Co-promotion of pharmaceutical products

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In October 2014 the co-promotion of pharmaceutical products became a top priority for the pharmaceutical sector – including pharmaceutical companies, leading non-profit associations and their legal counsel – after the Ministry of Health sent letters to certain pharmaceutical companies.

Cancellation of co-promotion permissions

The letters stated that the ministry was cancelling co-promotion permissions which had previously been granted to the pharmaceutical companies and demanded that they cancel their co-promotion agreements. The letters have been widely discussed in the sector and the question of whether co-promotion activities are prohibited by the ministry has arisen.

In order to understand the ministry's motive for issuing the letters, explain the need for co-promotion activities and ultimately reach a consensus on the matter, a meeting was held between ministry officials and sector representatives. The ministry explained that its main aim is not to prohibit co-promotion activities, but to clarify whether it is entitled to issue permissions for co-promotion activities. Responsibility for promotional activities will rest with the marketing authorisation holder, regardless of who is conducting the promotional activity. The ministry officials further explained that while some companies apply to the ministry to obtain permission to conduct co-promotion activities, others prefer merely to notify the ministry that such activities will be conducted, while others still neither ask for permission nor make notifications.

Promotion Regulation

The ministry underlined that the Promotion Regulation does not authorise it to issue permissions for such activities; therefore, the ministry decided to cancel the permissions it had already issued. However, ministry officials also questioned whether the Promotion Regulation provides a legal basis for co-promotion activities. While the definition of 'promotion' in Article 4/1(g) refers to both marketing authorisation holders and third parties that market pharmaceutical products with the contribution or support of the marketing authorisation holder, the ministry stated that there is no clear rule in the regulation in this regard.

The sector was seriously concerned about the ministry's statement at the meeting that companies should not enter into new co-promotion agreements and should cease co-promotion activities until the issue is clarified by the ministry.

Non-profit associations of both generic and innovator pharmaceutical companies have prepared a joint statement and provided it to the ministry. The statement emphasises that the regulation includes clear provisions on co-promotion activity and clearly points out that the responsibility for promotional activities always rests with the marketing

authorisation holder. Further, the regulation cannot prohibit such activities since it is in line with Article 98/3 of EU Directive 2001/83/EC, which states that "Member States shall not prohibit the co-promotion of a medicinal product by the holder of the marketing authorisation and one or more companies nominated by him".

Comment

The Promotion Regulation clearly demonstrates that the promotion of a pharmaceutical product may be conducted by a marketing authorisation holder or a third party. In both cases the marketing authorisation holder is responsible for such activity. The ministry is very sensitive to the subject and a revised definition of 'promotion' under the Promotion Regulation is expected. With this revision, the ministry is expected to re-emphasise that the marketing authorisation holder is the ultimate responsible party. It is also expected that third parties which carry out promotional activities with marketing authorisation holders will be subject to the notification requirement set out by the ministry.

Hence, marketing authorisation holders must pay specific attention to third-party companies and provisions included in the contracts to be concluded with them for promotional activities. Promotion of pharmaceutical products always carries a certain degree of risk and marketing authorisation holders must ensure that third parties are fully compliant with all local regulations, industry codes and global standards.

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