

**CMD(h) RECOMMENDATION ON
IMPLEMENTATION OF ARTICLE 30 DECISIONS
cf. DIRECTIVE 2001/83/EC, AS AMENDED FOR GENERIC/HYBRID/BIOSIMILAR
MEDICINAL PRODUCTS APPROVED THROUGH MRP/DCP**

Doc. Ref.: CMDh/090/2003

January 2003

Revision 4, June 2010

Revision 3, April 2009

1. At commencement of an Article 30 procedure

The CHMP press release and the CHMP monthly report will give information that an Article 30 (Divergent decision referral) on a compound/medicinal product has been initiated.

The press release and monthly report are available on the EMEA web site: <http://www.emea.europa.eu/> (What's New or Press Office, CHMP).

Information on applications referred in accordance with Article 30(2) of Directive 2001/83/EC as amended is also to be found on the HMA website, CMD(h), Products Information: <http://www.hma.eu/23.html>.

2. At completion of an Article 30 procedure

Information regarding an adopted CHMP opinion on an Article 30 referral is available in the CHMP press release and the monthly report of the meeting.

3. Following a Commission Decision

Following the issue of the European Commission Decision:

The summary information on CHMP Opinions after an Article 30 referral will be available at the EMEA website under Human Medicines, Article 30 referrals, List of Referrals-Article 30- 'harmonisation' referrals. The published information will include the background information on the referral and the adopted Summary of Product Characteristics, package leaflet and labelling. Starting from 2009 the information published includes also a Q & A Section on the referral.

The Commission Decision, the Summary of Product Characteristics, package leaflet and labelling are also published at the Commission [Directorate-General Health and Consumers Enterprise and Industry](http://ec.europa.eu/enterprise-and-industry) website under Community Register-, Access Register, EU Referrals, Human Medicinal Products: http://ec.europa.eu/enterprise/pharmaceuticals/register/refh_others.htm

The ~~tracking table information~~ on the HMA website (<http://www.hma.eu/23.html>) ~~regarding information on application referred in accordance with 30(2) of Directive 2001/83/EC AS AMENDED~~, is updated ~~on a~~ regularly ~~and, after finalisation, includes also a link to the published Commission Decision basis.~~

4. Compliance with Commission Decision after an Article 30 referral procedure

1. The CMD(h) **strongly encourages** the concerned generic companies to contact their national competent authority or - if the medicinal product is approved through the mutual recognition procedure (MRP) or the decentralised procedure (DCP) - the competent authority of the reference Member State to initiate the harmonisation of the Product Information (SmPC, PL and labelling) of the medicinal product to conform to the Commission Decision. In accordance with the legislation for medicinal product approved through the MRP or DCP, a change in the ~~SPC~~ Product Information of a generic/hybrid/biosimilar following a Commission Decision on a referral for an original/reference medicinal product in accordance with Article 30 of Directive 2001/83/EC, as amended, is ~~considered cf. Communication from the Commission- guideline on the details of the various categories of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (2010/C 17/01) a~~

Type IB variation: When the change implements the outcome of the referral and no new additional data are submitted by the MAH (C.I.1 b), ~~provided the conditions set up in the Commission Regulation (EC) No 1084/2003 are met:~~

or a

Type II variation: When the change implements the outcome of the referral with new data submitted by the MAH (C.I.1 c)

- ~~•The proposed SPC is identical for the concerned sections to that annexed to the Commission Decision on the referral procedure for the original/reference product.~~
- ~~•The application is submitted within 90 days after the publication of the Commission Decision.~~

~~The CMD(h) has furthermore agreed upon that it is acceptable that the labelling and package leaflet for harmonisation also can be submitted within the type IB variation provided that they are identical for the concerned sections to that annexed to the Commission Decision and the submission is taken place within the 90 days.~~

2. The CMD(h) should also ask all Associations of Generic/Hybrid/Biosimilar Companies within EEA to play an active role and notify and recommend to their members to follow the above-mentioned CMD(h) Recommendation.