purchased medication from the pharmacy and suffered adverse effects discovers that the medication was fake. The consumer, feeling aggrieved, can initiate a prosecution under Section 32(1)(c) of the Act.

Additionally, a consumer association, upon learning about the sale of counterfeit drugs, decides to take legal action against the pharmacy to protect public interest. As per Section 32(1)(d), even if the person affected by the counterfeit medication is not a member of the association, the association can still prosecute the pharmacy.

In accordance with Section 32(2), the case against the pharmacy for selling counterfeit drugs, which is a serious offence, is to be tried in a Court of Session, not in a lower court.

Finally, suppose the pharmacy's actions also violate another law, such as the Indian Penal Code. Section 32(3) clarifies that the pharmacy could face

prosecution under that other law as well, in addition to the prosecution under the Drugs and Cosmetics Act.

Section 32A: Power Of Court To Implead The Manufacturer, Etc

Where, at any time during the trial of any offence under this Chapter alleged to have been committed by any person, not being the manufacturer of a drug or cosmetic or his agent for the distribution thereof, the Court is satisfied, on the evidence adduced before it, that such manufacturer or agent is also concerned in that offence, then, the Court may, notwithstanding anything contained in sub-sections (1), (2) and (3) of section 319 of the Code of Criminal Procedure, 1973 (2 of 1974), proceed against him as though a prosecution had been instituted against him under section 32.

Simplified Act

Simplified Explanation of Section 32A - Power of Court to Include the Manufacturer in a Trial

If during a trial for a crime related to drugs or cosmetics someone other than the product's maker or their distribution agent is accused, and the court believes, based on the evidence shown, that the maker or agent is also involved in the crime, then the court has the power to add the manufacturer or agent to the trial as if they were originally charged with the crime. This can be done even if it goes against the rules in sections 1, 2, and 3 of section 319 of the Code of Criminal Procedure from 1973.

Explanation using Example

Imagine a local pharmacy is being prosecuted for selling a drug that has not been approved by the regulatory authorities. During the trial, evidence emerges suggesting that the manufacturer of the drug was aware that the drug was being sold without approval and may have even encouraged the pharmacy to do so. Based on Section 32A of The Drugs and Cosmetics Act, 1940, the court decides to also bring the manufacturer into the trial as a co-defendant, even though the initial charges were only against the pharmacy. This allows the court to hold all parties responsible for the violation accountable, not just the seller of the drug.

Section 32B: Compounding Of Certain Offences

(1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973, (2 of 1974) any offence punishable under clause (b) of sub-section (1) of section 13, section 28 and section 28A of this Act (whether committed by a company or any officer thereof), not being an offence punishable with imprisonment only, or with imprisonment and also with fine, may, either before or after the institution of any prosecution, be compounded by the Central Government or by any State Government or any officer authorised in this behalf by the Central Government or a State Government, on payment for credit to that Government of such sum as that Government may, by rules made in this behalf, specify:

Provided that such sum shall not, in any case, exceed the maximum amount of the fine which may be imposed under this Act for the offence so compounded:

Provided further that in cases of subsequent offences, the same shall not be compoundable.

(2) When the accused has been committed for trial or when he has been convicted and an appeal is pending, no composition for the offence shall be allowed without the leave of the court to which he is committed or, as the case may be, before which the appeal is to be heard.

(3) Where an offence is compounded under sub-section (1), no proceeding or further proceeding, as the case may be, shall be taken against the offender in respect of the offence so compounded and the offender, if in custody, shall be released forthwith.

Simplified Act

Simplified Explanation of Section 32B - Compounding of Certain Offences

(1) Even though the Code of Criminal Procedure, 1973 says something different, certain offences under the Drugs and Cosmetics Act, 1940 can be settled without going to trial. This can happen if the offence doesn't involve jail time alone, or jail time plus a fine. Offences that can be settled include those under section 13(1)(b), section 28, and section 28A. This applies to companies or their officers. The Central or State Government, or someone they authorize, can settle the case before or after legal action has started. The accused will have to pay a sum of money as decided by the government, but it can't be more than the maximum fine that could be imposed for that offence. However, if

someone has committed the same offence before, they can't settle the case in this way.

(2) If the accused is going to trial, or has been convicted and is appealing, they can't settle the case without the court's permission.

(3) Once an offence is settled this way, no further legal action will be taken against the person for that offence. If they are in jail, they will be released immediately.

Explanation using Example

Imagine a pharmaceutical company that has been charged with an offence under Section 28 of the Drugs and Cosmetics Act, 1940, for manufacturing a drug without a valid license. This offence is punishable with a fine but does not involve imprisonment. Before the case goes to trial, the company approaches the State Government and requests to compound the offence. The State Government, authorized by the Central Government, agrees and specifies a sum for the company to pay as per the rules made under this Act.

The company pays the specified sum, which does not exceed the maximum fine that could be imposed under the Act for this offence. Since this is the company's first offence, it is eligible for compounding. After the payment is made, the State Government ensures that no further legal proceedings are initiated against the company for this particular offence, and the matter is considered settled.

Section 33: Power Of Central Government To Make Rules

(1) The Central Government may after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter : Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may -

(a) provide for the establishment of laboratories for testing and analysing drugs or cosmetics;

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether a drug or cosmetic is of standard quality;

(d) prescribe, in respect of biological and organometallic compounds, the units or methods of standardisation;

(dd) prescribe under clause (d) of section 17A the colour or colours which a drug may bear or contain for purposes of colouring;

(dda) prescribe under clause (d) of section 17E the colour or colours which a cosmetic may bear or contain for the purposes of colouring;

(e) prescribe the forms of licences for the manufacture for sale or for distribution, for the sale and for the distribution of drugs or any specified drug or class of drugs or of cosmetics or any specified cosmetic or class of cosmetics, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same the qualifications of such authority and the fees payable therefor and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or the rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;

(ee) prescribe the records, registers or other documents to be kept and maintained under section 18B;

(eea) prescribe the fees for the inspection (for the purposes of grant or renewal of licences) of premises, wherein any drug or cosmetic is being or is proposed to be manufactured;

(eeb) prescribe the manner in which copies are to be certified under sub-section (2A) of section 22;

(f) specify the diseases or ailments which a drug may not purport or claim to prevent cure or mitigate and such other effects which a drug may not purport or claim to have;

(g) prescribe the conditions subject to which small quantities of drugs may be manufactured for the purpose of examination, test or analysis;

(h) require the date of manufacture and the date of expiry of potency to be clearly and truly stated on the lable or container of any specified drug or class of drugs, and prohibit the sale stocking or exhibition for sale, or distribution of the said drug or class of drugs after the expiry of a specified period from the date of manufacture or after the expiry of the date of potency;

(i) prescribe the conditions to be observed in the packing in bottles, packages and other containers of drugs or cosmetics, including the use of packing material which comes into direct contact with the drugs and prohibit the sale, stocking or exhibition for sale, or distribution of drugs or cosmetics, packed in contravention of such conditions;

(j) regulate the mode of labelling packed drugs or cosmetics, and prescribe the matters which shall or shall not be included in such labels;

(k) prescribe the maximum proportion of any poisonous substance which may be added to or contained in any drug, prohibit the manufacture, sale or stocking or exhibition for sale, or distribution of any drug in which that proportion is exceeded, and specify substances which shall be deemed to be poisonous for the purposes of this Chapter and the rules made thereunder;

(l) require that the accepted scientific name of any specified drug shall be displayed in the prescribed manner on the lable or wrapper of any patent or proprietary medicine containing such drug;

(n) prescribe the powers and duties of Inspectors and the qualifications of the authority to which such Inspectors shall be subordinate and specify the drugs or classes of drugs of cosmetics or classes of cosmetics in relation to which and the conditions, limitations or restrictions subject to which, such powers and duties may be exercised or performed;

(o) prescribe the forms of report to be given by Government Analysts, and the manner of application for test or analysis under section 26 and the fees payable therefor;

(p) specify the offences against this Chapter or any rule made thereunder in relation to which an order of confiscation may be made under section 31;

(q) provide for the exemption conditionally or otherwise, from all or any of the provisions of this Chapter or the rules made thereunder, of any specified drug or class of drugs or cosmetic or class of cosmetics and;

(r) sum which may be specified by the Central Government under section 32B.

Simplified Act

Simplified Explanation of Section 33 of The Drugs and Cosmetics Act, 1940

(1) The Indian government can create rules to enforce this part of the law. They usually talk to the Board and announce these rules publicly before they're made. If there's an urgent situation, they might skip talking to the Board at first, but they'll need to consult them within six months and consider their input on any rule changes.

(2) The rules they make can include things like:

(a) Setting up labs to test drugs and cosmetics.

(b) Defining what qualifications and responsibilities government analysts and inspectors should have.

(c) Deciding how drugs and cosmetics should be tested to make sure they are good quality.

(d) Establishing standards for biological and organometallic compounds.

(dd) Deciding which colors can be used in drugs.

(dda) Deciding which colors can be used in cosmetics.

(e) Outlining the process for getting licenses to make, sell, or distribute drugs or cosmetics, including the application, conditions, issuing authority, and fees. They can also cancel or suspend licenses if rules are broken.

(ee) Specifying what records and documents need to be kept.

(eea) Setting fees for inspecting manufacturing premises for license grants or renewals.

(eeb) Describing how to certify copies of documents.

