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Federal Office of Public Health FOPH
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CH-3003 Bern
FOPH

Registered mail
To all pharmaceutical companies concerned

Bern, 2 December 2019

Implementation of the triennial review of listing requirements in 2020

Dear Sir or Madam

Every three years, the Federal Office of Public Health (FOPH) reviews all pharmaceuticals included in the List of Pharmaceutical Specialties (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 2020. In the light of experience in 2017-19, the FOPH has set down additional rules for conducting the review, in particular with regard to cost-effectiveness; these rules are also described below. The rules on assessing efficacy, appropriateness and cost-effectiveness apply to all assessments of inclusion requirements, including, for example, assessments in the context of applications for first-time inclusion and applications to extend indications or alter limitations.

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1 Frequency of reviews

Under Art 65*d* para. 1 of the Health Insurance Ordinance of 27 June 1995 (KVV/OAMal; SR 832.102), every three years the FOPH reviews all pharmaceuticals 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 divided all SL pharmaceuticals into three similarly sized units, based on the therapeutic (IT) group to which they belong. Each year, one of these units is reviewed. It is thus 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. Under the 21 October 2015 amendment to the healthcare benefits ordinance of 29 September 1995 (KLV/OPAS; SR 832.112.31), the division of therapeutic groups into three units, and the assignment of these units to review years, was specified by the FDHA in Art. 34*d* para. 1bis KLV/OPAS.

In 2020, Unit A, comprising pharmaceuticals in the following IT groups, is to be reviewed (Art. 34*d* para. 1bis KLV in conjunction with para. 2 of the Transitional Provisions concerning the Amendment to the KLV/OPAS of 1 February 2017):

IT group	**REVIEW YEAR 2020**
4/54	GASTROENTEROLOGY
7/57	METABOLISM
15	ANTIDOTES
16	CATION EXCHANGERS

A list of the originator products to be reviewed in 2020 is published on the FOPH website.

2 Exemptions

In the following cases, pharmaceuticals in Unit A are exempted from the 2020 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 2020, 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 2019. These originator products in Unit C will not be subject to a triennial review until 2023.
- 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 internal reference price (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 A originator products for which an extension of indications or alteration of limitations occurred in 2019 will not take place until 2023 (Art. 34*d* para. 2 let. a KLV).
- Originator products listed in the SL for a limited period are not subject to a triennial review. For these products, a standard application for re-listing is to be submitted in good time prior to the expiry of the specified period. The listing requirements are reviewed in connection with this submission.

3 Online portal

To minimise the effort required for both parties and to shorten communication paths, the FOPH is making available an online portal where data on efficacy, appropriateness and cost-effectiveness is to be submitted. Relevant documents – such as covering 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 **by the deadline**. 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.

3.1 2020 online portal

The online portal will be accessible from 7 January 2020 at:

https://bag.hcisolutions.ch/Ueberpruefung2020

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:

Instructions are provided on the online portal for the individual criteria.

3.2 Previous years' online portal

The 2017, 2018 and 2019 portals can still be accessed. On 1 January 2020, however, the URLs of the websites will change. 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 the old address will remain valid for the time being: https://bag.e-mediat.net/Ueberpruefung2019

4 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.

5 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, such as new or updated study results, meta-analyses, guidelines, etc. They can also upload new data and information – in particular, publications on clinical studies.

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 Cost-effectiveness

6.1 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, authorisation holder and reimbursement status of the product in the reference country, and irrespective of whether the Swiss authorisation holder can influence the ex-factory price (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 different indications in Switzerland and the reference countries.

The effective date for the ERP is 1 January 2020 (Art. 34*e* para. 1 KLV). For the ERP, the EFP in the various reference countries is 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 wholesale prices (UK) are publicly accessible. For these reference countries, the EFP can be calculated by deducting the following wholesale margins, as specified in Art. 34*b* para. 1 KLV:

- Denmark: 6.5% of the pharmacy purchase price
- UK: 12.5% of the wholesale price
- Netherlands: 6.5% of the pharmacy purchase price
- Finland: 3% of the pharmacy purchase price
- Sweden: 2.7% of the pharmacy purchase price

The (publicly known) mandatory manufacturer's rebate in Germany is also taken into account for the ERP (Art. 65*b* para. 4 KVV in conjunction with Art. 34*b* para. 2 KLV). This generally amounts to 7% for

originator products (5.88% after sales tax) and 16% for off-patent originator products (13.44% after sales tax).

