# COMMISSION OF THE EUROPEAN COMMUNITIES

COM(81) 819 final
Brussels, 11 January 1982

Amendment to the
Proposal for a
COUNCIL DIRECTIVE

amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC
on the approximation of provisions laid down by law,
regulation or administrative action relating to
proprietary medicinal products

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(submitted by the Commission to the Council pursuant
to Article 149, second paragraph, of the EEC Treaty)

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## Explanatory Memorandum

1. On 4 December 1980, the Commission put forward a proposal for a Directive to the Council amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (OJ C 355, 31.12.1980).

2. In conformity with Article 100 of the Treaty the Economic and Social Committee and the European Parliament adopted an opinion on the proposal on 29 June 1981 (doc. CES 676/81) and 16 October 1981 (Doc. P.E. 74.859) respectively. These opinions contained certain amendments.

3. The Commission is willing to accept certain of these amendments and proposes the following amendments to its proposal:

   - In the English text, substitute the expression 'data-sheet' for 'product-summary'.
   - Article 1:
     paragraph 2, points 5.7 and 5.10
     paragraph 5.
   - Article 2, paragraph 2.
   - Article 3
     "Article 9, point 3
     Article 13, point 1
     Article 14, point 1."

Amendment to the proposal for a Council Directive amending Directives 65/65/EEC, 75/318/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

1. In the English version the expression 'data-sheet' which appears in the 3rd recital as well as in Article 1, paragraph 2, 2nd subparagraph, and paragraph 3, 2nd and 4th subparagraph, shall be replaced by the expression 'product-summary'.

2. Article 1, paragraph 2, shall be amended as follows:

5.7 Posology and method of administration for children and adults respectively

5.10 Effect on ability to drive a vehicle and operate machinery

3. Article 1, paragraph 5, shall be amended as follows:

The following Article 9a shall be inserted after Article 9:
"After an authorization has been issued, the person responsible for placing the product on the market must, in respect of the control method provided for in Article 4, point 7, take account of technical and scientific progress and introduce any changes that may be required to enable the proprietary medicinal product to be checked in accordance with generally recognized scientific methods."

4. Article 2, paragraph 2, shall be amended as follows:

In part I, C, the following paragraph 3 shall be inserted:

"3. Physico-chemical characteristics liable to affect bio-availability
The following items of information concerning active principles, whether or not listed in the pharmacopoeias, shall be provided as part of the general description of the active principles if they relate to the bio-availability of the medicinal product:
- crystalline form and solubility coefficients,
- particle size, where necessary after pulverization,
- state of hydration,
- oil/water partition coefficient,
the requirements of the first three indents not being applicable to substances used solely in solution."

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5. Article 3 shall be amended as follows:

"Article 9

3. The Committee shall forward this information immediately to the Member States.

Article 13

1. In order to facilitate any discussions by the Committee, the competent authorities shall draw up a report to assess the results of the analytical and toxico-pharmacological tests and clinical trials of any proprietary product containing a new active substance which is the subject of an application for a marketing authorization in the Member States concerned for the first time or of any other proprietary product that they may choose, particularly when the holder of the marketing authorization whishes to follow the procedure described in Article 9.

Article 14

1. When reference is made to the procedure described in this Article, the Committee shall consider the matter and express a reasoned opinion within 60 days of the date on which the matter was referred to it.
The person responsible for placing the product on the market may, at his request, explain himself verbally or in writing before the Committee expresses its opinion. He may also obtain the suspension of the above-mentioned time limit."