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European Federation of Pharmaceutical Industries and Associations

EGA
Making Medicines Affordable

Ministry of Health and Social Affairs
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SE - 103 33 Stockholm
Sweden

Goran.hagglund@social.ministry.se

Brussels, 12 December 2012

Dear Health Minister Hägglund,

Subject: Upcoming EU Shortages of Active Pharmaceutical Ingredients (APIs) - Calling for Immediate EU Action

The European Federation of Pharmaceutical Industries and Associations – EFPIA – and the European Generic medicines Association - EGA – (thereafter jointly referred to as the European pharmaceutical industry) represent leading manufacturers and suppliers of medicines (innovative and generic) across the EU and in your country.
6 months ahead of major changes in the rules governing the EU importation of active pharmaceutical ingredients (APIs) into the European Union (EU), we would like to share with you our concerns on our future ability to maintain the continuity of medicines supply for medicines produced in the EU.

While we have been supporting the EU approach to develop greater supervision and enforcement in the area of API quality and compliance to Good Manufacturing Practices (GMP) as laid out in the EU Falsified Medicines Directive[1] (FMD) adopted in the summer 2011, we believe the implementation of the new API importation rules from 2 July 2013 could threaten the ability of EU-based manufacturers of medicinal products to sustain their production.
European citizens could face major shortages of medicines caused by the delay in the issuing of the necessary 'written confirmations' for APIs by exporting third countries as required by the EU FMD.

Current information gathered from our own internal investigations as well as from our continuous and extended interactions with key stakeholders indicate that today there is still no predictability as to whether or not APIs will be able to reach the EU. None of the most significant API exporting 3rd country (eg, India, China or the USA) has either formally confirmed being in a position to issue the so-called 'written confirmations' by the deadline of

[1] Directive 2011/62/EU
http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

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2 July 2013 or made a formal request to the EU to initiate the assessment of EU equivalence (which, if positive would waive the importation administrative requirement).
Without knowing the viability of the first two options, the only remaining option available to the European pharmaceutical industry to mitigate the risk of shortages remains to seek to obtain an EU GMP certificate for the APIs concerned. However, from a practical standpoint the currently available EU inspection resources cannot, in the remaining 6 months, allow the undertaking and completion of the necessary EU inspections. As a consequence, regardless of the good track records of compliance to EU and international GMP of long existing API manufacturers, these remain unlikely to be eligible for the so-called 'exceptional circumstances' waiver.

In view of the above and acknowledging the recent intensified efforts by the European Commission (EC) to engage in bilateral discussions with key API exporting 3rd countries to resolve this matter, we would like to urge you to actively engage alongside the EC, the Heads of Medicines Agencies (HMA), the European Medicines Agency (EMA) and the European pharmaceutical industry to reflect on risk mitigating clauses while transposing and implementing nationally the EU FMD.
The European pharmaceutical industry has put forward a number of approaches to transitional arrangements which we trust are faithful to the legislation and achievable in the 6-month timeframe ahead of entry into force. Some of those have also being evoked by other member states. These transitional arrangements would limit the disruption of medicines availability in your country. EFPIA and the EGA have made detailed proposals in this regard to the EC.

We would like to highlight that quality and GMP compliant APIs supplied today cannot be considered unsafe on 2 July 2013 simply because of the lack of an administrative confirmation.
Awaiting scheduled inspections by EU authorities, and in anticipation of capacity building by key API exporting 3rd countries' authorities to issue written confirmation or apply for the EU list of equivalent countries, we encourage a pragmatic and phased approach which would reinforce the certification by Qualified Persons of EU-based marketing authorisation holders that API suppliers comply with GMP (mandatory since 2004) as sufficient proof of compliance with the EU FMD.

EFPIA and EGA members take the continuity of API and medicines supply very seriously and are determined to cooperate with the European Commission, the EMA and member states in resolving this important issue.

We would welcome an early opportunity to discuss this matter with you in a meeting to discuss in greater details a pragmatic approach forward.

Yours sincerely,

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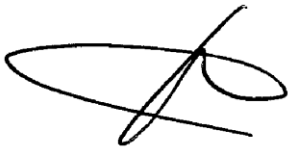
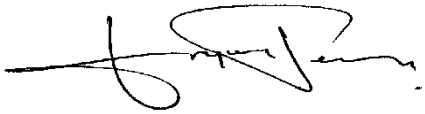


Richard Bergström
EFPIA Director General



Greg Perry
EGA Director General

Cc: Ms. Christina Åkerman, Local Head of Medicines Agency
Mr. Stefan Karlsson, Health Ministry
Ms. Paola Testori Coggi, Director General, DG SANCO
Mr. Aginus Kalis, Chairman, HMA
Mr. Guido Rasi, Director, EMA
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*The **European Federation of Pharmaceutical Industries and Associations (EFPIA)** represents the research-based pharmaceutical industry operating in Europe.*

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