If the authorisation holder can demonstrate that the actual wholesale margin, or the actual manufacturer's rebate, differs from the values given in Art. 34*b* para. 1 and 2 KLV, then the actual wholesale margin, or the actual manufacturer's rebate, will be deducted (Art. 34*b* para. 3 KLV). Confirmations of the price provided by the authorisation holder in the reference country, an authority or an association is to be uploaded to the portal as supporting documentation; these should also document divergent wholesale margins and/or any divergent manufacturer rebate. If the authorisation holder receives no information from a country on the EFP or the wholesale margin, then the above-mentioned wholesale margins are to be used.

Wholesale margins of 0% will not be accepted. If a foreign authorisation holder claims direct distribution and cannot document the level of the actual wholesale margin, then the following minimum margins are applicable (Section E.1.7 of the SL Manual, with cross-reference):

- Denmark: 3% of the pharmacy purchase price, but not more than DKK 224 for patented originator products; 5% of the pharmacy purchase price, but not more than DKK 224 for off-patent originator products
- UK: 2% of the wholesale 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.

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 2020, the average exchange rates for the period January 2019 to December 2019 are applicable, published by the FOPH by 6 January 2020 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.

The authorisation holder must report to the FOPH, via the online portal, by **17 February 2020** the EFP applicable on 1 January 2020 for the highest-selling package in each group in the reference countries (Art. 34*e* para. 1 KLV), as well as uploading confirmations from all the countries.

6.2 Determination of the internal reference price (IRP)

6.2.1 Choice of comparators

To determine the IRP in accordance with Art. 65*b* para. 2 let. b KVV, comparisons are made with originator products which are listed in the SL at the time of the review and used to treat the same condition (Art. 34*f* para. 1 KLV).

The factor determining the choice of comparator is use in the same indication (therapeutic alternative). This can be the case particularly for pharmaceuticals with the same class of active substance. Pharmaceuticals with other classes of active substance can, however, also be taken into account for the purposes of the IRP if advisable.

Pharmaceuticals used in different lines of treatment do not count as treatment alternatives. This does not apply to pharmaceuticals which because of 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 included, provided 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 on the grounds of lower efficacy or tolerability being more expensive than a therapy with better efficacy and tolerability.

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

Also relevant for the choice of comparators is the pharmaceutical form, or membership of a particular group (cf. Section 4 above, “Groups of dosage forms”). For example, oral forms are compared with oral forms, parenteral with parenteral, etc. Comparison with other pharmaceutical forms is possible if no comparators in the same form are listed in the SL and thus assigned to the same group. Pharmaceuticals in the oral and oral delayed release groups can be compared with pharmaceuticals in the oral and oral delayed release groups if they constitute treatment alternatives and the comparison correlates with the most beneficial price. 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.

In the assessment of patented originator products, research and development costs are generally taken into account; accordingly, they are normally 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 price level applicable for these products prior to the post-patent-expiration review is used for the comparison (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 a patented pharmaceutical is compared with a combination of more than one pharmaceutical (e.g. Drug A and Drug B) for the purposes of the IRP, consideration has to be given to whether the patent for the comparators has expired or not (this rule does not apply to combination drugs [fixed-dose combinations or FDCs]; for these see the separate rules below):

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

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

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

The authorisation holder must indicate to the FOPH whether a post-patent-expiration review has been carried out for the pharmaceutical marketed. If such a review has taken place, the date of the review is to be indicated. In addition, details of the relevant patents and their expiration dates are to be provided to the FOPH. The FOPH will consider patents entered by the authorisation holder in the online portal by 15 February 2020.

If an originator product is a “me-too” product, offering 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* para. 6 KVV). Determination of the IRP involves comparison with off-patent originator products. Pharmaceuticals approved by Swissmedic as products with a known active pharmaceutical ingredient and not listed as generics in the SL are also considered to be “me-too” products and are assessed as such.

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 on prevalence statistics (Section E.1.9.1 of the SL Manual). The FOPH has the option of setting terms and requirements for further indications so that the pharmaceutical also meets the efficacy requirement for 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 calculated for the main indication, reimbursement can be set separately for this specific indication. These different reimbursements can then be made by way of a reimbursement model defined as a requirement under Art. 65 para. 5 KVV/OAMal.

