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Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
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FOPH

Registered mail
To all pharmaceutical companies concerned

Reference no.: 733.4-14
Our ref.: FRY/AKU
Bern, 6 December 2023

Amendments to Ordinances effective from 1 January 2024 / Triennial review of listing requirements in 2024[1,2,3]

Dear Sir or Madam

With effect from 1 January 2024, in accordance with the decision of the Federal Council adopted on 22 September 2023, Amendments to the Health Insurance Ordinance of 27 June 1995 (KVV; SR 832.102) and the Healthcare Benefits Ordinance of 29 September 1995 (KLV; SR 832.112.31) come into force, affecting the inclusion of pharmaceuticals in the List of Pharmaceutical Specialties (SL) and reviews of listing requirements for reimbursable pharmaceuticals. The Amendments effective from 1 January 2024 are presented in the first part of this letter, and their implementation is explained where necessary. Throughout the letter, references to provisions of the KVV and KLV relate to the versions valid from 1 January 2024.

The second part of this letter concerns the triennial review of listing requirements in 2024. Every three

[1] La traduction française de cette lettre sera publiée sur le site internet de l'Office fédéral de la santé publique : https://www.bag.admin.ch/bag/fr/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html

[2] La traduzione italiana di questa lettera verrà pubblicata sul sito internet dell'Ufficio federale della sanità pubblica: https://www.bag.admin.ch/bag/it/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html

[3] The original German version is available on the website of the Federal Office of Public Health: https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html

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years, the Federal Office of Public Health (FOPH) reviews all pharmaceuticals listed in the SL to determine whether they still meet the requirements for listing. This letter provides a detailed description of the implementation of the triennial review of listing requirements in 2024. Considering in particular the experience in 2017–2019, the FOPH has defined additional rules for the conduct of the review, namely with regard to the assessment of cost-effectiveness. Most of these rules were already announced in the circular letter for the 2020 review and are described again below. Also introduced are further rules and modifications based on experience or jurisprudence since 2019.

The rules described herein, particularly the rules on the internal reference price (IRP), essentially apply to all assessments of the criteria of efficacy, appropriateness and cost-effectiveness. Specific rules may apply to assessments in the context of applications for first listing, alterations of limitations, etc.

Contents

A Amendments to Ordinances effective from 1 January 2024

A.1 Amendments to the KVV and the KLV

With the Amendments of 22 September 2023 to the KVV and the KLV, the Federal Council adopted in particular modifications concerning reimbursement in individual cases, the assessment of cost-effectiveness for off-patent products, and processes and transparency. For details of the Amendments, please refer to the new Ordinance provisions, the Comments of 22 September 2023 on the Amendments, and the Pharmaceutical Measures Factsheets dated 22 September 2023 on "Reimbursement in individual cases", "Optimising processes and enhancing transparency" and "Measures to promote generics and biosimilars". These publications are available online (in French/German/Italian) at: https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-revisionsprojekte1.html#236602659.

Below, brief explanations are given of, in particular, the modifications concerning off-patent products, and processes and transparency. Unless otherwise indicated below, the implementation of the new provisions is explained in Section B.

A.1.1 Modifications concerning the assessment of cost-effectiveness for off-patent products

A.1.1.1 Assessment of cost-effectiveness for generics and biosimilars

For purposes of listing and review, generics and biosimilars are now considered to be cost-effective if the following price differentials are observed vis-à-vis the originator or reference product.

Market volume	Generics: Price differential for listing	Generics: Price differential for review
Up to CHF 4 m	20% (unchanged)	15% (previously 10%)
CHF 4–8 m	40% (previously 30%)	25% (previously 15%)
CHF 8–16 m	50% (unchanged)	30% (previously 25%)
CHF 16–25 m	60% (unchanged)	35% (previously 30%)
> CHF 25 m	70% (unchanged)	40% (previously 35%)

Market volume	Biosimilars: Price differential for listing (previously 25% for all biosimilars)	Biosimilars: Price differential for review (previously 10% for all biosimilars)
Up to CHF 8 m	20%	10%
CHF 8–16 m	25%	15%
CHF 16–25 m	30%	15%
> CHF 25 m	35%	20%

A.1.1.2 Differentiated cost share

The cost share which an insured person usually has to make as a contribution to the costs of a medicinal product is 10%. Products which are overpriced compared to others containing the same active substance(s) now attract a cost share of 40% (instead of 20%, as previously).

Biologics (reference products and biosimilars) are now also subject to the differentiated cost share. Details on the setting of price thresholds and on price reductions to avoid increased cost shares can be

found in the circular letters dated 29 August 2023[4] and 31 October 2023.[5]

A.1.1.3 Assessment of cost-effectiveness for medicines with known active substances

The assessment of medicines with known active substances is now regulated in the KVV. The regulations essentially correspond to those previously set out in the circular letters concerning the triennial review. The FOPH assesses the cost-effectiveness of such medicines by determination of the external reference price (ERP) and internal reference price (IRP). In this process, no account is taken of research and development costs, unless a therapeutic improvement has been demonstrated. In general, to demonstrate therapeutic added value, clinically relevant improvements over the reference product, confirmed by studies, must be shown. It is now specified that, if at least one generic with the same composition is listed in the SL, the cost-effectiveness of the medicine with a known active substance – unless it offers a therapeutic improvement over the generic – is to be assessed exclusively by means of comparison with the generic in question. This is designed to ensure that the prices of medicines with known active substances correspond to those of previously listed generics, as it is not appropriate for such medicines to be more expensive than generics if they do not offer any advantages over the latter.

A.1.1.4 Assessment of cost-effectiveness for medicines authorised for parallel imports

The assessment criteria for medicines authorised for parallel imports are now also defined in the KVV. The regulations correspond to the existing provisions in Section C.11.2 of the SL Manual of 1 May 2017.

A.1.2 Modifications concerning the ERP

In Art. 34*b* KLV, the Federal Department of Home Affairs (FDHA) has now specified not only the usual deductions, but also the minimum margins which must be deducted from the foreign pharmacy purchase or retail prices (the minimum margins were previously defined in the SL Manual). These minimum margins, at least, are now to be deducted, although it must still be shown by the foreign authorisation holder that in Denmark and the UK the average, standard deductions specified in Art. 34*b* para. 1 KLV are not applicable.

A.1.3 Ex-factory price and retail price

In Art. 67 KVV, it is now specified that the ex-factory price (EFP) does not include value added tax (VAT), and that the retail price (RP) comprises the EFP plus the distribution component plus VAT. In addition, instead of the RP, the EFP is now determined by the FOPH, as the RP results from the values specified for the distribution component in Art. 38 KLV and the VAT rate. From 1 January 2024, the FOPH will thus no longer determine new RPs in the event of adjustments to the VAT rate or distribution component. This does not apply to medicines with special distribution conditions (e.g. blood products).

A.1.4 Modifications concerning processes

Under Art. 69*a* KVV, the authorisation holder may now, for more complex applications, request an early dialogue with the FOPH prior to submission of the application; this may include an initial assessment of possible challenges and discussion of pricing proposals.

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[4] The information letter of 29 August 2023 on the calculation of the limit value of the differentiated cost shares is available (in French/German) at: https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Differenzierter-Selbstbehalt-bei-Arzneimitteln.html

[5] The information letter of 31 October 2023 on the determination of the limits for the differentiated cost shares for biologics is available (in French/German) at: https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Differenzierter-Selbstbehalt-bei-Arzneimitteln.html

In the case of medicines with high medical need, the authorisation holder may – after a second early dialogue, involving Swissmedic – submit the application to the FOPH before the preliminary decision has been issued by Swissmedic (early access). Prerequisites for an early-access process are adequate documentation of the application through clinical studies, a clear indication, and a high likelihood of authorisation. With early submission, it is possible that the granting of marketing authorisation by Swissmedic and reimbursement with SL listing can occur simultaneously.

Early dialogue, or early access, can only be requested for the types of application specified in Art. 31*d* KLV and will only be agreed to in cases where the FOPH recognises the need for discussions in view of the complexity of the application and/or the high medical need, in accordance with the type of application for marketing authorisation. In addition, the FOPH must have the necessary resources available.

