Guidelines for price setting in Norway

The rules for setting, controlling and adjusting prices on medicinal products are described in regulation «Forskrift om legemidler» (chapter 12, in Norwegian).The Norwegian Medicines Agency (NOMA) provides the following guidelines for setting maximum prices.

NOMA will normally follow the main rules when setting prices for medicines. However, in some cases it will be necessary to deviate from these guidelines. NOMA will handle individual cases on a non-discriminatory basis.

Content

International price comparisons

According to forskrift om legemidler § 12-2, prices in other countries in the European Economic Area serve as the main basis for price settlements. The price of a prescription-only medication in Norway is set as the mean of the three lowest market prices of the product in a selection of countries.

The reference countries that are included in the price comparison are: Sweden, Finland, Denmark, Germany, UK, Netherlands, Austria, Belgium and Ireland. In a situation where market prices exist in three or fewer of these countries, the price will be set as the average price of the existing prices.

We request prices valid at the time of reporting.

NOMA will set prices according to its own estimates if price details which are considered necessary for pricing the medicinal product in Norway have not been received from the Marketing Authorisation Holder on request and within specified deadlines.

Market price as basis

NOMA’s price settlement is done on the basis of the actual market price for each of the countries in the price comparison group. The market price is defined as the price the greatest part of the market pays for the product.

Price is set as PPP

The price set by NOMA is the maximum sales price to the pharmacy (PPP – pharmacy purchasing price[1]). The product may freely be sold at a lower price than max PPP.

Exchange rates

Price comparisons are based on the price in local currency, converted to NOK. The mean exchange rate of the last six months, as presented by the Central Bank of Norway (www.norges-bank.no), is used to convert prices to NOK.

Reevaluation of the price in Norway

According to forskrift om legemidler § 12-5 the Marketing Authorization Holder or the NOMA may suggest a reevaluation of prices if this is justified by changes of circumstances or new information.

Prices are not normally reevaluated more than once per year. The prices of newly-launched products are exempt from this rule. In the two year period after a launch, NOMA may request information about new prices half-yearly from the MAH with regard to pricing in Norway.

Withdrawal of a product from one of the reference countries may affect the price in Norway. Documentation must be presented to show that a product has in fact been withdrawn from the market if this is to give cause for price changes.

Comparable pack-sizes

Pack sizes are not always directly comparable. Price comparisons with other countries are therefore done on the basis of units. This means that price per tablet, price per dose etc. is compared.

When setting the price, differentiation is normally made between the price per unit in large and small packages. A package containing 30 or fewer units is normally defined as small. Packages containing more than 30 units are defined as large.

For some medicinal products and pharmaceutical formulations there are exemptions from the general rule. Those are;

- Medicinal products for treatment of asthmatic conditions: a package containing 120 or fewer doses is normally defined as small and a package containing more than 120 doses is defined as large.

- Some products which are used in the treatment of acute migraine attacks and medicines for erectile dysfunction. Packages are defined as small if they contain 5 or fewer tablets and large if they contain more than 5 tablets

- Injectables/injections: Distinction is made as follows: 0 – 5 ml, 6 - 99 ml and 100 ml or more. Vials, bottles, ampoules etc. are compared per unit (with the same amount/number of ml) if each vial, bottle, ampoule etc contains up to and including 5 ml,

- Injectables/infusions: division is made as follows: 0 – 5 ml, 6 ml - 1000 ml.

Price per unit in large and small packages

[1] AIP in Norwegian (apotekenes innkjøpspris)

In some cases, when comparing prices from different countries, the price per tablet in a small package may be lower than the price per tablet in a large package. In such cases, the price per tablet in the large package is set equal to the price per tablet in the small package. If the price per tablet is higher in a small package than in a large package the price difference is accepted provided that the difference is not considered unreasonable.

Price ratios between different strengths

When setting the price, NOMA will aim at a reasonable price ratio between different strengths of a given product. This also applies when the products have different names, while they actually are the same.

Comparable medicines

When setting the price of a medicinal product in Norway, comparisons will mainly be made with the price of the same product in the reference countries. If medicinal products are marketed under different product names in different reference countries, they will still be compared in the pricing process. Different varieties of the same product may also be taken into consideration when comparing prices. Ex. tablets, capsules, melting tablets, soluble tablets and effervescent tablets will be considered as varieties of the same pharmaceutical. NOMA will only set a higher price for other varieties of the same medicine on exception.

Parallel import

The prices of medicinal products which are parallel imported to Norway are limited upwards to the maximum price of the directly imported medicinal product.

Generics

For ATC codes with no packages in the stepped price model, **generic** medicinal products[2] will get the lowest maximum PPP of medicines within the same ATC code, regardless of whether their marketing authorization is based on biosimilar, well-established use or full dossier applications.

In ATC codes with packages in the stepped price model, generics may get the same maximum price as the full dossier product[3].

There is no need to report prices from reference countries for generics.

Biosimilars and well-established use

In ATC codes with no packages in the stepped price model, medicinal products with marketing authorisation (MA) based on a **similar biological** application[4] or a **well-established use** application[5] get the lowest maximum PPP of the following:

- maximum PPP as calculated by price comparison with the reference countries

[2] Directive 2001/83/EC art. 10 (1) generic application and 10 (3) hybrid application

[3] Directive 2001/83/EC art. 8 (3) full dossier, 10b fixed combination and 10c informed consent application

[4] Directive 2001/83/EC art. 10 (4) similar biological application

[5] Directive 2001/83/EC art. 10a well-established use application

- lowest maximum PPP of medicinal products within the same ATC code, regardless of whether the MA-application is for similar biological, well-established use or full dossier.

Price applications for biosimilars and well-established use medicines shall therefore hold prices from the nine reference countries in cases where there are no packages in the stepped price model in the ATC code.

For ATC codes with packages in the stepped price model, biosimilars and well-established use medicines may get the same maximum price as the full dossier product. For these products there is no need to report prices from reference countries.

Exceptions to the general rules

In some situations, it may be appropriate to set a higher maximum PPP than the general rules indicate.

Two conditions must apply to justify deviation from the main rules:

1. There is a major risk that the medicine will not be available in the market if the calculated maximum price is implemented.

2. The absence of the medicine from the market could have negative consequences for the availability of cost-effective medicines.

If these conditions apply, NOMA will consider setting a higher price based on discretionary judgment. The following circumstances will be considered:

- Documented production costs

- Special circumstances regarding the basis for price-calculation.

The same principles apply in cases with very low stepped prices.

Time limit

NOMA shall set new prices within 90 days after receiving a price application, cf. forskrift om legemider § 12-16.