The price of the pharmaceutical under review itself is not taken into account in the IRP level calculation (Federal Administrative Court ruling C-6105/2013 of 13 February 2017). Co-marketing medicines for which the basic preparations are listed in the SL are likewise not taken into consideration for the IRP.

Combination drugs (fixed-dose combinations):

Combination drugs are deemed to be “me-too” products under the terms of Art. 65*b* para. 6 KVV/OAMal. The IRP is established taking the following criteria into account.

Under Section C.8.1 of the SL Manual, the IRP of combination drugs is established in line with the single preparations on the SL with the active substances contained in the combination drug, provided that these single preparations are already authorised for combination and reimbursed. Under Section C.8.1.3 of the SL Manual, comparable combination drugs are taken into account in the establishment of the IRP provided that they are authorised and must be reimbursed for treatment of the same condition. The FOPH can also take other single preparations into account to establish the IRP, particularly if these have been used as comparable therapies in head-to-head studies and must be reimbursed for the indication in question. Section C.8.1.3 of the SL Manual is hereby rescinded so that from 2020, combination drugs are generally to be compared with the single preparations with the same active agents that in combination are authorised for treatment of the same condition. This takes account of the principle that a combination drug should not cost more than the combination of single preparations. If the SL contains no corresponding single preparations, the IRP can be determined using other combination drugs for treating the same condition or single preparations that are comparable in terms of their efficacy.

The IRP using a combination of single preparations is established as follows:

a) All active agents are still patented (Section C.8.1.1 of the SL Manual): If all the active agents for a combination drug are still patented, the costs of the combination drug must not exceed the total costs of the single preparations that are still patented.

b) Not all active agents are still patented (Section C.8.1.2 of the SL Manual, rules for biopharmaceuticals): For originator products with a combination of active agents, each of which is already covered by health insurance and where a component is no longer patented, a “100 per cent plus a maximum of 50 per cent” applies. In other words, 100% of the patented component(s) and up to 50% of the off-patent component(s) are included in the calculation of the price. The 50 per cent is calculated on the basis of the average price of the generics on the SL. If the comparison is to include a biopharmaceutical whose patent has expired, the 50 per cent is calculated on the basis of the average price of the biosimilars on the SL. If the SL does not include any generics or biosimilars, the calculation is done on the basis of 50 per cent of the price of the originator or reference product.

c) All active agents are off-patent (new rules): If all the active agents for a combination drug are off-patent, the costs of the combination drugs must not exceed the total average costs of the single preparations with the same active ingredients. To calculate the average costs of the single preparations with the same active ingredients, both the originator or reference products and the generics or biosimilars are taken into account.

The comparison of combination drugs with single preparations is done on the basis of the smallest package with the lowest dose strength, unless the smallest package with the lowest dose strength does not allow an adequate comparison, for example because the lowest doses of the combination drug and the single preparation(s) do not match.

If the single preparations with the combination drug’s active agents are not authorised for combination, and if the combination of these active agents through a combination of single preparations has until now not been reimbursed accordingly, the IRP is determined on the basis of other single preparations or combination drugs for the treatment of the same condition.

6.2.2 Establishment of the IRP

As a rule the IRP is established on the basis of the smallest package with the lowest dosage strength, unless the smallest package and/or lowest dosage strength does not permit an appropriate comparison, particularly on account of differences in starting dosage or package size (Art. 65d para. 3 KVV).

Deviation from the principle of the smallest package and lowest dosage strength is possible if, for example, in the case of one of the products considered in the comparison, the lowest dosage strength is only required for initial dose titration, or if a comparator is not offered in a small package (Section E.1.9 of the SL Manual, with cross-reference). Deviation is also possible if a dosage strength is only used for a dose reduction specified in the prescribing information for the avoidance 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 established 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 30.41666 days.

For the IRP, the average maintenance dose, as specified in the prescribing information, is normally taken into account. If, from the prescribing information, a recommended or usual dose is clearly apparent as being a maintenance dose, this dose should be taken into account. If this is not the case, the entire dose range specified in the prescribing information can be taken into account, unless, for example, comparable maintenance doses from a direct comparative study can be taken into account. In the case of dose ranges, the average is employed. If the average maintenance dose is not clearly apparent from the prescribing information, dose equivalents can be derived from guidelines, clinical studies or foreign registration documents.

