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Federal Department of Home Affairs FDHA
Federal Office of Public Health FOPH
Health and Accident Insurance Directorate

CH-3003 Bern
FOPH

Registered mail
To all pharmaceutical companies concerned

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Triennial review of listing requirements in 2025[1,2,3]

Dear Sir or Madam

Every three years, the Federal Office of Public Health (FOPH) reviews all medicine listed in the specialities list (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 2025. 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 economic efficiency. 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 effectiveness, appropriateness and economic efficiency. Specific rules may apply to assessments in the context of applications for first listing, alterations of limitations,

[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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etc.

Due to the amendments to the ordinances as of 1 January 2024, the manual of 1 May 2017 on the SL is no longer fully up to date. An updated version of the manual is scheduled for publication at the start of 2025. References to the manual or deviations from it in this document refer to the 1 May 2017 version.

Contents

1 Frequency of reviews

Under Art. 65*d* para. 1 of the Ordinance of 27 June 1995 on Health Insurance (KVV; SR 832.102), every three years the FOPH reviews all medicines 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 medicines 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 medicines listed in the SL are reviewed per year, and that medicines in the same therapeutic group are reviewed in the same year.

In 2025, Unit C, comprising medicines in the following IT groups, is to be reviewed:

IT group	**REVIEW YEAR 2025**
2/52	Cardiovascular
3/53	Pulmonary and respiratory
8/58	Infectious diseases
9/59	Gynaecology
11/61	Ophthalmology
12/62	Otorhinolaryngology
20	Other medicines, complementary medicine

A list of the products (originator products[4] and generics with no corresponding originator product) to be reviewed in 2025 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

2 Exemptions

In the following cases, medicines in Unit C are exempted from the 2025 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 of the Health Insurance Benefits Ordinance of 29 September 1995 [KLV; SR 832.112.31]). Exempted from the review, therefore, are originator products which, as of 1 January 2025, 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 2024. These originator products in Unit C will not be subject to a triennial review until 2028.
- If an originator product has been reviewed in connection with an expansion of indications or an alteration of limitations, in accordance with Art. 65*f* para. 4 KVV, in the prior year 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 expansion of indications or alteration of limitations (Art. 34*d* para. 2 let. a KLV). The next triennial review of the listing requirements for these Unit C originator products for which an expansion of indications or alteration of limitations was performed in 2024, or will be performed before the completion of the triennial review in 2025, will not be carried out until 2028.

[4] 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.

- Generics, co-marketing medicines, parallel imported medicines and biosimilars are reviewed at the same time as the originator product, basic product or reference product containing the same active substances in the event of an alteration of limitations or expansion of indications for the originator product, basic product or reference product (Art. 65*d*^{bis}, 65*d*^{quinquies}, 66*b* KVV). The economic efficiency of generics, co-marketing medicines, parallel imported medicines and biosimilars is assessed in the same way as the assessment of economic efficiency in the triennial review. The next review of the generics, co-marketing medicines, parallel imported medicines and biosimilars concerned will not be carried out until 2028, provided that the triennial review for the originator product, basic product and reference product is also only carried out again in 2028.
- Originator products listed in the SL for a limited period or with temporary expansions 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 will be revoked accordingly. For these medicines, 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.

3 Electronic platform services (ePS)

The triennial review of listing requirements will take place via the ePS application for the first time in 2025 in which formal submissions as well as submissions on effectiveness, appropriateness and economic efficiency are required.

The development of the ePS application for the triennial review of the listing requirements is based on the previous internet application. There will, however, be adjustments to the way individual criteria are presented and the way some criteria are inquired about.

The input regarding the individual criteria is to be entered directly into the corresponding data fields. In addition, relevant documents such as cover letters, basis for calculations, references, etc. can be uploaded to the system in pdf format. Letters/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 make the submissions in the ePS application by 17 February 2025. Under Art. 68 para. 1 let. f KVV, a medicine will be removed from the SL if the authorisation holder refuses to submit the documentation necessary for the triennial review of listing requirements.

3.1 Access to the ePS application for the 2025 review

The review of the medicines for 2025 will be activated in the ePS application on **9 January 2025** via the following link:

https://epl.bag.admin.ch/

The ePS application is accessible via personal login, which requires prior registration in the ePortal https://ePortal.admin.ch/ with an AGOV login or CH login. Registration is possible at any time.

