

Cost containment in the pharmaceutical sector: Innovative approaches to contracting while ensuring fair access to drugs

Jakub Adamski, Anna Klim
Ministry of Health

Jacek Sławiński
Independent expert

Poland is currently performing legislative schedule reinforcing implementation of the provisions of the Transparency Directive. It brings deep system changes into the Polish reimbursement and pricing policy and decision-making process.

1. Fair access for patients to drugs

1.1 Current situation

1.1.1 Legal framework

Legal framework of the reimbursement system consists of two main acts and their executive regulations. The Act of 27th September 2004 on Health care services financed from the public funds regulates conditions of granting and a scope of health care services financed from the public funds.

The Act of 5th July 2001 on Prices regulates principles and procedures of setting prices of goods and services (health care services among them).

The fundamental goal of the Minister of Health is to provide citizens with proper access to pharmacotherapy which is: safe, effective and at lowest possible patient co-payment.

In 2005 Poland has implemented a therapeutic reference pricing (TRP) by which reimbursement rates are determined for an entire category (e.g. statins, proton pump inhibitors) rather than for products with identical active ingredients. This greatly increases probability that a generic version will be included in the comparison set. The subsidy level is equal to the price of the cheapest product in the group. Patients have to make up the difference between the reference price and the products' full cost.

Lately in Poland external reference pricing was introduced. Pharmaceutical company is obliged to include in the reimbursement application information on its product's price in all EU countries and in the country of origin. The Minister of Health policy is not to allow that the price of the newly reimbursed drugs included in the positive list exceed the level of the lowest price in any other EU country (this policy is implicit but this is yet to be changed).

1.1.2 Market trends

In Poland average price per package dispensed in pharmacy is growing systematically over last years, faster than inflation or GDP (gross domestic product) per capita. It results from one mechanism: notwithstanding with the fact that price per package of the majority of Rx drugs (reimbursed, being on the market for the long time) is dropping, physicians prescribe more and more novel therapies which are more expensive in comparison to the old treatments (per packaging cost or DDD): either when generic drugs are being changed by innovative drug or when patented drug is being superseded by a new one.

1.1.3 Recent changes

Poland comes forward to growing awareness of patients (raised by patient organizations and public initiatives) regarding available therapies and pharmaceuticals by introducing new regulation. The Act on Health care services financed from the public funds was significantly amended on 14th September 2007. This **amendment** includes:

- the obligation of pharmacist to inform patient about the possibility of buying cheaper drug than prescribed;
- the obligation of pharmacist to have such a drug on pharmacy stock;
- the obligation of pharmacist to dispense such drug on patient's request, excluded in situations when physician stated otherwise.

1.1.4 Future prospects

In general, Poland strongly supports the idea of reward for innovation and high IP standards. This support is, however, depend on two elements: **(i) correct appreciation of generics and (ii) appropriate evaluation of innovation, especially drugs with added therapeutic value**. The realisation of the first element may increase generics substitution with obvious consequences for payers' budgets and the second will ensure that only valuable innovations will be rewarded.

However, in Poland, due to the wrong perception of generics, prescribers generally do not allow for substitution of original drugs (see the third amendment above). Since registration of generics in Poland is performed according to high European standards (MRP and DCP) the quality of generics cannot be questioned, especially after January 2009, with the end of introduction of *acquis communautaire* process in field of the documentation of pharmaceuticals.

That is why there is a growing awareness that wise control of drugs expenditures, allowing greater patients' affordability for innovative drugs, could only be achieved when substitution for generics will be more general. For these reasons the cooperation of main stakeholders: physicians and pharmaceutical industry, is necessary. Looking for the cooperation with physicians, MoH (Ministry of Health) plans two main activities:

- introducing detailed information on generics (additional hours of teaching in the medical schools, series of MoH-sponsored lectures regarding generics) combined

with protective action against ill-constructed information, advertisements and articles regarding generics, usually sponsored by innovative industry that question quality of European systems of registration of generics (MRP, DCP);

- introducing MoH-sponsored formulary, with clear indication (developed with the co-operation of Physician Chamber, and in agreement with Polish and European guidelines) of quality and safety of each listed drug.

Both activities should reinforce the three amendments listed above.

To support innovative drugs appropriate evaluation of their added therapeutic value is necessary. It is true that innovations could be small, incremental and huge, breakthrough innovation, but between these two extremes there are different levels of innovations. It would be disastrous for patients' and payers' budget to value incremental and breakthrough innovations on the same financial level. **In Poland, with the help of recently created HTA agency and along the lines worked out by WG on Relative Effectiveness, the exact level of added therapeutic value will be evaluated for each candidate for reimbursement.** That evaluation will be entered into formulary, mentioned above.

