Labels & labeling

An overview

(Certainly not an exhaustive one.)
DRUG includes

Section 3 (b) of D&C Act 1940.

(i) 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;

(ii) such substances (other than food) intended to **affect the structure** or any **function** of 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;

contd.,
DRUG includes—contd.,

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

(iv) 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.
“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...
Statutes / competent Authorities

- The D & C Act, 1940 and Rules 1945,
- The DMR (OA) Act, 1954 and Rules 1955,
- DPCO, 1995 made under section 3 of EC Act 1955,
- The SoWM (pc) Rules 1976,
- B S I – specifications & standards,
- Drugs Controller General of India,
- State Drugs Control Administrations,
- (Regulations of importing countries) etc.,
Label & misbranded

- The term *Label* is **not defined** in the D & C Act,1940 and Rules,1945.

  But, its important to know that

- A drug / cosmetic is deemed to be **Misbranded**
  - if it is not labelled in the prescribed manner. (17(b), 17-C(b)
  - 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. 17(c),
  - if the label or container or anything accompanying the cosmetic bears any statement which is false or misleading in any particular. 17-C (c),
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 / cosmetic which is \textbf{Misbranded} ..... 

No person shall sell or distribute, any drug (including a patent / proprietary medicine) unless it is \textbf{labelled} in accordance with the Rules.

No person shall sell or distribute any cosmetic unless the cosmetic, if of Indian origin, is manufactured by a licensed manufacturer and is \textbf{labelled} and packed in accordance with the Rules.

No person shall alter, obliterate or deface any inscription or mark made or recorded by the manufacturer on the container, label or wrapper of any drug (excepting done at instance, direction or with the permission of the L.A.)
## Penal provisions.

<table>
<thead>
<tr>
<th>Sl.No</th>
<th>Name of The statute</th>
<th>Penalty in years (mandatory)</th>
<th>Fine in Rupees, not less than (mandatory)</th>
<th>Relevant Section of law</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>D&amp;C Act 1940 &amp; Rules</td>
<td>one to two years</td>
<td>Rs. 20,000/-</td>
<td>27(d)</td>
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<tr>
<td>2.</td>
<td>DMROA Act 1954&amp; Rules</td>
<td>0.5 to 1 year</td>
<td>Or with fine, Or with both fine</td>
<td>7</td>
</tr>
<tr>
<td>3.</td>
<td>DPCO 1995 (E.C.Act 1955)</td>
<td>0.25 to 7 years</td>
<td></td>
<td>7(1)a(ii)</td>
</tr>
<tr>
<td>4.</td>
<td>SoWM (pc) Rules 1976</td>
<td>-</td>
<td>Rs. 2,000/-</td>
<td>Rule 39</td>
</tr>
</tbody>
</table>
Penal provisions – contd., -

Who shall be the accused?
Proprietor of the organization
If, a partnership or a company –
- every partner/director
- every person responsible to the day to day affairs of the organization
- every person who was in charge when the offence was committed, including the employees
- the company, as well.
Label – why?

- Label is
  - a bridge between the producer and consumer,
  - Identification of the product, its contents, dosage form,
  - name and address of producer – to contact, if needed
  - cautions & warnings,
  - directions for use,
  - batch number, date of manufacture, date of expiry,
  - storage conditions,
  - maximum retail price,
  - and insures against counterfeiting/ spurious products,
Label - defined

- Label means any written, printed or graphic matter on the immediate package and on every other covering in which the package is placed or packed and includes any written, printed or graphic matter accompanying the insecticide. - (Insecticides Act, 1968.)

- Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, graphic, perforated, stamped or impressed on or attached to container, cover, lid or crown of any food package and includes a product insert. - (The Food Safety & Standards Act, 2006)
Label - defined

- Label means any written, marked, stamped, printed or graphic matter affixed to, or appearing upon any commodity (package) or packing containing any commodity. – (*The S o W&M Act 1976 and The Cigarette and other tobacco products etc., Act 2003*)
- Label means a display of written, marked, stamped, printed or graphic matter affixed to, or appearing upon any container. – (*Infants Milk Substitutes etc., Act 1992*)
Label — Pharmacopoeia-defines

- Label means any printed packaging material, including package inserts that provide information on the article. - (I.P. 2007)

- When the term LABEL is used in Pharmacopoeia, the labelling statement may appear on the container, the package, a leaflet accompanying the package, or a certificate of analysis accompanying the article, as decided by the competent authority. - (Ph.Eur,2009)

- The term LABELLING designates all labels and other written, printed or graphic matter upon an immediate container of an article or upon, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term label designates that part of labelling upon the immediate container. – (U.S.P, 30)
Label - defined

• A **label** is a piece of *paper, polymer, cloth, metal*, or other material affixed to a *container* or article, on which is *printed* a legend, information concerning the product, addresses, etc. A label may also be printed directly on the container or article. (Wikipedia, the free encyclopedia)

• FDA has asserted that oral statements by sales representatives, speeches in CME programs and lectures are “labeling” – Never litigated
Therefore

- Label means a display of any printed, written in indelible ink, marked, stamped, stencilled, embossed, etched, perforated, graphic, pictorial or other descriptive matter appearing on a piece of paper, polymer, cloth or other material, or on the immediate container, cover, lid, crown and includes a product insert / leaflet that provide information on the article, affixed to, or appear on ,or accompanying any commodity, as decided by the Competent Authority or the Statutes, as the case may be.

*(synopsis of sum total of all the definitions)*
Contents of a label.

- If, targeted for export –
- Regulations of the importing country shall be adhered to and shall contain the following minimum details:
  - name of the drug,
  - batch / lot number,
  - date of expiry, if any,
  - manufacturing license number,
  - name & address of the manufacturer /(code number)*

*(if not classified under Sch-F/F1, X, Blood products and ND & PS)*
Contents of a label.

- The name of the drug
  (proper name, conspicuously, and brand name, if any)
  - inclusion of the letters, I.P, NFI,B.P,USP,INN, or descriptive of the true nature or origin (generic name)
- The Net Contents,
- The contents of active ingredients,
- The name & address of the manufacturer,
- Batch Number/ B.No./ Batch/ Lot No./Lot,
- Date of manufacture & the date of expiry of potency,
Contents of a label. (contd.,)

- “Import licence” number, if of sch - c /c1 & imported,
- “Physician's sample – Not to be sold”,
- Percentage of Alcohol, if not less than 3%,
- Red vertical line - of not less than 1mm thickness,
  (falling under schedule G,H,X, narcotic analgesics, hypnotics, sedatives, tranquilizers, corticosteroids, hormones, hypoglycemics, antimicrobials, antiepileptics, anticancer drugs)
  (Exceptions – Vet. drugs, external use, ophthalmic preparations, ear drops, sterile sutures, surgical dressings, preparations for parenteral use)
- Mechanical contraceptives + Schedule R.
Contents of a label. (contd.,)-Medicines

Schedule G drug –

“Caution: it is dangerous to take this preparation except under medical supervision”
- conspicuously printed, - surrounded by a line, -no other words.
(exception topical / external preparations.)

Schedule H drug -

- Rx on the left top corner conspicuously

Schedule H drug – warning: to be sold by retail on the prescription of a Registered Medical Practitioner only
Contents of a label. (contd.,)

Medicines.

• Schedule H drug – falling under NDPS Act, 1985
  - NRx, in red colour, on the left top corner, conspicuously
  Schedule H drug – warning: to be sold by retail on the
  prescription of a Registered Medical Practitioner only

Schedule H drug – specified in Schedule X
XRx, in red colour, on the left top corner, conspicuously

Schedule X drug – warning: to be sold by retail on the
prescription of a Registered Medical Practitioner only.
* if it is a bulk packing - only XRx in red colour, displayed
  conspicuously
Contents of a label. (contd.,)

Medicines.

• Liniment, lotion etc., - ”For external use only.”

• Contains industrial methylated spirit ( for human use),
  - declare the fact & -”For external use only.”

