

## The Danish Medicines Agency's action against the sale of illegal medicinal products on the internet 2007

### Background

In September and October 2007, the Danish Medicines Agency launched an action against illegal medicinal products sold on the internet.

The purpose of the action was to investigate

- whether some companies still engage in the internet sale of medicinal products that were deemed illegal by the Danish Medicines Agency earlier this year, implying that they may not be sold to consumers.
- the illegal sale of products and advertising of such products of which the Danish Medicines Agency has been made aware through cooperation with foreign authorities, etc.

### Applicable law

According to section 2 of the Danish Medicines Act<sup>1</sup>, a medicinal product means any product that

- 1) is presented as a suitable product for the treatment or prevention of disease in human beings or animals, or
- 2) may be used in or administered to human beings or animals in order to restore, change or modify physiological functions by having a pharmacological, immunological or metabolic effect or to make a medical diagnosis.

The concept of medicinal product contains two independent medicinal product definitions: the first definition is based on the product designation, the second on the product's mode of action. A product is deemed to be a medicinal product when either definition can be applied.

According to section 2(i), presentation may be designation, display, recommendation, etc. – e.g. on packaging, an enclosed description of the product or mention at the website of the company – which may give the consumer the impression that the product is suitable for the treatment or prevention of disease. This definition covers both products that have a true therapeutic or clinical effect and products that do not have the effect that consumers may be lead to believe from the way the product is presented, including ineffective and harmless products presented as medicinal products.

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<sup>1</sup> Act no. 1180 of 12 December 2005.



According to section 2(2), products having one of the mentioned modes of action will be covered by the medicinal product definition, regardless of how they are presented if they may be used in or administered to human beings or animals in order to restore, change or modify physiological functions or to make a medical diagnosis.

According to section 7 of the Danish Medicines Act, a medicinal product may only be marketed or dispensed in Denmark when a marketing authorisation has been granted either by the Danish Medicines Agency pursuant to the Danish Medicines Act or by the European Commission (Community marketing authorisation) pursuant to the provisions laid down by the Council of the European Union.

Section 64(i) of the Danish Medicines Act prohibits any advertising of medicinal products that are not legally sold or dispensed in Denmark.

### **The investigation**

The actions of the Danish Medicines Agency focused on:

- Illegal sale of – including advertising for – 86 products deemed by the Danish Medicines Agency to have been sold as medicinal products without a valid marketing authorisation in the first seven months of 2007<sup>2</sup>. The companies behind the 86 products were previously instructed to remove the products from the market.
- Illegal sale of – and advertising for – 37 products of which the Danish Medicines Agency has been made aware through cooperation with foreign authorities, etc. The products concerned include products containing active substances that have not been described on the packaging or other places in connection with the promotion of the products.

Products containing one or several active substances that have not been authorised by the Danish Medicines Agency may be harmful due to adverse reactions among other things. The Danish Medicines Agency authorises products containing medicinal substances explicitly to protect consumers in the best possible way.

Products containing active substances are not downright harmful. However, if a product is advertised as having an effect which it does not have, the consumer taking the product concerned runs the risk of stopping another – and effective – therapeutic treatment, thereby potentially aggravating the disease.

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<sup>2</sup> The products classified as medicinal products by the Danish Medicines Agency and for which no marketing authorisation has been granted is available at the website of the Danish Medicines Agency (in Danish only).

[<http://www.laegemiddelstyrelsen.dk/include/5905/produkter.asp>]. The list includes a number of products and covers products classified as medicinal products after 15 August 2006.

The investigation was only launched at Danish websites opened by companies registered in Denmark, the reason being that the Danish Medicines Agency cannot take legal action against foreign companies' sale and promotion of medicinal products on the internet.

The investigation took place in September and October 2007. The search for the sale of illegal medicinal products on the internet is only a snapshot and does not necessarily pick up all products and distributors.

