

## Guidelines on Labelling

Rule 12 of the Regulations on Standards of Drugs has prescribed the labelling requirement for medicine and information that should be included on the label is given in Schedule 5 of the regulation. According to Schedule 5, name and quantity of medicine, system of medicine (Homeopathic, Auyrvedic etc), group of medicine (Ka, Kha, Ga), active ingredients, quantity, pharmacopoeia, manufacturing license number, batch number, date of manufacture, expiry date, price, method of storage, strength, dosage and method of administration, name, address and country of the manufacturer has to be mentioned on the label. The label should also mention, **"not to be sold without the prescription of registered medical practitioner"** in case of Group Ka and Kha medicines. Other information to be included on the label is also in that schedule. Information to be provided in the form of inserts is mentioned in rules 13 and schedule 6 of the regulations. The information on the label should be clear for the convenience of the consumer and important information for consumer should be in Nepali, hence the following guidelines has been issued.

1. Trade name of the medicine (Generic name if there is no trade name) should be in English as well as in Nepali. The area covered by Nepali name should not be less than half of the English name.
2. The following information should be in Nepali: Batch number, date of manufacture, expiry date, group of medicine (Ka, Kha, Ga) advise regarding dosage (e.g. As directed by the registered medical practitioner), precaution to be taken during use of medicine (e.g. Shake the bottle before use, avoid exposure to direct sunlight and moisture, keep medicine out of reach of children), method of reconstitution of the medicine before use (e.g. dispersible

tablets and dry syrup). Letter and figure of price, batch number, expiry date and date of manufacture can be in English). The date should be printed according to English calendar. However, dates on the medicines supplied to the government health facilities can be according to Nepali calendar if directed to do so.

3. The group of medicine should normally be printed at the top right corner of the label, rectangular or square in shape. Group Ka should be printed in white or as the colour of the labelling paper with red background. Group Kha should be in rectangular or square box with white background, or the colour of the paper and printed in any colour except red. Group Ga should be with white background the colour of the labeling paper and printed in any colour except red.
4. Other information to be printed in Nepali are as follows:  
System of medicine (e.g. Ayurvedic, Unani). Modern system of medicine (Allopathic) need not to be written. **"To be sold on prescription of Registered Medical Practitioner only"** on the label of group Ka and Kha medicines. Dosage of Ka and Kha medicines should be written **"as directed by registered medical practitioner"**. Dosage of Group Ga drugs should be mentioned (e.g. one tablet three times a day or as directed by the registered medical practitioner"); information on storage (e.g. protect from direct sunlight and moisture, keep medicine away from the reach of children). More information can be provided in Nepali. Information provided in Nepali can also be provided in English.
5. Printed material on the label should be readable by unaided eyes, and in any case should not be less than 5 point. Since aluminum blister and strip shine,

letters in such case should be bigger in size. If all information cannot be included on the label, it could be placed on the carton only and less information can be included on the label. (e.g., if the space on the label is not enough to print the method of reconstitution of dry syrup, mention as **"see carton for method of preparing the dry syrup"** and print the method on carton. On the carton of doxycycline capsule print as "Each capsule contains Doxycycline hyclate B.P. equivalent to Doxycycline 100 mg" and on the strip print as "Doxycycline 100 mg" only.

6. If space is not enough on the label for detail information, it can be included on the duplex box and only information directly related to consumer can be included on the label. (e.g. "Each capsule contains Amoxicillin trihydrate BP equivalent to Amoxicillin 500 mg" can be printed on the box but on the blister "Amoxicillin 500 mg" only can be written. If the content on the label has to be made short, DDA's consent is required.
7. In case of small label, if full information cannot be included on the label, the unit pack may contain the following minimum information: (Brand) name of the medicine, quantity of active ingredient, batch number, expiry date and manufacturer. (e.g. Hepatitis B vaccine, 1 ml, 024574, 12.8.2008, Biological Institute)
8. If part of a strip is expected to be sold, the brand name of the product should be on each tablet or capsule.
9. If the product is pharmacopoeial, the name of the product as in the pharmacopoeia should be printed above or below the trade name (e.g., Amoxicillin Oral Suspension BP), if the specification of the product is not as

per the pharmacopoeia but is manufacturers own specification, pharmacopoeial standard should not be mentioned (e.g. Sulphamethoxazole and Trimethoprim tablet). But the pharmacopoeial standards of the raw materiel has to be mentioned (e.g. Each tablet contains Sulphamethoxazole BP 800 mg, Trimethoprim BP 160 mg)

