European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 26 October 2007
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Direct Line +44 20 75 23 74 11

RECEIVED
29 OCT 2007

Mr. Bertrand Michel
MEDIWIN LIMITED
12-13 Martello Enterprise Centre
Courtwick Lane
Littlehampton
West Sussex BN17 7PA

Subject: EMEA NOTICE for Parallel Distribution
Your notification of 16 October 2007 for:

- **Ketek – 400 mg / 10 film-coated tablets - EU number: EU/1/01/191/001**

Member States of origin: Austria, Belgium, Denmark, Finland, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden and United Kingdom.
Member State of destination: France

Dear Mr Michel,

Further to your submission of a notification for parallel distribution of the above referenced Centrally authorised Medicinal Product, we notify you that the EMEA regulatory check has now been completed.

We also 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 EMEA will prospectively provide such annexes for a given product to all parallel distributors that have already obtained a Notice for that product.

Should the authorisation be amended affecting the product information (packaging and package leaflet) or in case any other information you previously provided to the EMEA has changed (e.g. change in repackager), you must send a completed "Notification of a change" form to the EMEA for review.

Further information is available on the EMEA Website http://www.emea.europa.eu.

We 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. We should highlight that this regulatory check is without prejudice to the rights of the trademark owner.

Yours sincerely,

Tony Humphreys
Head of Sector Regulatory Affairs and Organisational Support

cc: Aventis Pharma S.A., Regulatory Affairs Department, 20 avenue Raymond Aron,F-92165 Antony Cedex France

Mrs France ROUSSELLE, Agence Française de Sécurité Sanitaire des Produits de Santé, 143-147 Bd. Anatole France, F-93285 Saint Denis Cedex, FRANCE