The FOPH will send an invitation code by post to all authorisation holders for originator products and generics without a corresponding originator product, which will be reviewed in the triennial review of listing requirements in 2025. Detailed quick registration guides for the ePortal and redemption of the invitation code can be found at https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/elektronische-plattform-leistungen-e-pl.html (currently in German, French and Italian) under “Information for authorisation holders for medicines on the SL and GG-SL”.

These authorisation holders also received an invitation by e-mail to a training event in mid-December. All other authorisation holders will be required to register with the ePS at a later date. A demonstration and brief guide which explain how to carry out the review and detail the alterations compared to the previous application will be available from end of December 2024 at https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/elektronische-plattform-leistungen-e-pl.html (currently in German, French and Italian).

3.2 Previous years' applications

Until the triennial review of listing requirements in 2024, the submissions on the effectiveness, appropriateness and economic efficiency were entered in the application, which the FOPH made available to the authorisation holders for originator products and generics without corresponding originator products for the triennial reviews of listing requirements from 2017-2024. Data entered in the application in previous years will still be available to authorisation holders at the following URLs with the passwords generated for each of the years in question. It is planned that data from prior years will be migrated to the ePS at a later date where it will be available for viewing. The FOPH will inform licence holders promptly about the migration.

Access data:

Review year	**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
2024	https://bag.hcisolutions.ch/Ueberpruefung2024

4 Groups of dosage forms

The various dosage forms of a medicine 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 of a medicine.

5 Assessment of effectiveness and appropriateness

In the triennial review of listing requirements, effectiveness 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 medicine in the SL, it is not in itself decisive for a positive evaluation of effectiveness and appropriateness by the FOPH. Reference by the authorisation holder to the approval granted by Swissmedic is not sufficient to demonstrate that the effectiveness and appropriateness criteria are met.

Using the ePS application, authorisation holders comment separately on effectiveness and appropriateness. They are required to report, in particular, changes crucial for the evaluation compared to the last review, listing, alteration of limitations, or expansion of indications, such as new or updated study results, meta-analyses, guidelines, revised information for healthcare professionals, etc.

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.).

6 Assessment of economic efficiency

6.1 Determination of the internal reference price (IRP)

6.1.1 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 medicine 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 ePS application by 17 February 2025.

6.1.2 Determination of the main indication

In the case of medicines 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. Prevalence statistics are drawn up.

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

- The line of treatment in which a medicine is used, the dose and duration of therapy are 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 medicine with the highest prevalence, or if medicine is used under certain conditions/subject to restricted use or no longer used for the main indication as determined by prevalence.
- If a medicine is used both in combination with other medicines 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 medicine, which is not unequivocally possible when several medicines are used in combination.

The FOPH has the option of specifying conditions and requirements for other indications, so that the medicines also meet the criterion of economic efficiency in these indications (Section E.1.9.1 of the SL Manual). If the price level for a secondary indication is lower than the economically efficient 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 reimbursements. The economically efficient price of a secondary indication cannot exceed the price of the main indication.

6.1.3 Choice of comparators

6.1.3.1 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 is the factor determining the choice of comparator. This may be the case particularly for medicines belonging to the same class of active substance. Medicines belonging to other

classes of active substance may be taken into account for the purposes of the IRP if needed for treatment of the same indication and if stated as such.

Not decisive for the choice of comparator is authorisation for the treatment of specific patient groups, e.g. children and adolescents, unless the medicine 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.

Medicines used in different lines of treatment do not count as therapeutic alternatives. This does not apply to medicines which, due to lower effectiveness and/or tolerability, are only reimbursed in a later line of treatment. To determine the IRP in these cases, medicines from the earlier line of treatment can also be considered, provided that they cost less than the medicines 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 effectiveness or tolerability, being more expensive than a therapy with better effectiveness and tolerability.

For purposes of selection of comparator products, the information for healthcare professionals, 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) medicines. Exceptionally expensive medicines of equal effectiveness may be excluded from the comparison (Federal Supreme Court ruling BGE 143 V 369 E. 5.3.2). The exclusion of a product of above-average cost is only possible if alternative treatments are available.

The price of the medicine under review itself and other forms of the same medicine 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.

6.1.3.2 Pharmaceutical form

The pharmaceutical form, or membership of a particular group is to be taken into account for the choice of comparators (cf. Section 4, “Groups of dosage forms”). Oral forms are normally 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. Medicines in the oral and oral delayed-release groups can be compared with medicines in the oral and oral delayed-release groups if they represent therapeutic alternatives and are comparable in terms of economic efficiency. For example, a medicine in the oral group can be compared with medicines in the oral and oral delayed-release groups if the specified conditions are met.

