CBG MEB

MEDICINES EVALUATION BOARD

Terms and conditions for package fee and reduced fee for copy DCP application – human products

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Package fee

The term package fee entails that a group of products (each with an individual RVG number) is only billed once at the tariff corresponding to the product type of the procedure. In order to qualify for the package fee, the following terms and conditions apply:

1. The procedure must be requested for the products in question using a single (or 'overall') cover letter.
2. The products in question must have the same (future) marketing authorisation holder. A product in the 'package' may change marketing authorisation holder after the procedure.
3. The products in question must contain the same active substance (or substances). The excipients in the products do not need to be the same either quantitatively or qualitatively (e.g. due to a difference in colour for tablet strengths or different flavours).
4. The pharmaceutical form/forms must be exactly the same for the products in question.
   E.g.: a combination package containing various pharmaceutical forms (e.g. RiseCaD 35 mg tablets + 500 mg/880 IE effervescent granulate) and a combination package with the same pharmaceutical forms in different strengths (e.g. RiseCaD 35 mg tablets + 1000 mg/880 IE effervescent granulate) are a single package.
5. The products differ individually on at least one of the following characteristics:
   - quantitative composition of the active substance
   - number of active tablets (e.g. for contraceptives)
   - difference in excipients used to achieve a difference in flavour and applied for as such (different flavour)
   - multi-dose/single-dose.

   The package fee does not apply if all of the above characteristics are the same for the products in question.

Examples of package fee

Example 1

A national application for four simvastatin tablets in the following strengths: 10, 20, 30 and 40 mg. The application for the four strengths is submitted via a single cover letter and the future marketing authorisation holder for all four strengths is the same. The package fee applies in this case.

- Each strength receives its own RVG number.
- A single case is created for the four RVG numbers with product type 108 'national application with known active substance'.
- The tariff for this product type is billed once.

Example 2

A national application for two 20 mg simvastatin tablets. The application for both products is submitted via a single cover letter and the future marketing authorisation holder is the same for both. The package fee does **not** apply in this case, because the quantitative composition of the active substance is the same for both products.

- Each 20 mg tablet receives its own RVG number.
- A separate case is created for each 20 mg with product type 108 - 'national application for known active substance'.
- The tariff for this product type is billed for each case.

Example 3

A national application for two 0.60/1.20 mg tablets with amylmetacresol and dichlorobenzylalcohol as active substances. The application for both products is submitted via a single cover letter and the future marketing authorisation holder is the same for both. The products differ in terms of excipients so there is a difference in flavour, and this is applied for as such (difference in flavour is mentioned in the product name and listed in the product information). Although the quantitative composition of the active substances is the same for both products, the products meet condition 5 and the package fee applies.

- Each 0.60/1.20 mg tablet receives its own RVG number.
- A single case is created for both RVG numbers with product type 108 - 'national application with known active substance'.
- The tariff for this product type is billed once.

Example 4

A national application for a medicinal product in the form of a tablet and a medicinal product in the form of a solution for injection. The application for both products is submitted via a single cover letter and the future marketing authorisation holder is the same for both. The package fee does **not** apply in this case, because the pharmaceutical form for both products differs.

- Each pharmaceutical form receives its own RVG number.
- A separate case is created for each RVG number with product type 108 - 'national application for known active substance'.
- The tariff for this product type is billed for each case.

Example 5

A DCP NL=RMS application for three products, namely NL/H/1234/001-003/DC, with 001 and 002 being tablets and 003 a solution for injection. The application for the three products is submitted via a single cover letter and the future marketing authorisation holder is the same for all three. The package fee does **not** apply for the three products in this case, because the pharmaceutical form differs.

- Each product receives its own RVG number.
- Because splitting such an application procedure is undesirable from a regulatory perspective, a single case is created with product type 61 - 'DCP RMS application known active substance'.
- The tariff for this product type is billed twice.

Reduced fee DCP copy application

A DCP copy application is an additional DCP application for which the dossier is identical or almost identical to the dossier of the initial application (the original). If the conditions below are met, a reduced tariff applies for the DCP copy application:

1. **Cover letter**
   The cover letter must clearly state that it concerns a DCP copy application and that the conditions to qualify for the DCP copy application have been met.

