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1 New regulation on general conditional reimbursement

By Attorney-at-Law **Mikkel Vittrup** and Attorney-at-Law **Annika Valla Broman**



On 1 January 2010 a new regulation on general conditional reimbursement came into force. Previously it was only possible for the Danish Medicines Agency to grant general conditional reimbursement for the treatment of specific diseases. With the new regulation the Danish Medicines Agency also has the authority to grant general conditional reimbursement to specific groups of persons.

According to Section 144(1) of the Danish Health Act the Danish Medicines Agency can grant a medicinal product general reimbursement if the product has a safe and valuable therapeutic effect on a well-defined indication including that the price of the product is commensurate with the product's therapeutic value.

If the Danish Medicines Agency, however, determines that the criteria for granting general reimbursement are not fully met, it is possible for the Danish Medicines Agency to grant the product general conditional reimbursement, for example if the Danish Medicines Agency is of the opinion that a patient initially must be treated with a cheaper medicinal product. This is already the case today in relation to treatment of high cholesterol where a number of cholesterol lowering products (eg Atorvastatin or Colestyramin) are granted general condi-

tional reimbursement. A patient can therefore only receive reimbursement to one of these products if treatment with cheaper products (eg Simvastatin or Lovastatin) has shown to be inadequate.

Under the previous regulation on general conditional reimbursement it was only possible to grant general conditional reimbursement for the treatment of specific diseases such as high cholesterol or high blood pressure. With the new regulation it is also possible to grant general conditional reimbursement for the treatment of specific groups of persons, eg persons above the age of 70 years.

According to the remarks to the amendment of the Danish Health Act, the intention is not to change the administration of the regulation on general conditional reimbursement; the intention is only to give the Danish Medicines Agency the authority to target specific groups of persons.

2 Prohibition against marketing of health services in the media does not include marketing on the Internet

By Attorney-at-Law **Mikkel Vittrup** and Assistant Attorney **Caroline Thufason**

On 29 April 2009 the Eastern High Court ruled that the prohibition against marketing of health services does not include marketing on the Internet. A Danish website selling weight loss services had made links on its website directing the visitors to a TV-station's website showing previously sent television programmes, where the website was mentioned. The High Court ruled that such linking does not constitute breach of the prohibition of marketing of health services in the media.

Under Danish law marketing health services on the Internet is legal. However, the Danish Marketing of Health Services Act prohibits marketing of health services in television, film, video etc.

A Danish website advising on weight loss, Slankedoktor.dk, linked from its website to a regional TV-station website where the website was mentioned in some previously shown video clips. The video clips were programmes on overweight and weight loss in which the managing director of Slankedoktor.dk, a physician, participated in the programme as one of several experts on weight loss. The programmes also featured people who had lost weight through help from the website.

Prosecution was brought against the company providing the website stating that such linking to video clips were not in compliance with the prohibition of marketing health services in the media. The managing director of the company providing the website claimed that linking to a programme produced by an independent TV-station cannot be considered marketing in breach of the law regulating marketing of health services. Furthermore, he claimed that the matter does not concern actual marketing on TV, on the contrary, only linking to TV programmes on the Internet, which can be visited by anyone showing interest herein. The National Board of Health on the contrary claimed that all motion pictures are covered by the prohibition against marketing of health services in the media, and the Board further supported its view by the fact that the preparatory works to the law said that the prohibition concerns all forms of television.



In the case referred to in the Danish Weekly Law Reports 2009.2064, the Eastern High Court upheld the decision from the first instance court stating that the prohibition against marketing of health services in the media does not include marketing on the Internet. The High Court referred to the wording of the law compared to its background, which was considered a liberalisation of the law in force at the time. The first instance court had also emphasized that the website's visitors were looking for advice and information on various products and services in relation to weight loss. Furthermore, the High Court did not find that the prosecutor had proved that there had actually been marketing of the website and its health services in the video clips on the TV-station's website.

3 New council for assessment of the use of expensive medicines in hospitals

By Attorney-at-law **Mikkel Vittrup** and Attorney-at-Law **Annika Valla Broman**

Danish Regions has established a council for assessment of the use of expensive medicines in the Danish hospitals. The main task of the council is to develop a common national recommendation list for the use of expensive medicines in the Danish hospitals.

The interest organisation Danish Regions has established a council for assessment of the use of expensive medicines in the Danish hospitals (in Danish Rådet for Anvendelse af Dyr Sygehusmedicin (RADS)).



