EMA and EU Commission – Topical News

Handling of Duplicate Marketing Authorisation Applications in the Centralised Procedure (ENTR/F/RSR 380166)

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On 30 March 2010, the European Commission published a note on the handling of duplicate marketing authorisation applications in the centralised procedure. The note aims at the creation of more transparency and predictability regarding the criteria which have to be complied with in order to obtain a Commission authorisation to submit a duplicate marketing authorisation.

I. Legal basis of a duplicate application for marketing authorisation

The legal basis for the submission of a duplicate application for marketing authorisation is contained in Art. 82 (1) sentence 2 of Regulation (EC) No. 726/2004[1]. The general rule is that only one marketing authorisation may be granted for a specific medicinal product, Art. 82 (1) sentence 1. Provided special requirements are fulfilled, the Commission may authorise the applicant to submit more than one application for marketing authorisation for the medicinal product to the EMA. Art. 82 (1) 2 reads:

However, the Commission shall authorise the same applicant to submit more than one application to the Agency for that medicinal product when there are objective verifiable reasons relating to public health regarding the availability of medicinal products to health-care professionals and/or patients, or for co-marketing reasons.

In the note the Commission published the criteria which are applied with respect to requests for authorisations to submit duplicate applications in order to ensure predictability of the results and to avoid misuse of the possibility to apply for duplicate application.

II. Procedure

In the procedure of application for a duplicate marketing authorisation the EMA and the Commission have to co-operate. Whereas the Commission has to grant the authorisation to submit an application for duplicate marketing authorisation, the EMA has to perform the validation of the application for duplicate marketing authorisation as such, just as it does in case of validation of "normal" applications for marketing authorisation. Furthermore, the EMA has to validate whether the additional requirements for duplicate applications are complied with.

1. Authorisation granted by the Commission

Art. 82 (1) sentence 2 of the Regulation provides the criteria which have to be met in order to obtain an authorisation for submission of a duplicate application. These are:

- The application is submitted by *"the same applicant"* – as it will be mentioned below, this aspect will also be validated by the EMA on the basis of the criteria laid down in the 1998 Commission Communication and Chapter 2 of the Notice to Applicants
  and
- The public health or co-marketing reasons are met. The interpretation of these criteria is explained in the Annex to the Commission note. Details on the requirements are set out under III. below.

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[1] ABl EG Nr. L 136, 30. 04. 2004, p. 1.

Pharm. Ind. 72, Nr. 5, 822–824 (2010)

A duplicate application may not be granted unless the Commission has issued its authorisation. Even though the wording of Art. 82 (1) sentence 2 of the Regulation suggests that the Commission's authorisation should be achieved prior to submission of the application for duplicate marketing authorisation, the Commission seems to practice a more flexible interpretation. In the note the Commission sets out that the authorisation letter must be issued prior to the CHMP opinion on the duplicate application. Therefore, applicants have to apply for the Commission authorisation in a timely manner before the CHMP meeting at the latest one month prior to the CHMP opinion. As a consequence, pre-submission advice may also be applied for prior to having obtained the Commission authorisation.

The letter of authorisation to be issued by the Commission has to contain the following elements:

- The name of the holder of the duplicate marketing authorisation,
- Name of the product subject to the duplicate marketing authorisation,
- Condition that the authorisation is granted provided that the application is a "true duplicate" – the assessment of this requirement has to be performed by the EMA.
- Statement that the evidence of co-marketing reasons has been submitted at the latest one month prior to the CHMP opinion (if applicable);
- In case duplicates are asked for reasons of patent protection for certain therapeutic indications or pharmaceutical forms, the applicant has submitted a commitment letter undertaking to extend the indications/pharmaceutical forms as soon as the patent protection expires.