6.1.3.3 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 medicines before the first price reduction following patent expiry will be taken into account for the IRP (e.g. as part of a “review of the listing requirements following patent expiry” in accordance with Art. 65*e* KVV). For products for which the patent expired prior to listing in the SL or which were included in the SL before 2001 the first EFP of the product or the EFP as of 1 July 2001 are taken into account respectively. The current price is taken into account for products, which never had patent protection (e.g. blood products).

Off-patent originator products are compared with off-patent originator products (Art. 65*b*^{bis} para. 2 KVV). 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.[5]

If a patented medicine is compared with a combination of more than one medicine (e.g. medicine A and medicine 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 6.1.3.6:

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

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

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

6.1.3.4 Successor products and medicines with known active substances

The term “successor 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 effectiveness or offering any advantages in terms of effectiveness; a different dosage form with the same or a different route or frequency of administration – so-called pseudo-innovation). If an originator product is a successor product, which has shown no therapeutic improvement over the existing originator product listed in the SL especially in terms of effectiveness, safety or treatment adherence, 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, there is a 20% deduction from the EFP of the patented originator products (cf. Section 6.1.3.3).

Medicines authorised by Swissmedic as medicines with known active substances and not listed as generics in the SL are also considered to be successor products. The assessment of medicines with known active substances is as described in Section 9.

Successor products 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 9.

6.1.3.5 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 effectiveness may be excluded (cf. Section 6.1.3.1). 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.

[5] 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

6.1.3.6 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 the combination of both mono-products with the same active substances and other combination products may represent therapeutic alternatives to combination products. Since 2023, combination products have therefore been compared with the mono-products with the same active substances **and** combination products 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 (see following example). In the interest of consistency in determining the IRP, products of above-average cost may also be excluded from the comparison when calculating the IRP of combination products (cf. Section 6.1.3.1).

Example: IRP of a combination product

Combination product for review: Phenomenon-Exemplia-Plus

Mono products with active substances: Phenomenon and Exemplia

Combination products that represent therapeutic alternatives: combination product 1 and combination product 2

Dose: for the combination products (Phenomenon-Exemplia-Plus, combination product 1, combination product 2) the maintenance dose is based on the information for healthcare professionals. For the mono products (Phenomenon, Exemplia) the relevant dose is based on the combination product pending review (Phenomenon-Exemplia-Plus).

Product	Active substances	Dose [mg]	Package size [item]	Established dose	EFP [CHF]	Daily therapy costs [CHF]
Phenomenon-Exemplia-Plus	Active substance A Active substance X	10/5	28	10/5 mg twice a day	24.80	1.7714
Phenomenon	*Active substance A*	*10*	*20*	*10 mg twice a day*	*13.20*	*1.3200*
Exemplia	*Active substance X*	*5*	*30*	*5 mg twice a day*	*17.65*	*1.1767*
Amount of costs for for mono products						2.4967
Combination product 1	Active substance A Active substance Y	10/25	28	10/25 mg once a day	25.50	0.9107
Combination product 2	Active substance A Active substance Z	10/10	30	10/10 mg three times a day	18.60	1.8600
IRP level						1.7558
IRP price Phenomenon-Exemplia-Plus, 10/5 mg, 28 units [CHF]						24.58

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 benefit of the combination product is lower than that of the mono-products, the FOPH can take this into account in the cost-benefit analysis. If generics or biosimilars are listed in the SL for one or more active substances, only the prices of the originator product or reference product will be taken into account for the IRP.

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 (fixed-dose combination products) are considered to be successor 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 medicines. However, if an active substance in a combination product 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:

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

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

6.1.4 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 in particular, 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 information for healthcare professionals 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 last 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 a similar 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 365 days / 12 = 30.41667 days. A multi-year treatment duration usually comprises the number of years times 365 days.

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 information for healthcare professionals. If a recommended or standard maintenance dosage is explicitly mentioned and described as the recommended or standard dosage in the information for healthcare professionals (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 information for healthcare professionals. In this case, the mean value of the dosage range is taken into account. If the information for healthcare professionals does not specify a recommended or standard maintenance dosage, then the average of the entire dosage range required for maintenance therapy specified in the information for healthcare professionals 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 information for healthcare professionals, information may be taken from the patient information, foreign registration documents, guidelines or clinical trials. If direct comparison studies are available, the dosages may also be taken from these studies, if necessary.