2. **Time of submission of the copy application**
   If a DCP copy application is added at the beginning (simultaneously) or during the procedure, but at least prior to Day 106, the copy tariff applies. If a copy application is submitted after restart/Day 106, the normal (full) tariff is billed.

3. **Put-through time**
   The initial application and the copy/copies (from Day 106 or before) are handled at the same time through marketing authorisation. It is not possible to complete the national implementation/marketing authorisation for one of the copies or the initial application earlier (not even if one of both is authorised with further conditions).

4. **Applicant (aanvrager)**
   For the duration of the procedure (both the European part and the national implementation phase), the contact person acting on behalf of the applicant must remain the same for the initial application and the copy/copies. All correspondence goes to a single contact person. It is not possible to handle the national implementation of the initial and copy application with different contact persons.

   This entails the following for the application form:

   On the electronic application form under ‘Declaration and signature’ (page 3-4) it is common (but not mandatory) to list the same applicant for the initial application and for each copy. However, under ‘on behalf of the applicant’ the same person/company must be listed for the initial application and for each copy.

   In section 2.4.1 of the application form, a different organisation may be listed for the initial application and for each copy. This is where the future marketing authorisation holder is listed.

   In section 2.4.2 of the application form (‘Person/company authorised for communication on behalf of the applicant during the procedure in the

Community/each MS') for the copy, the same contact person and organisation as for the initial application must be listed. This person/company is also responsible for the national implementation phase of the procedure (Dutch translations) until the marketing authorisations have been issued.

In section 2.4.3 of the application form, a different contact person/organisation may be listed for the initial application and for each copy. This is where the contact person/organisation after marketing authorisation is listed.

5. Dossier and legal basis

The dossier (modules I through V) and the legal basis for the initial dossier and the copy must be the same. Exceptions are only allowed for the following items:

- Product name;
- Future marketing authorisation holder;*
- Package forms and sizes in Module I, on the condition that the copy dossier does not contain other package forms or sizes than included in the initial dossier (fewer is allowed);**
- The number of manufacturers (applies only for manufacturers responsible for packaging) in Module I, on the condition that the copy dossier does not contain other manufacturers than included in the initial dossier (fewer is allowed);**
- The number of strengths in Module I, on the condition that the copy dossier does not contain other strengths than included in the initial dossier (fewer is allowed);**
- CMSs, on the condition that the initial application and the copy are submitted at the same time. If the copy is submitted after the start, no CMSs may be included for the copy that are not already under consideration with the original.

*: The RMP of the future marketing authorisation holders must be the same in terms of content.

**: Modules II-V of the copy dossier must contain the full information, as included in the initial dossier (including all information relating to the packaging forms, packaging sizes, manufacturers responsible for packaging or strengths only requested for the initial dossier). The cover letter must clearly state that for the copy fewer packaging forms, packaging sizes, manufacturers responsible for packaging or strengths are applied for. In addition, in the cover letter the applicant should declare that Modules II-V of the copy and initial dossier are identical.

Examples of reduced fee DCP copy applications

Example 1

Two DCP NL=RMS applications with the same known active substance, both for two products, namely NL/H/1234/001-002/DC and NL/H/1235/001-002/DC. The 001 is a 10 mg strength and the 002 is a 20 mg strength. Both procedures are applied for at the same time. The NL/H/1235 application meets the conditions of the DCP copy application.

- The package fee applies to the strengths within each DCP application. Therefore, the corresponding tariff is billed once for the 10 and 20 mg.
- The normal tariff for an NL=RMS DCP application with known active substance applies for NL/H/1234. The reduced NL=RMS DCP copy application fee applies for NL/H/1235.
- Both DCP NL=RMS applications are processed in a single case with product type 59 - 'DCP RMS original + copy application(s) for authorisation of known active substance' and complete the procedure at the same time up to marketing authorisation.

Example 2

Two DCP NL=RMS applications with the same known active substance, both for two products, namely NL/H/1234/001-002/DC and NL/H/1235/001-002/DC. The 001 is a 10 mg strength and the 002 is a 20 mg strength. Both procedures are applied for at the same time. The NL/H/1235 application does **not** meet the conditions for the DCP copy application, despite the fact the applicant indicates this in the cover letter. For example, there is a different organisation in section 2.4.2 of the application form ('Person/company authorised for communication on behalf of the applicant during the procedure in the Community/each MS') of the copy compared to the initial application.

