A wind of change in Hungarian pharmaceutical regulations – a welcome breeze of fresh air or an unpleasant gale?

SPEED READ

On 8 July 2013, a new Hungarian law entered into force affecting the pharmaceutical sector. The new law brings about substantial changes for the industry and has sparked some heated debate. On the one hand, policy-makers stress the need for enhanced safety and quality control of medicines as well as reduction of costs in the healthcare system. On the other hand, the industry will be subject to wider-reaching powers of the Hungarian regulator to conduct unannounced inspections, allowing for only limited means of defence. Marketing authorisation holders will be put under a new obligation to supply wholesalers whenever necessary to satisfy national demand. Also, and in most cases, they must offer the lowest EEA price in order to secure a place for its medicines in the reimbursement system. Failure to comply with the new rules exposes pharmaceutical companies to substantial fines amounting up to HUF500 million (approximately EUR1.7 million). This alert discusses whether this “wind of change” in pharmaceutical regulation in Hungary is a welcome breeze of fresh air or whether it represents a more of an unpleasant gale that will lead to more confusion than certainty.
Dawn raids – new rules

Under the new law, the regulator gained substantial powers to conduct unannounced inspections (dawn raids) of the premises of pharmaceutical companies. Previously, the regulator was only entitled to conduct investigations concerning compliance with advertising and promotion of medicines rules; now, the regulator will have greater, more influential powers.

The Hungarian regulator is entitled to conduct unannounced inspections in order to verify compliance with any laws that fall within its jurisdiction, including, for instance, compliance with rules regarding manufacturing of pharmaceutical products, marketing authorisation, wholesale distribution, pharmacovigilance, quality defects, clinical trials and labelling. The regulator can investigate any entity that participates in the life-cycle of a medicinal product, including manufacturers, importers and wholesalers.

Interestingly, the new rules do not apply to manufacturers of medical devices. The question remains whether this is an intentional omission or only a legislative lacuna. A similar bipolarity of regulation appears also in other Central European jurisdictions – for instance, in Slovakia – so it is not an unprecedented case. At the same time, the duality of the regulation may pose a number of practical questions, for instance, whether the inspections of companies active in both medicines and medical devices sectors should be limited only to their medicines divisions.

In relation to dawn raids, the pharmaceutical regulator will have very similar powers to the Hungarian competition authority when conducting its own inspections. In particular, the pharmaceutical regulator will be entitled to enter the company’s premises, seize documents and computers, use forensic IT devices to copy hard drives, ask questions of employees and, in certain circumstances, enter the private premises of employees or search their personal belongings, such as their cars. However, there are a few significant differences between a dawn raid by the competition authority and a raid by the pharmaceutical regulator:

- In case of a raid by the pharmaceutical regulator, companies are not entitled to benefit from statutory legal privilege. This means that the pharmaceutical regulator may be able to seize emails and other documents containing client-attorney communications. In contrast, legal privilege may be exercised during competition authority dawn raids.

- Before a dawn raid, the Hungarian regulator needs an approval from the public prosecutor. In contrast, the competition authority needs a court approval.

Companies have an obligation to co-operate during dawn raids; failure to do so could amount to fines of up to HUF500 million (approximately EUR1.7 million).
Obligation to supply and minimum stock requirements

The second set of new rules could be compared to the construction of wind breaks, aimed at protecting the Hungarian medicine market and ensuring sufficient stocks of medicines in Hungary. The measures are two-fold – firstly, marketing authorisation holders are required to supply medicines to wholesalers to “meet the national demand” and secondly, a minimum stock of medicines must be maintained in the Hungarian market.

Under the new rules, marketing authorisation holders will be required to maintain a “minimum stock” of certain medicines in Hungary. Whilst, until now, the marketing authorisation holders were required to ensure certain minimum stocks in relation to their contracted wholesalers, the new legislation seems to expand this obligation so that it applies in relation to any other wholesaler as well. It is uncertain how the new rules would work in practice, for instance, whether marketing authorisation holders will be required to contract with any wholesaler if they are required to meet the minimum stock requirements. Although the ministry has had powers to set out the minimum stock levels and clarify the rules since November 2011, it has not yet done so. We can expect more clarity of these issues once the ministry adopts the implementing regulations.