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. This may not be necessary if it is apparent from the information for healthcare professionals 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. In these cases, the most suitable package (or combination of packages) per administration that leads to the lowest wastage and is the most economically efficient. 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. If the package combination with the lowest wastage is not also the most economically efficient option, then the most economically efficient 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 medicine is used exclusively for men or women.

	Adults	**Women**	**Men**
Body surface area[6]	1.79 m^2	1.71 m^2	1.91 m^2
Weight[7]	73 kg	65 kg	81 kg

6.1.5 Reporting of the IRP

The authorisation holder must report the IRP to the FOPH by **17 February 2025,** and also enter on, or upload to, the ePS application all data and references used for the comparison (Art. 34*f* para. 2 KLV). The authorisation holder must justify to the FOPH in the corresponding data field, in particular, the selection of medicines 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

6.1.6 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 medicine reviewed changes, or if packages of the medicine reviewed are included in the SL for the first time or removed from the SL, these changes will also be taken into account up to the date of the issue of the decree in connection with the triennial review. On the ePS application, 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.

6.1.7 No therapeutic alternative

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

6.2 Determination of the external reference price (ERP)

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 (Art. 65*b*^{quater} KVV in conjunction with 34*a*^{bis}

[6] 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.

[7] Federal Statistical Office, 2024

KLV). Comparisons are made with the same medicine 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. Medicines with the same active substance/s and similar dosage form are considered to be the same medicines. A comparison with a similar dosage form in the reference country is possible within the scope of the review, if the same dosage form does not exist in the reference country. No account is taken of medicines subject to parallel imports in the reference countries. Medical devices may be considered to be the same medicines and thus be taken into account in the determination of the ERP.

The cut-off date for the ERP is 1 January 2025 (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, as per Article 34*b* para. 2 KLV, not be less than:

- Denmark: both for patented and off-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 ePS application 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 2025, the average exchange rates for the period January 2024 to December 2024 are applicable, published by the FOPH by 6 January 2025 at the latest. The exchange rates are available on the ePS application.

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 package sizes and different dosage strengths are to be converted in a linear manner.

The authorisation holder must report to the FOPH, via the ePS application, by **17 February 2025** the EFP applicable on 1 January 2025 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.

6.3 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:

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

Next, the economically efficient 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

<u>Initial situation:</u>
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 + (CHF 95.00 * 13.31444759%) = CHF 107.6487252, expressed as CHF 107.65

Step 3: Economically efficient 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 – (CHF 35.30 * **1.2315789%)**= **CHF 34.8652526, expressed as CHF 34.87**

EFP_{new} 90 tablets = (CHF 95.00 – (CHF 95.00 * **1.2315789%)** = **CHF 93.83**

6.4 Extent of reduction of ex-factory price

If the triennial review of listing requirements indicates that the current highest price does not meet the economic efficiency 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 economic efficiency in accordance with Art. 65*b* para. 3 KVV (Art. 65*d* para. 4 KVV).

If no ERP or no IRP can be determined for originator products, economic efficiency 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 medicine 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 package.

7 Expansion of indications or alteration of limitations in the review year

If use of the prevalence model is requested in connection with an expansion of indications or an alteration of limitations, and if the medicine is subject to a triennial review of listing requirements in the same year, then the following applies: The notification of an expansion of indications or the application for an alteration of limitations must be completed by no later than the end of May 2025. An application for an alteration of limitations or procedure to extend indications 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, extended indication) has been implemented by 1 June 2025 at the latest. In the period from June 2025, no expansion of indications or alteration of limitations using the prevalence model can be ordered for medicines subject to a triennial review of listing requirements in 2025; this is only possible again after the triennial review has been completed. The 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 expansion of indications or alteration of limitations.

If the use of the ERP and IRP is requested in connection with an expansion of indications or alteration of limitations, and if the medicine 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 ePS application.

Generics, co-marketing medicines, parallel imported medicines and biosimilars will not undergo the review of listing requirements every three years or the review will not be continued if the originator product, basic product or reference product containing the same active substances is reviewed at the same time using ERP and IRP in connection with an expansion of indications or alteration of limitations, and the generics, co-marketing medicines, parallel imported medicines or biosimilars are 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, parallel imported medicines or biosimilars before the triennial review is concluded.