A.1.5 Modifications concerning enhanced transparency

In accordance with Art. 71 KVV, the FOPH now publishes the foundations for the triennial review assessment and the assessment of applications for price increases. Also to be published are the reasons for rejections of applications for SL listing of an originator product, price reductions and the removal of products from the SL. In addition, following receipt of an application for an originator product, details are also to be published of the originator product concerned and of the condition for which reimbursement of a treatment is sought.

Publication of amendments to the SL in the BAG Bulletin is being discontinued. Amendments to the SL can be found in the online SL (www.spezialitaetenliste.ch), which is updated on the 1st of each month.

A.2 Commencement and transitional provisions

The Amendments to the KVV and the KLV come into effect on 1 January 2024. Under the transitional provisions for the Amendments of 22 September 2023 to the KVV and the KLV, the Amendments of 22 September 2023 are also applicable for procedures pending with the FOPH when the Amendments come into force. An exception to this are procedures for the triennial review of listing requirements which are pending with the FOPH when the Amendments of 22 September 2023 come into effect. For these, current law is applicable.

A.3 SL Manual

As a result of the Amendments to Ordinances effective from 1 January 2024, the SL Manual of 1 May 2017 is no longer current in every respect. An updated version of the Manual is expected to be published in mid-2024. In this letter, any references to the Manual relate to the version dated 1 May 2017.

B Triennial review of listing requirements

B.1 Frequency of reviews

Under Art. 65*d* para. 1 KVV, every three years the FOPH reviews all pharmaceuticals listed in the SL to determine whether they still meet the requirements for listing. To ensure that the three-year review frequency can be complied with, the FOPH has assigned all SL pharmaceuticals to one of three similarly sized units, according to the therapeutic (IT) group. Each year, one unit is reviewed. Thus, it is assured that around a third of the pharmaceuticals listed in the SL are reviewed per year, and that pharmaceuticals in the same therapeutic group are reviewed in the same year.

In 2024, Unit B, comprising pharmaceuticals in the following IT groups, is to be reviewed:

IT group	**REVIEW YEAR 2024**
1/51	Nervous System
5/55	Kidneys and Water Balance
6/56	Blood
10/60	Dermatological Products
13	Odontostomatological Products
14	Diagnostic Agents

A list of the products (originator products[6] and generics with no corresponding originator product) to be reviewed in 2024 is published on the FOPH website at: https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html

B.2 Exemptions

In the following cases, pharmaceuticals in Unit B are exempted from the 2024 triennial review:

- The first triennial review is carried out at the earliest in the second year after listing in the SL (Art. 34*d* para. 2 let. b KLV). Exempted from the review, therefore, are originator products which, as of 1 January 2024, have been listed in the SL for less than 13 months – i.e. which were first listed in the SL on or after 1 January 2023. These originator products in Unit B will not be subject to a triennial review until 2027.
- If an originator product has been reviewed in connection with an extension of indications or an alteration of limitations, in accordance with Art. 65*f* para. 4 KVV, by determination of the external reference price (ERP) and IRP, then the next triennial review is carried out at the earliest in the second year after the extension of indications or alteration of limitations. The next triennial review of the listing requirements for these Unit B originator products for which an extension of indications or alteration of limitations was performed in 2023, or will be performed before the completion of the triennial review in 2024, will not be carried out until 2027 (Art. 34*d* para. 2 let. a KLV).
- Generics, co-marketing medicines and biosimilars containing the same active substances are reviewed at the same time as the originator product, basic product or reference product in the event

[6] In this letter, unless otherwise indicated, the term “originator product” is used to refer both to originator products in the strict sense and to reference products and products with known active substances which, like originator products, are reviewed by determination of the ERP and IRP.

of an alteration of limitations or extension of indications for the originator product, basic product or reference product (Art. 66*a*, 66*b* KVV). The cost-effectiveness of generics, co-marketing medicines and biosimilars is assessed in the same way as the assessment of cost-effectiveness in the triennial review, which is why the next review of the generics, co-marketing medicines and biosimilars concerned will also not be carried out until 2027, provided that the triennial review for the originator product, basic product and reference product is also only carried out again in 2027.

- Originator products listed in the SL for a limited period or with limited-period extensions of the limitation or with indications reimbursed for a limited period are not subject to a triennial review of listing requirements (Art. 34*d* para. 2 let. c KLV). Part of Section E.1.2 of the SL Manual of 1 May 2017 is accordingly revoked. For these pharmaceuticals, a standard application is to be submitted in good time prior to the expiry of the specified period. The listing requirements will be reviewed in connection with this submission.

B.3 Transfer of pharmaceuticals to treat congenital conditions to the List of Pharmaceutical Specialities for Congenital Conditions (GG-SL) and the SL

As previously noted by the FOPH and the Federal Social Insurance Office (FSIO) in the circular letter dated 14 July 2021,[7] the legal reform programme "Further development of Disability Insurance (IV)" (WEIV) was approved by the Swiss Parliament on 19 June 2020. The revised Federal Act of 19 June 1959 on Disability Insurance (IVG; SR 831.20) came into effect together with amendments to the relevant Ordinance provisions on 1 January 2022.

Under Art. 14ter para. 5 of the revised IVG, the competent Federal Office is to prepare a list of pharmaceuticals for the treatment of congenital conditions in accordance with Art. 13 of the Act. For this purpose, the List of Pharmaceutical Specialties for Congenital Conditions (GG-SL) was established. The GG-SL supersedes the existing Congenital Conditions Medication List (GGML) and the listing of pharmaceuticals in the IV Circular on medical integration measures (KSME). Accordingly, all pharmaceuticals listed in the KSME and in the GGML are to be transferred to the new GG-SL or to the SL, provided that they are authorised by Swissmedic for use in a congenital condition and meet the requirements for listing in the GG-SL or SL. Pharmaceuticals which are currently listed in the SL but meet the requirements for listing in the GG-SL will also be transferred to the GG-SL. Listing in the GG-SL or SL requires an assessment procedure involving evaluation of the efficacy, appropriateness and cost-effectiveness criteria, together with a price-setting procedure.

The transfer to the relevant list will be effected in connection with the triennial review of listing requirements. In 2024, pharmaceuticals on the GG-SL, KSME and SL that belong to a therapeutic group as per table in section B.1 above will be reviewed. For further details on the transfer of pharmaceuticals to treat congenital conditions to the GG-SL and SL, please refer to the supplement to the SL Manual of 20 December 2021[8] and the information letter of 10 December 2021 concerning the triennial review of listing requirements in 2022 / Listing of pharmaceuticals for the treatment of congenital conditions in the List of Pharmaceutical Specialities for Congenital Conditions (GG-SL) and in the List of Pharmaceutical Specialities (SL).[9]

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[7] Information letter by the FSIO and the FOPH dated 14 July 2021 on the inclusion of medicines to treat congenital conditions in the List of Pharmaceutical Specialities for Congenital Conditions (GG-SL) and List of Pharmaceutical Specialities (SL) is published (in German, French and Italian) at https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Mitteilungen-zur-Spezialitaetenliste.html

[8] The supplement of 20 December 2021 to the SL Manual is published (in German, French and Italian) at https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen/antrag-sprozesse/AntragsprozessArzneimittel.html

[9] Information letter dated 10 December 2021 concerning the triennial review of listing requirements in 2022 / Listing of pharmaceutical for the treatment of congenital conditions in the List of Pharmaceutical Specialities for Congenital Conditions (GG-SL) and in the List of Pharmaceutical Specialities (SL) is published at: https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html

B.4 Online portal

To minimise effort for both parties and to shorten communication paths, the FOPH grants authorisation holders for originator products and generics with no corresponding originator product access to an online portal where data on efficacy, appropriateness and cost-effectiveness is to be submitted. Relevant documents – such as cover letters, basis for calculations, references, etc. – can be uploaded to the portal in pdf format. Documentation is not to be sent to the FOPH via any other channels (post, e-mail).