(f) Stating what diseases or effects drugs cannot claim to treat or have an impact on.

(g) Setting rules for making small amounts of drugs for testing purposes.

(h) Requiring clear dates of manufacture and expiration on drug labels and banning the sale of drugs after these dates.

(i) Setting packing standards for drugs and cosmetics and banning the sale of items packed against these standards.

(j) Regulating how drugs and cosmetics should be labeled.

(k) Limiting how much poison can be in drugs and banning drugs that exceed this limit.

(l) Requiring scientific names to be shown on certain medicines.

(n) Defining the roles and qualifications of inspectors and their authorities.

(o) Outlining how government analysts should report and the process for requesting tests, including fees.

(p) Listing the offences that could lead to confiscation of products.

(q) Allowing for exceptions to the rules for certain drugs or cosmetics.

(r) Mentioning the fines that the government can impose.

Explanation using Example

Imagine a pharmaceutical company, "HealthPlus Pharma," is planning to introduce a new antibiotic drug to the Indian market. Before they can proceed, they need to ensure that their product complies with the regulations set out by the Central Government under the Drugs and Cosmetics Act, 1940. Specifically, they must adhere to the rules formulated under Section 33 of the Act.

As per these rules, HealthPlus Pharma must:

Have their drug tested and analyzed at an established laboratory to confirm it is of standard quality (as per rule (a))

Ensure that the drug packaging includes the date of manufacture and the expiry date, and that it is not sold after the expiry date (as per rule (h))

Comply with the prescribed methods of test or analysis to prove the drug's quality (as per rule (c))

Adhere to the rules regarding the labelling of the drug, ensuring that it does not claim to prevent or cure diseases or ailments not specified by the regulations (as per rules (j) and (f))

Apply for the appropriate license for manufacturing and selling the antibiotic, following the conditions provided for such licenses (as per rule (e))

If HealthPlus Pharma fails to comply with any of these rules, they could face the cancellation or suspension of their license as well as other penalties prescribed by the Act.

Section 33A: Chapter Not To Apply To Ayurvedic, Siddha Or Unani Drugs

Save as otherwise provided in this Act, nothing contained in this Chapter shall apply to Ayurvedic, Siddha or Unani drugs.

Simplified Act

Simplified Explanation of Section 33A:

This section means that the rules in this part of the law do not apply to traditional Indian medicines, which include Ayurvedic, Siddha, and Unani drugs, unless there are specific parts of the law that say otherwise.

Explanation using Example

Imagine a manufacturer in India who produces traditional Ayurvedic medicines. The company wants to launch a new herbal supplement that they claim can help with digestion. According to Section 33A of The Drugs and Cosmetics Act, 1940, the regulations contained in that particular Chapter of the Act do not apply to Ayurvedic medicines. This means the manufacturer does not need to follow the specific protocols and approvals outlined in that Chapter for allopathic drugs. However, they must still comply with other provisions of the Act and any other laws specifically pertaining to Ayurvedic, Siddha, or Unani drugs.

CHAPTER IVA: PROVISIONS RELATING TO AYURVEDIC, SIDDHA AND UNANI DRUGS

Section 33B: Application Of Chapter Iva

This Chapter shall apply only to Ayurvedic, Siddha and Unani drugs.

Simplified Act

Understanding Section 33B - Scope of Chapter IVA: This part of the law is specifically for traditional Indian medicines, including Ayurvedic, Siddha, and Unani treatments.

Section 33C: Ayurvedic And Unani Drugs Technical Advisory Board

(1) The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board) to advise the Central Government and the State Governments on Technical matters arising out of this Chapter and to carry out the other functions assigned to it by this Chapter.

(2) The Board shall consist of the following members, namely :

the Director General of Health Services ex officio;

the Drugs Controller, India, ex officio;

the principal officer dealing with Indian systems of medicine in the Ministry of Health, ex officio;

the Director of the Central Drugs Laboratory, Calcutta ex officio;

one person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government;

one Pharmacognocist to be nominated by the Central Government;

one Phyto-chemist to be nominated by the Central Government;

four persons to be nominated by the Central Government, two from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee;

one teacher in Darvyaguna, and Bhaishajya Kalpana, to be nominated by the Central Government;

one teacher in ILM - UL - ADVIA and TAKLIS - WA - DAWASAZI, to be nominated by the Central Government;

one teacher in Gunapadam to be nominated by the Central Government;

three persons, one each to represent the Ayurvedic, Siddha and Unani drug industry, to be nominated by the Central Government;

three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb systems of medicine to be nominated by the Central Government.

(3) The Central Government shall appoint a member of the Board as its Chairman.

(4) The nominated members of the Board shall hold office for three years but shall be eligible for renomination.

(5) The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it.

(6) The functions of the Board may be exercised notwithstanding any vacancy therein.

(7) The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

Simplified Act

Simplified Explanation of Section 33C of The Drugs and Cosmetics Act, 1940

Ayurvedic and Unani Drugs Technical Advisory Board
(1) The Indian government will create a special group called the Ayurvedic, Siddha, and Unani Drugs Technical Advisory Board. This group will give advice on technical issues related to traditional medicine and perform other tasks given to it by the law.

(2) This group will include:

The top health official of India;

The national drug controller;

The main person in charge of Indian traditional medicine in the health ministry;

The head of the main drug testing lab in Calcutta;

A government analyst from section 33F;

Experts in plant-based medicine and chemistry, chosen by the government;

Four people from committees that set standards for Ayurvedic, Unani, and Siddha medicines;

Teachers from traditional medicine fields, chosen by the government;

Three people representing the Ayurvedic, Siddha, and Unani medicine industries;

Three people who practice these types of traditional medicine.

(3) The government will pick a chairman for the group.

(4) People who are chosen to be part of the group can serve for three years and can be picked again after that.

(5) The group can make its own rules about how many people need to be there to make decisions and how to run meetings, as long as the government agrees.

(6) The group can still do its job even if some positions are empty.

(7) The government will choose a Secretary for the group and provide the staff needed to help it work.

Explanation using Example

Imagine a pharmaceutical company in India plans to launch a new Ayurvedic medicine. Before the product can be brought to market, it must comply with the regulations set by the Drugs and Cosmetics Act, 1940. The company's research and development team has created a formulation that they believe is effective and safe for public use.

However, to ensure that the product meets the necessary standards, the company must seek guidance and approval from the Ayurvedic and Unani Drugs Technical Advisory Board established under Section 33C of the Act. This Board is responsible for advising on technical matters related to Ayurvedic, Siddha, and Unani drugs.

The company submits its research data and product details to the Board, which includes experts like the Director General of Health Services and the Drugs Controller, India. The Board reviews the submission to ensure the medicine's ingredients and manufacturing process adhere to the traditional knowledge and quality standards.

After thorough evaluation, the Board might recommend specific changes or additional tests to verify the product's efficacy and safety. Once the company addresses these recommendations and receives a positive assessment from the Board, it can proceed with the registration and marketing of the new Ayurvedic medicine, contributing to the healthcare options available to the public.

Section 33D: The Ayurvedic, Siddha And Unani Drugs Consultative Committee

The Central Government may constitute an Advisory Committee to be called the Ayurvedic, Siddha and Unani Drugs Consultative Committee to advise the Central Government, the State Governments and the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board on any matter for the purpose of securing uniformity throughout India in the administration of this Act in so far as it relates to Ayurvedic, Siddha or Unani drugs.

The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall consist of two persons to be nominated by the Central Government as representatives of that Government and not more than one representative of each State to be nominated by the State Government concerned.

The Ayurvedic, Siddha and Unani Drugs Consultative Committee shall meet when required to do so by the Central Government and shall regulate its own procedure.

Simplified Act

Explanation of Section 33D - The Ayurvedic, Siddha and Unani Drugs Consultative Committee

The Indian government can set up a group called the Ayurvedic, Siddha and Unani Drugs Consultative Committee. Its job is to give advice to both the national and state governments, as well as another advisory group, on how to make sure the rules about Ayurvedic, Siddha, or Unani medicines are applied the same way all over India.

This committee will have two members chosen by the national government and up to one member from each state, chosen by that state's government.

The committee will meet whenever the national government says it's necessary and will decide on its own how to run its meetings.

Explanation using Example

Imagine a scenario where the government of India is planning to implement new labeling requirements for Ayurvedic medicines to ensure consumer safety. To ensure that the new regulations are effective and do not disrupt the traditional medicine industry, the Central Government decides to seek advice from experts in the field.

In accordance with Section 33D of The Drugs and Cosmetics Act, 1940, the Central Government establishes the Ayurvedic, Siddha and Unani Drugs Consultative Committee. The committee includes two members nominated by the Central Government and representatives from each state, nominated by their respective State Governments.

The committee is convened to discuss the proposed labeling standards and to provide their expert advice on how to balance consumer protection with the practicalities of the traditional medicine market. Their recommendations will help the Central and State Governments to administer the Act uniformly across India, specifically in regards to Ayurvedic, Siddha, and Unani drugs.

Section 33E: Misbranded Drugs

For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be misbranded -

(a) if it is so coloured, coated, powdered or polished that damage is concealed, or if it is made to appear of better or greater therapeutic value than it really is;

(b) if it is not labelled in the prescribed manner;

(c) if its label or container or anything accompanying the drug bears any statement, design or device which makes any false claim for the drug or which is false or misleading in any particular.

