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DANISH MEDICINES AGENCY

Guidelines on the collection of fees for applications for marketing authorisations, variations etc. in accordance with the Danish executive order no. 733 of 8 June 2017 on fees payable for medicinal products and pharmaceutical companies etc.

At 1 July 2017, a new fee structure and new fees became effective in the pharmaceutical area, including fees for applications for marketing authorisations, variations etc.

Applications for a new marketing authorisation (MRP, DCP and the national procedure) as well as later extensions
The application fee for applications for new marketing authorisations covers all strengths and pharmaceutical forms in the procedure, regardless of the application procedure. Later applications for an extension of the authorisation, e.g. with new pharmaceutical forms or strengths (extensions) are subject to a separate fee.

Additional fee for required assessment in addition to the standard procedure due to the complexity etc. of the submitted documentation
To establish a fee structure as similar as possible to the real assessment, a fee has been fixed for the assessment of an application for a new marketing authorisation based on a standard evaluation in relation to the documentation for quality, safety and efficacy typically submitted according to the type of application. However, the standard fee does not cover an assessment of bioequivalence data or any additional assessments of a non-clinical, clinical or veterinary clinical nature. In such cases, an additional fee will be charged.

Duplicate applications
Duplicate applications are applications for new marketing authorisations; instead of submitting separate application documentation, the applicant can refer to the assessment of an application for which a full fee has been charged and where the dossier (modules 1, 2, 3, 4 and 5), the legal basis and the time schedule are the same.

For example, the time schedule must be same so that applications which the Danish Medicines Agency receives after the authorisation of a similar application will not, in terms of fees, be considered as a duplicate application of the authorised application. In such cases, the Danish Medicines Agency will charge a full fee.

Denmark as Reference Member State (MRP-RMS) incl. RUP (Repeat Use Procedure)
Applications for marketing authorisations in other EU/EEA countries through the mutual recognition procedure (MRP) with Denmark as Reference Member State (RMS) are subject to the following fees:

1) Procedure with full updating
This fee is charged for applications requiring a full updating of the assessment report prior to the actual procedure.

2) Procedure with administrative updating
This fee is charged for applications requiring only minor administrative updating of the assessment report prior to the actual procedure.

3) Day 0 procedure
This fee is charged for applications that require no updating of the assessment report and the procedure is a day zero procedure.

In general, fees for applications requiring an updating of the assessment report will be charged in connection with the updating of the assessment report.

Variations and extensions
Applications for variations and extensions are subject to a fee per case /procedure, regardless of the number of changes or medicinal products covered by the case/procedure. As regards variations, the size of the fees will vary depending on whether the application is a single or a grouped application.

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Concepts and definitions in relation to variations
”Administrative” means applications for variations categorised as administrative in accordance with the European Commission’s categorisation of variations (classifications starting with the letter ”A”).

”Quality” means applications for variations categorised as changes to the quality or the PMF/VAMF of the medicinal product in accordance with the European Commission’s categorisation of variations (classifications starting with the letter ”B” or ”D”).

”Regulatory/clinical” means variations categorised as changes to the safety, efficacy or monitoring of the medicinal product in accordance with the European Commission’s categorisation of variations (classifications starting with the letter or ”C”).

Complex and simple quality variations
Complex quality variations mean applications for type II variations that will result in a complex assessment. The list includes the following changes.

- New manufacturer of active pharmaceutical ingredient or active substance (ASM) applied for with or without ASMF (B.I.z, B.I.a.1.b, B.I.a.1.c, B.I.a.1.e, B.1.a.1.g) or change to raw material manufacturing (B.I.a.2.c, B.I.a.3.c, B.I.a.5)
- Significant change of formulation with/without bioequivalence trials (B.II.a.3.b.2 or B.II.a.3.b.5)
- Significant change of composition of extract/herbal preparation, e.g. in connection with re-classification of extract from *standardised* or *other* to *quantified* extract (B.I.z, B.II.a.z)
- Introduction of real-time release or parametric release (B.II.d.3)
- Introduction of Design space (B.I.e.1, B.II.g.1)
- Introduction of post-approval management plan (B.I.e.2, B.II.g.2)
- New finished product manufacturer (B.II.b.1.c), change to finished product manufacturing (B.II.b.3.c) and change to batch size (B.II.b.4.c)
- Significant change of declaration (C.I.4) for natural medicinal product/traditional herbal medicinal product

If the variation application is not included on this list, the variation is considered to be simple.

Transition from old to new executive order
Applications, including notifications to Medicine Prices, will be subject to a fee in relation to the executive order and the rates applicable at the time when the Danish Medicines Agency receives the application or the notification**.**