

On 3 November 2008 the bill of amendments to the Pharmaceutical Law (“the Bill”) was released for external consultations. This new regulation should include provisions for a return to fixed official sale prices as well as wholesale and retail mark-ups with respect to reimbursed medical products and medical devices. More restrictive anti-consolidation regulations in respect of pharmacies and wholesalers are planned to be implemented. Also, regulations concerning the advertising of medical products will be amended.

The Bill includes regulations amending the Pharmaceutical Law itself as well as amending other corresponding legal acts concerning many areas essential for businesses of pharmaceutical companies. The amendments should affect among others the Act on Prices. The concept of the Bill may be recognized as a return to solutions implemented previously within the so called small amendments to the Pharmaceutical Law. For example, the term “distribution price” of a medical product or medical device reappears and is defined as the sale price of a medical product applied by MAH, the representative of MAH, the entity entitled to parallel import or the importer, as well as the sale price of a medical device applied by the entity entitled to launch the product onto the market and to use the medical devices. Official sale prices will be determined for reimbursed medical products and pharmaceutical products. The official wholesale mark-up will amount to 8,68 per cent

(of the distribution price), but the explicit regulation on dividing the mark-up between wholesalers is a new concept. The official sale prices as well as official wholesale and retail mark-ups will be of a fixed character. The proposed amendments may require pharmaceutical firms to adjust their current distribution models to the new regulations. The amendments may also significantly affect the transfer pricing policies applied with respect to transactions within pharmaceutical groups.

The Bill also provides for more restrictive anti-consolidation regulations, including a ban on combining in one entity wholesale with retail sale of medical products. Further restrictions will also be imposed on running more than 1 per cent of pharmacies within the region of a single voivodship. Under transitional regulations, adjustment to the new anti-consolidation regulations will be required as of 1 September 2013.

The new regulations will totally forbid any advertising of pharmacies, however, information regarding the localization and opening hours of a pharmacy will not constitute an advert. With reference to the change of the Regulation on marketing of medical products, MAH will be obliged to assert that a medical or trade representative arranges meetings with doctors after their working hours. Non-compliance with this obligation will result in a fine of up to 720 thousand PLN being imposed by the General Pharmaceutical Inspector. Similar fines will also be applied with respect to other breaches of provisions concerning the marketing of medical products.

According to the Bill, the new regulations should come in force 30 days after their publication. Taking into account the number and the character of the proposed amendments, the above transitional period seems to be relatively short.

The KPMG Pharmaceutical Team will be pleased to provide you with further information regarding the changes of pharmaceutical regulations and their tax and legal aspects as well assisting you in adapting your business in order to comply with the new rules.

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