WT Client Alert

Long-awaited changes in pharmaceutical promotion in Hungary

15 January 2025

Several amendments to pharmaceutical promotional laws in Hungary came into effect on 1 January 2025, with others following on 1 February 2025. Some of these amendments have long been urged by the pharmaceutical industry.

The changes primarily affect the following areas:

- the promotional regulation of the Act XCVIII of 2006 ("**Medicines Thrift Act**") and Decree No. 3/2009 (II. 25.) of the Ministry of Health ("**Promotional Decree**") which addresses
    - the costs of promotional events organised by promoter companies and
    - the obligation of promoter companies to submit proof of payments of the sales rep fee to the pharmaceutical authority;
- the reorganisation of the operation of institutional pharmacies.

Changes affecting pharmaceutical promotional practice

The amendment to the Medicines Thrift Act eliminates the obligation for promoter companies to submit proof of payment of the monthly sales rep fee to the National Public Health and Pharmaceutical Centre (**NNGYK**). From 1 January 2025, reporting of such payments is facilitated between the tax authority and the NNGYK. This change reduces administrative burdens for promoter companies, which previously faced frequent fines for non-compliance with this requirement.

Additionally, the amended Medicines Thrift Act establishes a new cost limit for hospitality at events of promoter companies organised for healthcare professionals (HCPs). The new hospitality limit may not exceed 15% of the monthly minimum wage per person per day, excluding VAT. This significantly alters existing legislation when a lower cost threshold applied to these events. Moreover, unlike previous restrictions, the amended law allows, under certain justifiable conditions, the invitation of individuals beyond the professional sphere.

The related rules in the Promotional Decree have also been amended, streamlining processes for promoter companies by removing redundant administrative steps and transitioning to more efficient electronic submissions. The requirement to provide proof of payment of the sales rep fee to the NNGYK has been removed, and the format of product sample and donation protocols has transitioned from paper-based to electronic submission. These must still be submitted to the NNGYK on a quarterly basis.

Changes affecting institutional pharmacies

New regulations have been adopted under the reorganised institutional pharmacy system in the Medicines Thrift Act, as outlined in our earlier Client Alert "*Hungarian legislation reform related to centralised procurement for institutional pharmacies*."

These amendments, effective from 1 February 2025, introduce key definitions of the new system, such as the *provider of unified institutional pharmacy services*, the *unified institutional pharmacy contributor services* and the *contributor*.

For public and private inpatient care institutions that voluntarily participate, the state may facilitate the use of a contributor for institutional pharmacy activities through unified institutional pharmacy contributor services. This contributor will be selected through a public procurement procedure. The winning bidder is then required to establish a project company to carry out the unified institutional pharmacy contributor services.

The inpatient care institution and the project company must collaborate to ensure the necessary conditions for operating the contributor services. This may include the partial delegation of employer rights over pharmacy staff to a person designated by the project company. The provider of the unified institutional pharmacy services is also responsible for other non-institutional pharmacy tasks related to the supply of medicines to patients.

Institutional pharmacies must ensure the separation of institutional and direct community pharmaceutical supply activities, with the professional and operational rules governing this separation defined by law. Additional requirements and rules governing the use of the contributor and its services are described in separate decrees.

To comply with the changed promotional rules or if you need further information on the reorganised institutional pharmacy system, contact your dedicated Wolf Theiss advisors.

About Wolf Theiss

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