For the procedure to run smoothly, the authorisation holder must enter the information in the online portal in good time. Under Art. 68 para. 1 let. f KVV, a pharmaceutical will be removed from the SL if the authorisation holder refuses to submit the documentation necessary for the triennial review of listing requirements.

B.4.1 2024 online portal

The online portal will be accessible from 8 January 2024 at:

https://bag.hcisolutions.ch/Ueberpruefung2024

The authorisation holder's data is protected by a user-specific password. Please note that User IDs and passwords are case sensitive. For your company, the User ID and password are as follows:

User ID:

Password:

For the individual criteria, instructions are provided on the online portal.

To ensure error-free operation of the online portal, it may only be opened in one browser window at a time.

B.4.2 Previous years' online portals

The 2017–2023 portals can still be accessed. The URLs of the websites changed on 1 January 2020. Data entered in the portal in previous years will still be available to authorisation holders at the new URLs with the passwords generated for each of the years in question.

Access data:

Review year	New URL
2017	https://bag.hcisolutions.ch/Ueberpruefung2017
2018	https://bag.hcisolutions.ch/Ueberpruefung2018
2019	https://bag.hcisolutions.ch/Ueberpruefung2019
2020	https://bag.hcisolutions.ch/Ueberpruefung2020
2021	https://bag.hcisolutions.ch/Ueberpruefung2021
2022	https://bag.hcisolutions.ch/Ueberpruefung2022
2023	https://bag.hcisolutions.ch/Ueberpruefung2023

B.5 Groups of dosage forms

The various dosage forms of a pharmaceutical are divided into **16 different groups** (Section E.1.3 of the SL Manual). A separate assessment of the listing requirements is carried out for each group.

B.6 Assessment of efficacy and appropriateness

In the triennial review of listing requirements, efficacy and appropriateness are assessed on the basis of Art. 65 and 65*a* KVV.

While approval by Swissmedic is a prerequisite for listing of a pharmaceutical in the SL, it is not in itself decisive for a positive evaluation of efficacy and appropriateness by the FOPH. Reference by the authorisation holder to the approval granted by Swissmedic is not sufficient to demonstrate that the efficacy and appropriateness criteria are met.

Using the online portal, authorisation holders comment separately on efficacy and appropriateness. They are required to report, in particular, changes crucial for the evaluation compared to the last review, listing, alteration of limitations, or extension of indications, such as new or updated study results, meta-analyses, guidelines, revised prescribing information, etc. They can also upload new data and information – in particular, publications on clinical trials – to the online portal.

The FOPH evaluates the fulfilment of the criteria on the basis of the information submitted. It may also take additional information into account (e.g. clinical studies, meta-analyses, Health Technology Assessments [HTA], guidelines, etc.).

B.7 Assessment of cost-effectiveness

B.7.1 Information on patent protection

The authorisation holder must inform the FOPH whether a "review of the listing requirements after patent expiry" has been conducted in accordance with Art. 65*e* KVV for the pharmaceutical concerned. If such a review has been carried out, the date of the decision, or of the most recent communication from the FOPH relating to this review, is to be indicated. In addition, details of the relevant patents and their expiry dates are to be provided to the FOPH. The FOPH will take into consideration any patents entered by the authorisation holder on the online portal by 15 February 2024.

B.7.2 Determination of the external reference price (ERP)

Under Art. 34*a*^{bis} KLV, the ERP is determined on the basis of a comparison with prices in Germany, Denmark, the UK, the Netherlands, France, Austria, Belgium, Finland and Sweden. Comparisons are made with the same pharmaceutical in the reference countries, irrespective of the name, indication, authorisation holder and reimbursement status of the product in the reference country, and irrespective of whether the Swiss authorisation holder can influence the EFP in the reference country. Originator products with the same active substance/s and the same dosage form are considered to be the same pharmaceuticals. No account is taken of pharmaceuticals subject to parallel imports in the reference countries. Medical devices may be considered to be the same pharmaceuticals and thus be taken into account in the determination of the ERP.

The cut-off date for the ERP is 1 January 2024 (Art. 34*e* para. 1 KLV). For the ERP, the EFP in the various reference countries is essentially to be taken into account. While the EFP is not published in Denmark, the UK, the Netherlands, Finland or Sweden, pharmacy purchase prices (Netherlands, Denmark, Finland, Sweden) or retail prices (UK) are publicly accessible. For these reference countries, the EFP can be calculated by applying the following deductions, as specified in Art. 34*b* para. 1 KLV:

- Denmark: for patented originator products: 6.5% of the pharmacy purchase price, but not more than DKK 224; for off-patent originator products: 5% of the pharmacy purchase price, but not

more than DKK 224

- UK: 12.5% of the retail price
- Netherlands: 6.5% of the pharmacy purchase price, but not more than EUR 30
- Finland: 3% of the pharmacy purchase price, but not more than EUR 30
- Sweden: 2.7% of the pharmacy purchase price, but not more than SEK 167

If the authorisation holder can demonstrate that in Denmark or the UK the actual deduction differs from the deduction specified in Art. 34*b* para. 1 KLV, then the actual deduction will be applied. However, the deduction from the pharmacy purchase price or from the retail price must not be less than:

- Denmark: for patented originator products: 3% of the pharmacy purchase price
- UK: 2% of the retail price.

The (publicly known) mandatory manufacturer's rebate in Germany is also taken into account for the ERP (Art. 65*b*^{quater} KVV in conjunction with Art. 34*b* para. 3 KLV). This generally amounts to 7% for originator products which are patented in Germany (5.88% after sales tax) and 16% for off-patent originator products (13.44% after sales tax). A different rebate provided by a pharmaceutical company can be taken into account if it is appropriately recorded in the Lauer-Taxe (cf. Section C.3.4 of the SL Manual) (Art. 34*b* para. 4 KLV). If the authorisation holder or the FOPH can demonstrate that the actual manufacturer's rebate differs from the values given in Art. 34*b* para. 3 KLV, then the actual manufacturer's rebate will be deducted (Art. 34*b* para. 4 KLV).

Confirmations of the price provided by the authorisation holder in the reference country, an authority or an association are to be uploaded to the portal as supporting documentation; if appropriate, differing deductions in Denmark and the UK or a differing manufacturer's rebate in Germany should also be documented. If the authorisation holder receives no information from a country on the EFP or on the deduction, then the deductions specified in Art. 34*b* para. 1 KLV are to be applied.

The EFP in the reference countries is converted to Swiss francs on the basis of a yearly average (Swiss National Bank) exchange rate determined by the FOPH (Art. 34*c* para. 2 KLV). For the triennial review of listing requirements in 2024, the average exchange rates for the period January 2023 to December 2023 are applicable, published by the FOPH by 4 January 2024 at the latest. The exchange rates are available on the online portal.

Serving as a basis for determination of the ERP is the **highest-selling** package in a group over the last twelve months in Switzerland (Art. 65*d* para. 2 KVV in conjunction with Art. 34*c* para. 2 KLV). To determine the highest-selling package, the FOPH can request the authorisation holder to provide the relevant sales figures.

If the package size or dosage strength of the highest-selling package is not available in the reference countries, then the prices of the most comparable package size and dosage strength available in these countries are to be indicated. The prices of different packages with the same dosage strength and different dosage strengths with the same package size are to be increased or decreased in a linear manner.

The authorisation holder must report to the FOPH, via the online portal, by **15 February 2024** the EFP applicable on 1 January 2024 for the highest-selling package in each group in the reference countries (Art. 34*e* para. 1 KLV), as well as uploading confirmations of the price from all the reference countries.

B.7.3 Determination of the internal reference price (IRP)

B.7.3.1 Determination of the main indication

In the case of pharmaceuticals with a number of different indications, the IRP is determined for the main indication. The authorisation holder must report the main indication to the FOPH and provide a justification, based for example on prevalence statistics. Market figures will not be taken into account.

