Non-pharmacy distribution of drugs: a controversial issue in Poland and Russia


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The outlook for sales of OTC medicines outside pharmacies differs from one Central and Eastern Europe country to the next. At present, the Russian authorities are considering giving the green light to the sale of drugs via general stores, a proposition which has aroused a great deal of controversy. Poland is one of the countries in which there is a very long tradition of selling drugs in general stores. The new list of drugs approved for sale was approved in October. Meanwhile, the Health Ministry, in another ordinance, prepared the criteria for the classification of medical products for non-pharmacy sales.

**Legal environment in Poland confusing**

In February 2009 the Health Ministry presented the long-awaited criteria which must be fulfilled by drugs admitted to non-pharmacy trade (Health Minister’s Ordinance of 2 February 2009 on criteria for classifying medicinal products which can be admitted to trade in non-pharmacy and pharmacy points) to enact order in this channel of distribution of OTCs. It is also important to note that products which do not comply with this ordinance but were purchased before it came into force could be sold no more than six months afterwards – this period expired in August.

At almost the same time, on 19 February 2009, the Health Ministry submitted, for social consultation, an ordinance pertaining to the lists of medicinal products suggested for non-pharmacy trade. The deadline for the submission of comments passed on 25 February. However, this ordinance waited for the sign of the health minister almost eight months (it was signed at the beginning of October). The document, presented on websites in February, contained many shortcomings and mistakes, pointed out by several dozen companies and other organisations. There were many mistakes in the spelling of the names of drugs, the doses and forms. Some products placed on the lists were no longer on the market, because of the lack of harmonisation of their documentation, among other things. Many companies and other organisations proposed the addition of other products.
One of the items removed from the list is Aviomarin, the popular motion-sickness drug. However, the list of medicines allowed to be sold in shops has been expanded as the previous version of 2006 contains 109 items (various pack sizes were presented as one item) plus simple herbs (removed in the current version), while the list of 2009 has around 180 items. The new list contains e.g. 13 versions of Apap, 17 of Aspirin, 16 of Panadol or 20 of Paracetamol. At the same time, retailers have been given until 6 April 2010 to sell out their existing stocks of the medicines removed from the list.

Most of the proposals to add other products were justified by the fact that such products meet the conditions of the 2 February Ordinance. This means that these two ordinances do not complement each other, as intended by the legislature, but are sometimes even contradictory. Furthermore, the previous ordinance pertaining to the lists of medical products was overturned in October 2008. As a result, the market has been left without a relevant act for almost a year despite the fact that, in accordance with an amendment to the 2007 Pharmaceutical Act, lists should be updated once a year.

**Russia considering non-pharmacy OTC drug sales**

Russia is not the only country which has, in the recent past, seriously considered permitting the sale of OTC drugs at general stores. For example, in Georgia sales of drugs at such stores will be permitted from mid-October 2009 onwards. However, in Russia such a move could carry much more risk than in other countries, according to Pharmexpert, a market research company. First of all, there are safety issues. Many drugs which have an Rx status in other countries, for example, Diclofenac, Nystatin and Korvalol, are available without prescription in Russia. Some include potentially dangerous substances, the distribution of which needs to be controlled by qualified persons such as pharmacists. Secondly, the approval of OTC drugs for non-pharmacy channels would lead to the bankruptcy of many Russian pharmacies, as such products are an important source of income for many of them. Estimates by DSM Group, a market research company, suggest that the total turnover of pharmacies could fall by 10-15% as a result of the liberalisation of the market. Taking into account the data for the overall pharmacy market, the value of non-pharmacy sales of OTC drugs could reach approximately RUB 24-35bn (€500-800m). This could, therefore, be a very attractive sales channel, assuming that sales of pharmaceuticals in Russia grow despite the crisis (in RUB).

**Consequences of allowing non-pharmacy sales in Russia**

According to a PMR analysis of the effect of allowing sales of OTC drugs in Russian general stores, the opening of non-pharmacy channels will not, in fact, increase the overall growth rate of the market – this will change only the channels of distribution of such products but will not have a positive effect on demand for OTC drugs. Of course, the situation is different in the case of particular OTC manufacturers. In other CEE countries if non-pharmacy sales are allowed they are restricted to a specific list. It is, therefore, probable that the Russian government will also approve a closed list of products for sale at grocery stores. Those manufacturers who succeed in placing their products on such lists will gain a substantial share of the market.
The categories which could be affected the most by such changes depend on the products placed on this list, but we expect analgesics to be to the fore. These are the subject of so-called “impulse” purchases at grocery stores, kiosks and petrol stations. To a certain extent sales of cold and cough remedies and digestive medicines might also develop well in stores.

Do non-pharmacy sales present opportunities for market entry?

Although Russia is one of the most promising OTC markets in the region, with considerable growth potential, the complex regulations and lengthy registration procedures can hinder the entry of new companies onto the market. Deadlines are not adhered to by Russian officials, and drug registration, which should take up to six months, may, therefore, take a few years. In addition, Russia’s national pharmacopeia and quality control methods are not harmonised with the regulations which are in force in the US or the European Union countries. This situation may also reflect the political turmoil Russia has experienced in the last few years. For example, during the last four years, three different people have been head of the Health Ministry, with each new appointee undoing his predecessor’s work. Despite those obstacles the OTC market is performing very well even in the times of crisis – in H1 2009 the growth dynamics was double-digit (in RUB). On the other hand, it is worthy of note, particularly from the perspective of foreign companies, that most changes in the value of the euro and dollar were negative in H1 2009.

More information on the non-pharmacy sales of drugs in Poland and other CEE countries can be found in PMR’s reports: “Distribution on the pharmaceutical market in Poland 2010. Development forecasts for 2010-2012” and “Distribution on the pharmaceutical market in CEE countries 2010. Development forecasts for 2010-2012” which are to be published in 2010.
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