8 Biosimilars, co-marketing medicines, generics and medicines authorised for parallel imports

8.1 Contact person

For the review of biosimilars, co-marketing medicines, generics (except generics with no corresponding originator product, cf. Section 8.4.1) and for the parallel import of authorised medicine, authorisation holders need enter no data in the ePS application. 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, generics and medicines authorised for parallel import are therefore requested to send details of a contact person to the FOPH at ueberpruefung@bag.admin.ch by **17 February 2025**, including an e-mail and postal address and telephone number. Any subsequent changes are to be sent to the FOPH at the same address.

8.2 Biosimilars

In connection with the triennial review of listing requirements, a biosimilar is in principle considered to be economically efficient if its 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 biosimilar per dosage form 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 biosimilar per dosage form 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 biosimilar per dosage form on average exceeds CHF 25 million per year during the three years before the review year.

At the first triennial review of biosimilars, which were included in the SL before the entry into force of the amendments of 22 September 2023, the economic efficiency will also be assessed on the basis of the price differentials at the time of listing (Art. 65*c*^{bis} KVV) (para. 4 of the transitional provisions on the KVV amendment of 22 September 2023). The price following expiry of the patent of the reference product of the biosimilar undergoing review is used and the price differential as per the new Article 65*c*^{bis} KVV, taking into account the market volume relevant to the triennial review, is deducted from this price. If the price level determined on the basis of the price differentials for listing is lower than the price level determined on the basis of the price differentials for the triennial review, the FOPH shall issue new EFP that correspond to the price level based on the price differentials for listing. If it is higher than the price level taking into account the price differentials for the triennial review, the FOPH issues new EFP that correspond to the price level taking into account the price differentials for the triennial review.

The FOPH determines the economically efficient 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 2022–2024). The economic efficiency of the biosimilar is assessed on the basis of the economically efficient 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 ePS application.

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 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).

8.3 Co-marketing medicines

After completing the review of a basic product, the FOPH determines the economically efficient price for the co-marketing medicine. A co-marketing medicine is at most economically efficient 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 ePS application.

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).

8.4 Generics

In connection with the triennial review of listing requirements, generics are considered to be economically efficient 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 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 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 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 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 per dosage form on average exceeds CHF 25 million per year during the three years before the review year.

The FOPH determines the economically efficient EFP for the originator product and the average Swiss market volume of the active substance per dosage form for the three calendar years preceding the triennial review of listing requirements (Swiss market volume for the years 2022–2024) (Section E.1.14 of the SL Manual). Economic efficiency is assessed, taking into account the above-mentioned price differentials in accordance with Art. 65*d*^{bis} KVV, on the basis of the economically efficient 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 8.4.1), no data needs to be entered on the ePS application.

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 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).

8.4.1 Generics with no corresponding originator product in the SL

If no corresponding originator product is listed in the SL, then the economic efficiency 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 2025 triennial review of listing requirements will be taken into account, if these are generics which are also reviewed in 2025 and for which corresponding originator products 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. The EFP on 1 July of the year of review applies for generic comparators, which are not reviewed in the same year, and for recognised generics without a corresponding originator product in the SL.

As the market volumes of the active substances per dosage form influence the assessment of the economic efficiency 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. also 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 to derive the conversion factor: Product to be reviewed would have a price differential of 25 percent vis-à-vis the originator product based on the market volume of the active substance of CHF 6.5 million, generic as a comparator with a (if need be 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 10 for originator products – is **17 February 2025.** Unlike the procedure for originator products, no ERP is to be determined for generics with no corresponding originator product. 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]	Maintenance dose	EFP* [CHF]	Daily treatment costs (DDC) [CHF]	**Conversion factor**	DDC with factor [CHF]
Generic with no originator (theoretical price differential 30%)	10	20	25 mg/d	13.20	1.6500	**-**	-
Generic A with price differential 40%	20	28	20 mg/d	29.80	1.0643	**1.1667**	1.2417
Generic B with price differential 15%	5	30	15 mg/d	18.65	1.8650	**0.8235**	1.5358
Generic C with price differential 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

* The EFP after completion of the triennial review of the listing requirements for the current year of review is applied for the comparators taken into consideration, provided they are generics that were reviewed in the same year as the generic pending review and and for which corresponding originator products are listed in the SL (Art. 65*d*^{bis} para. 2 KVV)

8.5 Medicines authorised for parallel imports

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

Parallel imports of generics or biosimilars are economically efficient if the EFP of the generic or biosimilar imported in parallel is at least 15% lower than the EFP of the Swiss generic or biosimilar on 1 December of the year of review.