In addition, in determining the main indication, the following points are to be considered:

- The line of treatment in which a pharmaceutical is used is to be taken into account in the determination of the main indication.
- It may be appropriate to deviate from prevalence as the sole criterion for determining the main indication, e.g. if there is a lack of clarity as to the indication of a pharmaceutical with the highest prevalence, or if a pharmaceutical is no longer used for the main indication as determined by prevalence.
- If a pharmaceutical is used both in combination with other pharmaceuticals and also as monotherapy, then the monotherapy is generally applicable as the main indication, irrespective of other criteria such as line of treatment. This is because, when used as monotherapy, the therapeutic effect can be attributed to the individual pharmaceutical, which is not unequivocally possible when several pharmaceuticals are used in combination.

The FOPH has the option of specifying conditions and requirements for other indications, so that the pharmaceutical also meets the criterion of cost-effectiveness in these indications (Section E.1.9.1 of the SL Manual). If the price level for a secondary indication is lower than the cost-effective EFP newly determined for the main indication, reimbursement levels can be set in an indication-specific manner. The different reimbursement levels can then be specified as a requirement in accordance with Art. 65 para. 5 KVV, using a reimbursement model.

B.7.3.2 Choice of comparators

B.7.3.2.1 Principle

To determine the IRP in accordance with Art. 65*b* para. 2 let. a KVV, comparisons are made with originator products, and with medicines with known active substances not listed as generics in the SL, which are listed in the SL at the time of the review and which are used to treat the same medical condition (Art. 34*f* para. 1 KLV).

Use in the same indication (therapeutic alternative) is the factor determining the choice of comparator. This may be the case particularly for pharmaceuticals belonging to the same class of active substance. Pharmaceuticals belonging to other classes of active substance may, however, also be taken into account for the purposes of the IRP if this is appropriate.

Not decisive for the choice of comparator is authorisation for the treatment of specific patient groups, e.g. children and adolescents, unless the pharmaceutical in question is explicitly or mainly authorised for the treatment of specific groups, or specific groups make up a relevant proportion of the patient population. It is thus, for example, irrelevant in the case of an IRP determined in relation to the adult patient population whether the comparators are authorised for the same age groups.

Pharmaceuticals used in different lines of treatment do not count as therapeutic alternatives. This does not apply to pharmaceuticals which, due to lower efficacy and/or tolerability, are only reimbursed in a later line of treatment. To determine the IRP in these cases, pharmaceuticals from the earlier line of treatment can also be considered, provided that they cost less than the pharmaceuticals used in the later line of treatment. This is because there is no justification for a therapy that is only used in a later line of treatment, due to poorer efficacy or tolerability, being more expensive than a therapy with better efficacy and tolerability.

For purposes of selection of comparator products, the prescribing information, the SL (limitations) and national and international guidelines are taken into account. The comparator group may also only consist of a selection of possible comparators – i.e. it need not be made up of all the eligible (i.e. comparable) pharmaceuticals. In particular, exceptionally expensive medicines of equal efficacy may be excluded from the comparison (Federal Supreme Court ruling BGE 143 V 369).

The price of the pharmaceutical under review itself and other formulations of the same pharmaceutical are not taken into account in the determination of the IRP level (Federal Administrative Court ruling

C-6105/2013 of 13 February 2017). Co-marketing medicines for which the base products are listed in the SL are likewise not taken into consideration for the IRP.

B.7.3.2.2 Pharmaceutical form

Relevant for the choice of comparators is the pharmaceutical form, or membership of a particular group (cf. Section B.5, "Groups of dosage forms"). For example, oral forms are compared with oral forms, parenteral with parenteral, etc. Comparison with other pharmaceutical forms is possible, especially if no comparators in the same form are listed in the SL and thus assigned to the same group for review. Pharmaceuticals in the oral and oral delayed-release groups can be compared with pharmaceuticals in the oral and oral delayed-release groups if they represent therapeutic alternatives and are comparable in terms of cost-effectiveness. For example, a pharmaceutical in the oral group can be compared with pharmaceuticals in the oral and oral delayed-release groups if the specified conditions are met.

B.7.3.2.3 Patent status

In the assessment of patented originator products, research and development costs are generally taken into account; accordingly, they are typically compared with patented originator products. If off-patent originator products are also to be considered in the determination of the IRP for patented originator products, the prices of these pharmaceuticals before the first price reduction following patent expiry will be taken into account for the IRP. If a "review of the listing requirements after patent expiry" was conducted in accordance with Art. 65*e* KVV, the prices before the price reduction will be taken into account in the context of this review (Section E.1.9 of the SL Manual).

Off-patent originator products are compared with off-patent originator products (Section E.1.9 of the SL Manual). If comparison with an off-patent originator product is not possible, the comparison may exceptionally be carried out with patented originator products, taking into account a 20% deduction from the EFP of the patented originator products. Background information on the determination of this deduction can be found in the letter of 9 May 2022 to the associations of pharmaceutical companies and health insurers.[10]

If a patented pharmaceutical is compared with a combination of more than one pharmaceutical (e.g. pharmaceutical A and pharmaceutical B) for the purposes of the IRP, consideration will be given to whether or not the patent for the comparators has expired (this rule does not apply to fixed-dose combination products [FDCs]; cf. Section B.7.3.2.6):

a) The comparators are still patented: the current prices of the comparators are taken into account.

b) One comparator is still patented (e.g. pharmaceutical A) and the second is off-patent (e.g. pharmaceutical B): the current prices of the comparators are taken into account, including pharmaceutical B, which is off-patent.

c) Both comparators are off-patent: the price before patent expiry is taken into account for the pharmaceutical (e.g. pharmaceutical A) whose patent expired later. For the other pharmaceutical (pharmaceutical B), the current price is taken into account.

B.7.3.2.4 Me-too products and medicines with known active substances

The term "me-too products" is used by the FOPH to refer to originator products which differ only slightly from another originator product (e.g. minor modification of the active substance molecule not affecting efficacy or offering any advantages in terms of efficacy; a different dosage form with the same or a

[10] The letter of 9 May 2022 to the associations of pharmaceutical companies and health insurers is available (in German and French) at https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Mitteilungen-zur-Spezialitaetenliste.html

different route or frequency of administration – so-called pseudo-innovation). If an originator product is a me-too product, which has shown no therapeutic improvement over the existing originator product listed in the SL, the research and development costs are not taken into account, irrespective of the patent status (Art. 65*b*^{bis} para. 2 KVV). Determination of the IRP involves comparison with off-patent originator products and medicines with known active substances not listed in the SL as generics; comparison with patented originator products is possible in exceptional cases if no off-patent therapeutic alternatives are available. In such cases, comparisons can be carried out with patented originator products, taking into account a 20% deduction from the EFP of the patented originator products.

Pharmaceuticals authorised by Swissmedic as medicines with known active substances and not listed as generics in the SL are also considered to be me-too products. The assessment of medicines with known active substances is as described in Section B.10.

Me-too products and medicines with known active substances may also be included in the determination of the IRP for off-patent originator products. This excludes medicines with known active substances which are listed in the SL as generics or are compared with generics in accordance with Section B.10.

B.7.3.2.5 Comparator subject to an appeal

If a comparator is the subject of an appeal, this product may be taken into consideration for the IRP, although exceptionally expensive comparators of equal efficacy may be excluded (see above). If a comparator which is the subject of an appeal is taken into consideration for the IRP, then, on completion of the review, it will be specified as a requirement that the price is to be reviewed once again if the prices of the comparator in question have to be adjusted as a result of a court ruling. In this case, the FOPH will take into consideration the new price of the comparator concerned. When the subsequent review is performed, the prices of other comparators taken into account in the triennial review of listing requirements and the prices in the reference countries will not be modified.

B.7.3.2.6 Fixed-dose combination products

The IRP is determined taking the following criteria into account.

