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Signs of increased focus on regulatory compliance in Poland

Recently, several Polish media outlets ran stories suggesting that pharmaceutical companies with operations in Poland are engaged in activities that violate the country's ethical codes and standards. As a result of this publicity, EU regulators are focusing on possible compliance violations by pharmaceutical companies which could result in a tighter regulatory atmosphere across the board for the industry.

The publications questioned the ethical aspects of pharma industry's sales and marketing policy towards medical professionals, citing coercive practices integrated into the sales training program used by a major pharma company. In the second situation the publications focused on the level of hospitality provided to group of medical professionals at sales promotion event, noting that such gifts and incentives raise ethical concerns. One physician was quoted as saying that sales representatives are able to find out from local pharmacists which drugs he prescribes, making him a target for increased sales pressure.

In May, the Minister of Justice initiated an investigation to determine whether any non-compliant or corrupt actions are resulting from the increasingly sophisticated sales and marketing tactics employed by pharmas. It is expected that the investigation will cover not only companies cited in the press coverage but also examine regulatory compliance standards for the whole pharma industry in Poland.

Moreover, the authorities in Poland are considering implementation of very restrictive regulations concerning the distribution and promotion of reimbursed products. This may have significant impact on the marketing, promotion and sales policies of pharma companies operating on this market. The limitations may affect the pharma market in several ways:

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Advertising/marketing expenditures—Currently, advertising expenses cannot exceed 10% of revenue gained in the preceding year from sale of the medicines manufactured in Poland. The new regulations propose a stricter limitation of marketing spending. This poses potentially significant business risk for all foreign manufacturers / suppliers of reimbursed medicinal products.

Medical professional outreach—The proposed regulations would penalize the offering or accepting of material benefits to or by physicians, pharmacists or hospital professionals who are dependent on any activities aimed at increase of the level of turnover of reimbursed medicinal products.

Availability of pharmacy data—The proposed regulations block the use of pharmacy data regarding product sales. Moreover, the authorities would be allowed to audit or examine all the contracts that pharmacies enter into to ensure that the arrangements do not offer any personal benefits. In the case of any non-compliant arrangements, apart from criminal responsibility for the pharmacist, the pharmacy license may be terminated.

Wholesaler agreements—Limitation for cooperation with wholesalers, since under the proposed regulations any entity engaged in the distribution of reimbursed medicinal products is not allowed to:

- differentiate the prices or other terms of trade between the purchasers
- make trade agreements dependent on additional actions to be taken by the purchaser

Clearly, the passage of any or all of these proposed regulations could have serious ramifications for pharmas already engaged in, or considering, business activities within Poland. Affected companies should assess their risk in light of the proposed regulations specific to the pharmaceutical industry, and if necessary work internally to establish guidelines that will help facilitate compliance and take measures to mitigate risk.■



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