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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

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2018 triennial review of inclusion requirements: priorities set to ensure timely implementation
Cost shares for drugs and medicinal products: Implementation of Article 38*a* of the healthcare benefits ordinance of 29 September 1995 (KLV/OPAS; SR 832.112.31) with effect 1 December 2018[1]

Dear Sir or Madam

We are writing to inform you about priorities that have had to be set to ensure that the triennial review of the inclusion requirements can be conducted on schedule. At the end of this letter you will also find information on the thresholds for the differentiated cost shares defined this year.

1. 2018 triennial review of inclusion requirements

Priorities for conducting the 2018 triennial review of the inclusion requirements
The regular review of the inclusion requirements every three years is a top priority for the FOPH. The goal of the FDHA and FOPH is to implement any price reductions resulting from the review with effect 1 December 2018. Delays such as those that occurred last year are to be avoided. However, work on the 2018 review is not as far advanced as planned. Implementation has been delayed because the 2017 review was not completed on time, and because there were an above-average number of objections to the office's rulings following last year's review. There have been additional delays because not all submissions from Marketing authorization holder have met the requirements of the ordinance and the FOPH. This has prompted the FOPH to set the following priorities:

[1] La traduction française de cette lettre est publiée sur le site internet de l'Office fédéral de la santé publique : www.ofsp.admin.ch > Thèmes > Assurances > Assurance-maladie > Prestations et tarifs > Médicaments > informations sur la liste des spécialités (LS) (https://www.bag.admin.ch/bag/fr/home/themen/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Mitteilungen-zur-Spezialitaetenliste.html)

- **28 August 2018 meeting of federal pharmaceutical commission (EAK/FPC) cancelled**

  Given the problems and delays outlined above, in the next two months the FOPH will not be able to process EAK/CFM applications and simultaneously conduct the triennial review of inclusion requirements. The FOPH has therefore decided to cancel the EAK/CFM meeting

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scheduled for 28 August 2018. This means that no applications are to be submitted for the 25 June 2018 deadline. If applications have already been received by the FOPH, the relevant licence holders will again receive written notification of the cancellation of the 28 August 2018 meeting, and the applications will be put on the agenda of the next meeting of the EAK/CFM. The next deadline for submitting applications is 27 August 2018. For applications, which are submitted due to a time limitation, the time limitation will be extended.

- **Prioritisation of current applications that have already been submitted to the EAK/CFM or are subject to a simplified assessment**

  There may be delays for such applications. The FOPH is prioritising applications as follows:

  1. Fast track applications
  2. Applications for first-time inclusion and changes to limitations where efficacy and expediency requirements are met
  3. Applications for first-time inclusion and changes to limitations where questions remain as to efficacy and expediency; applications for new review

  It is possible that it will take longer than usual for the FOPH to produce notifications and responses to statements from licence holders. If there are any delays, the FOPH will notify the licence holders affected accordingly.

  There will also be delays when it comes to processing applications for voluntary price reductions after 18 months and reviews following expiry of a patent. Finally, the FOPH would like to point out that wherever possible it responds to enquiries by phone, and does not send statements in writing.

In line with its legal remit, besides the review the FOPH gives high priority to first-time inclusions, especially in the case of new effective therapies. However, the FOPH believes that the priorities it has set at this time are unavoidable, and regrets any delays in first-time inclusions that may result. The FOPH will endeavour to ensure that by the time the 2018 review has been completed at the latest, it will be possible to again assess applications for first-time inclusion and other applications within the prescribed processes and timelines.

2. Cost shares for drugs and medicinal products:

Insured persons in general have to pay a cost share of 10 per cent for drugs and medicinal products. Under the terms of Article 38*a* para 1 of the KLV/OPAS healthcare benefits ordinance, a higher cost share of 20 per cent must be imposed on drugs and medicinal products that are too expensive compared with other drugs and medicinal products with the same active ingredient composition. Relevant changes thereto entered into force on 1 March 2017. The higher 20 per cent cost share for a drug or medicinal product applies if, on the basis of ex-factory prices, its cost exceeds the average of the cheapest one-third of all drugs and medicinal products on the specialities list (SL/LS) with the same active ingredient composition (Art. 38*a* para 1 KLV/OPAS). This higher cost share applies to original preparations, co-marketing preparations and generics. Article 38*a* paras 2-4 KLV/OPAS set down the calculation method.

The new provisions of Article 38*a* KLV/OPAS that entered into force on 1 March 2017 also specify that the average of the cheapest one-third (thresholds) must be defined every year on 1 December.

Below you will find a description of the individual steps in the calculation and how it is applied for 1 December 2018.

2.1. Calculation of the average of the cheapest one-third

The average of the cheapest one-third is calculated on the basis of the ex-factory prices of the highest-selling package for each dose strength of a commercial form of all drugs and medicinal products on the SL/LS with the same active ingredient composition. Not included in the calculation are packag-

es (at the dose strength level) for which there were no sales in April, May and June 2018 (Art. 38*a* para 2 KLV/OPAS in conjunction with section G.1.5 of the 1 May 2017 SL/LS handbook). Also not included in the calculation are preparations for which sales over the same period came to 0.3% or less of the total sales of the drugs and medicinal products with the same active ingredient composition

The following table specifies the precise number of preparations constituting the cheapest one-third in relation to the total number of all preparations with the same active ingredient composition.