In the autumn of 2006, the Danish Medicines Agency launched an action against the illegal sale of impotence medicine and weight-loss products on the internet. The report is available (in Danish only) at the website of the Danish Medicines Agency. [<http://www.laegemiddelstyrelsen.dk/1024/visLSArtikel.asp?artikelID=10143>].

### **Investigation result**

On the basis of the investigation of illegal sale of medicinal products on the internet, the Danish Medicines Agency draws the following conclusions:

A. Investigation of illegal sale of the 86 products that the Danish Medicines Agency earlier in 2007 deemed to constitute illegal medicinal products for which no valid marketing authorisation has been granted:

- 1) Apparently, six products from five companies are still being sold illegally, regardless of the fact that the Danish Medicines Agency previously instructed the companies to stop the illegal sale.  
The Danish Medicines Agency will report the five companies to the police.
- 2) Apparently, 13 products are being sold illegally by 13 companies that have not previously been linked to the sale of the said 13 products. The Danish Medicines Agency has notified the 13 companies, informing them that the Danish Medicines Agency finds that in selling the said products, the companies violate section 7 of the Danish Medicines Act since no marketing authorisations have been granted for the products. The companies have the opportunity to make a statement before the Danish Medicines Agency makes a final decision in the matter.

If the Danish Medicines Agency concludes that a company has violated section 7 of the Danish Medicines Act, the company concerned will be instructed to stop selling the products.

- 3) Apparently, six products from two companies are still being illegally advertised for – without actual sale of the products. The Danish Medicines Agency has notified the two companies, informing them that the Danish Medicines Agency finds that in advertising for the said products, the companies violate section 64(i) of the Danish Medicines Act since no marketing authorisations have been granted for the products.

The companies have the opportunity to make a statement before the Danish Medicines Agency makes a final decision in the matter.

If the Danish Medicines Agency concludes that a company has violated section 64(i) of the Danish Medicines Act, the company concerned will be instructed to stop advertising for the products.

- B. Investigation of illegal sale of the 37 products of which the Danish Medicines Agency has been made aware through cooperation with foreign authorities.
  - 4) Presumably, two products are being sold illegally on three websites opened by companies registered outside Denmark. The Danish Medicines Agency has referred these cases to the relevant foreign medicines authorities.

## **Conclusion**

The Danish Medicines Agency found that 15 out of the 123 investigated products are apparently still being sold illegally as medicinal products. The companies behind six of the products will be reported to the police. The companies behind the rest of the products have been asked to make a statement in the matter. Notification to the police may also be a possibility in these incidents.

The investigation also revealed that six out of the 123 investigated products are being advertised for – without a direct sale taking place. The companies advertising for the six products have been asked to make a statement in the matter to the Danish Medicines Agency. Notification to the police may also be a possibility in these incidents.

In addition, the Danish Medicines Agency found that two out of the 123 products investigated are presumably being sold from websites opened by companies registered outside Denmark. The Danish Medicines Agency has notified the relevant foreign medicines authorities.

The investigation shows that there is still good reason to monitor the sale of illegal medicinal products over the internet. In 2008, the Danish Medicines Agency will therefore undertake further investigations targeting medicinal products sold on Danish websites.

## **Take care of yourself – also when you take medicine**

The Danish Medicines Agency concurrently runs a campaign called “Take care of yourself – also when you take medicine”. You can find information about the campaign at the website of the Danish Medicines Agency (in Danish only). [<http://www.laegemiddelstyrelsen.dk/1024/visLSArtikel.asp?artikelID=9533>]. This page offers good advice on the buying of medicine on the internet.

## Appendix 1

The 18 products below represent the products against which the Danish Medicines Agency has taken procedural steps as a result of the investigation and search for products.

Appetil
Bogense Vital-kur
Buteless
Cialis Generic
EquiGarlic
Equipro Bio-Wormer
Equisupport
EW&F Hvidløgsflager
Glucoselevel
Kamagra
Let Løb Propolis Massage Balsam
LiDa
PSOrir
Scifil
Scilla
So-Kalm Plus
Viamax Power Tabs+
Womenra