In addition to maintaining “minimum stocks”, marketing authorisation holders have an obligation to supply any Hungarian pharmaceutical wholesaler if such wholesaler claims that a particular order is necessary to satisfy Hungarian demand. The national demand requirement is not specified but is in a category that is separate to minimum stocks. This new obligation clearly poses significant risks for marketing authorisation holders because they will be required to meet these orders even if, as a result, the requests of wholesalers exceed the “minimum stocks” requirements. It continues to be difficult to predict what consequences the new regulation will bring in practice and whether the demands of wholesalers will grow rapidly. If this is the case, pharmaceutical companies may be forced to review the allocation quotas of medicines for the Hungarian market.

The question that arises is whether the legislator has set certain limits to the supply obligation. Limitations to the supply obligations should be two-fold:

Firstly, if a wholesaler ordered medicines from a marketing authorisation holder and claimed that they were necessary to satisfy Hungarian demand, it must not export such medicines outside Hungary. To provide additional guarantees, the minister is expected to issue a decree which should specify the mechanism by which supplies and their retention in Hungarian territory would be monitored. Unfortunately, although marketing authorisation holders must comply with this supply obligation as of 6 July 2013, the minister has not yet issued guidance on it.

Secondly, the regulator will be entitled to prohibit exports of medicines if it is notified to the effect that: (i) the medicine is exported in quantities that threatens the continuous supply of such medicine in Hungary; and (ii) exports may disrupt the supply of the respective medicine in Hungary. Interestingly, these conditions are very similar to each other. It is difficult to see whether the regulator will ever establish that one can be met without the other. The law does not specify who is entitled to notify the regulator of these circumstances, should they arise. It can be expected, however, that notifications would be filed by health-care providers or market authorisation holders. The regulator will be entitled to prohibit exports for a period that is necessary for ensuring continuous supplies, but not for longer than one year.
### Pricing and reimbursement

Under the new law, marketing authorisation holders will be required to charge the lowest price that is currently charged in the EEA for their medicinal products in Hungary, if they wish to receive price reimbursement. The National Health Insurance Fund Administration (the OEP) will only admit a new product to its price reimbursement system, if:

(i) its Hungarian import price is not higher than the price of the same drug or a drug with an identical active ingredient marketed anywhere in the EEA; and

(ii) it is reimbursed under national reimbursement schemes in at least three EEA member states.

Under previous rules, marketing authorisation holders were required to meet these conditions only when they sought reimbursement for a product with a new active ingredient. However, they must now offer the lowest EEA price and prove their product is reimbursed in three EEA countries, whenever they ask the OEP to:

- admit to the reimbursement system:
  - a drug with an active ingredient that has not yet been admitted to the reimbursement system;
  - an existing pharmaceutical product in a new pharmaceutical form or with respect to a new route of administration;
  - an existing pharmaceutical product in a new indication;
  - a pharmaceutical product with a new active ingredient (ie, if the active ingredient is not currently reimbursed in Hungary);
  - a new combination, if any active ingredient in the combination is not currently reimbursed in Hungary;
  - a pharmaceutical product with a significantly beneficial therapeutic effect;
  - accept a price increase of a pharmaceutical product previously admitted to the reimbursement system; or
  - change a pharmaceutical product’s reimbursement category (eg, from a 25% reimbursement category to a 50% reimbursement category).

Unless a marketing authorisation holder offers the lowest EEA price and proves that the medicinal product is reimbursed in at least three member states, the product will not be admitted to the reimbursement scheme and patients would be required to pay the full price.
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Impact on pharmaceutical companies

The new rules will certainly have a significant impact on pharmaceutical companies and their daily operations.

The new legislation calls for compliance with all regulatory requirements under the threat of dawn raids and potential fines. Dawn raids always represent a disruption to daily business activities and require substantial time, cost and human resources allocations. It is, therefore, strongly suggested that pharmaceutical companies are prepared for potential inspections and that their staff as well as management are sufficiently trained in the procedure they should follow if inspectors appear at the door.

New requirements on obligatory supplies to wholesalers and minimum stocks still leave too many questions unanswered. Marketing authorisation holders usually decide on the amount of medicines allocated to a certain country according to the national demands of previous years often adding a certain security margin to ensure that national demands are met. Will the new system require them to act differently? Certain clarification of the new rules may come with the ministerial decrees that are yet to be issued. We will be monitoring developments closely.

The regulator has the discretion to impose fines that vary greatly in amount if pharmaceutical companies fail to comply with the new rules. Potential fines range from HUF100,000 to HUF500 million (approximately EUR340 to EUR1.7 million).

Key contacts

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