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Pharmaceuticals and Cosmetics

PHARM 264

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Subject : Use of covert markers in medicinal products

Background:
Covert markers are chemical substances which are added to medicinal products by the manufacturer of the original product for authentication purposes, in order to allow a quick and reliable distinction between counterfeit products and original products. To assure this aim, it is necessary to keep the identity of the covert marker confidential.

General remarks:
The authorisation of covert markers must– of course – comply with the general principles of Community pharmaceutical legislation:
- competent authorities must be informed by the applicant of the exact composition of the covert marker and an evaluation regarding quality and safety must be performed.
- once authorised, the composition of the covert marker must remain as authorised and the covert marker must be included in all the products covered by the marketing authorisation.

However, certain questions as to the legality of the use and the modalities of authorization and labelling of medicinal products containing such covert markers have arisen. In particular the following points were raised:

1. Should it be accepted – from a public health perspective – to include ingredients in a medicinal product that has no therapeutic value ?

Suggested answer: Community pharmaceutical legislation requires that any authorised medicinal product must fulfil the three basic criteria of Quality, Safety and Efficacy. Protection against counterfeiting may – in practical terms - contribute to the quality and

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safety of a given product and there is no provision in Community pharmaceutical legislation which would require that each constituent of the product must have a therapeutic value. The use of covert markers to prevent counterfeiting may therefore be acceptable.

2. Community legislation would require that all ingredients of a medicinal product be fully described in the SPC, the labelling and the package leaflet. It would therefore not be acceptable to keep the identity of the covert marker confidential.

Suggested answer: Point 2 of Article 4a of Directive 65/65 provides that the SPC shall contain information on the "*qualitative and quantitative composition in terms of the active ingredients and constituents of the excipient,* ***knowledge of which is essential*** *for proper administration of the medicinal product*". Article 7 (1) a second indent of the Labelling Directive 92/27 provides that the package leaflet shall include "*a* ***full statement*** *of the active ingredients and excipients* ***expressed qualitatively*** *and a statement of the active ingredients expressed quantitatively, using their common names, in the case of each presentation of the product*". Both provisions seem to provide enough scope to allow to indicate the presence of a covert marker just in general terms (e.g.: "authentication marker" or "identification marker") and not to mention the exact chemical composition.

3. Covert markers might be used by companies in their attempts to partition markets.

Suggested answer: Authorising medicinal products and commercial behaviour of companies are two different issues which must be dealt with separately. It is logically not possible to say that an authorisation of a covert marker will automatically and always imply future illegal partitioning of markets by companies (even though this can – of course – not be excluded in some specific cases). The problem of partitioning of markets must be individually addressed by appropriate instruments of Community law on a case by case basis. It is, however, not possible to link this aspect in a general way with the authorisation procedure for medicinal products.

Action to be taken:

For discussion and possible endorsement of the relevant paragraph of the proposed "Update on guidance of SPC", CPMP/1697/98, Draft 4 – Revision 2 (June 1999):

"If the medicinal product contains a covert marker for identification, its presence should be declared in general terms (e.g. "authentication factor" or "identification marker") but the substance need not be named."