



CH-3003 Berne

POST CH AG  
FOPH

## By email

To the associations of the pharmaceutical industry

File reference: 733.9-12  
Berne, 28 March 2023

## Information letter concerning the manufacturer's rebate for reimbursable, patent-protected medicinal products in Germany in 2023

Dear Sir/Madam

The Federal Office of Public Health (FOPH) is providing information about the change to the manufacturer's rebate for reimbursable, patent-protected medicinal products in Germany.

### 1. General background

From 1 January to 31 December 2023, a manufacturer's rebate of 12% now applies to the above-mentioned medicinal products in Germany (see §130a para. 1b Book V Social Code - Statutory Health Insurance, available at <https://www.sozialgesetzbuch-sgb.de/sgbv/130a.html>). This increase arises from the German Financial Stability Act in relation to Statutory Health Insurance (GKV) of 2022. Article 34b paragraph 2 letters a and b of the FDHA Ordinance on Compulsory Health Insurance Benefits (Health Insurance Benefits Ordinance, HIBO; SR 832.112.31) stipulates that, as of 1 June 2015, the manufacturer's rebate applicable in Germany must be deducted from the German ex-factory prices. Until now, the relevant manufacturer's rebates have been 7% for patent-protected products and 16% for patent-expired products.

### 2. Taking the new manufacturer's rebate into consideration

In connection with the inclusion of drugs on the Specialities List and the checking of the inclusion conditions every three years, as well as other foreign price comparison checks, with immediate effect the FOPH will take into account the increased manufacturer's rebate of 12%, or 10.08% after taking a VAT rate of 19% into account, in the calculation of ex-factory prices of patent-protected medicinal products from Germany. Any change to the VAT rate will be applied accordingly.

In order to comply with the requirement of Article 34b paragraph 3 HIBO, whereby the effective manufacturer's rebate can be taken into account, the FOPH will also continue to apply the manufacturer's rebate to be considered according to the entries in the *Lauer-Taxe* [pharmacy price schedule] (see point C.3.4 of the Handbook dated 1 May 2017 concerning the Specialities List).

Federal Office of Public Health FOPH  
Authorisation of Pharmaceuticals  
Schwarzenburgstrasse 157, 3003 Berne  
Tel. +41 58 462 90 35  
[eak-sl-sekretariat@bag.admin.ch](mailto:eak-sl-sekretariat@bag.admin.ch)  
<https://www.bag.admin.ch>



### 3. Rationale

The immediate application accords with the provision of Article 34b HIBO, which aims to take into account the mandatory, publicly disclosed manufacturer's rebate as specified by law, associations or authorities (point 2.1 of the explanatory notes on the amendment dated 29 April 2015 of the HIO and the HIBO [available at <https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-revisionsprojekte1.html>]). If the rebate changes in Germany – even if only on a temporary basis – the specified provision also requires the modified rebate to be applied (temporarily) by the FOPH.

Paragraph 3 of the specified provision also explicitly requires the effective manufacturer's rebate to be deducted. For the year 2023, this effective manufacturer's rebate in Germany is 12% (or 10.08% after deduction of VAT), hence the need to apply this rebate in accordance with Article 34b paragraph 3 HIBO.

The effective manufacturer's rebate of 10.08% is also shown in the *Lauer-Steuer*, which is regularly consulted by the FOPH.


### 4. Amending the ordinance to ensure legal certainty

For reasons of legal certainty, the wording of Article 34b paragraph 2 letter a HIBO is to be adapted to the changed circumstances in Germany as soon as possible by stipulating the new rebate of 12% instead of the previous rebate of 7%. The HIBO is currently being amended accordingly. Since this situation is clear and very urgent, a consultation process is not necessary. If the rebate were to be reduced again in future, the ordinance would likewise be promptly amended again.

The above-mentioned statement on the manufacturer's rebate in Germany replaces the corresponding statement in point C.3.2 of the Handbook concerning the SL dated May 1, 2017.

Yours sincerely

Federal Office of Public Health



Head of Authorisation of Pharmaceuticals