

RECOMMENDATIONS ON MULTIPLE/DUPLICATE APPLICATIONS IN MUTUAL RECOGNITION AND DECENTRALISED PROCEDURES

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This document was produced by the CMD(h) in order to facilitate and harmonise the regulatory issues for submission of multiple applications so called “duplicates” in mutual recognition and decentralised procedures.

For so-called “informed consent” applications (article 10c of Directive 2001/83/EC), when the marketing authorisation holder (MAH) allows use to be made of the pharmaceutical, preclinical and clinical documentation contained in the file on the previously authorised medicinal product, please refer to CMD(h) recommendations on informed consent applications in mutual recognition and decentralised procedures:
http://www.hma.eu/uploads/media/recinfo_app.pdf.

DEFINITION

As a duplicate is an independent authorised medicinal product, there is no definition of a “duplicate” in the pharmaceutical legislation. However, for practical purpose, a duplicate application is defined by reference to the first application or marketing authorisation as follows:

- same dossier (copy of modules 1, 2, 3, 4 and 5);
- same legal basis according to Directive 2001/83/EC, as amended;
- different tradename;
- same or different applicant/marketing authorisation holder.

GENERAL PRINCIPLES

- According to the European Commission’s position – which is shared by all Member States of the EEA - it is legally not acceptable for a Concerned Member State (CMS) to recognise more than once the marketing authorisation granted by the Reference Member State (RMS).
- An application for a duplicate from the same applicant/MAH has to be submitted to the Member State of the initial application/authorisation. In the framework of mutual recognition this is the RMS. Simultaneous or subsequent duplicate applications in another Member State of the EEA has to follow either the DCP or MRP.
- If the applicant is independent from the applicant/MAH of the initial application/authorisation, the duplicate application can be submitted for authorisation in any Member State of the EEA.
- All applications for marketing authorisation have to fulfil the requirements stated in Directive 2001/83/EC, as amended (risk management plan, consultation with target patients groups for the package leaflet etc.);

this also applies to duplicates. Therefore, the documentation for the first application referred to has to be in line with the current legislation before a duplicate application can be submitted.

- Applications for duplicates result in independent marketing authorisations which can be varied independently. However, MAH are strongly encouraged to keep the SPC, PL and labelling of the duplicates harmonised, whenever possible.

SUBMISSION OF DUPLICATE APPLICATIONS

By submitting simultaneously or subsequently duplicate applications, the applicants should indicate in the cover letter and in the Module 1 of the dossier:

- that the application is a duplicate;
- that the dossier is identical to the medicinal product taken as reference (first application or marketing authorisation);
- if other duplicate applications are pending or submitted simultaneously. The applicants should indicate the procedure number(s), the RMS and all CMSs and in the case of several applicants, if they are linked or not.

SUNSET CLAUSE

According to Article 24 (4-6) of Directive 2001/83/EC, the so-called “sunset clause” applies to medicinal products which are not marketed for a period of three consecutive years, whether originally marketed or not.

The sunset clause should be applied individually to each duplicate marketing authorisation granted by the national competent authorities independently from the initial marketing authorisation.

Following a mutual recognition or decentralised procedure, where a duplicate is not marketed for a consecutive period of three years in the RMS, in order to maintain the marketing authorisation in the CMSs, a change of the RMS should be considered by the MAH (see also CMD(h) position on changing the Reference Member State: http://www.hma.eu/uploads/media/position_rms.pdf). However, in exceptional circumstances and on public health grounds, the RMS may grant exemptions from the application of the sunset clause.

For more information, a CMD(h) agreement on sunset clause and its application to marketing authorisation granted in more than one Member State is available on the CMD(h) website: http://www.hma.eu/uploads/media/Sunset_clause_Duplicates.pdf

SPECIFIC SITUATIONS

If the same or different applicants/MAHs wish to have several marketing authorisations for the same product in the Member State(s) of EEA, usually for purpose of co-marketing they may submit duplicate applications for marketing authorisations. The position given in this document applies regardless of the legal basis of the application (e.g. generic application, extension application etc.). However, the duplicate application must always have the same legal basis as the first application/marketing authorisation.

Different situations may occur depending on whether the applicant/MAH are the same (or linked) or independent and where the application is submitted.

1. The duplicate application is submitted in the Reference Member State

Irrespective of whether the applicants for the duplicates are the same or independent, the RMS will initiate independent MRPs/DCPs, characterised by different procedure numbers. The CMSs could be different in the first application and in the duplicate application(s).

For purpose of consistency, the RMS should maintain the harmonisation of the product information (SPC, PL

and labelling), whenever possible, between the duplicate(s) and the first application and should mention in the final assessment report(s) any differences in the product information of the duplicate(s).

2. The duplicate application is submitted in a Concerned Member State

The situation should be considered differently if the applicants/MAHs are independent or are the same (or linked).

2.1 Applicants/MAHs are independent

A mutual recognition or decentralised procedure is finalised by the first MAH/applicant in several CMSs. In one of these CMSs, a duplicate application is submitted subsequently through the national (case 1) or decentralised procedure (case 2). As the two applicants are independent, a national/decentralised application is acceptable in any Member State. However, in the 1st case, if the second applicant wishes to have a marketing authorisation in another Member State(s), a mutual recognition procedure should be initiated.

2.2 Applicants/MAHs are the same or linked

A mutual recognition or decentralised procedure is started by the first MAH/applicant in several CMSs. In one of these CMSs, a duplicate application is submitted in parallel (or subsequently) to the first application. As it is not acceptable to recognise more than once the marketing authorisation granted by the RMS and because the MAH are the same or linked, a parallel/subsequent duplicate application is invalid in any Member State. The MAH should either first obtain a duplicate marketing authorisation in the RMS, then apply for a mutual recognition of the duplicate approved in the RMS or initiate for the duplicate a decentralised procedure, where the RMS of the initial marketing authorisation is automatically the RMS for the duplicate application.

3. The duplicate application is submitted in Member States where the first authorisation was granted purely nationally before 1998

Before 1st January 1998, a MAH has obtained several national marketing authorisations for the same product in different Member States. Afterwards, if the same MAH (or linked MAH) wishes to obtain an authorisation for a duplicate application in one of these Member States, different situations may occur:

The MAH can choose either to submit a national duplicate application (case 1) or to choose a RMS in order to obtain a duplicate marketing authorisation through a mutual recognition or decentralised procedure (case 2). However, in the 1st case, if the applicant wishes to have a marketing authorisation (for the same duplicate) in another Member State, then the mutual recognition procedure of the first duplicate has to be followed.

In case of a mixture of national and mutual recognition procedures granted before 1998, a national submission of the first duplicate application is still allowed in any Member State where a national marketing authorisation was granted or in the RMS of the MRP. However, if the applicant wishes to have a marketing authorisation (for the same duplicate) in another Member State, then the mutual recognition procedure of the first duplicate has to be followed.