Simplified Act

Understanding Misbranded Drugs When talking about Ayurvedic, Siddha, or Unani medicines, here's what makes them "misbranded":

(a) If they've been altered in color, coating, powdering, or polishing to hide damage or to look more effective than they actually are;

(b) If the label doesn't follow official guidelines;

(c) If the label, container, or any accompanying material has any false or misleading claims about what the drug can do.

Explanation using Example

Imagine a company named "HerbalHeal" manufactures an Ayurvedic cough syrup called "KofAway". A customer, Priya, purchases it because the label claims it is a "100% cure for chronic cough", which is a false claim since no Ayurvedic medicine can guarantee a 100% cure rate. After using it for several weeks with no improvement, Priya learns that the claim was not based on any scientific evidence or clinical trials.

In this scenario, "KofAway" cough syrup could be deemed misbranded under Section 33E(c) of The Drugs and Cosmetics Act, 1940, because its label made a false claim about the drug's therapeutic value, which is misleading to consumers like Priya.

Section 33Ee: Adulterated Drugs

For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be adulterated,

(a) if it consists, in whole or in part, of any filthy, putrid or decomposed substance; or

(b) if it has been prepared, packed or stored under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or

(c) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(d) if it bears or contains, for purposes of colouring only, a colour other than one which is prescribed; or

(e) if it contains any harmful or toxic substance which may render it injurious to health; or

(f) if any substance has been mixed therewith so as to reduce its quality or strength.

Explanation - For the purpose of clause (a), a drug shall not be deemed to consist, in whole or in part, of any decomposed substance only by reason of the

fact that such decomposed substance is the result of any natural decomposition of the drug: Provided that such decomposition is not due to any negligence on the part of the manufacturer of the drug or the dealer thereof and that it does not render the drug injurious to health.

Simplified Act

Simplified Explanation of Adulterated Drugs

A traditional medicine (Ayurvedic, Siddha, or Unani) is considered to be tainted if:

(a) it contains any dirty or rotten parts;

(b) it was made or packaged in dirty conditions that could have polluted it or made it harmful;

(c) its packaging includes harmful materials that could make the medicine dangerous;

(d) it has added colors that are not approved;

(e) it has any dangerous ingredients that could harm your health;

(f) something has been added to it that lowers its quality or strength.

Note: A medicine isn't automatically considered tainted if it has naturally broken down, unless this breakdown was caused by someone's carelessness or makes the medicine harmful.

Explanation using Example

An example of the application of Section 33EE of The Drugs and Cosmetics Act, 1940:

A consumer purchases an Ayurvedic cough syrup from a local pharmacy. After using the syrup, the consumer falls ill and reports severe adverse effects. An investigation is conducted, and it is discovered that the syrup was made using herbs that were stored in a damp warehouse, leading to the growth of mold and bacteria. As a result, the drug falls under the category of being 'adulterated' as per Section 33EE(b), because it was stored under insanitary conditions, leading to contamination that made it injurious to health.

The manufacturer of the cough syrup could be held liable for violating the Drugs and Cosmetics Act, and appropriate legal action may be taken to prevent further harm to consumers.

Section 33Eea: Spurious Drugs

For the purposes of this Chapter, an Ayurvedic, Siddha or Unani drug shall be deemed to be spurious:

if it is sold, or offered or exhibited for sale, under a name which belongs to another drug; or

if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive, or bears upon it or upon its label or container the name of another drug, unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or

if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or

if it has been substituted wholly or in part by any other drug or substance; or

if it purports to be the product of a manufacturer of whom it is not truly a product.

Simplified Act

Understanding Spurious Drugs

In simple terms, a traditional medicine (Ayurvedic, Siddha, or Unani) is considered fake or "spurious" if:

It is being sold with the name of a different medicine.

It copies or tries to replace another medicine, or it looks so similar to another medicine that it could easily be mistaken for it. This also applies if the packaging or label has the name of another medicine, unless it's clearly marked to show what it really is and that it's different.

The label or packaging lists a manufacturer that doesn't exist or is made up.

Part or all of the medicine has been replaced with something else.

It claims to be made by a certain manufacturer, but it's not actually made by them.

Explanation using Example

Imagine a scenario where a local herbal store is selling a traditional cough syrup under the name "HerboCure," which is actually the name of a well-known cough syrup produced by a reputable company. Upon inspection, it is discovered that the store's "HerboCure" is not the genuine product but a different formulation made to look like the original. This situation would fall under Section 33EEA of The Drugs and Cosmetics Act, 1940, specifically under point (a), as the store is selling a drug under a name that belongs to another drug.

Section 33Eeb: Regulation Of Manufacture For Sale Of Ayurvedic, Siddha And Unani Drugs

No person shall manufacture for sale or for distribution any Ayurvedic, Siddha and Unani drug except in accordance with such standards, if any, as may be prescribed in relation to that drug.

Simplified Act

Regulation of Making Ayurvedic, Siddha, and Unani Medicines for Sale

A person is not allowed to make Ayurvedic, Siddha, or Unani medicines for the purpose of selling or giving them to others unless they follow certain quality standards that may be set for those medicines.

Explanation using Example

Imagine a company named 'HerbalHeal' wishes to manufacture and sell an Ayurvedic cough syrup. Before they can do so, according to Section 33EEB of The Drugs and Cosmetics Act, 1940, they must ensure that their product meets certain prescribed standards set by the government for Ayurvedic drugs. If 'HerbalHeal' fails to comply with these standards, they would be in violation of the law, and could face regulatory action such as fines or a ban on their product.

Section 33Eec: Prohibition Of Manufacture And Sale Of Certain Ayurvedic, Siddha And Unani Drugs

From such date as the State Government may, by notification in the Official Gazette, specify in this behalf, no person, either by himself or by any other person on his behalf, shall:

manufacture for sale or for distribution:

any misbranded, adulterated or spurious Ayurvedic, Siddha or Unani drug;

any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true list of all the ingredients contained in it; and

any Ayurvedic, Siddha or Unani drug in contravention of any of the provisions of this Chapter or any rule made thereunder;

sell, stock or exhibit or offer for sale or distribute any Ayurvedic, Siddha or Unani drug which has been manufactured in contravention of any of the provisions of this Act, or any rule made thereunder,

manufacture for sale or for distribution, any Ayurvedic, Siddha or Unani drug except under, and in accordance with the conditions of, a licence issued for such purpose under this Chapter by the prescribed authority:

Provided that nothing in this section shall apply to Vaidyas and Hakims who manufacture Ayurvedic, Siddha or Unani drug for the use of their own patients:

Provided further that nothing in this section shall apply to the manufacture, subject to the prescribed conditions, of small quantities of any Ayurvedic, Siddha or Unani drug for the purpose of examination, test or analysis.

Simplified Act

Simple Explanation of Section 33EEC - No Making or Selling of Certain Traditional Medicine Without Following Rules

Starting from a date the local government decides and announces, the following rules apply to everyone:

You are not allowed to make or prepare for selling:

any Ayurvedic, Siddha, or Unani medicine that is falsely branded, contaminated, or fake;

any special or exclusive medicine unless the ingredients are clearly listed on the label or container as required; and

any Ayurvedic, Siddha, or Unani medicine if it breaks any rules of this law or the regulations made under it;

You cannot sell, keep in stock, show, or offer to sell or give away any Ayurvedic, Siddha, or Unani medicine that was made breaking any part of this law or the rules set under it,

You can only make Ayurvedic, Siddha, or Unani medicine for selling or distribution if you have a license to do so, which must be obtained under this law:

However, this rule does not apply to traditional Indian doctors known as Vaidyas and Hakims who make medicine only for their own patients.

Also, this rule does not stop the making of small amounts of medicine for testing, examining, or analysis, as long as certain conditions are met.

Explanation using Example

An example application of Section 33EEC of The Drugs and Cosmetics Act, 1940 could be as follows:

Imagine a local manufacturer, 'Herbal Remedies Pvt. Ltd.', produces an Ayurvedic cough syrup. The State Government has notified that all Ayurvedic medicines must list their ingredients on the label. 'Herbal Remedies Pvt. Ltd.' fails to do so and continues to sell the product.

Under Section 33EEC, the company is in violation of the law for not displaying the true list of ingredients on their cough syrup's label. The authorities can take legal action against the company, prohibiting the manufacture, sale, and distribution of the mislabeled product.

Section 33Eed: Power Of Central Government To Prohibit Manufacture, Etc, Of Ayurvedic, Siddha Or Unani Drugs In Public Interest

Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied on the basis of any evidence or other material

available before it that the use of any Ayurvedic, Siddha or Unani drug is likely to involve any risk to human beings or animals or that any such drug does not have the therapeutic value claimed or purported to be claimed for it and that in the public interest it is necessary or expedient to do so, then, that Government may, by notification in the Official Gazette, prohibit the manufacture, sale or distribution of such drug.

Simplified Act

Simple Explanation of Government's Power to Ban Certain Traditional Medicines

The government has the right to stop the making, selling, or sharing of Ayurvedic, Siddha, or Unani medicines if it believes that:

These medicines could be harmful to people or animals, or

They don't actually provide the health benefits they claim to.

If stopping these medicines is in the best interest of the public, the government can announce this ban through an official notice in the Gazette.

