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New Belgian legislation to tackle shortage of medicinal products

Belgium has passed new legislation on the distribution of medicinal products, in order to ensure their uninterrupted supply to the Belgian market. This legislation will need to be implemented by royal decree.

Published on 3 February 2020, this new Act ("Act") completes the legislative measures taken in 2019 (by the Act of 7 April 2019) to tackle medicinal product shortages.

What are the Act's key features?

Obligation to supply full-line distributors and pharmacists within three working days

The Act obliges wholesalers ("*distributeurs en gros*" / "*groothandelaars*") to supply the following actors in the supply chain, within a period of three working days:

- So-called "full-line distributors", i.e. distributors with special public service obligations who should maintain, at all times, the supply of a range of medicinal products corresponding to the needs of a given geographic territory, ensuring such supply at short notice for the entirety of this territory ("*grossistes-répartiteurs*"/ "*groothandelaars-verdelers*"); and

- (public and hospital) pharmacies.

The Act indicates that this specific obligation only applies to deliveries completed as part of their special public service obligations.

Obligation to announce temporary supply interruptions

The Act reinforces the obligation for marketing authorisation holders to notify the Federal Agency for Medicinal and Health Products ("FAMHP") of temporary supply interruptions. Companies are now required to indicate the exact cause behind the temporary supply interruption.

Notifications that include a manifestly inaccurate cause or term of supply interruption are equivalent to a lack of notification.

Partial supply interruptions (i.e. when the requested amounts are not or not fully delivered) are equivalent to a temporary interruption.

These notifications should be made through the FAMHP's recently launched online application "PharmaStatus" (www.pharmastatus.be), which contains information about all medicinal products authorised in Belgium that are temporarily unavailable, or the commercialisation of which is at a temporary or definitive stop.

Temporary export limitations

Medicinal products affected by an interruption of supply may be subject to a temporary export limitation or prohibition. This procedure needs to be further implemented by royal decree.

Unlike the previous general export prohibition, which was annulled by the Constitutional Court in 2019 (case number 146/2019), this export restriction procedure aims at limiting the export of specific medicinal products for which a shortage is notified or established.

Costs resulting from supply interruption

A royal decree will determine the conditions under which pharmaceutical companies will need to bear any additional costs consequent to a supply interruption of their medicinal products (e.g. the extra costs resulting from a switch to a more expensive alternative product).

Pharmacists' right of substitution

The Act also entitles pharmacists to substitute an unavailable medicinal product with an alternative product consisting of the same active substance or combination of active substances, dosage, administration and frequency route. The prescribing healthcare professional is entitled to make a "therapeutic objection" to such substitution, on a patient per patient basis. The reasons for such therapeutic objection should be mentioned in the patient file. The pharmacist must inform the patient of such substitution.

Monitoring of compliance

On its website (www.afmps.be and www.fagg.be), the FAMHP indicates that it will monitor the new notification and supply obligations. It also confirms that its previous circular letter (n°605) about notifications of supply interruptions is no longer applicable, and that it will adopt a new circular letter to take into account the new measures under the Act.

At the time of writing, no royal decrees have been published yet. An update will be issued after the royal decrees are public.

Contacts

If you have any questions concerning the items in this newsflash, please get in touch with your usual Deloitte Legal - *Lawyers* contact at our office in Belgium or:

- Christel Brion, cbrion@deloitte.com, + 32 2 800 71 16

For general inquiries, please contact: bedeloittelegal@deloitte.com, + 32 2 800 70 00

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