# Registration and Reimbursement Changes on the Horizon in Poland

*Katarzyna Bondaryk* and *Dominika Kołodziejska* report on major legislative changes concerning marketing authorisation and reimbursement decision-making procedures.

The regulatory landscape in Poland for the registration of pharmaceutical products and their reimbursement is undergoing a transformation. The Polish Ministry of Health has drafted two pieces of legislation that propose to change the current framework regarding who has the final decision on whether certain drugs (ie those not approved via the European Union's centralised procedure) are approved for marketing and how products to be paid for from public funds will be chosen.

*The health ministry has drafted legislation on drug approval and reimbursement*

The proposals are designed to strengthen and make more transparent the current rules governing each area. They have undergone the official public consultation rule-making process, comments from which are now being reviewed by the Ministry of Health. Early indications suggest, however, that they might not be to everyone's liking.

## Product registration

In the area of product registration, the Ministry of Health has drawn up an act that is designed to boost the role and achievements of the country's Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

The Registry Office is currently responsible for making an assessment concerning the quality, efficacy and safety of medicines and biocidal products; it then delivers the assessment to the minister of health, who then decides whether or not to grant marketing authorisation. The Registry Office had earlier this year come under criticism from the Ministry of the Economy, which in a report raised concerns about rapid staff turnover due to poor wages and insufficient technology for effective and efficient operation[1].

The proposed legislation, called the Act of Registry Office of Medicinal Products, Medical Devices and Biocidal Products[2], will broaden the role of the president of the Registry Office. The president, who is appointed by the prime minister pursuant to a motion from the minister of health, will gain the right to grant marketing authorisations for medicinal products and biocidal products.

*One piece of legislation will expand the role of the president of the Registry Office*

To cope with the breadth of the new responsibilities, the president is to be supported by more vice presidents and special opinion and advisory commissions that cover the areas concerning human medicinal products, the preparation and issuance of the Polish pharmacopoeia, medical devices, biocidal products, veterinary matters and borderline products – ie products that feature characteristics of two product types, a frequent example being a product with features of a medicine and cosmetic. The commission concerning borderline products is new and reflects the fact that the number of borderline products in Poland is on the rise.

Under the new legislation, the Registry Office will gain an opportunity to conduct training and issue publications relating to its activities; the minister of health will issue an ordinance with details regarding training and publications. To help accelerate the product registration process, it will be allowed to pay for scientific advice on product quality safety and efficacy. The proposed act includes anticorruption provisions, which are designed to ensure that the Registry Office is a strong organisation focusing on the proper fulfillment of its duties.

However, some of the comments from the public consultation on the proposed legislation showed that there is concern that the anticorruption provisions do not apply to all employees in the Registry Office. In addition, there is criticism of the proposal to have the Registry Office pay for scientific advice; the worry here is that there might be a potential for conflicts of interest. There is also concern that the act does not specify the term of office of the president.

*Some stakeholders have criticised the proposal for the office to pay for scientific advice*

## Reimbursement

Concerning the proposed rules for reimbursement, the health minister drafted legislation that amends the Act of Healthcare Services Financed by Public Funds[3].

The amended act will change the Polish system of healthcare services considerably. Its purpose is to set out a procedure for decision-making in healthcare services and the public financing of such services.

**Katarzyna Bondaryk** is head of the pharmaceuticals and biotechnology practice and **Dominika Kołodziejska** is a lawyer at the Warsaw, Poland, branch of the law firm Hogan & Hartson.

The proposed rule introduces a "basket" of healthcare services that will be split into a positive basket of guaranteed services or a negative basket of non-guaranteed services. Guaranteed services are to be paid in whole or in part by public sources, while non-guaranteed services are to be paid for by the patient.

*The health minister felt current legislation was confusing and should be regulated more broadly*

While the current act also regulates which healthcare services are paid for by public funds and which are paid for by the patient, the health minister felt that it was too confusing and there was a need to regulate the matter more broadly. The current act, for example, fails to regulate the decision-making process in terms of which healthcare services should not be paid for using compulsory health insurance. Establishing the decision-making process was deemed necessary for the transparency of financing healthcare services from public funds.

The health minister believes that the scope of the baskets should be transparent and leave no doubt for the patient as to the range of healthcare services that are guaranteed. The act has a provision for the health minister to issue ordinances establishing the negative and positive baskets. It was felt that baskets established by ordinances would be easier to change in the future than if they had been established by a regulation in the form of an act. This would cater for rapid developments in medical science.

*Some comments said the new procedure would not comply with the Polish constitution*

However, during the public consultation period of the proposed rule, it was claimed that the new procedure would not comply with the Polish constitution. The argument was that the rights of citizens to equal access to healthcare services should be regulated by an act and not in an ordinance.

## Agency of Health Technology Assessment

The assessment and grouping of healthcare services in the appropriate baskets will fall into the jurisdiction of the Agency of Health Technology Assessment (AOTM). The AOTM was founded in 2005 as an advisory body to the Ministry of Health. Its current duties involve issuing an opinion and recommendation to the health minister on whether products should be reimbursed. It was felt, however, that the position of the AOTM and its objectives were not sufficiently transparent and the legislator decided to resolve the matter by the means of a statute.

The proposed act stipulates the role, functioning, organisation and objectives of the AOTM. The AOTM will be a public entity with a separate legal personality, supervised by the health minister; the AOTM is currently financed by public funds but is not regulated by statute. By gaining a legal personality, it can act on its own behalf and is subject to rights and duties. It will operate on the basis of bylaws, issued in a form of an ordinance by the health minister. It will comprise specialists from different disciplines, and will play the role of an expert in the process of qualifying the healthcare services for appropriate baskets. A consultancy board will act as an advisor to both the health minister and the AOTM.

*The proposed rule stipulates that the AOTM would assess reimbursement applications and issue reports*

The proposed rule stipulates that the AOTM would make a formal and factual assessment of the reimbursement applications, and its chairman would issue a report. The report would constitute the basis for the recommendation of the consultancy board. The final decision on reimbursement lies with the health minister. The minister is not bound by the consultancy board opinion and recommendations.

Again, comments from the public consultation period of the proposed amendments show that there is concern over the new rule. The pharmaceutical industry, for example, believes that the AOTM should be more independent.

*References*


1. Information regarding accomplishment of actions subsequent to document "Strategy for pharmaceutical industries until 2008", status of implementation 31 December 2005, www.mg.gov.pl/Gospodarka/Przetworstwo+przemyslowe/przemysl+farmaceutyczny/
2. The Act of Registry Office of Medicinal Products, Medical Devices and Biocide Products, 24 September 2008, www.mz.gov.pl/wwwfiles/ma_struktura/docs/projekt_ustawy_urplwmipb_zal_3102008.pdf
3. Act of Healthcare Services Financed by Public Funds, www.mz.gov.pl/wwwfiles/ma_struktura/docs/ustawa_20102008.pdf