Under Section C.8.1 of the SL Manual, what is decisive for the IRP in the case of combination products are the SL mono-products with the active substances contained in the combination product, provided that these mono-products are authorised for treatment of the same condition and are reimbursed. Section C.8.1.3 of the SL Manual specifies that comparable combination products are to be taken into account for the IRP provided that they are authorised for treatment of the same condition and are reimbursable. Likewise, the FOPH may take other mono-products into account for the IRP, particularly if these have been used as comparison therapies in head-to-head studies and are reimbursable for the indication in question. Section C.8.1.3 of the SL Manual was revoked with the circular letter of 2 December 2019, insofar as, since 2020, combination products are generally to be compared with the mono-products containing the same active substances which are authorised for treatment of the same condition and are reimbursed, since a combination product should not cost more than the mono-products combined. With the circular letter of 9 December 2022, Section C.8.1.2 of the SL Manual was also revoked. It was also specified that both mono-products and combination products with the same active substances may represent therapeutic alternatives to combination products. Since 2023, combination products have therefore been compared with the mono-products **and** combination products with the same active substances that represent therapeutic alternatives. Here, mono-products containing the same active substances represent one possible therapeutic alternative and each combination product represents an additional therapeutic alternative; accordingly, the comparison with the mono-products containing the same active substances is accorded the same weight as the comparison with a combination product: if the comparison is made with the mono-products and with one combination product, then the comparison with the mono-products receives a 50% weighting; if the comparison is made with the mono-products and with two combination products, then the comparison with the mono-products

receives a one-third weighting, and so on. In the interests of consistency in determining the IRP, products that are exceptionally expensive may be excluded from the comparison, in accordance with the corresponding general rule (see above).

For the comparison with mono-products containing the same active substances, at most, the sum of the costs of the relevant mono-products is taken into account. If the cost-benefit comparison shows that the combination offers a lower benefit than the mono-products, then this may be taken into account by the FOPH. If generics or biosimilars are listed in the SL for one or more active substances, then, for the active substance(s) concerned, the average cost of the originator product or reference product and the generics or biosimilars is used. Co-marketing medicines of the originator product or reference product are not taken into account.

If no comparable combination products are available or, conversely, if no comparable mono-products containing the same active substances are available (or not for all active substances), then the IRP is determined solely using the only possible option.

Combination products are considered to be me-too products in accordance with Art. 65*b*^{bis} para. 2 KVV. Accordingly, the costs of research and development are not taken into account, and they are essentially treated as off-patent pharmaceuticals. However, if an active substance is currently patented, then the costs of research and development will be taken into account. Accordingly, the determination of the IRP is dependent on the patent status of the mono-products, while the patent status of the combination product is irrelevant for the determination of the IRP:

a) All active substances are still patented: the comparison is made with all mono-products containing the same active substances and the combination products containing only patented active substances.

b) One active substance is still patented and the second (or other) is now off-patent: the comparison is made with all mono-products containing the same active substances and the combination products that also contain at least one patented and at least one off-patent active substance.

c) All comparators are now off-patent: the comparison is made with all mono-products containing the same active substances and the combination products whose active substances are also off-patent.

If the mono-products with the active substances contained in the combination product are not reimbursed in combination, the IRP is determined on the basis of other mono-products or combination products for the treatment of the same condition.

B.7.3.3 Determination of the IRP

As a rule, the IRP is determined on the basis of the smallest package of the lowest dosage strength, unless an adequate comparison is not possible with the smallest package of the lowest dosage strength, particularly on account of differences in the starting dosage or package size of the comparator products, or because the various dosage strengths of the comparators are the same price (Art. 65*d* para. 3 KVV). Deviation from the principle of the smallest package of the lowest dosage strength is thus possible, for example, if, for one of the products considered in the comparison, the lowest dosage strength is only required for initial dose adjustment, or if a comparator is not available in a small package (Section E.1.9 of the SL Manual). Deviation is also possible if a dosage strength is only used for a dose reduction specified in the prescribing information for the prevention of adverse effects or for the treatment of specific patient groups, or if individual comparators are subject to flat pricing. In this case, for all originator products considered in the comparison which are not subject to flat pricing, use is to be made of notional daily treatment costs, determined by averaging the costs of the various dosage strengths.

The IRP is generally determined on the basis of daily, monthly or yearly treatment costs, or the costs of a course of treatment. The IRP is based on daily, monthly or yearly treatment costs in cases of long-term therapy or if the treatments to be compared are administered for the same length of time. In cases where treatments of different duration produce comparable effects, the costs of a course of treatment are considered (e.g. antibiotics or cytostatics). For calculations of treatment duration, a year consists of 365 days and a month of 30.41667 days. A multi-year treatment duration usually comprises x times 365

days where x is the number of years.

For the IRP, the maintenance dosage for adults is normally taken into account. Specific uses in children and adolescents are essentially irrelevant for the IRP, unless the product in question is authorised exclusively for children and adolescents or use in children and adolescents represents its main indication. The determination of the maintenance dosage to be taken into account is essentially based on the details given in the prescribing information. If a recommended or standard maintenance dosage is explicitly mentioned and described as the recommended or standard dosage in the prescribing information (similar expressions such as “in general” are also applicable), then this dosage should be taken into account. A dosage range may also be listed as the maintenance dosage in the prescribing information. In this case, the mean value of the dosage range is taken into account. If the prescribing information does not specify a recommended or standard maintenance dosage, then the average of the entire dosage range required for maintenance therapy specified in the prescribing information can be taken into account. Low or high doses used in exceptional cases are not generally taken into account. If the maintenance dosage is not clearly apparent from the prescribing information, information may be taken from the patient information, guidelines, clinical trials or foreign registration documents. If direct comparison studies are available, the dosages may also be taken from these studies.

In the case of **parenteral agents** where dosage forms (e.g. ampoule, vial) once opened cannot subsequently be used for the next administration or in a new treatment cycle, **whole** ampoules, vials, etc. are taken into account for the IRP, even if whole ampoules, vials, etc. would not be required, given the average maintenance dosage. Exceptions may be made if it is apparent from the prescribing information that opened ampoules or vials will keep for a sufficient period to allow them to be used for the continuation of therapy or for renewed treatment in the same patient (e.g. in the next cycle of cancer treatment). In such cases, opened packages are to be counted as whole packages only for treatments administered for a limited period (e.g. cytostatics, parenteral antibiotics) and only at the end of treatment or in the last cycle.

For oral therapies administered for a limited period (e.g. cytostatics, antibiotics), opened packages are counted as whole packages only in the last cycle or at the end of treatment, since in the preceding cycles an opened package can continue to be used in the next cycle.

For parenteral **cancer drugs,** it is possible to deviate from the principle of the smallest package of the lowest dosage strength and instead take into account the most suitable package (or combination of packages) per administration that leads to the lowest wastage and is the most cost-effective. If, given the shelf life and dosage form, it is possible for opened ampoules, vials, etc. to be used for more than one administration within a cycle or for an entire course of treatment, then the most suitable package (or combination of packages) for the treatment course may be taken into account, with the last opened package (or combination) being fully counted in the case of treatments administered for a limited period (e.g. cytostatics, antibiotics). If the package combination with the lowest wastage is not also the most cost-effective option, then the most cost-effective package or combination of packages is to be taken into account in determining the IRP.

If dosing is based on bodyweight or body surface area, the following average values are generally used for adults. The values applicable to men and women are only considered if a pharmaceutical is used exclusively for men or women.

	Adults	**Women**	**Men**
Body surface area[11]	1.79 m^2	1.71 m^2	1.91 m^2
Weight[12]	73 kg	65 kg	81 kg

[11] Sacco JJ et al. The Average Body Surface Area of Adult Cancer Patients in the UK: A Multicentre Retrospective Study, PLoS ONE, 2010 Jan 28;5(1): e8933.

[12] Federal Statistical Office, 2019

B.7.3.4 Reporting of the IRP

The authorisation holder must report the IRP to the FOPH by **15 February 2024,** and also enter on, or upload to, the online portal all data and references used for the comparison (Art. 34*f* para. 2 KLV). In a separate letter, the authorisation holder must justify to the FOPH, in particular, the selection of pharmaceuticals and the dosages considered for the IRP. The calculation of the IRP level must be comprehensible for the FOPH; a tabular representation is desirable, as in the following example:

Product	Dose [mg]	Package size [units]	Maintenance dose	EFP [CHF]	Daily treatment costs [CHF]
Phenomenon	10	20	25 mg once daily	13.20	1.6500
Exemplia	20	28	20 mg once daily	29.80	1.0643
Beispieleia	5	30	5 mg three times daily	17.65	1.7650
IRP level					1.4146
IRP price Phenomenon, 10 mg, 20 units [CHF]					11.32

B.7.3.5 Changes during the review year

The FOPH takes into account changes in the data required for the IRP and in the EFP applicable for comparators up to and including 1 July of the review year (Art. 34*f* para. 3 KLV). An exception to this are removals of comparator products or individual packages thereof from the SL (Federal Administrative Court ruling C-588/2018 of 5 December 2019 E. 7.2.5.6). Delistings already implemented are taken into account up to the date of the decree issued in connection with the review.

