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Press release

Availability of medicinal products in small markets.

Cooperation within the Nordic Countries

Availability of medicinal products is an issue in small markets in EEA. Task forces on behalf of Heads of Medicines Agencies have been looking into availability problems for both veterinary and human medicinal products and possible solutions. Non-availability of medicinal products has also been discussed at the meeting of the Nordic Council's Ministers of Health.

Consequently a Nordic working group was established to explore the possibility of a more harmonized Nordic market for medicinal products. Decision was taken to start a pilot project in January 2008 with the participation of Iceland and Sweden. This project comprised cooperation with regard to applications for marketing authorisations for medicinal products by Mutual recognition or Decentralised procedures. When Sweden, as a Reference Member State, received an MRP/DCP request the applicant was approached and asked to add Iceland to the procedure if Iceland was not already a Concerned Member State. The cooperation between Iceland and Sweden preempted that the Icelandic Authorities fully accepted the Swedish assessment of the application. The pilot project has now been finalized with Iceland being added to more than thirty procedures.

The Nordic Group is now exploring the possibilities to expand this cooperation to the other Nordic Countries. There is an advantage for the industry to apply for marketing authorisations in all the Nordic countries at the same time since this creates the possibility for industry to produce multilingual Nordic packages. The group is looking at ways to harmonize, even more, the labeling issues and decrease national requirements to help industry with producing multilingual packages.