

New price cap for medicinal products

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In general, Austrian patients pay a €5.85 fee for prescription-only medications, whereas the actual price of medicinal products is paid by the social security institutions.

Theoretically, manufacturers of medical products were free to establish the price for their medicinal products. Practically, however, social security – with an important exception – pays only the costs of medicinal products listed in the Reimbursement Code, established by the Federation of Austrian Social Security Institutions according to the General Social Security Act. ⁽¹⁾ The price for products listed in the Reimbursement Code must correspond to the average EU price.

The exception to this rule is that medicinal products not listed in the Reimbursement Code (so-called 'no-box products') will be paid where the prescription is approved by the social security's head physician in well-founded individual cases. This is particularly the case with innovative products for which no alternative treatments are available and which – in most cases – are expensive. Over the past few years, the industry has increasingly used this exemption by not applying to list innovative (and expensive) medicinal products in the Reimbursement Code.

After 14 months of negotiations between the Federation of Austrian Social Security Institutions and the pharmaceutical industry, and lengthy discussions within the government coalition, Parliament adopted a new price cap for expensive medicinal products and a new price regime for generics and biosimilars on March 30 2017.

Overview of amendment

No-box products

The amendment to the General Social Security Code ⁽²⁾ provides for a new Section 351c(9a), which applies to medicinal products not listed in the Reimbursement Code. The price for a medicinal product which achieved a turnover above €750 million over the past 12 months on the basis of the ex-factory price must not exceed the average EU price. The federation must inform the Price Commission ⁽³⁾ immediately if this threshold is surpassed. Within eight weeks of notification, the Price Commission must establish the average EU price. The Price Commission must then re-evaluate the average price after 18 months, a further 24 months and another 18 months.

Generics and biosimilars

The second amendment to the General Social Security Code concerns the pricing of original medicinal products, generics and biosimilars. On market entry of a generic or biosimilar, the manufacturer of the original product will be requested to reduce the price by 30% (otherwise, the product is removed from the Reimbursement Code). To be listed in the Reimbursement Code, the manufacturer of the generic must agree to a price which is 28.6% lower than the reduced price of the original product. Additional generics will be included in the Reimbursement Code provided that their manufacturer agrees to a price which:

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- in the case of a second generic, is 18% lower than the price of the first generic; and
- in the case of a third generic, is 15% lower than the price of the second generic.

Before the act was amended, the first generic's price had to be only 25.7% lower than the reduced price of the original product and the prices of further generics had to be only "sufficiently lower" than the price of the first generic.

For biosimilars (which had been treated as generics until the amendment), the price of the first biosimilar must be 11.4% lower than the reduced price of the original product, the price of the second biosimilar must be 15% lower than the price of the first biosimilar and the price of the third biosimilar must be 10% lower than the price of the second biosimilar. (4)

As a consolation, until the transition period ends on October 1 2020, original medicinal products which are no more than 30% more expensive than the price of the cheapest product with identical active ingredient may remain in the Reimbursement Code.

Comment

The government, social security institutions and the legislature hope that these amendments will create further savings in relation to expenses for medicinal products. Whether the amendment will improve the supply and availability of medicinal products in Austria is a different matter. While in some case the industry may charge excessive prices for innovative products, the pharmaceutical industry (like any other industry) has a reasonable interest in making a profit. If a small market such as Austria does not offer the possibility of making a reasonable profit, this could reduce the global industry's motivation to serve this market.

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Endnotes

(1) *Allgemeines Sozialversicherungsgesetz, Federal Law Gazette 189/1955* as amended.

(2) *Federal Law Gazette I 49/2017*.

(3) A body established with the Federal Ministry for Health composed of representatives from the Ministry for Finance, the Ministry of Economy and Science, the Chamber of Commerce, the Chamber of Agriculture and the Chamber of Workers.

(4) Section 351c(10) of the General Social Security Code.

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