According to the chairman of Danish Regions, Bent Hansen, the purpose of RADS is to cut down the expenses in relation to the use of expensive medicines as RADS' main task is to develop a common national recommendation list for the use of expensive medicines in the Danish hospitals. The recommendation list is intended to ensure that the Danish Regions will obtain higher discounts. Further, the recommendation list is intended to ensure rational and consistent use of expensive medicines throughout Denmark, especially the biological medicines used in the treatment for cancer, arthritis etc.

The pharmaceutical industry must expect that RADS' recommendations will have an impact on future AMGROS tenders and the use of expensive medicines in general.

RADS has the following composition:

- 1 chairman - appointed jointly by the Danish Regions
- 1 representative from Danish Regions
- 2 representatives from each of the five regions
- 1 representative from AMGROS
- 1 representative from the National Board of Health
- 1 representative from the Institute for Rational Pharmacotherapy
- 1 representative appointed from the Danish Association of Clinical Pharmacology

4 The Supreme Court confirms the European Court of Justice's practice regarding re-packaging of parallel imported pharmaceutical products

By Attorney-at-Law **Per Håkon Schmidt** and Attorney-at-Law **Annika Valla Broman**

On 21 September 2009 the Supreme Court ruled that Orifarm A/S had violated Sanofi-aventis Denmark A/S' trademarks when repackaging and de-branding parallel imported pharmaceutical products. The Supreme Court's ruling is in accordance with long standing Danish case law which was not changed by the European Court of Justice (ECJ) ruling C-348/04 (Boehringer II). Sanofi-aventis Denmark A/S was represented by Attorney-at-Law Per Håkon Schmidt.

Background

In the period 1996 to 2000 Orifarm A/S (Orifarm) had marketed parallel imported pharmaceutical products from Sanofi-aventis Denmark A/S (Sanofi-aventis). Orifarm repackaged the parallel imported pharmaceutical products. On the repackaged products Orifarm placed the logo "Orifarm" with a particular font and a triangle logo with additional geometric shapes illustrating whether the drug in the pack consisted of tablets, capsules, drops or ointment. Orifarm's logo and triangle logo were placed in close connection with Sanofi-aventis' trademark. Orifarm had placed the logos on both outer packages and inner packages consisting of tubes and smaller packages.

The Supreme Court's decision

In the case referred to in the Danish Weekly Law Reports 2009.2956, the Supreme Court ruled in accordance with long standing ECJ case law according to which a parallel importer is not entitled to repackage, and in doing so, to reapply the trademark on the new packages unless the repackaging is necessary for the parallel importer in order to market the product in the importing country. Furthermore, a number of additional conditions must be met, including that the name of the repackaging manufacturer must be clearly marked on the package and that the presentation of the repackaged pharmaceutical product may not be of such nature that it discredits the trademark holder.



In this case it was undisputed that Orifarm had been entitled to repackage and reapply the trademark on the packages of the pharmaceutical products subject of the proceedings in order to market the products in Denmark. The Supreme Court considered, however, that both the Orifarm logo and the Orifarm triangle logo were so dominant and were placed in such a connection to Sanofi-aventis' trademark that both logos - also when rated separately - were likely to discredit Sanofi-aventis' trademark. The fact that it was specified on the packages that Orifarm had repackaged the pharmaceutical products including that Sanofi-aventis was the producer of the product and the fact that the courts in Germany and United Kingdom to a greater extent have accepted that the parallel importer can place logos on the repackaged packages did not change the Supreme Court's assessment.

The Supreme Court was also of the opinion that the inner packages consisting of tubes and smaller packages were intended to serve as independent packages after being removed from the outer package. Therefore Sanofi-aventis could also oppose against the labelling of these packages, and Sanofi-aventis could also oppose against Orifarm's marketing of the logos on its website.

When parallel importers repackage a pharmaceutical product they must notify the trademark owner of the repackaging. The Supreme Court emphasized that if the notification system is to work properly, it must imply that the trademark owner responds to the proposed

design of the package within a reasonable time if the trademark owner does not find the design acceptable. As the Supreme Court found that Sanofi-aventis had responded too late after Orifarm's notification no claims for damages were awarded to Sanofi-aventis.

Any questions to the decision can be directed to Attorney-at-Law Per Håkon Schmidt.

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