

Legal Alert

Amendments to the Pharmaceutical Law

April 2007

The Act amending the Pharmaceutical Law was passed by Parliament (*Sejm*) on 30 March (the "Act") and will enter into force on 1 May 2007. The amendment, known as the "major amendment", introduces numerous changes to the Law.

The most important of these are:

Mail order

The new regulations allow chemists and dispensaries to conduct mail orders of non-prescription drugs, and therefore also allow internet chemists to conduct activities of this nature.

Inherited chemists

Permits to operate a chemist do not expire on the death of the person who conducts it, if at least one of his legal successors meets the criteria stipulated in the Act that determine whether a particular person is eligible to conduct such activities.

Advertising

The Act introduces a ban on advertising, to the general public, the **operations** of chemists and dispensaries referring **directly** to refundable products or products with an identical name.

Changes concerning the advertising of drugs:

the Act prohibits announcements informing the general public of changes to packaging or undesirable effects; if such information is directed at professionals it may not contain information pertaining to the properties of a product a more precise definition is provided for what trade catalogues or price-lists may contain without being subject to advertising regulations reminder advertisements, besides the proper and generally used name of the product, may only contain its trademark (which may not include any reference to recommendations, the form and dosage of a product or advertising slogans or content)

samples supplied to professionals may not be larger than one example of the smallest package for a particular medicinal product

the Act prohibits the use in advertising directed at the general public not only of the image of scientists and persons that have or appear to have medical qualifications, but also the image of generally defined public figures; also prohibited is any reference to the recommendations of such persons the Act also introduces a ban on giving professionals items that are unrelated to medical or pharmaceutical practice with a value exceeding PLN 100, as well as banning professionals from accepting such items.

The amendment introduces numerous changes concerning statutory definitions and the marketing of medicinal products, as well as their marking etc. The criminal provisions have also been amended. Two further amendments to the Pharmaceutical Law are being prepared. One of them, known as the "minor amendment", proposes changes, e.g. to regulations on clinical trials. The second amendment currently in preparation concerns the side effects of medicinal products and their reporting.

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