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CH-3003 Bern
FOPH

Registered mail
To all pharmaceutical companies concerned

Bern, 06 December 2018

Implementation of the triennial review of listing requirements in 2019

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. On 1 February 2017, the Federal Council and the Federal Department of Home Affairs (FDHA) adopted amendments to the Health Insurance Ordinance of 27 June 1995 (KVV; SR 832.102) and the Healthcare Benefits Ordinance of 29 September 1995 (KLV; SR 832.112.31), which also affect the procedure for the pharmaceutical review and which came into effect on 1 March 2017. This letter provides a detailed description of the implementation of the triennial review of listing requirements in 2019.

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1 Frequency of reviews

Under Art. 65*d* para. 1 KVV, the FOPH reviews all pharmaceuticals that are included in the SL every three years 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 Amendment to the KLV of 21 October 2015, 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.

In 2019, Unit C, 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 of 1 February 2017):

IT group	**REVIEW YEAR 2019**
02/52	CARDIOVASCULAR
03/53	PULMONARY AND RESPIRATORY
08/58	INFECTIOUS DISEASES
09/59	GYNAECOLOGICAL
11/61	OPHTHALMIC
12/62	OTORHINOLARYNGOLOGICAL

A list of the originator products to be reviewed in 2019 is published on the FOPH website.

2 Exemptions

In the following cases, pharmaceuticals in Unit C are exempted from the 2019 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 2019, 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 2018. These originator products in Unit C will not be subject to a triennial review until 2022.
- 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. Originator products for which an extension of indications or alteration of limitations occurred in 2018 will be reviewed again at the earliest in 2020 (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, or for an extension of limitations, 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).

The online portal will be accessible from 7 January 2019 at:

https://bag.e-mediat.net/Ueberpruefung2019

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 will be provided on the online portal.

To ensure that the procedure runs smoothly, the authorisation holder must submit the required data via the online portal **by the specified deadline**. Under Art. 68 para. 1 let. f KVV, a pharmaceuticals listed in the SL will be removed if the authorisation holder refuses to submit the documentation necessary for the triennial review of listing requirements.

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 cost-effectiveness 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 thus 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 2019 (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). Appropriate confirmation 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. 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). The relevant average exchange rates are calculated by the FOPH twice a year and published at the beginning of January and the beginning of July. For the triennial review of listing requirements in 2019, the average exchange rates for the period January 2018 to December 2018 are applicable. These exchange rates will be published on the FOPH website on 3 January 2019. The exchange rates are available on the online portal.

Serving as a basis for determination of the ERP is the **highest-selling** package for each dosage form and dosage strength in a group with the same active substance 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 **15 February 2019** the EFP applicable on 1 January 2019 for the highest-selling package for each dosage form 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 factors determining the choice of comparators are, in particular, use in the same indication (therapeutic alternative) and/or the same substance class and use in the same line of treatment. For this purpose, 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, delayed-release with delayed-release, 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.

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).

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.

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 price of the pharmaceutical under review 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.

6.2.2 Establishment of the IRP

The IRP is established on the basis of the smallest package and dosage, unless the smallest package and dosage does not permit an appropriate comparison, particularly on account of differences in starting dosage or package size (Art. 65d para. 3 KVV) (cf. also Section C.2.1.3 of the SL Manual).

Deviation from the principle of the smallest package and lowest dosage 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). 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 the prescribing information indicates a maintenance dose range, the average of this range is generally 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.

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	1.73 m^2	1.60 m^2	1.90 m^2
Weight	72 kg	65 kg	80 kg

6.2.3. Reporting of the IRP

The authorisation holder must report the IRP to the FOPH by **15 February 2019**, 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 dosage 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:

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).

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

The FOPH draws attention to the fact that in 2019 price increases in accordance with Art. 67 para. 2 KVV are excluded. The FOPH may, in exceptional cases, permit price increases to ensure the provision of care for the Swiss population if no therapeutic alternatives are available (Art. 35 KLV, in force since 1 January 2018, extended with effect from 1 January 2019 to 31 December 2019).

7 Review after extension of indications or alteration of limitations, using the prevalence model

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 2019. 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. In the period from June to November, 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 2019; this is only possible again after 1 December 2019.

8 Biosimilars

Biosimilars are considered to be cost-effective if their EFP are at least 10% lower than the EFP of the corresponding reference product applicable on 1 December of the review year (Section E.1.15 of the SL Manual). If the review of the reference product leads to a price reduction, the FOPH determines the cost-effective price for the biosimilar. After the reference product has been reviewed, the authorisation holders are informed of any price reductions which may be required. 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.

9 Co-marketing medicines

If the review of a basic preparation leads to a price reduction, 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 any price reductions which may be required. 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.

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 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 2016–2018) (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 suspensive effect also applies for 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 **15 February 2019**. 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 2019. 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 15 February 2019.

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 take effect on **1 December 2019**. 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 2019.

Effective date for EFP in other countries	1 January 2019
Effective date for prices, facts relevant for IRP	1 July 2019
Data to be entered on online portal by	15 February 2019
Correspondence via online portal	February to August 2019
Notification for generics/co-marketing medicines/ biosimilars	End of August 2019
Price reduction decree issued by FOPH	September 2019
Publication of price reductions	End of October 2019
New prices come into effect	1 December 2019
Publication of price reductions in FOPH Bulletin	December 2019

The above schedule is subject to modifications. Please note in particular that decrees effective on 1 December 2019 can still be issued in October 2019.

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

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