■ 2. Validation to be performed by the EMA

The EMA has to validate the following criteria:

(1) The application is a *"duplicate application"*, i. e. an application for marketing authorisation must already be submitted or a marketing authorisation already granted;
(2) *The same applicant* submits the application for duplicate marketing authorisation, i. e. the criteria laid down in the 1998 Commission Communication and Chapter 2 of the Notice to Applicants must be satisfied;
(3) The definition of a *"true duplicate"* must be complied with, i. e. there may only be certain minor differences between the original application for marketing authorisation or the marketing authorisation already granted;
(4) The *letter of consent* from the holder of the reference marketing authorisation must be included in the application in case the duplicate application is submitted on the basis of an informed consent application;
(5) The *authorisation to submit a duplicate application* must be granted by the Commission.

III. Requirements to be satisfied

The requirements which have to be satisfied in order to achieve a duplicate marketing authorisation are the following:

(1) The application is a *"duplicate application"*, i. e. the applicant must either already have applied for a marketing authorisation for that product or already has been granted a marketing authorisation. If this requirement is fulfilled, the EMA will process the application as a duplicate application.
(2) *The same applicant* submits the application for duplicate marketing authorisation:
According to Art. 82 (1) sentence 2 of the Regulation a duplicate application may only be submitted by the *same applicant*. This also has to be verified by the EMA. In this respect, the criteria laid down in the Commission Communication of 1998 for "the same entity" and the interpretation contained in the Notice to Applicants, Chapter 2, for "same applicant" apply. This means that if the applicant is not identical to the applicant of the first marketing authorisation or marketing authorisation application the applicant either has to belong to the same group of companies as the applicant of the original marketing authorisation (application) or the applicant may be an independent company which has concluded a licence agreement or other kind of marketing agreement the subject of which is the placing on the market of the product. An agreement between independent companies the subject of which is not the placing on the market of the product or an agreement regarding the purchase and/or use of data from the original applicant does not satisfy the criteria of the "same applicant".
(3) The original marketing authorisation must be valid, i. e. it must not be withdrawn, revoked or suspended and it must not have ceased to be valid, e. g. for failure to submit a renewal application.
(4) The definition of a *"true duplicate"* must be satisfied, i. e. the duplicate application must refer to the specific medicinal product which is already covered by the original marketing authorisation. Consequently, only slight differences are allowed between the medicinal products. These are differences regarding:
   - the name of the marketing authorisation holder,
   - the name of the product,
   - the manufacturer or manufacturing site – however, in case of biological medicinal products this will be assessed on a case-by-case basis,
   - excipients, provided they are justified,

- the number of therapeutic indications, if they are due to patent protection in certain Member States.

(5) A letter of consent must be submitted in case of informed consent applications
and

(6) The Commission authorisation must be issued, i. e. evidence has been submitted to the Commission that public health reasons or co-marketing reasons are existing.
The existence of public health or co-marketing reasons is assessed by the Commission. With respect to this assessment, the Annex to the note contains information how this assessment is performed.
a. Public health reasons
Public health reasons have to be linked to the availability of the product. Their existence is assessed on a case-by-case basis. No. 1 of the Annex to the note merely mentions patent protection of indications or pharmaceutical forms in one or more Member States as acceptable public health reason. However, in this case the applicant has to provide a commitment letter that he will either accordingly extend the marketing authorisation or withdraw the restricted duplicate marketing authorisation as soon as the patent restrictions no longer exists. To the contrary

- pricing and reimbursement considerations,
- classification considerations of the medicinal product
and
- considerations based on differences in national legislation which might be contrary to or incompatible with EC law

shall not be accepted as public health reason for the authorisation for duplicate marketing authorisation.

b. Co-marketing reasons
The assessment of these reasons is based on the interpretation of "co-marketing" as *"an agreement between two parties to commercialise a specific medicinal product under different tradenames"*. Consequently, an authorisation for duplicate application will not be granted if the co-marketing partners

- belong to the same group of companies,
- already practise co-marketing in the EU.

The evidence to be submitted comprises the name of the co-marketing partner and proof of co-marketing agreement.
All evidence to be submitted according to the note has to be submitted to the Commission at the latest one month prior to adoption of the CHMP opinion.

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