10. The total quantity of the medicine in liquid, semisolid and powder dosage form has to mentioned on the pack (e.g. 60 ml, 25 g). But the quantity in case of tablet and capsule can be printed on the outer packet only (e.g. 20X10tablets)
11. If medicine with same brand name is available in different dosage forms and strengths, strength and dosage form should be mentioned along with the brand name (e.g. Procid 10, Procid 20, Ardiron, Ardiron SR, Kalinac 50, Kalinac 100 SR)
12. Therapeutic group should not be mentioned on the label of Group Ka and Kha drugs. Therapeutic group can be mentioned on the label of Group Ga drugs, (e.g., Meryl expectorant; Diamegel tablet, Antacid; Paracetamol tablet, Analgesic and Antipyretic)
13. Quantity of active ingredient in unit pack should be mentioned clearly and in unambiguous manner to avoid confusion. (e.g. Each capsule contains Indomethacin BP 100 mg; Each 5 ml contains Paracetamol BP 500 mg, Each Gram contains Lindane BP 100 mg) Quantity of medicine may also be expressed in percentage (e.g. Dextrose BP 5%; Diclofenac diethylamine BP 1.16%)
14. The type of the tablet should be clearly mentioned. But plain tablet need not be mentioned. (e.g. Each film coated tablet contains Aceclofenac BP 100 mg; Each

enteric coated tablet contains : Pentaprazole 40 mg; Each tablet contains Aspirin BP300 mg)

15. Since DS is generally abbreviated for **Double Strength**, it should not be used to denote **Dry Syrup**.
16. Active ingredients should be written as expressed in the pharmacopoeia (e.g. Amoxicillin trihydrate BP equivalent to Amoxicillin 500 mg; Tetracycline Hydrochloride BP 250 mg; Doxycycline hyclate BP equivalent to Doxycycline 10 mg; Ciprofloxacin hydrochloride BP equivalent to Ciprofloxacin 500 mg;) If the active ingredient and salt is different, the active ingredient can be mentioned as per pharmacopoeia but quantity of salt as well as active ingredient can be mentioned (e.g Ferrous fumarate BP 350 mg equivalent to elemental Iron 60 mg; or, Ferrous fumarate BP equivalent to elemental Iron 60 mg) Riboflavin sodium phosphate BP 3.7 mg equivalent to Riboflavin 2.5 mg or Riboflavin Sodium Phosphate BP equivalent to Riboflavin 2.5 mg)
17. Colour used should be mentioned (e.g. , Colour : Sunset yellow)
18. Quantity of the excipients should also be mentioned in case of injection. (Example Diclofenac injection. Each ml contains Diclofenac Sodium BP 25 mg; Benzyl alcohol IP 4%v/v (as preservative), Water for injection IP q.s.)
19. For the sake of uniformity on the packet of Oral Rehydration Salt, the information should be as per the attached sample.
20. The serial number provided by the DDA should be written as Manufacturing license number and system of medicine should be mentioned in all medicines

except modern (Allopathic). It could be written as Manufacturing License No or Mfg Lic No or M.L.No. as per the appropriateness of the space. (e.g., Manufacturing License No. 2654; Mfg. Lic No Ayur 2532; M.L.No Vet1234 )

21. Batch number, manufacturing date, expiry date, price should not be printed over the already printed text. This information should be printed on the blank space of the strip, blister of packet.
22. The label of the bottles of capacity 30 ml or above should not cover the whole circumference of the bottle to facilitate visual inspection of the content.
23. The label should bear complete name of the company, place of the manufacturing premises (at least city or the village, and name of the country)
24. Batch number of the product should be assigned according the approved SOP of the manufacturer in such a manner that the same number is not repeated at lest for ten years. System of having same batch number of different products should not be applied. For example batch number of various products should not be continued as 1, 2, 3 and so on. If numerically continuous batch number is assigned, code for each product can be placed before the numerical. Product code followed by the date of manufacture is another method of assigning batch number (for example, AA0206, AA0306, AC0306, AC0406 etc).
25. The following are the example of some of the statements in Nepali  
Dosage: As directed by the registered medical practitioner (or, physician)  
Protect from direct sunlight and moisture  
Keep medicine out of the reach of children  
For external use only

Keep in cool, dry place, do not put inside refrigerator

Not to be sold without prescription of registered medical practitioner

26. Some samples of the labels are annexed as example. The industry should submit their proposed label to the DDA. DDA will provide comment within 15 days if necessary. The industry can proceed for printing after 15 days if no comment is received.

(The foreign manufacturer should put DDA Registration No.in place of manufacturing license number of Nepali industry. To avoid confusion, foreign manufacturers should get approval of the label before printing)

*Guidelines issued from the Department of Drug Administration on 8th Asadh, 2064  
(June 22, 2007)*