Roaccutan® has been Removed from the Medicines Register in Denmark

Interview with Marketing Director Hanne Schultz Kapel of Roche a/s, Denmark

Hanne Schultz Kapel, Copenhagen

Marketing Director Hanne Schultz Kapel in this interview comments on the brief statement of the withdrawal of Roaccutan® from the Danish market according to company letter to Danish dermatologists in April.

In 1968, Roche initiated a development program for vitamin A-like substances, which are also known as retinoids. Over the years, various medications for treatment of mild and severe skin conditions have been developed, including Roaccutan® (isotretinoin). In 1982, Accutane®, as it is known in the USA, was launched there. Ireland followed in April 1983, and after this Roaccutan® was launched in all the other EU countries. Isotretinoin is now registered in more than 90 countries throughout the world. Up until today, Roaccutan® has been used by more than 14 million people around the globe.

The indication is severe acne, such as nodular acne, conglobata acne or acne that constitutes a risk of permanent scar formation.

Isotretinoin was only available in Denmark on prescription from specialists who have experience in use of systemic retinoids.

Many patients have benefited greatly from treatment with Roaccutan®, experiencing both physical and psychological improvement. A large proportion of the patients are young people who are adversely affected psychologically by their acne.

Because isotretinoin is extremely teratogenic, this medicine is contraindicated in women who are pregnant or breastfeeding. Furthermore, the medicine is contraindicated in fertile women unless reliable contraception is used.

In order to avoid exposure of pregnant women to isotretinoin, the Authorities decided that holders of marketing authorizations for isotretinoin must implement a monitoring system and provide information material for use by specialists, pharmacists and patients – in Roche known as the Pregnancy Prevention Program (PPP). This system is to stress the warnings on the teratogenic risks associated with isotretinoin, as well as to advise on contraception before and during treatment, and of the need for pregnancy testing. Roche has complied with these requirements from the Authorities, and has prepared and updated these materials continuously through the years.

Twice a year, Roche submits an overview statement to the Authorities of the amount of PPP materials delivered within Europe.

Generic substitution has existed in Denmark since 1991. The Danish Medicines Agency decides which generic medications can be mutually substituted (interchanged). This means that the pharmacist will provide the patient with the cheapest product, unless the doctor and/or the patient want an alternative. Because of the competition between the manufacturers of original medicines and generic medicines, there will often be a large price difference between the individual medicines. The national health care insurance supplement is given in accordance with the substitution rules and means that a supplement can only be given for the price of the cheapest products. If the patient, for medical reasons, cannot use the cheapest product, an increased supplement can be given for an alternative product. The physician must send an application for the increased supplement to the Danish Medicines Agency.

Currently in Denmark, there are six generic isotretinoin products on the market resulting in extremely tough competition.

Roche in Denmark has therefore decided to remove Roaccutan® from the Danish market as of 9 April 2007.

We have had a fantastic collaboration with the Danish dermatologists. The decision has been taken purely because of the price. The prices are changed by the companies every 14 days and if you are not the cheapest you do not sell. It's like playing Russian roulette.

We have experienced that people call us, because we are the original manufacturer, for enquiries about side effects, medical aspects and materials, even if the patient has been given a generic medicine by the pharmacy. Often, the dermatologist does not know which product the patient is being treated with.

Over the last years, we have had to recognize that the resources invested in Roaccutan® are not balanced by sales, and now have had to act on the consequences of the system's regulations.

With these words Hanne Schultz Kapel concludes the interview.

Jørgen Serup
Chief Editor