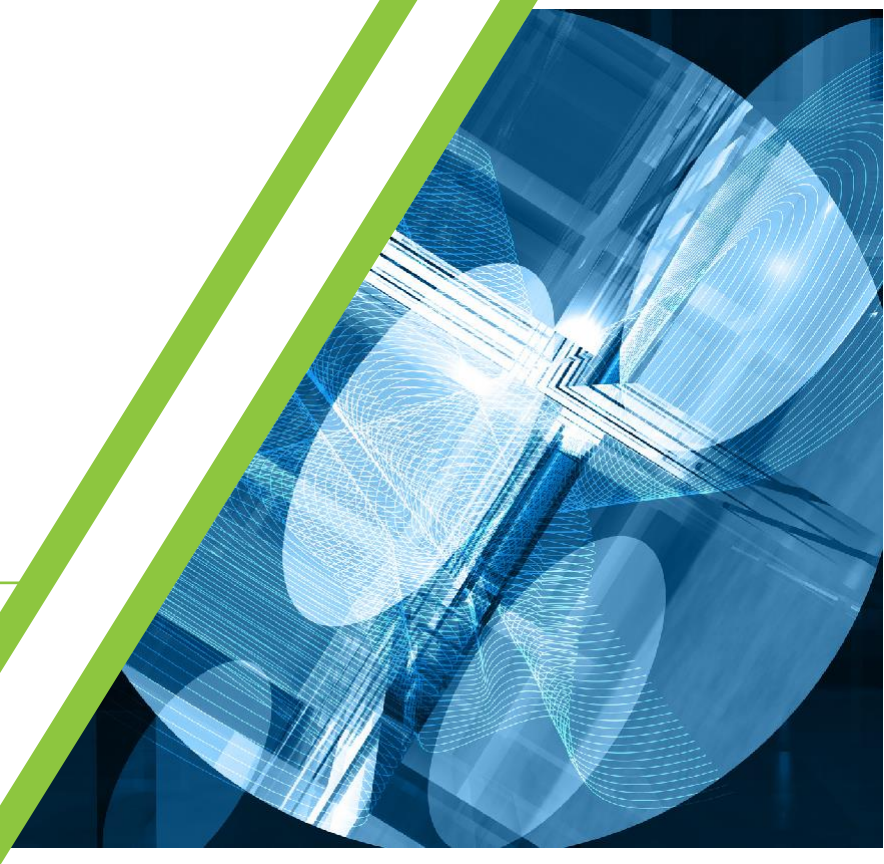
Recommendation of the Council on Procedure for Labelling Pharmaceutical Specialities



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Background Information

The Recommendation on Procedure for Labelling Pharmaceutical Specialities was adopted by the OECD Council on 2 April 1963 on proposal of the Trade Committee. The Recommendation aimed to harmonize and simplify the procedure for the labelling of pharmaceutical products, thereby facilitating trade in such products. To this end, the Recommendation set out the criteria for labelling pharmaceutical specialities. The Recommendation was abrogated on 12 July 2017 because since its adoption, international initiatives, like the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and the World Health Organisation, have been established to achieve the Recommendation's objectives and they has been considered fulfilled.

THE COUNCIL[1]**,**

HAVING REGARD to Article 5 b) of the Convention on the Organisation for Economic Co-operation and Development of 14 December 1960;

HAVING REGARD to the Recommendation of the Council of 3 July 1962 on Administrative and Technical Regulations which Hamper the Expansion of Trade [C(62)108(Final)];

HAVING REGARD to the Recommendation of the Council of 25 September 1962 on Procedure for the Registration of Pharmaceutical Specialities [C(61)106(Final)];

CONSIDERING the desirability of eliminating discrimination and facilitating trade in pharmaceutical products between Member countries;

RECOMMENDS Governments of Member countries to harmonize and simplify as far as possible the procedures in force or foreseen for the labelling of pharmaceutical products, taking into account the criteria set out in the Annex to this Recommendation.

ANNEX

CRITERIA FOR THE LABELLING OF PHARMACEUTICAL SPECIALITIES

The following list gives the maximum information which, from the public health point of view, should be shown on the outside of a package containing a pharmaceutical speciality or on the container (bottle, tube, etc.) containing the speciality.

This list should not be considered to preclude the insertion on labels of other information (such as price data) which national regulation require to be shown, insofar as this additional data is called for on grounds other than those of public health.

It is recognised that the information to be included on ampoules and other small containers must be left to the discretion of the authorities.

1. Name of speciality;
2. Composition (formula):
    a) Qualitative;
    b) Quantitative of active principles;
3. Reference number for identifying production (batch number);
4. The number of the marketing authorisation;
5. Name and address of:
    a) Manufacturer, or
    b) Responsible vendor;
6. Restricted distribution, where applicable
7. Pharmaceutical form and contents[2];
8. Methods of use;
9. Date of expiry (if necessary);
10. Special conservation precautions (if necessary);
11. Special distinctive marks under legislation relating to poisons and narcotics.

NOTE. The information required under Items 8, 9 and 10 should be given in the language or languages of the country in which the pharmaceutical speciality is being sold.

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[1] Canada abstained. The United States abstained "temporarily". This Recommendation does not apply to Australia.

[2] This information should only be shown on the outside of the package. It should be noted that, under the Norwegian regulations, the pharmaceutical form and contents should be indicated on bottles, tubes, etc. unless the container is very small.

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