Explanation using Example

Imagine a company, 'HerboCure', manufactures an Ayurvedic medicine named 'LiverFix', which they claim can completely cure liver diseases. After several reports of liver failure among users, a government health agency investigates and finds that 'LiverFix' not only lacks the therapeutic value claimed but also contains harmful substances. In response, the Central Government exercises its power under Section 33EED of The Drugs and Cosmetics Act, 1940, and issues a notification to ban the manufacture, sale, and distribution of 'LiverFix' to protect public health and safety.

Section 33F: Government Analysts

The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications, to be Government Analysts for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

Notwithstanding anything contained in sub-section (1), neither the Central Government nor a State Government shall appoint as a Government Analysts

any official not serving under it without the previous consent of the Government under which he is serving.

No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be a Government Analysts under this section.

Simplified Act

Understanding Government Analysts Appointments

The Central or State Government can announce the appointment of qualified individuals as Government Analysts through a public notice. These analysts are assigned specific areas to work in.

However, a government cannot appoint someone as a Government Analyst if they work for a different government, unless they have that government's permission first.

Also, if someone has a financial interest in the drug-making or selling business, they cannot be appointed as a Government Analyst.

Explanation using Example

Imagine a scenario where the State Government of XYZ recognizes the need to ensure the quality and safety of drugs being distributed within its jurisdiction. To address this, the government decides to appoint a new Government Analyst who will be responsible for testing and certifying drugs in the state.

The State Government issues a notification in the Official Gazette, stating the qualifications required for the position, and invites applications. After careful consideration, they select Dr. Jane Smith, a qualified individual with a Ph.D. in Pharmaceutical Sciences and extensive experience in drug testing, for the role.

Dr. Smith is currently employed by a federal research lab, so as per Section 33F(2) of The Drugs and Cosmetics Act, 1940, the State Government of XYZ seeks and obtains the consent of the Central Government before finalizing her appointment.

Furthermore, to comply with Section 33F(3), the State Government ensures that Dr. Smith does not have any financial interest in pharmaceutical companies to avoid any conflict of interest in her role as a Government Analyst.

Once appointed, Dr. Smith begins her duties, providing her expertise to guarantee that all drugs sold in the state meet the necessary safety standards, thus protecting public health.

Section 33G: Inspectors

The Central Government or a State Government may, by notification in the Official Gazette, appoint such persons as it thinks fit, having the prescribed qualifications to be Inspectors for such areas as may be assigned to them by the Central Government or the State Government, as the case may be.

The powers which may be exercised by an Inspector and the duties which may be performed by him and the conditions, limitations or restrictions subject to which such powers and duties may be exercised or performed shall be such as may be prescribed.

No person who has any financial interest in the manufacture or sale of any drug shall be appointed to be an Inspector under this section.

Every Inspector shall be deemed to be a public servant within the meaning of section 21 of the Indian Penal Code (45 of 1860) and shall be officially subordinate to such authority as the Government appointing him may specify in this behalf.

Simplified Act

Simple Explanation of Section 33G - Inspectors

The Central or State Government can announce the appointment of qualified individuals as Inspectors for certain areas through official announcements.

Inspectors have specific powers and responsibilities, which must be carried out according to certain rules and limitations that will be defined.

Anyone with a financial interest in the drug manufacturing or selling business cannot become an Inspector.

Inspectors are considered public officials as per the law and must answer to the authority specified by the Government that appointed them.

Explanation using Example

Imagine a scenario where the Central Government decides to enhance the regulation of pharmaceuticals due to a rise in reports of substandard drugs being sold in the market. To ensure compliance with drug safety standards, the government issues a notification in the Official Gazette appointing qualified individuals as Inspectors for different regions.

One such Inspector, after receiving his official appointment, is assigned to oversee the pharmaceutical manufacturing units in a particular area. His duties include conducting surprise inspections, collecting drug samples for testing, and ensuring that all the manufacturing units comply with the prescribed safety and quality standards. He is aware that he cannot have any financial interest in the drug manufacturing or sales sector to maintain impartiality in his role.

During one of his inspections, he discovers a manufacturing unit with questionable practices and collects samples that are later found to be non-compliant with the set standards. Utilizing the powers conferred upon him, he initiates legal proceedings against the unit for violating the Drugs and Cosmetics Act, 1940. As a public servant, his actions are protected under the Indian Penal Code, providing him with the authority to carry out his duties effectively.

Section 33H: Application Of Provisions Of Sections 22, 23, 24 And 25

The provisions of sections 22, 23, 24 and 25 and the rules, if any, made thereunder shall, so far as may be, apply in relation to an Inspector and a Government Analyst appointed under this Chapter as they apply in relation to an Inspector and a Government Analyst appointed under Chapter IV, subject to the modification that the references to "drug" in the said sections, shall be construed as references to Ayurvedic, Siddha or Unani drug.

Simplified Act

Understanding Sections 22, 23, 24, and 25 for Ayurvedic, Siddha, or Unani Drugs

The rules for inspecting and analyzing drugs that are mentioned in sections 22, 23, 24, and 25, along with any additional rules made, also apply to inspectors and analysts who specialize in Ayurvedic, Siddha, or Unani medicines. However, whenever these sections mention "drug," it should be read as "Ayurvedic, Siddha, or Unani drug" for these specific inspectors and analysts.

Explanation using Example

Imagine a scenario where a local Ayurvedic medicine manufacturer is suspected of producing substandard products. An Inspector appointed under Chapter IV-A of the Drugs and Cosmetics Act, which deals with Ayurvedic, Siddha, and Unani drugs, decides to investigate the facility. Section 33H ensures that the same powers and procedures that apply to Inspectors checking allopathic drugs under sections 22, 23, 24, and 25 also apply to this Inspector, with the understanding that all references to "drug" in those sections are now to be read as references to Ayurvedic, Siddha, or Unani drugs. Therefore, the Inspector has the authority to enter the premises, inspect the manufacturing process, take samples, and ensure compliance with the Act in the same manner as would be done for allopathic drugs.

Section 33-I: Penalty For Manufacture, Sale, Etc, Of Ayurvedic Siddha Or Unani Drug In Contravention Of This Chapter

Whoever himself or by any other person on his behalf -

manufactures for sale or for distribution,

any Ayurvedic, Siddha or Unani drug -

deemed to be misbranded under section 33E,

deemed to be adulterated under section 33EE, or

without a valid licence or in violation of any of the conditions thereof, as required under section 33 EEC,

shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more;

any Ayurvedic, Siddha or Unani drug deemed to be spurious under section 33EEA, shall be punishable with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of

less than one year and of fine of less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more; or

any Ayurvedic, Siddha or Unani drug in contravention of the provisions of any notification issued under section 33EED shall be punishable with imprisonment for a term which may extend to three years and with fine which may extend to fifty thousand rupees or three times the value of the drugs confiscated, whichever is more.

Contravenes any other provisions of this Chapter or of section 24 as applied by section 33H or any rule made under this Chapter, shall be punishable with imprisonment for a term which may extend to six months and with fine which shall not be less than ten thousand rupees.

Simplified Act

Simple Explanation of Penalty for Illegal Activities Related to Ayurvedic, Siddha, or Unani Drugs

If a person does any of the following acts:

Makes, sells, or distributes

any Ayurvedic, Siddha, or Unani drug that

is labeled in a misleading way,

is tainted or impure,

is made or sold without a proper license or breaks the license rules,

they could face up to one year in jail and a fine of at least ₹20,000 or three times the value of the seized drugs, whichever is higher.

any Ayurvedic, Siddha, or Unani drug that is fake, the punishment could be between one to three years in jail and a fine of at least ₹50,000 or three times the value of the seized drugs, whichever is higher.

However, the judge can give a lighter sentence for specific, well-explained reasons.

any Ayurvedic, Siddha, or Unani drug in a way that goes against certain government notices, they could be jailed for up to three years and fined up to ₹50,000 or three times the value of the seized drugs, whichever is higher.

Breaks any other rules in this part of the law or related regulations, they could be jailed for up to six months and fined at least ₹10,000.

Explanation using Example

Imagine a local manufacturer, "HerbalHeal," produces an Ayurvedic cough syrup. The company claims that the syrup is effective against chronic cough and is made from natural herbs. However, the company has not obtained a valid license as required by law and has also been adding a synthetic drug to the syrup without declaring it, making the product both adulterated and unlicensed.

Upon inspection by the authorities, it is found that "HerbalHeal" has violated section 33 EEC by manufacturing without a license and section 33EE by adding an undeclared synthetic substance. As per section 33-I of The Drugs and Cosmetics Act, 1940, the manufacturer could face imprisonment for up to one year and a fine of at least twenty thousand rupees or three times the value of the confiscated drugs, whichever is more, for each of the offenses.

Section 33J: Penalty For Subsequent Offences

Penalty for subsequent offences Whoever having been convicted of an offence,

(a) under clause (a) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which may extend to two years and with fine which shall not be less than fifty thousand rupees or three times the value of the drugs confiscated, whichever is more;

(b) under clause (b) of sub-section (1) of section 33-I is again convicted of an offence under that clause, shall be punishable with imprisonment for a term which shall not be less than two years but which may extend to six years and with fine which shall not be less than one lakh rupees or three times the value of the drugs confiscated, whichever is more:

Provided that the Court may, for any adequate and special reasons to be mentioned in the judgment, impose a sentence of imprisonment for a term of less than two years and of fine of less than one lakh rupees or three times the value of the drugs confiscated, whichever is more;

(c) under sub-section (2) of section 33-I is again convicted of an offence under that sub-section, shall be punishable with imprisonment for a term which may extend to one year and with fine which shall not be less than twenty thousand rupees or three times the value of the drugs confiscated, whichever is more.

