EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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18 January 2011
EMA/H/PD/2011/7032/001/N
Patient Health Protection

Subject: NOTICE for Parallel Distribution
Your notification of 14 January 2011 for:
Ganfort - 300 µg/ml + 5 mg/ml - Eye drops, solution - 1 bottle - EU number: EU/1/06/340/001
Member State(s) of origin: Austria, Belgium, Cyprus, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Sweden, United Kingdom, Spain, Poland, Portugal, Norway, Malta
Member State(s) of destination: France

Dear Sir/Madam,

Further to your submission of a notification for parallel distribution of the above-mentioned Centrally Authorised Medicinal Product, I notify you that the regulatory check by the European Medicines Agency has now been completed.

I take this opportunity to remind you that a Centrally Authorised Medicinal Product may be distributed in parallel only if it is in conformity with the latest annexes to the Community Marketing Authorisation for the product. For this purpose, the Agency will prospectively provide such annexes to all parallel distributors.

You must send a completed "Notification of a change" form with supportive documentation to the Agency for review if the information that you previously provided to the Agency has changed (e.g. change in repackager). However, you should implement any change in the packaging and/or leaflet if the Community Marketing Authorisation is amended affecting the product information without the need to inform the Agency, unless informed to the contrary (e.g. changes due to safety reasons).

I would also like to remind you that, according to the current case-law of the Court of Justice of the European Communities, the trade mark owner must be given advance notice by the parallel distributor that the repackaged product is to be put on sale. I should highlight that this regulatory check is without prejudice to the rights of the trademark owner.

Further information is available in the Post-Authorisation Guidance on Parallel Distribution on the Agency's website http://www.ema.europa.eu.

Yours faithfully,

Francisco Penaranda

Head of Parallel Distribution and Certificates

cc:
- Mrs France Rousselle, Agence Française de Sécurité Sanitaire des Produits de Santé, 143-147 Bd. Anatole France, F-93285 Saint Denis Cedex, France
- Allergan Pharmaceuticals Ireland, Castlebar Road, Westport, Co. Mayo, Ireland