If the price of the pharmaceutical reviewed changes, or if packages of the pharmaceutical reviewed are included in the SL for the first time or removed from the SL, these changes will be taken into account up to the date of the decree issued in connection with the triennial review. On the online portal, any criteria already concluded will be revoked by the FOPH to ensure that the new data are correctly presented and taken into account for the review.

B.7.3.6 No therapeutic alternative

If the pharmaceutical to be reviewed is the only one in the relevant indication, and no therapeutic alternative is thus available, then an IRP is not to be determined.

B.7.4 Example: calculation of the reduction rate

The ERP and the IRP are equally weighted (Art. 65*b* para. 3 KVV).

The reduction rate determined from the IRP is applied to the highest-selling package, with the existing price ratios being maintained:

$EFP_{\text{old highest-selling package}}$ + reduction rate IRP = EFP $IRP_{\text{highest-selling package}}$

Next, the cost-effective EFP of the highest-selling package is calculated, and the reduction rate is determined as a percentage:

$EFP_{\text{new highest-selling package}}$ = (EFP $ERP_{\text{highest-selling package}}$ + EFP $IRP_{\text{highest-selling package}}$) / 2

Reduction rate = ($EFP_{\text{old highest-selling package}}$ - $EFP_{\text{new highest-selling package}}$) / $EFP_{\text{old highest-selling package}}$ * 100

This reduction rate is applied to all packages in the same dosage-form group.

The reduction rate is calculated from the ERP and the IRP, rounded to two decimal places, with the result being expressed to 7 decimal places.

Example

Initial situation:
Oral dosage-form group, two different package sizes
Highest-selling package: 90 tablets
Smallest package: 30 tablets

Step 1: Calculation: ERP for highest-selling package and IRP for smallest package		
EFP_{old} 90 tablets: CHF 95.00	ERP 90 tablets = CHF 80.00	
EFP_{old} 30 tablets: CHF 35.30	IRP 30 tablets = CHF 40.00	Difference: +13.31444759%

Step 2: Calculation: IRP for highest-selling package
IRP 90 tablets = CHF 95.00 + 13.31444759% = CHF 107.6487252, expressed as CHF 107.65

Step 3: Cost-effective price level: 50 : 50 weighting of ERP and IRP
EFP_{new} 90 tablets: **= (CHF 80.00 + CHF 107.65)/2 = CHF 93.825, expressed as CHF 93.83**

Step 4: Determination of reduction rate as a percentage
Percentage reduction rate: (CHF 95.00 – CHF 93.83)/CHF 95.00 * 100 = 1.2315789%

Step 5: Result The reduction rate is applied to all packages in the same dosage-form group.
EFP_{new} 30 tablets = CHF 35.30 - **1.2315789%**= **CHF 34.8652526, expressed as CHF 34.87**
EFP_{new} 90 tablets = CHF 95.00 - **1.2315789%** = **CHF 93.83**

B.7.5 Extent of reduction of ex-factory price

If the triennial review of listing requirements indicates that the current highest price does not meet the cost-effectiveness requirement, the FOPH will order that the price be reduced, with effect from 1 December of the review year, to the EFP resulting from the assessment of cost-effectiveness based on the ERP and IRP in accordance with Art. 65*b* para. 3 KVV (Art. 65*d* para. 4 KVV).

If no ERP or no IRP can be determined, cost-effectiveness is assessed on the basis of the results of one of the two pricing criteria.

If, after the determination of the ERP and IRP and the weighting of the prices resulting from these two criteria, it is shown that the existing EFP of the pharmaceutical is below the price level calculated, then no price reduction is ordered by the FOPH.

If, in the triennial review of listing requirements, the FOPH determines that certain packages in a dosage-form group have a higher price than another comparable package (e.g. different dosage form) and if this difference in price is neither intended nor justifiable on medical/therapeutic grounds, then the FOPH, after completing the triennial review of listing requirements, will reduce the price of the more expensive package to the price level of the comparable cost-effective package.

B.8 Extension of indications or alteration of limitations in the review year

If use of the prevalence model is requested in connection with an extension of indications or an alteration of limitations, and if the pharmaceutical is subject to a triennial review of listing requirements in the same year, then the following applies: The notification of an extension of indications or the application for an alteration of limitations must be completed by no later than the end of May 2024. An application for an alteration of limitations is considered to be completed if the FOPH has issued a decree and any amendment required to the SL (e.g. price reduction, new limitation) has been implemented by 1 June 2024 at the latest. In the period from June 2024, no extension of indications or alteration of limitations using the prevalence model can be ordered for pharmaceuticals subject to a triennial review of listing requirements in 2024; this is only possible again after the triennial review has been completed. These procedures (extending indications or altering limitations and reviewing listing requirements every three years) run in parallel independently of one another. The triennial review of listing requirements will be continued after the completion of the extension of indications or alteration of limitations.

If the use of the ERP and IRP is requested in connection with an extension of indications or alteration of limitations, and if the pharmaceutical is undergoing the triennial review of listing requirements in the same year, both review procedures are continued in parallel. If the procedure to extend indications or alter limitations is completed and a decree issued before the decree date of the triennial review of listing requirements, then the triennial review of listing requirements will not be continued for the originator product in question. The FOPH will flag this product accordingly on the online portal.

Generics, co-marketing medicines and biosimilars will not undergo the triennial review or the review will not be continued if the originator product, basic product or reference product containing the same active substances was reviewed using ERP and IRP in connection with an extension of indications or alteration of limitations, and the generics, co-marketing medicines or biosimilars were reviewed at the same time with the originator product, basic product or reference product. The review procedure to extend indications or alter limitations must be completed and the corresponding decree issued for the originator product, basic product or reference product and the generics, co-marketing medicines or biosimilars before the triennial review is concluded.

B.9 Biosimilars, co-marketing medicines and generics

B.9.1 Contact person

For biosimilars, co-marketing medicines and generics (except generics with no corresponding originator product, cf. Section B.9.4.1), no data is entered on the online portal. For this reason, the FOPH does not have any contact data. It is evident, however, that such information facilitates rapid communication by e-mail and the dispatch of notifications and decrees by post. Authorisation holders for biosimilars, co-marketing medicines and generics are therefore requested to send details of a contact person to the FOPH at ueberpruefung@bag.admin.ch by **15 February 2024**, including an e-mail and postal address and telephone number. Any subsequent changes are to be sent to the FOPH at the same address.

B.9.2 Biosimilars

In connection with the triennial review of listing requirements, biosimilars are in principle considered to be cost-effective if their EFP is lower than the EFP of the corresponding reference products applicable on 1 December of the review year, or after the reference product has been reviewed, by one of the following percentages at least (Art. 65*d*^{ter} KVV):

- 10%, if the Swiss market volume of the reference product and its biosimilars on average does not exceed CHF 8 million per year during the three years before the review year;
- 15%, if the Swiss market volume of the reference product and its biosimilars on average lies between CHF 8 million and 25 million per year during the three years before the review year;
- 20%, if the Swiss market volume of the reference product and its biosimilars on average

exceeds CHF 25 million per year during the three years before the review year.

The implementation of paragraph 4 of the transitional provisions for the Amendment of 22 September 2023 to the KVV regarding the cost-effectiveness of biosimilars is still under review.

