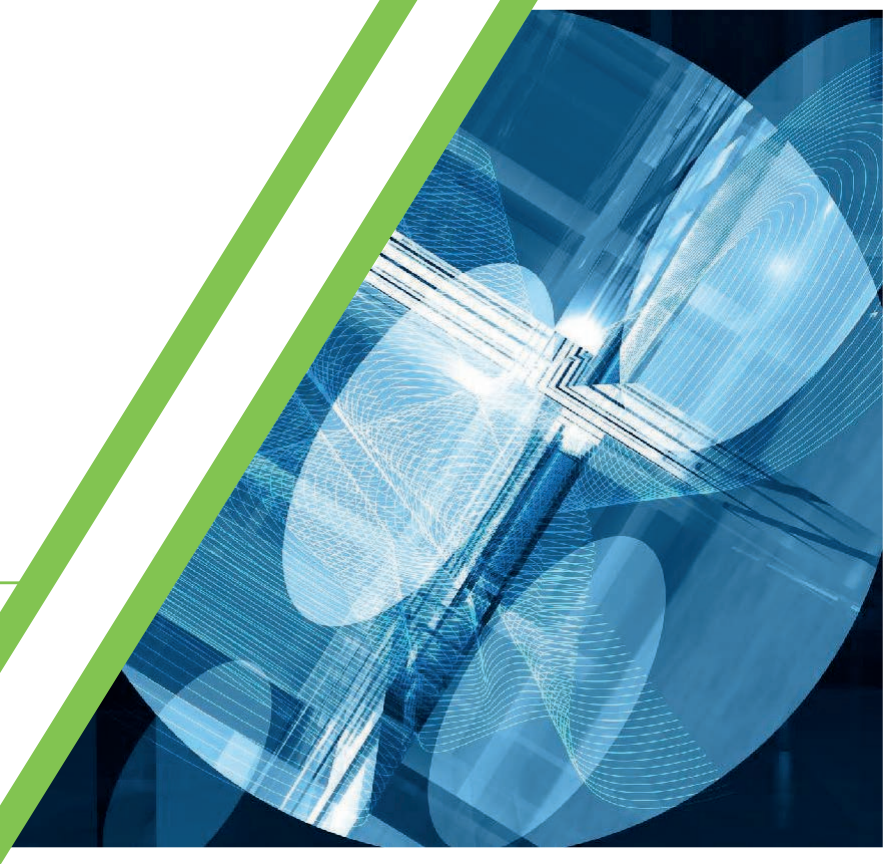
Recommendation of the Council on Procedure for the Registration of Pharmaceutical Specialities



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Please cite this document as:
OECD, *Recommendation of the Council on Procedure for the Registration of Pharmaceutical Specialities* , OECD/LEGAL/0051

Series: OECD Legal Instruments

Date(s)

Adopted on 25/09/1962
Amended on 02/04/1963
Abrogated on 12/07/2017

THE COUNCIL,

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)];

CONSIDERING the desirability to eliminate discrimination and to facilitate trade in pharmaceutical products between Member countries;

RECOMMENDS Governments of Member countries:

1. To harmonize and simplify as far as possible the procedure in force or foreseen for registration of pharmaceutical products, taking into account the criteria set out in the Annex to this Recommendation;

2. To move towards the reciprocal recognition of national registrations.

ANNEX

REGISTRATION CRITERIA FOR PHARMACEUTICAL SPECIALITIES

Definition

A pharmaceutical speciality is any medicine with a specific composition, prepared in advance and offered for supply to the public in a distinctive packing and under a trade name.

1. Documentation for Registration[1]

All applications for registration of a pharmaceutical speciality should be accompanied by documents containing the following information, which is to be regarded as necessary and adequate, subject to the special note below.

i) Name and address of the manufacturer or responsible importer;

ii) Name of the speciality;

iii) Description of the pharmaceutical presentation;

iv) Information concerning labelling and packaging;

v) Declaration of the qualitative and quantitative composition of all ingredients;

vi) Statement of qualitative and quantitative testing methods to be employed;

vii) Statement of stability;

viii) Therapeutic indications, contra-indications, side-effects and dosage;

ix) Results of pharmaceutical, physiological and clinical tests of any origin of adequate reliability, showing in particular that:

a) The therapeutic indications are based on medical facts;

b) The product has no harmful effects exceeding what is acceptable in the present state of medical knowledge.

2. Duration of Registration Procedure

Time limits should be fixed by the competent authorities in the various Member countries for dealing with registration applications so that administrative delays may be avoided in the interests of public health.

The time limits adopted by the various Member countries should be standardized and should be as short as possible.

3. Rejection of an Application for Registration

An application for registration should only be rejected for reasons of public health and not for economic reasons.

Furthermore, an application should not be rejected on the following grounds:

a) Lack of medical need,

b) The fact that the product is not registered in other countries.

Any rejection of an application for registration of a pharmaceutical speciality should be justified. There should be provision for an appeal in the event of rejection.

4. Suspension, withdrawal, and duration of registration

Registration of a speciality with a view to distribution may be suspended or withdrawn if the authorities find that the original supporting documents presented do not correspond with the facts concerning the product or if the product no longer corresponds with these documents or if the product, although used as directed, is subsequently found to be harmful to public health as a result of scientific or therapeutical knowledge or if misleading publicity continues to be conducted after warnings have been given.

Excepting any untoward circumstances, there should preferably be no time limit for the period of registration.

5. Naming of a speciality

The naming of a pharmaceutical speciality, and especially the free choice of a trade name, subject to international conventions, should be vested in the manufacturer but no name which is likely to be misleading should be chosen.

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[1] As the price of a pharmaceutical speciality is controlled in some countries by the public health authorities, whereas in others this control is carried out by a different body or price control does not exist, no indication of the need for price control has been included in paragraph 1 of this Annex.

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