Simplified Act

Simple Explanation of Penalty for Repeated Offenses
If a person is found guilty more than once for breaking the drug laws:

(a) If they are caught again after a first conviction for a certain offence, they could be jailed for up to two years and must pay at least ₹50,000 or three times the worth of the seized drugs, whichever is higher.

(b) If they repeat a different specific offence, they face a minimum of two years to a maximum of six years in jail. The fine must be at least ₹1 lakh or three times the worth of the seized drugs, whichever is higher. However, if there's a strong reason, the judge can lower the sentence to less than two years and the fine to less than ₹1 lakh or three times the value of the seized drugs, whichever is higher, but this must be clearly explained in the judgement.

(c) For repeating yet another specific offence, the punishment can be up to one year in jail and a fine of at least ₹20,000 or three times the value of the seized drugs, whichever is more.

Explanation using Example

Imagine a pharmaceutical company owner, Mr. Gupta, who was previously convicted for manufacturing a drug without a valid license, violating clause (a) of sub-section (1) of section 33-I of the Drugs and Cosmetics Act, 1940. He was fined and served a brief period of imprisonment. A year later, during a random inspection, authorities discover that Mr. Gupta has once again engaged in the production of drugs without the necessary license. This time, under Section 33J of the Act, since it is a subsequent offence, Mr. Gupta faces a harsher penalty. He is now sentenced to a mandatory two years of imprisonment and a minimum fine of fifty thousand rupees, or three times the value of the confiscated drugs, whichever is higher, to deter him from repeating the offence in the future.

Section 33K: Confiscation

Where any person has been convicted under this Chapter, the stock of the Ayurvedic, Siddha or Unani drug, in respect of which the contravention has been made, shall be liable to confiscation.

Simplified Act

33K Confiscation (Simplified)

If someone is found guilty of breaking the rules in this section of the law, any stock of Ayurvedic, Siddha, or Unani medicine involved in the violation can be taken away by the authorities.

Explanation using Example

Imagine a company named "HerbalHeal" produces an Ayurvedic cough syrup. However, they include an ingredient not permitted under the Ayurvedic drug regulations. The authorities discover this and charge the company with violating The Drugs and Cosmetics Act. After the legal process, the court convicts HerbalHeal under the relevant chapter of the Act. As a result of Section 33K, all the stock of that specific cough syrup in HerbalHeal's inventory can be confiscated by the authorities because it was the product involved in the contravention of the law.

Section 33Ka: Disclosure Of Name Of Manufacturer, Etc

Every person, not being the manufacturer of any Ayurvedic, Siddha or Unani drug or his agent for the distribution thereof, shall, if so required, disclose to the Inspector the name, address and other particulars of the person from whom he acquired the Ayurvedic, Siddha or Unani drug.

Simplified Act

Simplified Explanation of Section 33KA - Who Made This Medicine?

If you're selling or giving out Ayurvedic, Siddha, or Unani medicine but didn't make it yourself, and an Inspector asks you, you must tell them who actually made the medicine, including their full name, address, and other important details.

Explanation using Example

Imagine a scenario where an Inspector from the Drug Control Department visits a local pharmacy to ensure compliance with the Drugs and Cosmetics

Act. The Inspector asks the pharmacist about a specific Unani medicine that's on display. According to Section 33KA, the pharmacist, who isn't the manufacturer or the manufacturer's distribution agent, must provide the Inspector with the details of the supplier from whom he purchased the Unani medicine. This includes the supplier's name, address, and other relevant information. This requirement helps maintain the traceability of drugs and ensures accountability in their distribution.

Section 33Kb: Maintenance Of Records And Furnishing Of Informantion

Maintenance of records and furnishing of information Every person holding a licence under clause (c) of section 33EEC shall keep and maintain such records, registers and other documents as may be prescribed and shall furnish to any officer or authority exercising any power or discharging any function under this Act such information as is required by such officer or authority for carrying out the purposes of this Act.

Simplified Act

Simplified Explanation of Section 33KB - Keeping Records and Providing Information

If you have a license under section 33EEC clause (c), you must:

Keep all the records, registers, and documents that the law says you need to keep.

Give any information that officers or authorities ask for under this Act, to help them do their jobs related to this Act.

Explanation using Example

A pharmaceutical company, XYZ Pharma, holds a license to manufacture a drug as per clause (c) of section 33EEC of the Drugs and Cosmetics Act, 1940. To comply with Section 33KB, XYZ Pharma maintains detailed records of the drug's manufacturing processes, batch numbers, quality control tests, and distribution logs. When the Drug Controller General of India conducts a surprise inspection, XYZ Pharma is required to furnish all relevant information from these records to demonstrate adherence to the prescribed standards and regulations, thus fulfilling their obligations under the Act.

Section 33L: Application Of Provisions To Government Departments

The provisions of this Chapter except those contained in section 33K shall apply in relation to the manufacture for sale, sale, or distribution of any Ayurvedic, Siddha or Unani drug by any department of Government as they apply in relation to the manufacture for sale, sale, or distribution of such drug by any other person.

Simplified Act

This section means that all the rules in this part of the law, except for the rules in section 33K, also apply to government departments that make, sell, or distribute Ayurvedic, Siddha, or Unani medicines, just like they apply to any other individual or company doing the same.

Explanation using Example

Imagine a government-run hospital that has a department dedicated to traditional medicine, where they prepare and distribute Ayurvedic medicines to patients. According to Section 33L of The Drugs and Cosmetics Act, 1940, the hospital must comply with the same regulations that apply to private manufacturers and distributors of Ayurvedic drugs. This means they need to ensure the quality, safety, and efficacy of their medicines just like any other private Ayurvedic drug provider. If they fail to comply, they would be subject to the same penalties and actions as a private entity.

Section 33M: Cognizance Of Offences

No prosecution under this Chapter shall be instituted except by an Inspector with the previous sanction of the authority specified under sub-section (4) of section 33G.

No Court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under this Chapter.

Simplified Act

Understanding Legal Action for Offences

Only a designated official, known as an Inspector, can initiate legal action for any violations under this specific section of the law, but they must first get

approval from a higher authority mentioned in a different part of the law (section 33G, subsection 4).

Only a higher-level court, such as one presided over by a Metropolitan Magistrate or a Judicial Magistrate of the first class, is allowed to handle cases related to these violations. Less powerful courts cannot try these offences.

Explanation using Example

Imagine a scenario where a local drug inspector discovers that a pharmacy is selling a new drug without the required approval from the Drug Control Authority. According to Section 33M of The Drugs and Cosmetics Act, 1940:

The drug inspector cannot initiate legal proceedings against the pharmacy on their own. They must first obtain permission from the specified authority under Section 33G(4) of the Act.

If the inspector gets the necessary sanction and a case is filed, the trial cannot be conducted in any court less than that of a Metropolitan Magistrate or a Judicial Magistrate of the first class. This ensures that the case is handled by a court with the requisite authority and expertise.

Section 33N: Power Of Central Government To Make Rules

(1) The Central Government may, after consultation with, or on the recommendation of, the Board and after previous publication by notification in the Official Gazette, make rules for the purpose of giving effect to the provisions of this Chapter: Provided that consultation with the Board may be dispensed with if the Central Government is of opinion that circumstances have arisen which render it necessary to make rules without such consultation, but in such a case, the Board shall be consulted within six months of the making of the rules and the Central Government shall take into consideration any suggestions which the Board may make in relation to the amendment of the said rules.

(2) Without prejudice to the generality of the foregoing power, such rules may -

(a) provide for the establishment of laboratories for testing and analysing Ayurvedic, Siddha or Unani drugs;

(b) prescribe the qualifications and duties of Government Analysts and the qualifications of Inspectors;

(c) prescribe the methods of test or analysis to be employed in determining whether any Ayurvedic, Siddha or Unani drug is labelled with the true list of the ingredients which it is purported to contain;

(d) specify any substance as a poisonous substance;

(e) prescribe the forms of licences for the manufacture for sale of Ayurvedic, Siddha or Unani drugs and for sale of processed Ayurvedic, Siddha or Unani drugs, the form of application for such licences, the conditions subject to which such licences may be issued, the authority empowered to issue the same and the fees payable therefor; and provide for the cancellation or suspension of such licences in any case where any provision of this Chapter or rules made thereunder is contravened or any of the conditions subject to which they are issued is not complied with;

(f) prescribe the conditions to be observed in the packing of Ayurvedic, Siddha and Unani drugs including the use of packing material which comes into direct contact with the drugs, regulate the mode of labelling packed drugs and prescribe the matters which shall or shall not be included in such labels;

(g) prescribe the conditions subject to which small quantities of Ayurvedic, Siddha or Unani drugs may be manufactured for the purpose of examination, test or analysis;

(gg) prescribe under clause (d) of section 33EE the colour or colours which an Ayurvedic, Siddha or Unani drug may bear or contain for purposes of colouring;

(gga) prescribe the standards for Ayurvedic, Siddha or Unani drugs under section 33EB;

(ggb) prescribe the records, registers or the documents to be kept and maintained under section 33KB;

(h) any other matter which is to be or may be prescribed under this Chapter.