The FOPH determines the cost-effective EFP for the reference product and the Swiss market volume of the reference product and its biosimilars for the three calendar years preceding the triennial review of listing requirements (Swiss market volume for the years 2021–2023). The cost-effectiveness of the biosimilar is assessed on the basis of the cost-effective price of the highest-selling package of the reference product and of the corresponding package of the biosimilar. The reduction rate determined is applied to all packages/dosage strengths in the same dosage-form group.

Should a price reduction be necessary, the authorisation holder is notified, in order to guarantee the right to a legal hearing, and subsequently has an opportunity to comment. In the event of any changes in the EFP of the reference product after the notification has been sent to the biosimilar authorisation holders, the FOPH informs the authorisation holders concerned via a second notification.

If the FOPH decrees a new limitation for the reference product, or if the existing limitation is altered, the same limitation is also decreed for the biosimilars.

Taking into account the price decreed and any alteration of the limitation for the reference product, the FOPH decrees the corresponding price reduction and/or alteration of the limitation for biosimilars. For biosimilars, no data needs to be entered on the online portal.

If an appeal is lodged against a reduction in the price and/or alteration of the limitation for a reference product, the decreed price reduction and/or altered limitation is not implemented for the biosimilars with the same composition either. This means that biosimilar authorisation holders are also required to repay any surplus revenues obtained during the appeal procedure (arising from the difference in the EFP during and after completion of the procedure) (Art. 67*a* para. 3 KVV).

B.9.3 Co-marketing medicines

After completing the review of a basic product, the FOPH determines the cost-effective price for the co-marketing medicine. A co-marketing medicine is at most cost-effective at the same price as the basic product (Art. 66*b* para. 1 KVV). After the basic product has been reviewed, the authorisation holders are informed of the results. Should a price reduction be necessary, the authorisation holder is notified, in order to guarantee the right to a legal hearing, and subsequently has an opportunity to comment. In the event of any changes in the EFP of the basic product after the notification has been sent to the co-marketing medicines authorisation holders, the FOPH informs the authorisation holders concerned via a second notification.

If the FOPH decrees a new limitation for the basic product, or if the existing limitation is altered, the same limitation is also decreed for the co-marketing medicines.

Taking into account the price decreed and any alteration of the limitation for the basic product, the FOPH decrees the corresponding price reduction and/or altered limitation for co-marketing medicines. For co-marketing medicines, no data needs to be entered on the online portal.

If an appeal is lodged against a reduction in the price and/or alteration of the limitation for a basic product, the decreed price reduction and/or altered limitation is not implemented for the associated co-marketing medicines either. This means that authorisation holders for co-marketing medicines are also required to repay any surplus revenues obtained during the appeal procedure (arising from the difference in the EFP during and after completion of the procedure) (Art. 67*a* para. 3 KVV).

B.9.4 Generics

In connection with the triennial review of listing requirements, generics are considered to be cost-effective if their EFP is lower than the EFP of the corresponding originator products applicable on 1 December

of the review year, or after the originator product has been reviewed, by the following percentages at least (Art. 65*d*^{bis} KVV):

- 15%, if the Swiss market volume of the originator product and its co-marketing medicines and generics with the same composition per dosage form on average does not exceed CHF 4 million per year during the three years before the review year;
- 25%, if the Swiss market volume of the originator product and its co-marketing medicines and generics with the same composition per dosage form on average lies between CHF 4 million and 8 million per year during the three years before the review year;
- 30%, if the Swiss market volume of the originator product and its co-marketing medicines and generics with the same composition per dosage form on average lies between CHF 8 million and 16 million per year during the three years before the review year;
- 35%, if the Swiss market volume of the originator product and its co-marketing medicines and generics with the same composition per dosage form on average lies between CHF 16 million and 25 million per year during the three years before the review year;
- 40%, if the Swiss market volume of the originator product and its co-marketing medicines and generics with the same composition per dosage form on average exceeds CHF 25 million per year during the three years before the review year.

The FOPH determines the cost-effective EFP for the originator product and the average Swiss market volume of the active substance for the three calendar years preceding the triennial review of listing requirements (Swiss market volume for the years 2021–2023) (Section E.1.14 of the SL Manual). Cost-effectiveness is assessed, taking into account the above-mentioned price differentials in accordance with Art. 65*d*^{bis} KVV, on the basis of the cost-effective price of the highest-selling package of the originator product and of the corresponding package of the generic. The reduction rate determined is applied to all packages/dosage strengths in the same dosage-form group. Should a price reduction be necessary, the authorisation holder is notified, in order to guarantee the right to a legal hearing, and subsequently has an opportunity to comment. If changes arise for the EFP of the originator product after a notification has been sent to the generics authorisation holders, the FOPH will inform the authorisation holders concerned via a second notification.

If the FOPH decrees a new limitation for the originator product, or if the existing limitation is altered, the same limitation is also decreed for the generics.

Taking into account the price decreed and any alterations of the limitation for the originator product, the FOPH decrees the corresponding price reduction and/or altered limitation for generics. For generics (except generics with no corresponding originator product, cf. Section B.9.4.1), no data needs to be entered on the online portal.

If an appeal is lodged against the reduction in the price and/or alteration of the limitation for an originator product, the decreed price reduction and/or altered limitation is not implemented for the generics with the same composition either. This means that generics authorisation holders are also required to repay any surplus revenues obtained during the appeal procedure (arising from the difference in the EFP during and after completion of the procedure) (Art. 67*a* para. 3 KVV).

B.9.4.1 Generics with no corresponding originator product

If no originator product containing the same active substance is listed in the SL, then the cost-effectiveness of generics is to be assessed in the review exclusively by determining an IRP using other generics. For this comparison, only generics with a different composition will be considered which are authorised for treatment of the same condition and are reimbursed. For the generics used as comparators, the prices applicable on completion of the 2024 triennial review of listing requirements will be taken into account, if these are generics which are also reviewed in 2024 and for which originator products with the same composition are listed in the SL (Art. 65*d*^{bis} para. 2 KVV). The IRP for generics with no

corresponding originator product can thus only be determined when the review of the comparable generics has been completed.

As the market volumes of the active substances influence the assessment of the cost-effectiveness of generics, they are also to be taken into account in the determination of an IRP among generics. For this purpose, the following conversion factors are applied (for their use, cf. the example below). For the calculation of factors, the ratio is determined between the specified price differential of the product under review and the specified price differential of the comparator.

Example: calculation of conversion factor

Product to be reviewed with a theoretical price differential of 25 percent vis-à-vis the originator product based on a market volume of the active substance of CHF 6.5 million

Generic comparator with a (theoretical) price differential of 15 percent vis-à-vis the originator product based on a market volume of the active substance of CHF 2.7 million

Factor calculation: (1-0.25) / (1-0.15) = 0.8824

		Theoretical price differential of generic under review				
		15%	**25%**	**30%**	**35%**	**40%**
Price differential of generic comparator	**15%**	1.0	0.8824	0.8235	0.7647	0.7059
	25%	1.1333	1.0	0.9333	0.8667	0.8000
	30%	1.2143	1.0714	1.0	0.9286	0.8571
	35%	1.3077	1.1538	1.0769	1.0	0.9231
	40%	1.4167	1.2500	1.1667	1.0833	1.0

The deadline for data entry for generics with no corresponding originator product – in line with the deadline specified in Section B.12 for originator products – is **15 February 2024.** Unlike the procedure for originator products, no ERP is to be determined for generics with no corresponding originator product. This is to be duly indicated under the ERP criterion on the online portal. For the determination of the IRP, the FOPH will take into account the EFP of the comparators applicable on 1 December of the review year or after completion of the review of the comparators. As these prices are not available when data is entered by authorisation holders, the calculations are to be made using the EFP applicable at the time of data entry.

Example: Determination of an IRP for a generic with no corresponding originator product

Average market volume of the generic under review and any other generics with the same composition during the three years before the review year: CHF 10 million

→ Theoretical price differential vis-à-vis the originator product: 30 percent

Generic comparators have different market volumes and must accordingly observe the following different price differentials vis-à-vis the originator products:

Generic A: price differential 40 percent

Generic B: price differential 15 percent

Generic C: price differential 30 percent

By applying the above-mentioned conversion factors, allowance is made for the various price differentials in the determination of the IRP after the calculation of the daily treatment costs (or possibly treatment course costs, etc.).