From 2020, **whole** ampoules, vials, bottles, packages, etc., will be used for IRP purposes, even if whole ampoules, vials, bottles, packages, etc., would not be needed in light of the average maintenance dose. Exceptions are possible if it is apparent from the information on secondary shelf life provided in the prescribing information that broken or opened ampoules, vials, bottles, packages, etc., can be kept for long enough to still be usable in the continuation of the therapy (e.g. in the next cycle of cancer treatment).

If dosing is based on bodyweight or body surface area, the following average values are generally used for adults:

	Adults	**Women**	**Men**
Body surface area[1]	1.79 m^2	1.71 m^2	1.91 m^2
Weight[2]	72 kg	65 kg	80 kg

6.2.3. Reporting of the IRP

The authorisation holder must report the IRP to the FOPH by **17 February 2020**, and also enter or upload to the online portal all the data and references used for the comparison (Art. 34*f* para. 2 KLV). 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:

[1]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.

[2] Federal Statistical Office, 2017

Pharmaceutical/package size	Active substance	Average dosage considered	EFP	Daily treatment/ course costs
Phenomenon 10 mg 20 units	*Fantasia*	*25 mg once daily*	*CHF 13.20*	*CHF 1.65*
Exemplia 20 mg YY28 units	Idea	20 mg once daily	CHF 29.80	CHF 1.06
Beispieleia 5 mg YY30 units	Musterol	5 mg three times daily	CHF 17.65	CHF 1.77
IRP level (average cost of comparators)				CHF 1.415
IRP level Phenomenon				**CHF 11.32**

6.2.4 Changes during the review year

The FOPH takes account of changes in the data required for the IRP and in the EFP applicable for comparators until 1 July of the review year (Art. 34*f* para. 3 KLV).

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

6.2.5 No therapeutic alternative

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

6.3 Example: calculation of the reduction rate

The ERP and the IRP are equally weighted (Art. 65*b* para. 5 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: +13.3144476%

Step 2: Calculation: IRP for highest-selling package
IRP 90 tablets = CHF 95.00 + 13.3144475% = 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**

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 cost-effectiveness requirement, the FOPH will order that the price be reduced, with effect from 1 December of the review year, to the highest price (retail price) resulting from the assessment of cost-effectiveness based on the ERP and IRP in accordance with Art. 65*b* KVV, in conjunction with the provisions of Art. 67 para. 1^{quater} concerning the distribution component (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.

7 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 2020. 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 2020 at the latest. In the period from June 2020, 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 2020; 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 even once the extension of indications or alteration of limitations is complete.

If the use of the ERP and IRP is requested in connection with an extension to 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 the corresponding decree issued before the decree on the basis of the triennial review of listing requirements is issued, the triennial review of the listing requirements for the originator product in question will not be continued. The FOPH will flag the originator product in question accordingly on the online portal.

8 Biosimilars

Biosimilars are considered to be cost-effective if their EFP is at least 10% lower than the EFP of the corresponding reference product applicable on 1 December of the review year or after the reference product has been reviewed (Section E.1.15 of the SL Manual). After the reference product has been reviewed, the FOPH determines the cost-effective price for the biosimilar. After the reference product has been reviewed, the authorisation holders for the biosimilars are informed of the result. In the event of any price reduction, in order to preserve the right to be heard the authorisation holder receives notification and subsequently has an opportunity to comment. The FOPH then issues a decree. For biosimilars, no data needs to be entered on the online portal.

If an appeal is lodged against a reduction in the price of a reference product, the decreed price reduction is not implemented for the biosimilars with the same composition either. In such cases, the provisions of Art. 67*a* para. 2 KVV/OAMal concerning repayment of surplus revenues during the appeal procedure are also applicable to the relevant biosimilars. This means that authorisation holders for biosimilars are also required to repay any surplus revenues obtained during the appeal procedure (arising from the difference in the EFP during and after the procedure).

