1 Can the procedure with prior notification (PPN) be applied to medicinal products with orphan drug status?

Yes. The procedure with prior notification (PPN) can be applied to new authorisation applications and indication extensions for medicinal products with orphan drug status. The additional fee for fast-track processing will always be applied. However, the flat-rate fee for new authorisation applications will be waived in view of the product's orphan drug status.

2 Do changes in status abroad have to be notified if orphan drug status is based on Swiss prevalence data?

No. If orphan drug status derives from Swiss prevalence data, there is no obligation to actively notify Swissmedic of changes in status abroad.

3 Does the fee of CHF 80,000 charged for applications for temporary authorisation include the preceding application for the appropriate procedure, or does this cost an additional CHF 5,000 (similarly to applications for an FTP in accordance with Annex 1 section I no. 9.1 FeeO-Swissmedic)? How is this fee calculated for medicinal products with orphan drug or MUMS status?

Applications for a temporary authorisation procedure are charged separately on the basis of the work involved.

Medicinal products with orphan drug or MUMS status are only exempt from the fee charged for new authorisation applications. All other applications (i.e. including applications for the procedure itself) are subject to the fees set out in the Fees Ordinance.

4 According to FeeO-Swissmedic, all applications for variations involving medicinal products with orphan drug or MUMS status are now subject to fees. Does this also apply to medicinal products with orphan drug or MUMS status that were authorised under the "old law" prior to 2019?

Whether or not the new Fees Ordinance is applied is determined by the date on which the application for a variation is received and not by when orphan drug or MUMS status was awarded, or by when the medicinal product in question was authorised. That means that applications for variations to medicinal products with orphan drug or MUMS status received on or after 1 January 2019 are subject to a fee.

5 Is it correct that "significant benefit" still has no impact on ODS in Switzerland?

"Significant benefit" still plays no role in assessing eligibility for and awarding ODS in Switzerland. The criteria set out in Art. 4 para. 1 let. a^{decies} TPA are authoritative.

6 On the subject of reporting obligations, will Swissmedic withdraw a medicinal product's ODS if it is withdrawn abroad (e.g. after an indication extension)?

As long as the Swiss prevalence criteria set out in Art. 4 para. 1 let. a^{decies} (1) TPA continue to be fulfilled, ODS will not be withdrawn in Switzerland.

7 Does the reporting obligation for changes in status abroad only apply to the same company or also to its partners?

The reporting obligation set out in Art. 5 para. 2 TPLO applies to the applicant/marketing authorisation holder in question.

8 On the subject of OD status related to decisions in countries with comparable medicinal product control, must proof be provided that prevalence is not different in Switzerland?

No, Swissmedic issues ODS on the basis of statuses in countries with comparable medicinal product control and without reference to prevalence in Switzerland. Swiss prevalence data only become relevant if the status in other countries changes in any way (see Art. 6 TPLO).

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