PRESS RELEASE

STAKEHOLDER MEETING HELPS EXCIPIENT CERTIFICATION PROJECT MOVE FORWARD

Summary:

- The European Commission's decision not to develop a directive for certain excipients lends greater urgency to the creation of an effective certification scheme
- EFCG, IPEC Europe, FECC and PQG convened a meeting of stakeholders to discuss a way forward in developing a scheme to improve excipient safety and quality
- Certain key issues – such as excipient classification and the role of the regulatory authorities – have been identified

---

Brussels, 22 June 2009. Representatives from pharmaceutical manufacturers, suppliers of excipients and regulatory authorities met in Brussels, Belgium, recently to discuss the role of third-party certification of excipient suppliers in improving quality assurance in pharmaceutical manufacturing and distribution.

The meeting was a key stage in a process started last year when the European Fine Chemicals Group (EFCG) and International Pharmaceutical Excipients Council (IPEC) Europe signed a memorandum of understanding to start work on a certification system for Good Manufacturing Practice and Good Distribution Practice(1).

With the European Commission shelving its plans to implement a Directive on GMP for 'certain' pharmaceutical excipients(2) there is more need than ever to develop alternative methods for assuring the quality and safety of these ingredients.

A significant proportion of medicines may consist of a range of excipients, ingredients which are covered by limited regulation. This joint initiative supports not only better protection of the health of citizens, but also the implementation of what is already widely accepted practice for many reputable excipient suppliers and distributors.

Certification, in which companies can be externally audited by an independent third party, is intended to ease the administrative burden on excipient suppliers, users and competent authorities. Additionally it will provide GMP and GDP standards which will improve assurance of excipient quality and safety, and as with any standardisation process, facilitate trade.

The certification scheme has four main components: classification of excipients according to risk; GMP; GDP; and auditor competency.

By including a classification system which matches the requirement for enhanced implementation of GMP with potential risks to the patient, the scheme becomes more holistic and inclusive.

The plans for certification are ambitious and the stakeholder meeting made it clear that some significant obstacles need to be overcome, including developing a classification scheme that is agreed upon by both users and suppliers of excipients, as well as establishing a workable system which will allow regulators to accept a third-party audit.

The excipient landscape is complicated and the list of purposes for which excipients are used - as defined in international pharmacopoeias - is extremely long. Yet despite this complexity the feedback at the stakeholders' meeting was for a "simple" certification scheme – a tall order indeed!

"This meeting was invaluable as it raised a number of challenges that will need to be addressed as the third-party certification project moves forward," said Patricia Rafidison, chair of IPEC Europe. "It was encouraging to see the high level of engagement shown on this topic by both industry and regulatory bodies, and I look forward to further dialogue on this important project."

References:

(1) EFCG-IPEC Europe Memorandum of Understanding – June 11, 2008
(2) DG ENTR Conclusions on Study on Pharmaceutical Excipients – June 3, 2009

Note for Editors:

EFCG

The European Fine Chemicals Group (EFCG) - a sector group of CEFIC, the European Chemicals Industry Council - was formed in 2004 to be the forum, the focus and the voice for European Fine Chemical Manufacturers. The issues affecting its members' competitiveness drive EFCG. One such issue is the need for certifiable, enforceable, adequate and appropriate quality standards for pharmaceutical excipients destined for use in European medicines.

For further information, contact: Arnulf Heubner, Merck, arnulf.heubner@merck.de

For further information on EFCG, visit http://efcg.cefic.org.

IPEC EUROPE

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed in 1991 by manufacturers and end-users of pharmaceutical excipients. It is an association comprising three regional pharmaceutical excipient industry associations covering the United States, Europe and Japan (which are known respectively as IPEC-Americas, IPEC Europe and JPEC). IPEC's objectives are to contribute to the development and harmonization of international excipient standards, the introduction of useful new excipients to the marketplace and the development of good manufacturing practice for excipients.

For further information, contact: Iain Moore, Croda Chemicals, iain.moore@croda.com

For further information on IPEC Europe, visit www.ipec-europe.org .

PQG

The PQG was formed in 1977 to promote development of a consistent approach to pharmaceutical quality and good manufacturing practice. As a special interest group of the UK's Chartered Quality Institute, the PQG has published many guidance documents covering all aspects of pharmaceutical quality and standards for pharmaceutical packaging materials and excipients.

For further information see www.pqg.org

FECC

FECC is the Brussels-based body representing the European chemical distribution industry to the EU Institutions. Its member companies generate sales of more than 30 billion euro. FECC members – most of them SMEs - are actively involved in the promotion and implementation of environmental, health and safety standards such as the Responsible Care programme. FECC members create value in the supply chain by meeting the demands of over one million downstream users ranging over all branches of industry. They distribute and regularly import substances and preparations vital for the success of the European economy.

For further information see www.fecc.org