• If for veterinary use – “ Not for human use;
  for animal treatment only ”

  Names of the approved colours added, if any.

• Non sterile surgical ligatures & sutures –
• “non sterile surgical ligature ( suture ) – not to be used
  for operations upon the human body unless efficiently
  sterilised.”
Contents of a label. (contd.,)

• Directions & guide lines – Pharmacopoeia
• Directions & guide lines - D & C Rules
• Directions & guide lines - SoW&M (PC) Rules
• Directions & guide lines - BIS specifications
• Directions & guide lines - DCG (I), SLAs
Contents of a label. (cosmetics)

- If, targeted for export –
- Regulations of the importing country shall be adhered to
- Shall contain name & address of the manufacturer (code number - if requested by the consignee)

- If targeted for sale or consumption in India
  - shall be manufactured by a licensed manufacturer,
  - shall be labeled as prescribed,
  - shall not contain misleading / false claims
Contents of a label. (cosmetics)

- Shall be labeled on inner and outer label
  - name of the cosmetic,
  - name and address of the manufacturer (if the container is so small the name and principal place of business)
  - Use before …...
  - Net contents (On outer label),
  - Adequate directions for use, warning, caution or special directions, names and quantities of hazardous / poisonous materials added --(where hazard exists)
Contents of a label. (cosmetics) contd.,

- Batch number, preceded by “B”,
- Manufacturing license number – preceded by “M”,
- List of ingredients of more than or equal to 1%, in the order of addition, in descending order (exemption to less than 60ml / 30 g), preceded by the words “INGREDIENTS”
- Schedule- S, r.w. BSI specifications, if any (directions issued by licensing authority)
Contents of a label. *(cosmetics)* contd.,

- Toothpaste containing fluoride
  - content of fluoride in ppm *(shall not be more than 1000 ppm)*
  - date of expiry on tube and cartoon.

Note :-Medicated toothpastes are drugs.

- Hair dyes containing dyes, colours, pigments – shall bear a caution *(R-149)*
Contents of a label. (cosmetics) contd.,
Hair dyes containing dyes, colours

• “Caution—This product contains ingredients which may cause skin irritation in certain cases and so a preliminary test according to the accompanying direction should first be made. This product should not be used for dyeing the eye-lashes or eye-brows as such a use may cause blindness”.

• Each package shall also contain instructions in English and local languages on the following lines for carrying out the test:
“This preparation may cause serious inflammation of the skin in some cases and so a preliminary test should always be carried out to determine whether or not special sensitivity exists. To make the test, cleanse a small area of skin behind the ear or upon the inner surface of the forearm, using either soap and water or alcohol. Apply a small quantity of the hair dye as prepared for use to the area and allow it to dry. After twenty-four hours, wash the area gently with soap and water. If no irritation or inflammation is apparent, it may be assumed that no hypersensitivity to the dye exists. The test should, however, be carried out before each and every application. This preparation should on no account be used for dyeing eye-brows or eye-lashes as severe inflammation of the eye or even blindness may result”.
Your comments please – 1.
Risperidone And Trihexyphenidyl Hcl Tablets

2 X 5 X 10 Tablets

Each film coated tablet contains:
Risperidone     3 mg.
Trihexyphenidyl Hcl. I.R.  2 mg.

COLOUR: Red Iron Oxide & Titanium Oxide

DOSAGE: As directed by the Psychiatrist.

STORAGE: Store between 15°C to 30°C in dry place, protect from light.
Keep medicine away from reach of the children.

WARNING: To be sold by retail on the prescription of a Psychiatrist only.
Your comments please – 3.
Your comments please -4.
Your comments please – 5.
Your comments please – 6.
Your comments please – 7.
Thank you all

and

let me try to ANSWER your

?
misleading:

 Factors that make claims misleading:

– Lack of adequate basis for comparative claims
– Reliance on inadequate studies
– Manipulation of data, statistical analysis
– Lack of sufficient emphasis on adverse effect information
– Promotion of uses beyond approved NDA