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IMPORTANT NOTICE:

Pharma companies in Hungary can apply for beneficiary status for their reimbursed medicinal products

Year 2014 began with several changes in the Hungarian pharmaceutical legislation that were first introduced by the Parliament in the last days of December 2013. These legislative changes range from the introduction of the new reimbursement term "beneficiary medicine status", through some more specific powers of the GYEMSZI, to certain new pharmacovigilance related obligations of pharma companies. The latter were introduced to conform to Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 amending Directive 2001/83/EC as regards pharmacovigilance.

Beneficiary medicine status

As a special category, pharma companies can petition the granting of the newly introduced beneficiary status for their medicinal products at the same time when they submit an application for the inclusion of their products into social reimbursement. Beneficiary medicine status carries financial advantages for the marketing authorisation holders (MAH) and exempt them from the payment of:

- the yearly maintenance fee of the marketing authorisation (HUF 180,000 or €575 per year for allopathic medicines except allergens)
- the fee of an amendment to the marketing authorisation (HUF 180,000 for type-IA and type-IB variations, HUF 270,000 (€862) for type-II variations, in case of allopathic medicines in national procedure)
- the administrative service fees related to any reimbursement procedure; and
- the 20% claw-back type tax imposed on the monthly sales of reimbursed products.

The fee for the reimbursement application that includes a request for beneficiary status is HUF 300,000 (€956), whereas the regular reimbursement application is HUF 1.5m (€4,780). The National Health Insurance Fund (OEP) must decide on this special reimbursement application within 60 days instead of the general 90-day deadline.

OEP will grant beneficiary status to the medicinal product if:

- it has a valid marketing authorisation (including marketing authorisations issued ex officio on grounds of patient care interests deserving special consideration)
- the product is essential for the particular therapy, treatment of the individual patient with another authorised medicinal product, according to the summary of product characteristics, is not possible or unsuccessful, or the patient's access to a medicinal product with marketing authorisation for the specific indication is hindered to such a disproportionately great extent that the delay in the commencement of the medical treatment may cause irreversible health impairment; and
- the MAH undertakes to conclude a price volume agreement with OEP for five years, under which it will perform yearly payments of the difference between the total amount of annual reimbursement paid for the product in the therapeutic indication concerned and the yearly limit value of HUF 30m (€97,000) calculated on the basis of the producer price.

The MAH must ensure continuous supply of its medicinal product having beneficiary status throughout the period during which this status exists. If the MAH fails to meet the supply obligation due to its own fault, the MAH will be obliged to pay back the amounts of all financial advantages it has received because of the beneficiary status. Should the competent Hungarian authority be forced to purchase the product from a non-local distributor, the MAH will be also obliged to pay the additionally incurred costs.

Beneficiary medicine status is granted for five years. During this period, it is not possible to acquire beneficiary medicine status for another medicinal product with the same active substance, the same administration route, and the same therapeutic indication. The MAH must apply for renewal of the beneficiary medicine status six months prior to the expiry of the five-year term. If the MAH of another medicinal product used in the same therapeutic indication has also applied for the beneficiary status, OEP will chose between them on grounds of cost-effectiveness.

Once a medicinal product loses the beneficiary medicine status, OEP simultaneously excludes it from the social reimbursement system.

Numerical changes in the social reimbursement of medicines

The preferred reference price bounds, first introduced on 1 July 2011, have been expanded to include among the medicines that are subject to the fixation procedure:

- products whose daily therapy cost exceeds by not more than 15% (instead of the earlier 10%) the daily therapy cost of the reference product, and whose daily therapy cost is lower than the daily therapy cost of the reference product in the case of active ingredient based fixed amount reimbursement; and
- products whose daily therapy cost exceeds by not more than 15% (instead of the earlier 10%) the average daily therapy cost, and whose daily therapy cost is lower than the average daily therapy cost in the case of therapeutic efficacy based fixed reimbursement in the normative reimbursement category.

Exclusion criteria for medicinal products became again less stringent and:

- in the active substance based fixed group, products whose daily thera-

py cost, or price per unit of active substance, is 100% higher (instead of the earlier 50%) than the daily therapy cost of the reference product will be excluded
- in the therapy based fixed group, products whose daily therapy cost is 100% higher (instead of the earlier 60%) than the mathematical average of the daily therapy costs of the products belonging to the same therapy based fixed group will be excluded; and
- in case of biological medicinal products, products whose daily therapy cost is 50% higher (instead of the earlier 30%) than the daily therapy cost of the preferred biological medicinal products with the lowest daily therapy cost will be excluded.

The list of exclusion criteria has been completed with the case where a medicinal product loses the beneficiary medicine status.

Powers of GYEMSZI

The powers of the National Institute for Quality and Organisational Development in Healthcare and Medicines (GYEMSZI) in monitoring compliance with the rules of pharmaceutical promotion already included the examination of the legal relationship between the pharma company performing promotion ("promoter") and the healthcare professional authorised to prescribe or dispense medicines, as well as the actual activity carried out on the basis of their contract. Now GYEMSZI can also examine the legal relationship and the actual activities of:

- the MAH and the promoter company performing promotion on behalf of the MAH; and
- other person/s acting on behalf of the promoter company and the healthcare professional authorised to prescribe or dispense medicines.

GYEMSZI's position has also been reinforced from a procedural perspective; its decisions made with respect to the violation of the rules of pharmaceutical promotion, as well as in any authorisation or inspection procedures concerning marketing authorisations, medicine manufacturing, distribution, pharmacovigilance, brokerage and supply, and the clinical studies of investigational medicinal products (in fact, any and all medicine related decisions of GYEMSZI) are enforceable even if challenged before the courts and irrespective of a possible request for suspension of enforcement (preliminary injunction) submitted during the court proceedings.

Self-initiated suspension or termination of marketing

If the MAH intends to temporarily suspend or permanently discontinue the marketing of a specific medicinal product in the territory of Hungary, it must notify its wholesalers as well as GYEMSZI at the time of delivery of the last production batch to a wholesaler but not later than two months (instead of the earlier three months) before the scheduled suspension or termination. The MAH must also explain to GYEMSZI the reason of suspension or termination, and specifically state whether the suspension or termination is necessary because:

- it became aware of data suggesting that the medicinal product is harmful
- it became aware of data suggesting that the medicinal product lacks therapeutic efficacy
- it became aware of data suggesting that the risk-benefit balance of the medicinal product has changed in a way that created doubts about the safe use of the product
- the qualitative and quantitative composition of the medicinal product is not such as declared in the marketing authorisation
- or the controls on the medicinal product and/or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out, or some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled.

The MAH must also immediately inform GYEMSZI of any and all measures it has taken in any country of the European Economic Area to suspend the marketing of a product, withdraw it from the market, or initiate withdrawal of a marketing authorisation, or if it did not apply for the renewal of the marketing authorisation. The MAH must specifically state whether these measures were necessary for any of the above listed reasons, and if so, it must also notify the European Medicines Agency (EMA). If the MAH has taken such measures in a third country for any of the above listed reasons, it must also inform GYEMSZI and EMA.

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