

New Medicine Act brings important changes to Poland

As reported in *Regulatory Brief* (October 2002, pp23-24), Poland has introduced new laws governing all aspects of the pharmaceuticals industry. Here, Agnieszka Buksowicz, of APC Instytut, assesses key changes in the law.

After almost a year of drafting, debate and amendments the new pharmaceutical law was accepted by Parliament and signed by the President. The Medicine Act came into force on 1 October 2002. Moreover, a decree with more detailed rules on advertising is planned by the end of 2003. These controversial proposals are now being discussed by industry and medical representatives.

Public advertising of OTCs

Previously, OTC marketers had a lot of freedom to advertise their products to the public. Under the old regulations, marketers were able to use advertising depicting pharmacists, doctors and public persons endorsing their products. However, this is no longer permitted. Children, public figures, doctors and people connected with the medical profession are now barred from advertising medicines.

According to the proposed decree, OTC ads will not be permitted to broadcast before, during or just after TV programmes for children, nor after medical programmes in which the product's action is mentioned. Publishing information on contra-indications and adverse reactions would be made obligatory. There is also an unworkable proposal that ads must list all ingredients and dosages. In the case of multivitamins, this would require a TV or radio ad lasting at least two minutes!

Sales representatives

Historically, the costs of employees working as sales representatives have been treated as fully deductible for

POLAND: key facts

Population: 38.6mn

Pharmacies: 10,000

OTC distribution: pharmacy + some mass market sales

The Medicine Act: key changes

- Greater restrictions on public advertising
- Non-pharmacists permitted to own pharmacies
- Pharmacy ownership restricted to 10% of market, opening way for superchains of up to 1,000 stores
- Sales force costs treated as deductible from income
- Heavy restrictions on sampling and corporate gifts

tax purposes. These costs – which include salaries, car allowances and travel expenses – are usually significant. In its interpretation of tax laws issued on 7 May 2002, the Ministry of Finance announced that the activity of sales reps should be treated as non-public advertising and therefore be subject to the limit of 0.25% of the taxpayer's turnover. However, after intensive lobbying by the industry, the new law was amended to describe these activities as public advertising – meaning that these costs can be fully deducted again.

Other promotions

The new law also limits non-media forms of promotion. While medicine producers will be able to continue sponsoring scientific conferences and doctors' meetings, they will no longer be able to organise conferences, during which the hospitality exceeds the scientific purpose of the meeting. The regulations are also designed to uproot the practice of rewarding doctors for prescribing certain medicine – for example, with expenses-paid trips abroad. The doctor or pharmacist is now entitled to receive only small gifts from medical reps.

Sampling has also been limited – marketers can only give each doctor five samples per year of the smallest pack of any registered drug. All samples have to be recorded.

Pharmacy sector shakeup

Parliament rejected a draft rule stipulating that only qualified pharmacists could own a pharmacy. The ratified law now states that any person can own a pharmacy. This has opened up the market for big pharmacy chains, which has worried owners of small pharmacies. The law was amended to prevent monopolisation by limiting pharmacy ownership to 10% of the total number. But with 10,000 pharmacies, a chain of up to 1,000 stores could be established in Poland.

“The law opens the way for big chains and the pharmacy sector seems set for a revolution”

It seems that the Polish pharmacy market is about to face a revolution, like that experienced by the FMCG market, when big supermarket chains started business in Poland. Already, the two largest pharmacy chains are planning to take advantage of the relaxation in regulations by opening more stores. Apteki 21 now owns 35 pharmacies and plans to double this by the end of 2005. The Israeli chain, Super-Pharm, plans to have 50 pharmacies by the end of 2005. The pharmacy chains can offer lower prices to consumers, as they negotiate better prices on bigger purchases from the wholesalers.

The Pharmacists' Chamber, Polish Pharmacy, has devised a plan to respond to these changing market conditions. It intends to create a cooperative organisation of Polish pharmacies that can compete with major chains by making bulk purchases for its members and then sharing negotiated discounts. Industry observers believe that there will always be place on the market for both big chains and independent pharmacies. However, one thing is certain – in the new climate, pharmaceutical margins will drop and prices of drugs will go down. The effect of this will be felt especially in the OTC sector, where margins are not regulated by the Health Ministry and presently range anywhere from 20% up to 50% of the wholesaler's price.

Dereimbursement drive

Since his appointment, the new Minister of Health, Mariusz Lapinski, has begun to rationalise the drug reimbursement system. The system has four types of lists:

a hospital list with set prices, as well as 100%, 50% and 30% reimbursement lists. No fewer than 378 drugs were removed from the list published in April this year. Pharma companies were forced to lower prices by up to 30% in order to keep at least some of their products on the list. The Minister's aim was to make drugs cheaper for patients and to save part of the healthcare budget for other purposes. But while the Government has saved money, many people now have to pay more, as the medicines they used have either been removed from the list or moved to a lower reimbursement threshold. Since April, the lists have been modified several times after consultation with physicians and the industry lobby.

Minister Lapinski also proposed the “1 Zloty program” for pensioners – whereby 2mn people over 65 or 70 would be entitled to buy 121 essential drugs, described as most important by the World Health Organisation (WHO), for just PZL1 (about US\$0.25 / €0.28). While the Ministry of Finance finally rejected the proposal as too expensive (see last month's *Newsbrief*, p50), there are now discussions about subsidising a list of 19 essential life-saving drugs at that price (see this month's *Newsbrief*, p73). ☒

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