Number	1/3 of this	Number	1/3 of this	Number	1/3 of this
1	0	11	4	21	7
2	0	12	4	22	7
3	1	13	4	23	8
4	1	14	5	24	8
5	2	15	5	25	8
6	2	16	5	26	9
7	2	17	6	27	9
8	3	18	6	28	9
9	3	19	6	29	10
10	3	20	7	30	10

2.2. Calculation of the threshold (average of the cheapest one-third plus 10 per cent)

Ten per cent is added to the figure calculated for the average of the cheapest one-third. If the ex-factory price of the highest-selling package of a dose strength of a preparation is at or above this threshold, a cost share of 20 per cent is imposed for the relevant dose strength. This then applies to all package sizes of this dose strength. The cost share will only be reduced to 10 per cent again if the ex-factory price of the highest-selling package of a dose strength of the preparation falls below this threshold.

In the Excel spreadsheet published on the FOPH website on 17 September 2018 (see section 3), the highest-selling package for each dose strength of a commercial form of all drugs and medicinal products with the same active ingredient composition is marked with an M (“modal package”). To calculate the average of the cheapest one-third plus ten per cent (threshold per unit), all providers of this dose strength meeting the sales criteria (see section 1 above) are included. If the ex-factory price per unit of a package corresponding to the modal package is above this threshold, this is marked with a Y

The system then also automatically marks all other package sizes of the same dose strength with a Y.

If the licence holder reduces the ex-factory price of the package size corresponding to the modal package to below the threshold, the cost share for all package sizes of this dose strength goes back to 10 per cent. However, when it comes to a voluntary price reduction, all package sizes of a dose strength must be reduced by the same percentage to retain the existing price structure (Art. 38*a* para 4 KLV/OPAS).

Ex-factory prices on 1 August 2018 are used as the basis for calculating the threshold.

The threshold for active ingredients that become generic for the first time in the course of the year is calculated as soon as there are three preparations with the same active ingredient composition on the SL/LS (see section G.1.4 of the 1 May 2017 SL/LS handbook). No new threshold is calculated for drugs and medicinal products for which the threshold was set four months or less before the

1 August 2018 cut-off date (no or only minimal sales of generics in the months relevant for sales). In this case the old threshold is retained until the next time thresholds are set (see section G.1.4 of the 1 May 2017 SL/LS handbook).

2.3. Publication of the thresholds

The FOPH will publish the new thresholds to take effect on 1 December 2018 on its website on **17 September 2018**. They are available via the following link (German):
https://www.bag.admin.ch/bag/de/home/themen/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife/Arzneimittel/Differenzierter-Selbstbehalt-bei-Arzneimitteln.html

The corresponding classification in the electronic specialities list and SL/LS generics list on the basis of the newly defined thresholds will only apply from **1 December 2018**. This gives licence holders time to respond to any 20 per cent cost shares by voluntarily reducing prices before the new thresholds are applied on 1 December 2018. Voluntary price reductions to qualify for the 10 per cent cost share are possible at any time on the first of any month, even after 1 December. The final deadline for submitting a voluntary price reduction to take effect on 1 December 2018 is 12 November 2018.

2.4. Classification and labelling

In the electronic list of SL/LS generics the FOPH marks packages subject to a cost share of 20 per cent in excess of the annual deductible with a **red bar**. The red bar automatically changes to a **white bar** once the cost share goes back to 10 per cent. In the electronic SL/LS, packages subject to a 20 per cent cost share are marked with a black X on a red background in the cost share column.

If the licence holder for an original or co-marketing preparation reduces the ex-factory price in a single step to the generic price level so that the cost share of 10 per cent in excess of the annual deductible cost applies to this drug or medicinal product in the first 24 months following the price reduction, the FOPH marks these packages with a **yellow bar** in the electronic SL/LS list of generics.

2.5. Coordination with the triennial review of inclusion requirements

Any price reductions resulting from the triennial review of inclusion requirements with effect 1 December 2018 will not be included in the calculation of the threshold as of 1 December 2018, since these are set on the basis of ex-factory prices on the 1 August 2018 cut-off date. The publication of new thresholds on **17 September 2018** will thus include and specify the ex-factory prices valid on 1 August 2018. Price reductions resulting from the triennial review of inclusion requirements and thus also valid as of 1 December 2018 are not visible in the publication of 17 September 2018.

Independent of the determination of the average of the cheapest one-third, the FOPH will set the prices resulting from the triennial review of inclusion requirements with effect 1 December 2018. If, despite the price reduction resulting from the triennial review of inclusion requirements, the ex-factory price of a package is still above the threshold, and if as a result the package is subject to a 20 per cent cost share from 1 December 2018, the licence holder is free to voluntarily reduce the price by applying for a price below the prices set by the FOPH with effect from 1 December 2018 so that the package is again subject to a cost share of 10 per cent.

3. Hotline

If you have any questions about **differentiated cost shares** you can call our hotline on Mondays, Tuesdays and Thursdays:

T 058 462 90 17

If you have questions not related to differentiated cost shares, please email eak-sl-sekretariat@bag.admin.ch or call 058 462 90 35.

Yours sincerely

Health Care Services Division
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