Hungary: new regulations on tax and promotional activities in the pharma sector

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On 27 June 2011 the Hungarian Parliament adopted a bill amending, inter alia, the Medicinal Thrift Act (Act No. XCVIII of 2006).

The bill is currently awaiting the signature of the President in order to become law and is expected to enter into force on 1 July 2011. Once signed, it will significantly change the regulation of promotional activities of pharmaceutical companies, the price support mechanism applicable for subsidised medicinal products on the Hungarian market and the financial burden market participants will face in the future.

The most onerous provisions include, among others:

— the doubling of the sales representative tax (payable by the employer for each sales representative employed to promote medicinal products) from a monthly HUF 416,000 to 832,000 (approx. EUR 3,100).

  Small and medium enterprises ("**SME**") holding a valid manufacturing licence in Hungary with a maximum of 12 sales representatives will only need to pay a tenth of the increased amount.

— the 12% tax payable by medicinal product manufacturers/importers with regard to subsidised products will increase to 20%;

— the possibility to set-off R&D expenses against certain sums payable under the Medicinal Thrift Act (such as the tax payable for subsidised products or the sales representative tax) will be limited: whereas previously the entire amount of the above mentioned items could be set off against R&D expenses upon satisfaction of certain conditions, in the future the amount of the payable sums that may be credited will depend on the ultimate R&D spending of the respective pharmaceutical group;

— the pharmaceutical company's obligation to notify the competent authority when sponsoring scientific and/or professional events (including the sponsoring of health care professionals' ("**HCPs**") attendance at such event) at least 30 days prior to the event;

— the obligation to hold events sponsored or organised by pharmaceutical companies at locations where the relevant resource and/or expertise connected to the object or subject matter of the event are available;

— the right of the competent authorities to review agreements concluded between pharmaceutical companies and HCPs;

— the right and obligation of HCPs to verify the entitlement of the sales representative to carry out promotional activities prior to the commencement of such activity;

— the right to impose fines up to HUF 500,000,000 (EUR 1,886,800) if the marketing authorisation holder or the manufacturer does not comply with the regulations on promotional activities.

  Lower value fines can be imposed on others, including distributors who will face a fine of up to HUF 25,000,000 (EUR 93,000) and sales representatives up to HUF 5,000,000 (EUR 18,600) for violating the regulations on promotional activities.

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