- The package fee applies to the strengths within each DCP application. Therefore, the corresponding tariff is billed once for the 10 and 20 mg.
- Because the condition for a reduced DCP copy fee is not met, the normal tariff for an NL=RMS DCP application with known active substance applies for each application.
- Both DCP NL=RMS applications are processed individually (and separate cases with product type 61 - 'DCP RMS application for known active substance' are created) and the procedure is also completed independently for each.

Example 3

Four DCP NL=RMS applications with the same active substance:
NL/H/1236/001-004/DC
NL/H/1237/001-004/DC
NL/H/1238/001-003/DC
NL/H/1239/002-004/DC
With the 001 being the 10 mg, 002 the 20 mg, 003 the 40 mg and 004 the 80 mg strength. These procedures are applied for at the same time. As may be derived from the procedure numbers, the 10 and 80 mg are not requested for every procedure. The NL/H/1237, NL/H/1238 and NL/H/1239 meet the requirements for the DCP copy application.

- The package fee applies to the strengths within each DCP application. Therefore, the corresponding tariff is billed once for each application.
- The normal tariff for an NL=RMS DCP application with known active substance applies for NL/H/1236. The reduced NL=RMS DCP copy application fee applies for NL/H/1237, NL/H/1238 and NL/H/1239.
- The four DCP NL=RMS applications are processed in a single case with product type 59 - 'DCP RMS original + copy application(s) for authorisation of known active substance' and complete the procedure at the same time up to marketing authorisation.

Example 4

Six DCP NL=RMS applications with the same known active substances:
1. NL/H/1241/001-002/DC: Drospirenon/EE 3/0.03 mg and Drospirenon/EE 3/0.02 mg; 21 tablets
2. NL/H/1242/001-002/DC: Drospirenon/EE 3/0.03 mg and Drospirenon/EE 3/0.02 mg; 21 tablets
3. NL/H/1243/001-002/DC: Drospirenon/EE 3/0.03 mg and Drospirenon/EE 3/0.02 mg; 21 tablets
4. NL/H/1244/001/DC: Drospirenon/EE 3/0.02 mg; 24+4 tablets
5. NL/H/1245/001/DC: Drospirenon/EE 3/0.02 mg; 24+4 tablets
6. NL/H/1246/001-002/DC: Drospirenon/EE 3/0.03 mg and Drospirenon/EE 3/0.02 mg; 21+7 tablets

EE = Ethinylestradiol
The six procedures above were submitted at the same time. The procedures differ from one another with regard to the number of tablets with active substances and/or the presence of (a number of) placebo tablets and/or the strength of the tablets.
The NL/H/1242 and NL/H/1243 applications fulfil the conditions of the copy application with NL/H/1241 as the initial application. The NL/H/1244, NL/H/1245 and NL/H/1246 also contain placebo tablets and the NL/H/1244 and NL/H/1245 applications also have a different number of tablets with active substance. Therefore, these three procedures do not qualify for the DCP copy conditions with NL/H/1241 as the initial application. The NL/H/1245 application

can be considered a copy with NL/H/1244 as the initial application if the conditions of the copy application are met. The NL/H/1246 application cannot be considered a copy with NL/H/1244 as the initial application, because the number of placebo tablets differs.

- The package fee applies to the products within each DCP application. Therefore, the corresponding tariff is billed once for each application.
- The normal tariff for an NL=RMS DCP application with known active substance applies for NL/H/1241, NL/H/1244 and NL/H/1246. The reduced NL=RMS DCP copy application fee applies for NL/H/1242, NL/H/1243 and NL/H/1245.
- The first three DCP NL=RMS applications (NL/H/1241, NL/H/1242 and NL/H/1243) are processed in a single case with product type 59 - 'DCP RMS original + copy application(s) for authorisation of known active substance' and complete the procedure at the same time up to marketing authorisation.
- The fourth and fifth DCP NL=RMS applications (NL/H/1244 and NL/H/1245) are processed in a separate case with product type 59 - 'DCP RMS original + copy application(s) for authorisation of known active substance' and complete the procedure at the same time up to marketing authorisation.
- The sixth DCP NL=RMS application (NL/H/1246) is processed in a separate case with product type 61 - ‘DCP RMS application for known active substance'.