Simplified Act

Simplified Explanation of the Government's Power to Make Rules Regarding Drugs

(1) The Central Government can create rules regarding drugs and cosmetics after discussing with a specialized Board or based on the Board's suggestions. They'll announce these rules in a public government document. If there's an

urgent situation, the Government can skip the initial talk with the Board but must discuss with them within six months and consider their input for any rule changes.

(2) The rules the Government can make include:

(a) Setting up labs to test traditional Indian medicines (Ayurvedic, Siddha, or Unani).

(b) Defining the qualifications and responsibilities of official drug analysts and inspectors.

(c) Deciding how to test traditional Indian medicines to ensure they contain what the label says.

(d) Naming certain substances as poisonous.

(e) Outlining the process for getting licenses to make and sell traditional Indian medicines, including application forms, conditions, issuing authority, fees, and what happens if rules are broken.

(f) Setting rules for packaging and labeling these medicines, including what the labels must and mustn't include.

(g) Laying down conditions for making small amounts of these medicines for testing purposes.

(gg) Specifying the colors that can be used in these medicines.

(gga) Setting quality standards for these medicines.

(ggb) Deciding what records and documents must be kept by manufacturers.

(h) Any other matters that need rules under this section of the law.

Explanation using Example

Imagine a scenario where the Central Government of India, recognizing a need for standardization in the traditional medicine sector, decides to implement new regulations for Ayurvedic, Siddha, and Unani drugs. Under Section 33N of The Drugs and Cosmetics Act, 1940, the government initiates the process of drafting rules to ensure the quality, safety, and efficacy of these drugs.

For example, the government may propose a rule requiring that all Ayurvedic medicines be tested for potency and purity before they are sold. To do this, the

government decides to establish state-of-the-art laboratories specifically for analyzing these traditional drugs. This action is taken under the provision of Section 33N(2)(a).

Additionally, the government might set qualifications for Government Analysts who would be responsible for testing these drugs, ensuring that only qualified individuals are appointed to maintain high standards of drug safety, as per Section 33N(2)(b).

Furthermore, to protect consumers, the government could specify certain toxic substances as poisonous under Section 33N(2)(d), thereby restricting their use in Ayurvedic, Siddha, and Unani drugs.

These rules are published in the Official Gazette, and the government ensures that the Board is consulted, or if urgent circumstances require immediate action, the Board is consulted within six months as per the proviso to Section 33N(1).

Section 33-O: Power To Amend First Schedule

The Central Government, after consultation with the Board and after giving, by notification in the Official Gazette, not less than three months' notice of its intention so to do, may, by a like notification, add to or otherwise amend the First Schedule for the purposes of this Chapter and thereupon the said Schedule shall be deemed to be amended accordingly.

Simplified Act

Explanation of Section 33-O - Changing the First Schedule: The Central Government has the authority to make changes to the First Schedule of this law, which relates to specific regulations. Before making any changes, the government must discuss them with a specialized advisory board and must also inform the public by publishing a notice in an official publication (Official Gazette) at least three months in advance. Once the government officially announces the changes through a similar publication, the First Schedule is considered to be updated with those changes.

Explanation using Example

A pharmaceutical company, "HealthPlus," is manufacturing a new drug called "CureAll" that has recently been approved for use. However, after a year on the

market, new research suggests that "CureAll" might have long-term side effects that were not previously known. The Drug Technical Advisory Board (DTAB) reviews the new evidence and recommends that additional warnings and contraindications should be included in the labeling of "CureAll."

The Central Government decides to act on this recommendation to ensure public safety. It initiates the process outlined in Section 33-O of The Drugs and Cosmetics Act, 1940. The government issues a notification in the Official Gazette, indicating its intention to amend the First Schedule to include the new warnings for "CureAll." The notification specifies that stakeholders have three months to provide feedback on the proposed changes.

After considering all the inputs and maintaining the required consultation period, the Central Government issues another notification, officially amending the First Schedule. As a result, "HealthPlus" must now update its packaging and promotional materials for "CureAll" to include the new warnings as mandated by the updated First Schedule.

CHAPTER V: MISCELLANEOUS

Section 33P: Power To Give Directions

The Central Government may give such directions to any State Government as may appear to the Central Government to be necessary for carrying into execution in the State any of the provisions of this Act or of any rule or order made thereunder.

Simplified Act

Power to Give Instructions: The Central Government has the authority to tell any State Government what to do to make sure they are properly implementing the laws, rules, or orders that are part of this Drugs and Cosmetics Act.

Explanation using Example

Imagine a scenario where a new drug has been introduced in the market and the Central Government has evidence suggesting that the drug might not comply with certain safety standards as per the provisions of the Drugs and Cosmetics Act, 1940. To ensure public safety, the Central Government can use Section 33P to issue directions to the State Governments to inspect all

pharmaceutical facilities manufacturing this drug and enforce compliance with the Act's safety regulations.

Section 34: Offences By Companies

(1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly.

Explanation - For the purposes of this section -

(a) "company" means a body corporate, and includes a firm or other association of individuals; and

(b) "director" in relation to a firm means a partner in the firm.

Simplified Act

Simplified Explanation of Section 34 of The Drugs and Cosmetics Act, 1940

34 Offences by companies

(1) If a company breaks the law under this Act, both the company and the people who were in charge at the time will be considered guilty. They can be taken to court and punished if found guilty.

However, if the person in charge can show that they didn't know about the offence or that they tried their best to stop it from happening, they won't be punished.

(2) Even so, if the offence happened because a company director, manager, secretary, or other officer agreed to it, helped make it happen, or ignored it, then that individual will also be considered guilty. They too can be taken to court and face punishment.

Definitions:

(a) "company" includes any business entity like corporations, partnerships, or groups of people.

(b) "director" for a partnership means a partner in that partnership.

Explanation using Example

Imagine a pharmaceutical company, 'HealthFirst Pharma', produces a batch of medications that are found to be contaminated and do not meet the safety standards prescribed under the Drugs and Cosmetics Act, 1940. The contaminated drugs are sold in the market, leading to several cases of adverse reactions among patients who used them.

Upon investigation, it is determined that the offence occurred due to negligence in the company's quality control department. According to Section 34 of the Drugs and Cosmetics Act, 1940, not only would 'HealthFirst Pharma' as a company be held responsible for this offence, but also the individuals in charge of the company at the time the offence was committed.

If the Quality Control Manager was overseeing the production and failed to ensure the necessary safety checks, he or she, along with the company, could be deemed guilty and liable for punishment. However, if the Quality Control Manager can prove that the offence occurred without their knowledge and that they had exercised all due diligence to prevent such an offence, they may not be liable for punishment under this Act.

Furthermore, if evidence suggests that the contamination was a result of deliberate negligence or consent by higher management, such as a director or other officers, those individuals would also be held accountable and face legal consequences as per the provisions of this section.

Section 34A: Offences By Government Departments

Where an offence under Chapter IV or Chapter IVA has been committed by any department of Government, such authority as is specified by the Central Government to be in charge of manufacture, sale, or distribution of drugs or where no authority is specified, the head of the department shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this section shall render any such authority or person liable to any punishment provided in Chapter IV or Chapter IVA, as the case may be, if such authority or person proves that the offence was committed without its or his knowledge or that such authority or person exercised all due diligence to prevent the commission of such offence.

Simplified Act

Simplified Explanation of Section 34A of The Drugs and Cosmetics Act, 1940:

If a government department breaks the law regarding drugs (as stated in Chapter IV or IVA of the Act), the person in charge of making, selling, or distributing drugs, as appointed by the Central Government, will be considered responsible for the crime. If no specific person is appointed, then the leader of that department is held accountable. This person can face legal action and punishment.

However, the person in charge won't be punished if they can show that they didn't know about the illegal activity, or if they can prove they did everything they could to stop the crime from happening.

Explanation using Example

Imagine a scenario where a local health department, operating under government authority, is responsible for the distribution of vaccines. If this department distributes a batch of vaccines without ensuring they are stored at the correct temperature, as required by regulations under Chapter IV of the Drugs and Cosmetics Act, 1940, it could result in the vaccines being ineffective or harmful.

In such a case, the department could be held responsible for an offence under the Act. If no specific authority within the department was designated to ensure the proper handling of the drugs, the head of the department would be

deemed guilty of the offence and could face legal proceedings and potential punishment for this oversight.

However, if the head of the department can demonstrate that the offence occurred without their knowledge and that they had taken all necessary precautions to prevent such an incident (exercising due diligence), they may not be held liable under Section 34A of the Act.

Section 34Aa: Penalty For Vexatious Search Or Seizure

Any Inspector exercising powers under this Act or the rules made thereunder, who:

(a) without reasonable ground of suspicion searches any place, vehicle, vessel or other conveyance;

(b) vexatiously and unnecessarily searches any person;

(c) vexatiously and unnecessarily seizes any drug or cosmetic, or any substance or article, or any record, register, document or other material object;

(d) commits, as such Inspector, any other act, to the injury of any person without having reason to believe that such act is required for the execution of his duty,

shall be punishable with fine which may extend to one thousand rupees.

Simplified Act

Simplified Explanation of Section 34AA - Penalty for Unfair Searches or Seizures

If an Inspector who is supposed to enforce this law or its rules does any of the following without a good reason:

(a) Searches any place, vehicle, boat, or other means of transport;

(b) Searches a person in a way that causes annoyance and is not necessary;

(c) Takes away drugs, cosmetics, substances, articles, or important papers, records, or objects when it's not needed and is just to bother someone;

(d) Does something else that harms a person and doesn't really believe it's part of their job;

Then that Inspector can be fined up to one thousand rupees.

