

CLIENT ALERT

Contracts & E-Commerce

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Belgian Council of Ministers approves draft decree on internet sales of medicines

Immediately after the meeting of the Council of Ministers on 26 September 2008, Belgian Minister of Social Affairs and Public Health Ms. Laurette Onkelinx inter alia announced that one of the measures that the Council had adopted, related to a new legal framework for the internet sales of medicinal products.

Introduction

Over the past years, the Belgian Federal Agency for Medicinal Products found that more and more medicinal products were purchased over the internet by Belgian consumers. Since the safety, quality and efficacy of medicinal products sold over the internet could not be guaranteed, the Agency already posted a general warning against the purchase of medicinal products over the internet on its website.

Article 28-30 EC-Treaty - Free movement of medicinal products

However, this warning was primarily aimed at the prevention of internet sales of counterfeit medicines, which posed a genuine threat to public health.

The Agency, however, was struggling with the online sales of medicines by legitimate online or virtual pharmacies established in other Member States. First of all, Directive 2001/83/EC provided that individuals should be able to purchase and receive from another Member State a reasonable quantity of medicinal products intended for their personal use (see Recital 30 of the Directive). And secondly, following the ruling of the European Court of Justice of 11 December 2003 (Case C-322/01, *DocMorris*), Member States could no longer prevent the mail order and internet sales by pharmacies which were legitimately established in and according to the laws of another Member State. The Court explicitly stated that such a ban would be disproportionate as long as OTC ("over the counter" or non-prescription) products were concerned. For prescription only medicines ("POM"), however, the Court ruled that it would not be disproportionate if Member States would limit the mail order and internet sales of such products.

A legal basis for the internet sales of OTC products

Since Belgium lacked an explicit legal framework regulating the online sales of OTC medicines and/or POM, the Agency lacked a legal basis to effectively prevent or control the online sales of products. Ever since the DocMorris ruling, it was expected that the Belgian legislator would quickly adopt legislation banning the sales of POM. Instead, a more general approach was chosen, which led to a proposal which completely amends the Royal Decree of 31 May 1885 laying down the pharmacist's duties.

As announced on [Ms. Onkelinx website](#), not only will the government lay down detailed rules on the internet sales of medicinal products, but also describe the "pharmaceutical care" which will in general have to be provided by pharmacists to patients.

The basic rules for allowing internet sales of medicines in Belgium are the following:

- The internet sales are prohibited for prescription only products;
- The internet sales have to be performed by an authorized pharmacy open to the public;
- The concerned products have to be authorized in Belgium;
- The patient privacy rules have to be respected;
- The delivery has to take place in the pharmacy or has to be sent in a sealed packaging;
- Certain minimum information will have to be mentioned on the website to ensure the rational use of medicinal products;
- The pharmacists wishing to sell products over the internet will have to notify the Agency and the Association of Medical Doctors;
- Strict rules will apply to ensure that the quality of the product is guaranteed during the delivery.

Conclusion

So far, the draft Royal Decree has not yet been published in the Belgian Official Journal. It remains to be seen whether or not the Decree will take into account the intra-community aspects of internet sales, and will for instance not discriminate pharmacies established at the Belgian border in other neighboring Member States. We will provide more detail about the content of the Decree as soon as it has been published in the Belgian Official Journal and entered into force.

[Link: PressCenter.org: De ministerraad vergaderde op vrijdag 26 September 2008 in de Wetstraat 16 onder het voorzitterschap van eerste minister Yves Leterme.](#)

For more information, contact: [Benito Boone](#) or [Thomas De Meese](#).

EU proposal to update IT trade rules

On 17 September 2008, the European Commission presented at the World Trade Organization (WTO) a proposal to update and expand the Information Technology Agreement (ITA).

Introduction

The IT industry will recall the significant achievement that was reached in 1996 by 29 WTO Members, all of whom agreed to

eliminate, on a reciprocal basis, import tariffs on nearly 200 IT products, such as computers, semi-conductors, and telecommunications equipment. Currently over 70 WTO Members, including Australia, Canada, China, the EU's 27 Member States, Japan, and the United States, together representing about 97% of world trade in IT products, have agreed to be bound by the ITA. The European Commission has now made a proposal for updating and expanding the ITA.

Contents of the proposal

The Commission's proposal of 17 September would:

- eliminate customs duties on *new* products that have entered the market since the original 1996 agreement;
- tackle non-tariff barriers as well as problems caused by the non-functioning of some of the mechanisms and procedures provided for in the current ITA; *and*
- extend membership of the ITA to other WTO Members who manufacture and trade in IT products but are not yet part of the ITA.

The Commission hopes that WTO Members will engage in discussions on these proposals in the near future. However, agreement amongst the ITA Members may be hard to come by, especially in view of pending WTO litigation. Earlier in 2008, the U.S., Japan, and Chinese Taipei lodged a complaint against the EU with the WTO, claiming that the EU was undermining the ITA by increasing duties on some TV set-top boxes, flat screens and printers able to scan, copy, and fax. Consultations held in June and July did not resolve the dispute and the complainants requested the establishment of a panel at the WTO Dispute Settlement Body meeting of 29 July 2008.

Not surprisingly, the Commission has rejected claims that the EU is not fulfilling its obligations under the ITA. The Commission considers that certain items in the past decade have moved from being classified as IT goods into common consumer goods. The EU believes that tariffs could be raised on those products because they are no longer purely for businesses.

Conclusion

The IT industry should keep abreast of both of these developments as they are likely to affect the prices of goods that they export to WTO Members. Businesses are also encouraged to make representations to regulatory authorities of WTO Members if one of their products is affected or likely to be affected by a change in a tariff rate.

Link: [Press Release: EU proposes major update to IT trade pact](#)

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