DC-DT-14011(11)/8/2024-eoffice

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Enforcement Division)

FDA Bhawan, Kotla Road
New Delhi-110002
Date:

NOTICE

09 SEP 2025

Subject: Inviting comments on consideration of the proposal regarding problem faced by the blind or visually impaired people to read medicines tablets/capsules strips-reg.

This Directorate has received representations regarding problem faced by blind or visually impaired peoples in reading the strips of medicines. These special peoples face difficulty to know the name / expiry of the medicines and depends on others therefore, requested for a provision under Drugs and Cosmetics Act and Rules to label the drugs with Braille inscriptions.

In view of above, the issue was deliberated in 58th Drugs Consultative Committee (DCC) meeting on 14.07.2020 which recommended to constitute a sub-committee to examine the issue in detail for further consideration.

Whereas, a sub-committee was constituted on DCC recommendation which had submitted its report and recommended following points for consideration: -

1. To support the ease of access of medication to the visually impaired persons, this guideline regarding additional labeling in Braille language is proposed to be implemented "initially on voluntary basis" for the drugs, which are supplied in mono carton pack size.
2. Particular consideration should be given to medicinal products likely to be used by a high visually impaired target population, e.g. certain eye drop preparations.
3. Such braille labels are not applicable for the products dispensed/given under supervision of health care professional's e.g. Injectable, Vaccine etc.
4. The Braille artwork as developed by manufacturer should be got validated from the nodal agency like National Institute for the Empowerment of Persons with Intellectual Disabilities (NIEPID) through the Braille Council of India (BCI) or any other agency recommended by the NIEPID.
5. As per the European Commission guideline of the Readability of the Labelling and Package Leaflet of Medicinal Products for Human use Revision I. 12 January 2009, the type size should be as large as possible to aid readers. A type size of 9 points, as measured in font 'Times New Roman' not narrowed. with a space between lines of at least 3 nun, should be considered as a minimum.

6. The marketing authorization holder may ensure that the package information leaflet is made available on request from patients/stakeholders in formats appropriate for the blind and the partially sighted.
7. Issuance of advisory by the competent authority for the retailers under their jurisdiction to guide such population verbally about the dosage form, Name of the medicines, indication and uses along with any other information like expiry date etc. that can be routinely followed up by the Enforcement Officers.

Further, discussion on the sub-committee's report took place during the 66th DCC meeting held on June 17, 2025. The DCC after deliberation opined that the recommendations of the sub-committee may be placed on the CDSCO website for public comments along with the below mentioned additional points:

1. Secondary packaging containing more than 10 units of medicines may have some braille cards for giving to such population as and when required.
2. Medicines can have QR code linked with voice assistance.

Accordingly, the recommendations of the sub-committee etc. as above are uploaded in CDSCO website for seeking public comments in the matter and all stakeholders may send their comments on email id's: dci@cdsco.nic.in., and dccdtab@cdsco.nic.in for further necessary action in the matter.

Yours faithfully,

Dr. Rajeev Singh Raghuvanshi
Drugs Controller General (India)

To: All Stakeholders through CDSCO website