Product	Dose [mg]	Package size [units]	Mainten-ance dose	EFP* [CHF]	Daily treatment costs (DDC) [CHF]	**Conversion factor**	DDC with factor [CHF]
Generic with no originator (theo-retical price differ-ential 30%)	10	20	25 mg/d	13.20	1.6500	**-**	-
Generic A with price differ-ential 40%	20	28	20 mg/d	29.80	1.0643	**1.1667**	1.2417
Generic B with price differ-ential 15%	5	30	15 mg/d	18.65	1.8650	**0.8235**	1.5358
Generic C with price differ-ential 30%	15	25	10 mg/d	39.40	1.0507	**1**	1.0507
IRP level							1.2761
IRP price generic with no originator, 10 mg, 20 units [CHF]							10.21

* For the determination of the IRP for generics with no corresponding originator product, the EFP resulting from the 2024 triennial review is decisive for the generic comparators.

B.10 Medicines with known active substances

Medicines with known active substances are listed in the SL as generics if their bioequivalence to an originator product is certified by Swissmedic. For medicines of this kind with generic status, the review takes the form described for generics in Section B.9.4.

If bioequivalence is not certified by the regulatory authority, the product concerned is essentially treated in the same way as an originator product. Consequently, the efficacy, appropriateness and cost-effectiveness criteria are assessed by the FOPH using the standard procedure, and cost-effectiveness is assessed by determination of the ERP and IRP (No. 2 of the Comments of 22 September 2023 on the Amendments to the Ordinances). The IRP is usually determined using off-patent originator products and other medicines with known active substances which are not listed in the SL as generics (Art. 65*c*^{ter} para. 2 KVV). Deviation from this principle is possible if a clinically relevant therapeutic improvement over the existing originator product listed in the SL has been demonstrated for the medicine with known active substance. In general, to demonstrate therapeutic added value, clinically relevant improvements over the reference product, confirmed by studies, must be shown. The necessary information is to be entered on the online portal. For fixed-dose combination products, the IRP is determined in accordance with the rules given in Section B.7.3.2.6.

If at least one generic with the same composition is listed in the SL and if the medicine with known active substance offers no therapeutic improvement over this generic, then the cost-effectiveness of the medicine with known active substance is assessed exclusively by means of comparison with the generic with the same composition, with no ERP or IRP being determined using other medicines. If several generics are listed in the SL, then the comparison is based on the average price of these generics (Art. 65*c*^{ter} para. 3 KVV). For the calculation of the cost-effective price, every package of the medicine with known active substance is compared to the average EFP of the corresponding package of generics with the same composition.

The deadline for data entry for medicines with known active substances, i.e. also for medicines of this type whose cost-effectiveness is determined on the basis of a price comparison with generics – in line with the deadline specified in Section B.12 for originator products – is **15 February 2024.** To be submitted is information on efficacy, appropriateness, patent status, and either an ERP and IRP or, if generics with the same composition are listed, under the IRP criterion a price comparison with generics with the same composition. In the latter case, no ERP is to be determined. This is to be duly indicated under the

ERP criterion on the online portal. For the price comparison with generics, the FOPH will take into account the EFP of the generics applicable on 1 December of the review year or after completion of the review of the generics. As these prices are not available when data is entered by authorisation holders, the calculations are to be made using the EFP applicable at the time of data entry.

B.11 Medicines authorised for parallel imports

The triennial review of listing requirements for a medicinal product authorised for parallel imports is based on the provisions for the assessment of cost-effectiveness in Art. 65*c*^{quater} KVV (Art. 65*d*^{quinquies} KVV). Accordingly, a medicinal product authorised for parallel imports is considered to be cost-effective if its EFP is at least 15% lower than the price of the product authorised in Switzerland.

B.12 Deadlines

The deadline for data entry for originator products on the online portal is **15 February 2024**. The FOPH reminds authorisation holders that, under Art. 13 of the Federal Act of 20 December 1968 on Administrative Procedure (APA; SR 172.021), the parties are obliged to cooperate in establishing the facts of the case if they are subject to a duty to provide information or a duty of disclosure.

The authorisation holder is usually granted a period of two weeks in which to comment on the FOPH's conclusions concerning the review of the listing requirements. Extensions of this deadline are only granted in exceptional cases and only once for each criterion to be reviewed for a pharmaceutical; extensions will not exceed 14 days. The **application for an extension** must be sent by **e-mail**, stating the reasons, to ueberpruefung@bag.admin.ch. The application for an extension should **not be submitted via the online portal**.

If the triennial review of the listing requirements results in an amendment to the SL (price reduction, alteration of limitations or removal), the authorisation holder has the opportunity, at the end of the review, to comment once again on the entire review as part of the concluding legal hearing. The deadline for the submission of comments as part of the concluding legal hearing is two weeks, and cannot be extended. No extensions are granted for the legal hearing.

The FOPH provides advance notification of new prices and any other changes (e.g. limitations, conditions) to the authorisation holders.

If the review results in a price reduction, limitation, alteration of a limitation, condition or removal, the FOPH issues a decree. If the pharmaceutical is considered to remain effective, appropriate and cost-effective without any adjustments, the FOPH issues a notification. The decrees and notifications are sent to all authorisation holders by post.

Authorisation holders are free to forward new prices to wholesalers and service providers. In addition, price reductions are published on the FOPH website.

Any price reductions will generally take effect on **1 December 2024**. The new prices and any alterations of limitations will be published in December at www.spezialitaetenliste.ch.

The following table provides an overview of the schedule for the triennial review of listing requirements in 2024. This information is subject to changes.

Cut-off date for EFP in other countries	1 January 2024
Cut-off date for prices, facts relevant for IRP	1 July 2024
Data to be entered on online portal by authorisation holder by	15 February 2024
Correspondence via online portal	From end of February 2024
Notification for generics/co-marketing medicines/biosimilars	July, August and September 2024
FOPH sends decree/notification	September and October 2024
Publication of price reductions effective 1 December	End of October 2024
Decreed changes come into effect	1 December 2024
Publication of changes at www.spezialitaetenliste.ch	December 2024

B.13 Fees

The fees for the triennial review of listing requirements amount to CHF 500 for originator products and reference products and CHF 200 for all other medicines (generics, biosimilars, co-marketing medicines, medicines with known active substances and medicines authorised for parallel imports) (Art. 70*b* in conjunction with Annex 1 KVV).

The fees specified in Art. 70*b* in conjunction with Annex 1 KVV are charged for each dosage-form group of a pharmaceutical. Invoices are expected to be issued at the end of October 2024 or after completion of the triennial review of listing requirements. The fees are to be paid within 30 days after receipt of the invoice.

No fees will be charged if, as a result of the triennial review of listing requirements, removal of the pharmaceutical or dosage–form group from the SL is decreed. Likewise, no fees will be charged if the triennial review of listing requirements becomes irrelevant prior to the issue of a decree/notification in connection with the review.

In accordance with Art. 68 para. 1 let. e KVV, a pharmaceutical will be removed from the SL if the fees or costs specified in Art. 70*b* are not paid in a timely manner.

B.14 Publication

In connection with the triennial review of listing requirements, the FOPH publishes the foundations for the assessment of efficacy and appropriateness of the originator product, insofar as they lead to a change in the SL; the price arising from the average of the prices in reference countries for the ERP; and the basis for the determination of the IRP, in particular a tabular overview of the comparator products and the costs thereof (Art. 71 para. 1 let. g KVV). Information on publication is expected to be available from December 2024 at: https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html

B.15 Hotline

In the event of technical problems with the online portal, if a product has been completed prematurely by mistake, or if any other queries arise, please send an e-mail to ueberpruefung@bag.admin.ch or contact the FOPH hotline: +41 (0)58 483 96 48 (09:00 to 12:00 and 14:00 to 16:00).

Yours sincerely

Health Insurance Benefits Division

Head of Review of Pharmaceuticals Section

Andrea Rizzi