9 Co-marketing medicines

After a basic preparation has been reviewed, 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 preparation (Art. 66*b* para. 1 KVV). After the basic preparation has been reviewed, the authorisation holders are informed of the result of the review. If a price reduction is necessary, in order to preserve the right to be heard the authorisation holder receives notification and subsequently has an opportunity to comment. The FOPH then issues a decree. 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 of a basic preparation, the decreed price reduction is not implemented for the relevant co-marketing medicines either. In such cases, the provisions of Art. 67*a* para. 2 KVV/OAMal concerning repayment of surplus revenues during the appeal procedure are also applicable to the relevant co-marketing medicines. 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 the procedure).

10 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. 34*g* KLV):

- 10%, 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;
- 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 lies between CHF 4 million and 8 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 8 million and 16 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 16 million and 25 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 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 2017–19) (Section E.1.14 of the SL Manual). Cost-effectiveness is assessed, taking into account the above-mentioned price differentials in accordance with Art. 34*g* KLV, 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. If the review leads to a price reduction, the authorisation holder is notified of the cost-effective prices of its generics. The authorisation holder 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 generics authorisation holders concerned via a second notification.

The FOPH, taking account of the price decreed for the originator product, orders the corresponding price reduction for generics. For generics, no data needs to be entered on the online portal.

If an appeal is lodged against the price reduction for an originator product, the decreed price reduction is also not applied to generics with the same composition. In such cases, the provisions of Art. 67a para. 2 KVV concerning the repayment of surplus revenues obtained during appeal procedures are also applicable for generics. 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 the procedure).

11 Medicines with known active pharmaceutical ingredients

Medicines with known active pharmaceutical ingredients are listed in the SL as generics if their bioequivalence with an originator product is certified by Swissmedic. For products of this kind with

generic status, the review takes the form described for generics in Section 10. If bioequivalence is not certified by the regulatory authority, the product concerned is treated in the same way as an originator product. Consequently, the efficacy, appropriateness and cost-effectiveness criteria are assessed by the FOPH in the standard procedure, and cost-effectiveness by determination of the ERP and IRP (Section B.1.2.3 of the SL Manual, with cross-reference). The necessary information is entered on the online portal (cf. the explanations given for originator products in Section 6 of this letter).

12 Deadlines

The deadline for data entry for originator products on the online portal is **17 February 2020**. 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 FOPH divides the pharmaceuticals to be reviewed into two blocks. The assessment of and dispatch of initial feedback on pharmaceuticals in the first tranche by the FOPH will be completed by mid-February 2020. The assessment of and dispatch of initial feedback on pharmaceuticals in the second tranche is expected to begin around mid-May. The assignment of pharmaceuticals to the two tranches is visible on the online portal in the “blocks” field. Regardless of whether the pharmaceutical is to be assessed by the FOPH in the first or the second tranche, the data must be entered by the authorisation holder by 17 February 2020.

If the triennial review of the listing requirements results in an amendment to the SL (price reduction, alteration of limitations or removal), at the end of the review the authorisation holder has the opportunity to comment the entire review during the concluding legal hearing. The deadline for submitting comments in the concluding legal hearing is two weeks, and cannot be extended.

The FOPH provides advance notification of new prices to the authorisation holders of originator products and pharmaceuticals with known active pharmaceutical ingredients (via the online portal) and to the authorisation holders of biosimilars, co-marketing medicines and generics. Price reduction decrees 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 required for originator products, co-marketing medicines, generics and biosimilars basically take effect on **1 December 2020**. The new prices are published in the first December issue of the FOPH Bulletin.

The following table provides an overview of the schedule for the triennial review of listing requirements in 2020. This information is subject to change.

Effective date for EFP in other countries	1 January 2020
Effective date for prices, facts relevant for IRP	1 July 2020
Data to be entered on online portal by authorisation holder by	17 February 2020
Correspondence via online portal	From end of February 2020
Notification for generics/co-marketing medicines/ biosimilars	August and September 2020
FOPH sends decree/notification[3]	September and October 2020
Publication of price reductions effective 1 December	End of October 2020
Decreed changes come into effect	1 December 2020
Publication of changes in FOPH Bulletin	December 2020

13 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 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

[3] If the review results in a price reduction, limitation, alteration of a limitation or removal, the FOPH issues a decree. If the pharmaceutical is deemed to still be effective, appropriate and cost-effective without amendment, the FOPH issues a notification.