1.2 Comment and suggestions

There is also an important neglected topic, not mentioned in Peer Review: **the role of adherence to treatment.** Recent meta-analysis (2006) that include 46 847 participants, indicate that adherence to treatment is the major factor limiting treatment success. Roughly, **only 20% to 30%** of patients adhere to the prescribed therapy 12 months following its initiation, whereas in general, the benefit of therapy is not fully attained until years of treatment. Therefore, the search for means that would ensure adherence to drugs is strongly supported by MoH, as the role of MoH is to guard proper availability of drugs and their proper usage.

2. Price negotiations and tendering procedures

2.1 Price negotiations

2.1.1 Current situation

Price negotiations in Poland are not explicit.

Drug Management Team was established in Act on Prices to support the Minister of Health with its (not binding) positions concerning creation of positive reimbursement lists and setting statutory prices of pharmaceuticals and medical devices.

According to the Act on Prices the Team informs pharmaceutical company of the reasons of rejection of its application for including a given product on the reimbursement list or application for setting the statutory price which was suggested by the company. Within 14 days from the day when they received the opinion rejecting their application entrepreneur may apply for reconsideration of their application.

These provisions developed into price negotiations practice. The practice is widespread. Government's intention is to diminish prices. The team, during their proceedings usually seeks for experts' advice and the person in the position of National Consultant is asked in such situation.

2.1.2 Future prospects

Preparations are being made to establish a standing negotiation team. Members of this team will be appointed from the experts of Drug Policy and Pharmacy Department trained and having extended knowledge on current situation in the pharmaceutical sector and pharmaceutical companies operating on the Polish market.

2.2 Tendering procedures

2.2.1 Current situation

Tendering procedures are being applied to hospital medicines (and other hospital products, materials, services for hospitals; health services are also contracted in a tendering procedure by the National Health Fund).

Hospitals have to use a public procurement procedure. It can be omitted in certain specific conditions, e.g. there is only one supplier of a particular medicine. According to Law on public procurement, dated 29th January 2004, tendering procedures are obligatory in case when the purchase value exceeds the sum of 14 000 Euros.

Tenders apply for all kinds of pharmaceuticals used in hospitals; in real most often these procedures are held in case of vaccines.

Within tenders best price (or best deal – offer for a tender may include different kinds and amounts of pharmaceuticals) must be chosen by hospitals. For pharmaceuticals where a maximum hospital price is set by the Ministry of Health the price can not exceed that limit to be reimbursed.

3. Risk-sharing agreements between pharmaceutical companies and health care providers

3.1 Current situation

Risk-sharing agreement although being a very interesting extension of the price negotiation does not function in the Polish drug policy system. This is partly due to the fact that the Polish market is dominated by generics with 85% of volume and 60% of value. The vast majority of the category is made up of branded generics. Reimbursement levels are based on the cost of the least expensive option, and patients must pay any costs difference, a practice that strongly favours the generic sector.

3.2 Future prospects

In Poland currently, there is a debate over introducing provisions allowing the State to purchase pharmaceuticals via **price-volume agreements**. It is commonly considered that these agreements will bring relief to the reimbursement system in the situation of continuous growth of demand for pharmaceuticals, and thus growth of expenditure.

Two categories of drugs, i.e. orphans and drugs used in oncology, needs special consideration, especially because of the character and consequences of illness the drugs are used for. In most cases full evaluation of added therapeutic value is not possible and if registration is prolonged (to obtain full therapeutic data) candidate patients may not benefit from potential valuable drugs. For this reason it is believed that the appropriate system of *conditional reimbursement*, possibly at the European level, should be worked out.

4. Agreements on budgets for the treatment of illnesses

4.1 Current situation

Agreement on budget so called *capped budget agreement* in a form as described in New Zealand example does not exist in the Polish drug policy. Due to limited public means foreseen for pharmaceutical reimbursement in a given year the Ministry of Health sets the reimbursement limits. It means that the National Health Found (NFZ) is allow to reimburse only to the certain set limit in a certain therapeutic group. Once the limit is exceeded the medicinal product, although officially being on the positive list, can not be reimbursed any longer and patient has to pay 'out of pocket'.

4.2 Future prospects

Currently there are no plans to include agreements on budgets for the treatment in the Polish health care system.