NOVARTIS

[redacted]
Global Program Regulatory Manager

Novartis Pharma AG
[redacted]
CH-4056 Basel
Switzerland

[redacted]

To: CHMP chairman: Dr Eric Abadie,
Agence Française de Sécurité Sanitaire des Produits de Santé
143-147 boulevard Anatole France
93285 Saint-Denis Cedex
France

Cc: Rapporteur: [redacted]
Medicines and Healthcare products Regulatory Agency

Co-Rapporteur: [redacted]
Läkemedelsverket

EMA Product Team Leader: [redacted]
European Medicines Agency (EMA)

15 April 2011

Withdrawal of original application for Joicela® (lumiracoxib), EMEA/H/C/002104

Dear Dr Abadie,

We would like to inform you that Novartis has taken the decision to withdraw the Marketing Authorisation Application for Joicela® (lumiracoxib) 100 mg film-coated tablets, which was intended to be used for symptomatic relief in the treatment of osteoarthritis of the knee and hip in patients who are non-carriers of the DQA1*0102 allele.

This decision was taken after CHMP indicated that in order to conclude a favorable approval decision, additional new data would be required, which could not be generated within the timeframe allowed in the Centralised Procedure.

This withdrawal has no impact on the countries where lumiracoxib is currently marketed. Novartis continues to support the positive benefit/risk of the product, when used according to its approved label, and will continue to make lumiracoxib available to patients in these countries.

Novartis remains committed to personalized medicines and biomarker programs that help address the needs of individual patients by targeting the right drug to the right patient.

Novartis reserves the right to make further lumiracoxib submissions in Europe at a future date, in this or other therapeutic indications.

Novartis agrees for this letter to be published on the EMA website.

Yours sincerely,

Novartis Pharma AG on behalf of Novartis Europharm Limited

[redacted]
Global Program Regulatory Manager

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Global Program Regulatory Director