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Federal Department of Home Affairs (FDHA)

Federal Office of Public Health (FOPH)
Health Insurance Benefits Division

CH-3003 Bern FOPH; POST CH AG

By e-mail
To the associations of the pharmaceutical industry

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Bern, 28 September 2023

Information letter concerning the publication process

Dear Sir/ Madam

The Federal Office of Public Health (FOPH) publishes the basis of its evaluation when new admissions are made to the specialities list (SL), indications are extended or limitations are amended for original formulations. With this letter, the FOPH would like to inform you about the planned changes to the publication process. The updated procedure will be implemented as of 1 January 2024. We kindly ask that you inform your members accordingly. This letter will be published on the FOPH website (accessible at: Information related to the specialities list (admin.ch)).

1. Legal context

After completing the procedure in connection with new admissions to the SL, the extension of indications and the amendment of limitations for original preparations in accordance with Art. 71(2) of the Ordinance on Health Insurance (KVV), the FOPH publishes the basis for its evaluation of the efficacy, appropriateness and cost-effectiveness of the drug in question. The FOPH also publishes the duration of any possible limitation on admission to the SL (Art. 71(3) of the KVV). The contents of the relevant ruling that are intended for publication are published on the FOPH website (Art. 71(2) and (6) of the KVV). Section A.8.3 of the manual on the SL governs the details of the publication.

2. Procedure

a. Procedure to date

After the FOPH issued its ruling, the draft publication was previously sent to the marketing authorisation holder in advance so as to grant them their right to be heard and thus to provide them with the opportunity to comment on the planned publication (see section A.8.3 of the manual on the SL).

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b. New procedure

The marketing authorisation holder will now be granted the right to be heard regarding the publication at the same time as the draft ruling is served. The marketing authorisation holder will continue to have the opportunity to comment on the planned publication. However, a draft publication will in future no longer be provided. After the right to be heard has been granted and any amendments to the publication text have been made, the text will then be published without any further exchange of written submissions. Section A.8.3 of the manual on the SL is to be partially repealed or amended accordingly with this letter. The following text describing the contents to be published will now be integrated in the ruling or notification under the legal basis.

"Upon an original drug being added to the specialities list (SL), indications being extended or limitations being amended, the FOPH publishes the basis for its evaluation of the efficacy, appropriateness and cost-effectiveness of the drug in question, the internal reference price and the innovation premium as well as information about the international price comparison (Art. 71(2) and (3) of the KVV). The contents intended for publication are published on the FOPH website in accordance with Art. 71(2) and (6) of the KVV.

The publication does not include a) details of prices relating to reimbursements that are not publicly known (comparator drug and international reference price table, innovation premium, reimbursement amounts and international price comparison), b) details of confidential volume models, c) forecast total sales within the framework of a prevalence model, d) information regarding patent issues, e) data from unpublished studies whose rights are not held by the marketing authorisation holder, with the exception of cases in which the consent of the holder of the rights in question has been obtained, f) names of experts and g) information pertaining to the general issue and the exchange of written submissions."

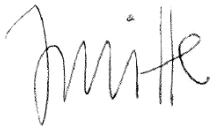
In principle, the non-publication of further information is still not intended and a specific reason will have to be provided for each piece of information not to be published according to the market authorisation holder.

3. Purpose of the change to the publication process

The aim is to ensure the timely and legally uniform publication of the FOPH's evaluation of drugs that are subject to the publication obligation (new additions, the extension of indications and the amendment of limitations) following the completion of the SL admission procedure.

Kind regards

Federal Office of Public Health



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