9 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. For medicines of this kind with generic status, the review takes the form described for generics in Section 8.4.

The three-year review of the economic efficiency of a medicine with known active substances not listed as a generic in the SL is based on the provisions to assess economic efficiency in Article 65*c*^{ter} and Article 65*d*^{quater} KVV. 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 originator product with the same composition, confirmed by studies, must be shown. The necessary information is to be entered on the ePS application. For fixed-dose combination products, the IRP is determined in accordance with the rules given in Section 6.1.3.6.

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 economic efficiency of the medicine with known active substance is assessed exclusively by means of comparison with generics 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).

The deadline for data entry for medicines with known active substances, i.e. also for medicines of this type whose economic efficiency is determined on the basis of a price comparison with generics – in line with the deadline specified in Section 10 for originator products – is **17 February 2025.** To be submitted is information on effectiveness, appropriateness and economic efficiency. Evaluation of economic efficiency needs to take into account whether the IRP was calculated using generics or not (Art. 65*c*^{ter} para. 3 KVV). If a medicine with known active substances is not compared to generics, an ERP and IRP must be submitted. If generics with identical substances are listed and the IRP is based on these generics, only a comparison with these generics containing the same substances must be performed and submitted for the IRP. An ERP does not need to be performed and submitted. For the 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 initially to be made using the EFP applicable at the time of data entry.

10 Deadlines

The deadline for data entry for originator products on the ePS application is **17 February 2025**. 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 14 days in which to comment on the FOPH's conclusions concerning the review of the listing requirements. Extensions of this deadline for feedback are only granted in exceptional cases and only once for each criterion to be reviewed for a medicine; 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.

If the triennial review of the listing requirements results in an amendment to the SL (price reduction, alteration of limitations or removal, etc.), 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 14 days, and **cannot be extended**.

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 medicine is considered to remain effective, appropriate and economically efficient without any adjustments, the FOPH issues a notification, which concludes the procedure. 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, envisaged price reductions are published on the FOPH website at the end of October 2025 at https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html.

Any changes (price reductions, alterations of limitations, cancellations) will generally take effect on **1 December 2025** (Art. 34*h* para. 2 KLV), provided the review is completed in October 2025. Subsequent implementation dates are possible if complex clarifications are necessary. The alterations will be published in December or following completion of the review at www.spezialitaetenliste.ch.

The following table provides an overview of the schedule for the triennial review of listing requirements in 2025. This information is subject to changes.

Cut-off date for EFP in other countries	1 January 2025
Cut-off date for prices, facts relevant for IRP	1 July 2025
Data to be entered on ePS application by authorisation holder by	17 February 2025
Correspondence via ePS application	From end of February 2025
Notification for generics/co-marketing medicines/biosimilars	July, August and September 2025
FOPH sends decree/notification	September and October 2025
Publication of price reductions effective 1 December	End of October 2025
Decreed changes come into effect	1 December 2025
Publication of changes at www.spezialitaetenliste.ch	December 2025

11 Fees

The fees for the triennial review of listing requirements amount to CHF 500 for originator products and reference products as well as medicines with known active substances and CHF 200 for all other medicines (generics, biosimilars, co-marketing medicines and medicines authorised for parallel imports) (Art. 70*b* para. 1 let. c 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 medicine. Invoices are issued 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 medicine 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 or notification in connection with the review.

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

12 Publication

In connection with the triennial review of listing requirements, the FOPH publishes, following completion of the procedure for originator products, reference products and medicines with known active substances, the economic efficiency of which is evaluated via ERP and IRP, the foundations for the assessment of effectiveness and appropriateness 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). The publication on the review is available from December 2025 at: https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Ueberpruefung-der-Aufnahmebedingungen-alle-drei-Jahre.html

13 Hotline

If you have any questions regarding the content of the triennial review of the listing requirement, please contact ueberpruefung@bag.admin.ch by email or call the FOPH on: +41 (0)58 483 96 48 (09:00 to 12:00 and 14:00 to 16:00).

In the event of technical problems with the ePS application or if any other queries arise, please contact epl@bag.admin.ch by email or call the FOPH on: +41 (0)58 463 87 00 (09:00 to 12:00 and 14:00 to 16:00).

Yours sincerely

Federal Office of Public Health

Jörg Indermitte

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