Explanation using Example

Imagine a scenario where a local drug inspector, suspecting illegal activities, conducts a search of a pharmacy without any substantial evidence or reasonable grounds. The inspector does not find any illegal drugs or violations of the Drugs and Cosmetics Act, 1940. However, during the search, the inspector unnecessarily opens and scatters medical records, creating a mess and causing distress to the pharmacy owner.

The pharmacy owner, feeling that the search was conducted without a valid reason and was excessive in nature, decides to take legal action against the inspector for the inconvenience and potential damage to their reputation. Under Section 34AA of the Drugs and Cosmetics Act, 1940, the inspector could be held accountable for conducting a search without reasonable suspicion and unnecessarily seizing items, in this case, the medical records. If found guilty, the inspector could be fined up to one thousand rupees for the vexatious act.

Section 35: Publication Of Sentences Passed Under This Act

(1) If any person is convicted of an offence under this Act, the Court before which the conviction takes place shall, on application made to it by the Inspector cause the offender's name, place of residence, the offence of which he has been convicted and the penalty which has been inflicted upon him, to be published at the expense of such person in such newspapers or in such other manner as the Court may direct.

(2) The expenses of such publication shall be deemed to form part of the costs relating to the conviction and shall be recoverable in the same manner as those costs are recoverable.

Simplified Act

(1) If someone is found guilty of breaking this law, the judge can, if asked by the Inspector, order that the guilty person's name, where they live, what they did wrong, and the punishment they received be made public. This information can be shared in newspapers or other ways as decided by the judge, and the guilty person must pay for it.

(2) The cost of sharing this information is part of the overall legal costs of the case. This means the guilty person must pay for these costs too, and they will be collected in the same way as other legal fees.

Explanation using Example

Imagine a scenario where a local pharmacy owner is found guilty of selling expired medications. Under Section 35 of The Drugs and Cosmetics Act, 1940, after the court convicts the pharmacy owner, the prosecuting Inspector requests the court to publicize the conviction. The court orders that the details of the conviction, including the pharmacy owner's name, address, the nature of the offence, and the imposed fine, be published in a widely read local newspaper. The cost of this publication is to be borne by the pharmacy owner and is considered part of the legal costs associated with the conviction, recoverable in the same manner as court costs.

Section 36: Magistrate?S Power To Impose Enhanced Penalties

Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), it shall be lawful for any Metropolitan Magistrate or any Judicial Magistrate of the first class to pass any sentence authorized by this Act in excess of his powers under the said Code.

Simplified Act

Even though the Code of Criminal Procedure, 1973 sets certain limits on the power of Magistrates, this section of the Drugs and Cosmetics Act, 1940, allows Metropolitan Magistrates and Judicial Magistrates of the first class to impose sentences that are more severe than those limits when dealing with offenses related to drugs and cosmetics.

Explanation using Example

Imagine a situation where a local manufacturer has been found guilty of producing and selling counterfeit drugs, which is a serious offense under the Drugs and Cosmetics Act, 1940. The case is brought before a Judicial Magistrate of the first class who, according to the Code of Criminal Procedure, 1973, typically has the authority to impose a sentence of up to three years imprisonment for offenses. However, the Drugs and Cosmetics Act, 1940 prescribes a higher punishment for the offense committed by the manufacturer. Section 36 of the Drugs and Cosmetics Act, 1940 empowers the

Magistrate to impose a sentence that is prescribed by the Act, even if it exceeds the usual three-year limit that the Magistrate can impose under the Code of Criminal Procedure. Consequently, the Magistrate is able to pass a sentence that aligns with the gravity of the offense as per the Act, ensuring that justice is served.

Section 36A: Certain Offences To Be Tried Summarily

Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974), all offences except the offences triable by the Special Court under section 36AB or Court of Session under this Act punishable with imprisonment for a term not exceeding three years, other than an offence under clause (b) of sub-section (1) of section 33-I, shall be tried in a summary way by a Judicial Magistrate of the first class specially empowered in this behalf by the State Government or by a Metropolitan Magistrate and the provisions of sections 262 to 265 (both inclusive) of the said Code shall, as far as may be, apply to such trial:

Provided that, in the case of any conviction in a summary trial under this section, it shall be lawful for the Magistrate to pass a sentence of imprisonment for a term not exceeding one year:

Provided further that when at the commencement of, or in the course of, a summary trial under this section it appears to the Magistrate that the nature of the case is such that a sentence of imprisonment for a term exceeding one year may have to be passed or that it is, for any other reason, undesirable to try the case summarily, the Magistrate shall, after hearing the parties, record an order to that effect and thereafter recall any witness who has been examined and proceed to hear or rehear the case in the manner provided by the said Code.

Simplified Act

Summary Trials for Certain Offences Regardless of what the Code of Criminal Procedure, 1973 says, most crimes under the Drugs and Cosmetics Act, 1940 that can result in imprisonment for up to three years (with the exception of one specific offence mentioned in section 33-I clause (b) sub-section (1)) can be dealt with quickly in a simple court process. This process is handled by a Judicial Magistrate of the first class or a Metropolitan Magistrate who has been given special authority by the State Government. The rules for this kind of

quick trial are similar to those in sections 262 to 265 of the Code of Criminal Procedure.

However, if someone is found guilty in this quick trial, the Magistrate can only give them a jail sentence of up to one year.

Moreover, if the Magistrate realizes at the start or during the quick trial that the case might require a jail sentence longer than one year, or if there's another good reason not to have a quick trial, they can make a note of this. After doing so, they will call back any witnesses who have already spoken and continue the trial in a more formal way, as outlined in the Code of Criminal Procedure.

Explanation using Example

An example of the application of Section 36A of The Drugs and Cosmetics Act, 1940, could be a scenario where a local pharmacy is charged with selling medicines without a valid license. The offense is punishable with imprisonment for less than three years. A specially empowered Judicial Magistrate of the first class or a Metropolitan Magistrate decides to conduct a summary trial, which is a simplified and faster procedure.

During the trial, it becomes evident that the pharmacy not only sold medicines without a license but also sold counterfeit drugs, which is a more serious offense possibly warranting imprisonment beyond one year. Realizing the gravity of the case, the Magistrate decides that a summary trial is no longer appropriate. The Magistrate records this decision and switches to a formal trial process as per the Code of Criminal Procedure, ensuring that the case is given the detailed attention it requires.

Section 36Ab: Special Courts

The Central Government, or the State Government, in consultation with the Chief Justice of the High Court, shall, for trial of offences relating to adulterated drugs or spurious drugs and punishable under clauses (a) and (b) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and clause (b) of sub-section (1) of section 30 and other offences relating to adulterated drugs or spurious drugs, by notification, designate one or more Courts of Session as a Special Court or Special Courts for such area or areas or for such case or class or group of cases as may be specified in the notification. Explanation - In this sub-section, "High Court" means the High Court of the State in which a Court of Session

designated as Special Court was functioning immediately before such designation.

While trying an offence under this Act, a Special Court shall also try an offence, other than an offence referred to in sub-section (1), with which the accused may, under the Code of Criminal Procedure, 1973 (2 of 1974), be charged at the same trial.

Simplified Act

36AB Special Courts

The Indian government, both at the central and state level, will work with the head judge of the High Court to set up special courts. These courts will handle cases about drugs that are fake or have been tampered with. The specific sections of the law that these courts will deal with include section 13 clauses (a) and (b), section 22 sub-section (3), section 27 clauses (a) and (c), sections 28, 28A, 28B, and section 30 sub-section (1) clause (b). A public notice will announce the creation of these courts, specifying the areas they cover or the types of cases they will take on. Explanation: "High Court" refers to the main court for the state where the special court is set up.

When a special court is handling a case about drug offenses, it can also try other related crimes at the same time. This is allowed under the 1973 Code of Criminal Procedure.

Explanation using Example

Imagine a pharmaceutical company, XYZ Pharma, has been accused of manufacturing and distributing a batch of drugs that were later found to be spurious. The government, after investigating the matter, decides to prosecute XYZ Pharma under the Drugs and Cosmetics Act, 1940. Given the seriousness of the offence, involving potentially harmful or ineffective drugs, the case qualifies under the provisions mentioned in Section 36AB.

The Central Government, in consultation with the Chief Justice of the High Court, designates a Court of Session as a Special Court to handle this case, focusing specifically on the offences of manufacturing and distributing spurious drugs. This Special Court is empowered to handle all the legal proceedings related to the case against XYZ Pharma, ensuring a more efficient and specialized trial process. Additionally, if XYZ Pharma is accused of any other related offences, this Special Court can also try these offences at the same trial.

Section 36Ac: Offences To Be Cognizable And Non-Bailable In Certain Cases

(1) Notwithstanding anything contained in the Code of Criminal Procedure, 1973 (2 of 1974),

(a) every offence, relating to adulterated or spurious drug and punishable under clauses (a) and (c) of sub-section (1) of section 13, clause (a) of sub-section (2) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and sub-sections (1) and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be cognizable.

