1 Are SwissPARs created for applications for the authorisation of biosimilars?

No, SwissPARs are created and published for approved or rejected applications for the authorisation of human medicinal products with new active substances, for indication extensions for those products and for transplant products that were notified for authorisation after 1 January 2019.

2 Can a SwissPAR be used for advertising purposes?

Since they are official reports, published SwissPARs and the elements contained in them are not protected by copyright (Art. 5 para. 1 let. c CopA). As regards the use of SwissPARs for advertising purposes, the applicable provisions of the Therapeutic Products Act (particularly Art. 31 f. TPA; SR 812.21) and the Therapeutic Products Advertising Ordinance (TPAO; SR 812.215.5) must be observed.

3 Do applicants have to submit the English translation of the Swiss Information for healthcare professionals needed to create the SwissPAR with their application for authorisation or an indication extension?

No. When a new application for authorisation is approved, authorisation holders will be asked to submit the English version of the Swiss Information for healthcare professionals within ten calendar days of receiving the decision.

4 Are SwissPARs updated, for example if the Information for healthcare professionals is modified?

No, SwissPARs document the material result of the scientific evaluation of a new application for authorisation, from receipt through to the official decision. Swissmedic creates a supplementary SwissPAR for approved or rejected applications for indication extensions if a SwissPAR has already been published as part of the authorisation process for the medicinal product.

5 Is a SwissPAR created if an application for authorisation or an indication extension is withdrawn?

No, a SwissPAR will not be published if an application for authorisation is withdrawn.

6 What quality-related data are published in a SwissPAR?

The Quality Aspects section gives information on the active substance and finished product, and provides a summary assessment of the new medicinal product's quality. However, the applicant's business or manufacturing secrets and confidential data belonging to third parties are never published (see also guidance document *SwissPAR HMV4*).

7 What happens if an applicant objects to the texts due to be published in the SwissPAR?

Swissmedic grants applicants a once-only hearing when the preliminary decision on the authorisation is issued. The applicant has to individually justify its requests for non-disclosure of parts of the documentation (see also the explanation in 5.2.3–5.2.5 and 6.1.2 f. of guidance document *SwissPAR HMV4*). Swissmedic examines requests in the light of the applicable legal requirements, makes its decision, then publishes the SwissPAR. The data relating to any request for non-disclosure that Swissmedic accepts are not published in the SwissPAR. If Swissmedic rejects any of the applicant's requests for non-disclosure, it will list each of the text passages or elements associated with a rejected request in its authorisation decision. The final text of the SwissPAR and the public evaluation report are an integral part of the authorisation decision. An appeal may be lodged against requests rejected in the official decision within 30 days of issue of the decision.

8 Can applicants only respond to confidential information?

Yes. Swissmedic sends applicants the draft public evaluation report, including existing text elements from the SwissPAR, as part of the hearing process so that applicants can flag up text passages or elements that they feel are confidential and should not be published in the SwissPAR. Requests for non-disclosure must be substantiated in each case. Swissmedic is responsible for formulating the text

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of the SwissPAR. Swissmedic will not consider any feedback that applicants provide on text formulations (regardless of confidentiality).

9 Do applicants have to submit requests for non-disclosure of data in the public evaluation report with their response to the preliminary decision on their application?

Yes. Applicants receive the draft public evaluation report with the preliminary decision on the authorisation procedure so they can respond to Swissmedic concerning confidential data that they feel should not be published in the SwissPAR. Their response, including their reasons for requesting non-disclosure, must be submitted to Swissmedic with their reply to the preliminary decision on their authorisation application. The time limits for doing so are based on the guidance document *Time limits for authorisation applications HMV4*.

10 How should responses to public evaluation reports be submitted to Swissmedic?

Feedback on public evaluation reports should be supplied as additional information in the reply to the preliminary decision in the eCTD sequence under Module 1.

11 In what format does Swissmedic supply public evaluation reports to applicants so they can comment on the non-disclosure of confidential data?

Draft public evaluation reports are supplied in MS Word format. Confidential text passages should be marked up in Track Changes mode.

12 The clinical section of the public evaluation report is not complete when the preliminary decision on the authorisation application is issued. How should applicants comment on this section?

The Clinical Review division's draft public evaluation report is available when the preliminary decision is issued and will be sent to applicants. The Clinical Review division's draft SwissPAR is not available when the preliminary decision is issued because Swissmedic generally specifies the conditions that have to be fulfilled to achieve approval in its preliminary decision on authorisation. Applicants respond to these conditions during the hearing process in their reply to the preliminary decision. Furthermore, certain aspects of the Information for healthcare professionals are not addressed with applicants until the text review stage. These aspects are relevant and may be incorporated into the SwissPAR. In their response to preliminary decisions, applicants should flag up in the draft public evaluation report text passages that they feel are confidential (CCI) as well as elements that are subject to the Data Protection Act (FADP), CopA and PatA, and individually state their reasons for requesting non-disclosure. If an applicant submits additional documents to Swissmedic with its response, these documents should also be marked up for CCI, FADP, CopA and PatA compliance and reasons provided for requesting non-disclosure (see *Guidance document SwissPAR HMV4*).
As part of its evaluation of the reply to the preliminary decision in the authorisation procedure, Swissmedic assesses applicants' requests in terms of CCI, FADP, CopA and PatA requirements. Swissmedic approves justified requests by not publishing the relevant information in the SwissPAR.

13 If an application that has been rejected or withdrawn once is resubmitted, will the fact that it is a second submission be published in the SwissPAR?

The published SwissPAR sets out the logic underpinning the evaluations and decisions of Swissmedic. It will therefore be apparent if an application has been rejected or withdrawn in the past. However, since the revised Therapeutic Products Act entered into force on 1 January 2019, Swissmedic already publishes rejections and withdrawals in the Swissmedic Journal at the time the decision is made in accordance with Art. 68 para. 1b and c TPO.

14 Data from ongoing clinical trials are not published to avoid jeopardising the integrity of the study. What are the rules regarding publication of trial data in SwissPARs?

Data from ongoing trials may appear in SwissPARs. Interim results from ongoing trials are frequently published or presented at conferences. To protect data integrity within an ongoing trial, applicants can

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mark up confidential data – i.e. data that have not yet been made public – and explain their reasons for requesting non-disclosure of those data in their reply to the preliminary decision on their application for authorisation. When it evaluates the reply to the preliminary decision during the authorisation procedure, Swissmedic assesses applicants' requests in terms of data protection, CCI, FADP, CopA and PatA requirements. Swissmedic approves justified requests by not publishing the relevant information in the SwissPAR.

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