(b) no person accused, of an offence punishable under clauses (a) and (c) of sub-section (1) of section 13, clause (a) of sub-section (2) of section 13, sub-section (3) of section 22, clauses (a) and (c) of section 27, section 28, section 28A, section 28B and sub-sections (1) and (2) of section 30 and other offences relating to adulterated drugs or spurious drugs, shall be released on bail or on his own bond unless

the Public Prosecutor has been given an opportunity to oppose the application for such release; and

where the Public Prosecutor opposes the application, the court is satisfied that there are reasonable grounds for believing that he is not guilty of such offence and that he is not likely to commit any offence while on bail:

Provided that a person, who, is under the age of sixteen years, or is a woman or is sick or infirm, may be released on bail, if the Special Court so directs.

(2) The limitation on granting of bail specified in clause (b) of sub-section (1) is in addition to the limitations under the Code of Criminal Procedure, 1973 (2 of 1974) or any other law for the time being in force on granting of bail.

(3) Nothing contained in this section shall be deemed to affect the special powers of the High Court regarding bail under section 439 of the Code of Criminal Procedure, 1973 (2 of 1974) and the High Court may exercise such powers including the power under clause (b) of sub-section (1) of that section as if the reference to "Magistrate" in that section includes also a reference to a "Special Court" designated under section 36AB.

Simplified Act

Simplified Explanation of Section 36AC of The Drugs and Cosmetics Act, 1940

(a) If someone commits a crime related to selling or making fake or contaminated drugs, this crime is serious enough for the police to arrest them without a warrant, and these crimes cannot be resolved by simply paying a fine to avoid arrest (non-bailable).

(b) A person accused of such a crime cannot be released from jail on bail unless:

The prosecutor has had a chance to argue against releasing the person on bail.

If the prosecutor does argue against it, the court must believe the accused person is probably not guilty and won't commit more crimes while out on bail.

However, if the accused is a minor under 16, a woman, or someone who is very sick or weak, the court can choose to let them out on bail.

(2) These rules about bail are in addition to any other rules that might already exist in other laws or the Code of Criminal Procedure.

(3) This section doesn't stop the High Court from using its special powers to grant bail, and it can treat Special Courts the same as regular Magistrates for these matters.

Explanation using Example

Example Application of Section 36AC of The Drugs and Cosmetics Act, 1940:

Imagine a pharmaceutical company is found manufacturing and selling a drug that has been deliberately adulterated to increase profits. The drug is supposed to treat hypertension but contains harmful substances that could lead to serious health complications for patients. The authorities conduct a raid and seize the spurious drugs.

Under Section 36AC of The Drugs and Cosmetics Act, 1940, the offences committed by the company are considered cognizable, which means the police can arrest those responsible without a warrant and start an investigation without the permission of a court. Additionally, the offences are non-bailable, meaning that the accused cannot be released on bail easily.

The CEO of the pharmaceutical company is arrested. According to the law, he cannot be granted bail unless the Public Prosecutor has had the opportunity to

oppose the bail application. Even if the Public Prosecutor does oppose, the court must be convinced that there are reasonable grounds to believe that the CEO is not guilty of the offence and will not commit any further offences while on bail. However, if the CEO was a woman, under sixteen, sick, or infirm, the Special Court might choose to grant bail.

This section is designed to ensure that those accused of serious offences related to adulterated or spurious drugs are not able to evade the legal process easily, reflecting the seriousness with which the law treats such offences given the potential risk to public health and safety.

Section 36Ad: Application Of Code Of Criminal Procedure, 1973 To Proceedings Before Special Court

Save as otherwise provided in this Act, the provisions of the Code of Criminal Procedure, 1973 (2 of 1974) (including the provisions as to bails or bonds), shall apply to the proceedings before a Special Court and for the purposes of the said provisions, the Special Court shall be deemed to be a Court of Session and the person conducting the prosecution before the Special Court, shall be deemed to be a Public Prosecutor:

Provided that the Central Government or the State Government may also appoint, for any case or class or group of cases, a Special Public Prosecutor.

A person shall not be qualified to be appointed as a Public Prosecutor or a Special Public Prosecutor under this section unless he has been in practice as an advocate for not less than seven years, under the Union or a State, requiring special knowledge of law.

Every person appointed as a Public Prosecutor or a Special Public Prosecutor under this section shall be deemed to be a Public Prosecutor within the meaning of clause (u) of section 2 of the Code of Criminal Procedure, 1973 (2 of 1974) and the provisions of that Code shall have effect accordingly.

Simplified Act

Explanation of Special Court Procedures

Except for specific differences mentioned in the Drugs and Cosmetics Act, the rules from the Code of Criminal Procedure of 1973 apply to the trials in Special Courts. These courts focus on cases related to drugs and cosmetics. They are

considered equivalent to a Court of Session, and the prosecutor in these courts is treated as a Public Prosecutor. The government can appoint a Special Public Prosecutor for certain cases.

To be a Public Prosecutor or Special Public Prosecutor for these Special Courts, a person must have at least seven years of experience as a lawyer. This experience should involve a significant understanding of the law.

Once appointed, these prosecutors are officially recognized as Public Prosecutors according to the Code of Criminal Procedure, and all relevant legal rules apply to them.

Explanation using Example

Imagine a pharmaceutical company has been charged with manufacturing and selling a drug without the necessary approvals from the Drug Controller General of India, violating the Drugs and Cosmetics Act, 1940. The case is significant and complex, so it is brought before a Special Court designated to handle such matters. According to Section 36AD of the Act:

The trial in the Special Court will be conducted as per the procedures laid down in the Code of Criminal Procedure, 1973, which includes provisions for bail and the appointment of a Public Prosecutor or a Special Public Prosecutor.

The government decides to appoint a Special Public Prosecutor with over seven years of experience as an advocate, particularly one with expertise in pharmaceutical law, to ensure the prosecution is conducted by someone with specialized knowledge.

The appointed Special Public Prosecutor will operate under the same legal framework as any Public Prosecutor assigned under the Code of Criminal Procedure, ensuring consistency in the application of the law.

Section 36Ae: Appeal And Revision

The High Court may exercise, so far as may be applicable, all the powers conferred by Chapter XXIX or Chapter XXX of the Code of Criminal Procedure, 1973 (2 of 1974), on a High Court, as if a Special Court within the local limits of the jurisdiction of the High Court were a Court of Session trying cases within the local limits of the jurisdiction of the High Court.

Simplified Act

Simplified Explanation of Section 36AE - Appeals and Revisions: The High Court has the authority to review and change decisions made by Special Courts in drug and cosmetic cases. It can use the same powers that are outlined in Chapters 29 and 30 of the Code of Criminal Procedure from 1973. This means that the High Court can handle appeals and revisions as if the Special Court was a Court of Session under its own jurisdiction.

Explanation using Example

Imagine a pharmaceutical company is convicted by a Special Court for manufacturing and selling a drug without the necessary approval from the Drug Control Authority, violating the Drugs and Cosmetics Act, 1940. The company believes the verdict is unjust and wants to challenge the decision. As per Section 36AE, the company can appeal to the High Court. The High Court will then review the case, applying the same powers it has in criminal cases under Chapters XXIX (Appeals) or XXX (Reference and Revision) of the Code of Criminal Procedure, 1973, as if the Special Court were a Court of Session under its jurisdiction.

Section 37: Protection Of Action Taken In Good Faith

No suit, prosecution or other legal proceeding shall lie against any person for anything which is in good faith done or intended to be done under this Act.

Simplified Act

37. Protection for actions done with good intentions

No one can be sued or legally charged for actions they took or planned to take with honest intentions under the rules of this law.

Explanation using Example

Imagine a scenario where a government inspector, under the Drugs and Cosmetics Act, 1940, conducts a raid on a pharmacy suspected of selling counterfeit medications. The inspector seizes the drugs and files a report against the pharmacy owner. The owner, in retaliation, decides to sue the inspector for harassment and loss of business. However, Section 37 of the Act provides the inspector with protection from such legal action, as long as the inspector acted in good faith and within the boundaries of the law. Therefore,

the court would likely dismiss the lawsuit against the inspector, recognizing the actions taken were part of their lawful duty to enforce the Act.

Section 38: Rules To Be Laid Before Parliament

Every rule made under this Act shall be laid as soon as may be after it is made before each House of Parliament while it is in session for a total period of thirty days which may be comprised in one session or in two or more successive sessions, and if, before the expiry of the session immediately following the session or the successive sessions aforesaid, both Houses agree in making any modification in the rule or both Houses agree that the rule should not be made, the rule shall thereafter have effect only in such modified form or be of no effect, as the case may be; so, however, that any such modification or annulment shall be without prejudice to the validity of anything previously done under that rule.

Simplified Act

38. Rules to be presented to Parliament

Every rule created under this law must be shown to both houses of Parliament as soon as possible. It should be available for review for 30 days, which can be during one session or across multiple sessions. If both houses decide to change the rule or agree that it shouldn't be created before the next session ends, the rule will only be effective in the new form or not at all. However, this decision won't affect anything that was already done based on the rule before the change or cancellation.

Explanation using Example

Imagine the government introduces a new rule under The Drugs and Cosmetics Act, 1940, that requires all pharmacies to digitally record prescriptions. Once this rule is made, it must be presented to both the Lok Sabha and the Rajya Sabha when they are in session. The rule has to be laid before each House for a total of thirty days, which can span across one or multiple sessions. If during this period, both Houses decide that a change is needed in the rule, or that it should not be implemented at all, the rule will only take effect in the modified form or not at all, depending on the decision. However, any actions taken based on the rule before such a decision will remain valid.