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A year ago the European Commission published its 'pharmaceutical package', a suite of legislative proposals which included a proposed Directive on counterfeits.

This [proposal](#) (see also *Excipients Insight's* October and November editions) is now being discussed under a co-decision procedure by the European Council and Parliament.

The scope of the proposed Directive is the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source.

The draft proposal as drawn up by the Commission's DG Enterprise contains a number of measures to improve oversight of the supply chain and quality of active pharmaceutical ingredients, but did not extend to excipients. Some delegations within the Council have proposed to include excipients

in the scope, but others have expressed scrutiny reservation on the way to treat excipients in this Directive.

The latest appraisal document from the Council has been prepared but is not yet accessible to the public. However, a prior version - released in October - notes that some have asked that elements of the draft on manufacturing and importation be applied to high-risk excipients.

Another delegation agreed in principle with this assertion, but asked for a cost:benefit analysis, as well as asking whether the Council deemed current standards for excipients sufficient.

Other suggestions from delegations include that a definition be included that describes excipients themselves, and also caters for the import and production of APIs and excipients. Some felt excipient manufacturers should be covered in Article 111, which

governs inspections.

Compliance with GMP and self-verification/accreditation should also be applied to excipients, according to some delegations, although one commentator suggested that it should not be compulsory to use an accredited body.

Regarding self-verification, questions were raised about how often, and with what means, this should take place.

Meanwhile, the Environment, Public Health and Food Safety Committee (ENVI) is leading the assessment within the European Parliament. A draft report by the rapporteur - MEP Marisa Matias - should be available in January. The ENVI Committee is planning to vote in April, and the Parliament should vote in plenary in May 2010.

IPEC Europe is playing its part in the ongoing debate about falsified medicinal products, focusing on the importance of the supply chain. At the IPEC Europe seminar in January 2010 the aim is to dedicate a full session to supply chain security.

Dr. Bernd Renger; Chairman of the European Qualified Person (QP) Association will give a presentation on challenges of compliance, while Dr. Iain Moore (from Croda, and excipient certification coordinator) will present the certification project from the angle of how it will help enhance supply chain security.

The word from the chair

Dear Members,

December 15, 2009

Welcome to the last edition of Excipients Insight for 2009, which has been a productive year for IPEC Europe. We grew our membership to 79 companies and continued to share the excipients story via seminars, training contributions, conferences and our newsletters.

The Committees can be congratulated for achieving a phenomenal amount of work. The Harmonization team improved efficiency and dialogue in supporting PDG activities. The Regulatory Affairs and GMP Committee pushed the excipient master file agenda, launched its activities on Quality by Design and signed off on the new composition guide. Meanwhile, the GDP Committee devoted much of its time to the advancement of the certification project. Certification is arguably the most ambitious undertaking ever undertaken by IPEC Europe and has demanded considerable investment of resources and the involvement of various partners from industry, as well as dialogue with regulators.

2009 also saw our organisation take on a more global view with the setting up of the IPEC Federation, and we continue to develop closer relationships with key stakeholders to the benefits of our members in the area of supply chain risk, innovation and quality.

Despite limited resources we were able to achieve a great deal, thanks to the sterling efforts of our members. Many thanks for your support.

On behalf of the board, I wish you all happy holidays and a Merry Christmas!

Patricia Rafidison

Chair to IPEC Europe

Certification Project Update

All members have received the request to review the excipient classification and GMP annex that is build around it and the IPEC-PQG GMP Guide.

Members' input and considerations now are critical to the project. IPEC Europe members are invited to provide their views about the risks identified that would drive the need for enhanced GMPs for excipients. In particular the coordinator, [Iain Moore](#), would like to address the following questions:

- Are these risks ever seen in practice? Does the additional GMP specified match up with the risks so that they are controlled?
- Are there things in the GMP Annex that you now have to do that you do not do now? - have we raised the bar?

The development team will be meeting in Cannes on 27 January, so please have your comments sent in well before so that that can consider them.

Feel free to contact the coordinator or the Classification and GMP team leaders. We hope to be issuing the GDP Annex for review very shortly in the same manner.

Also the Auditor Competency team and scheme teams are making good progress, and their outputs will be available for review in the first quarter of 2010.

This is a critical part of the development of these standards. Your broader experience and knowledge will be absolutely invaluable in setting a standard that is achievable and which delivers the benefits we all want to see. Meantime the authorities on both sides of the Atlantic and Rx-360 look at our progress in eager anticipation that we can deliver a scheme that moves the whole industry forward.

For all team members and those of you who have provided comments and a review, the coordinator would like to express his sincere thanks for your contribution, wishing to all of you a very happy and relaxing holiday season.

News from the IPEC Europe committees



Quality/Regulatory Affairs Committee

The **inaugural meeting** of the IPEC Europe Quality and Regulatory Affairs Committee, which will take place at the Hotel Gray d'Albion, Cannes on Wednesday 27 January 2010.



Harmonisation Committee

Formaldehyde testing in PEG: the Committee was involved in the EDQM activity on formaldehyde testing in polyethylene glycol. An HPLC-method provided by EDQM was compared to the compendial test. The results support the view that antioxidants present in macrogols influence the existing test, and can give rise to false negative results, whereas the HPLC-method gives reliable results even in the presence of antioxidants.

If you are interested in joining an IPEC Europe committee or would like to participate in some of their activities please contact the chairs:

- Certification Project Committee: [Iain Moore](#)
- Quality and Regulatory Affairs Committee: [Carl Mroz](#)
- Harmonization Committee: [George Mansveld](#), or the vice-chair [Bernhard Fussnegger](#)
- GDP Committee: [Frank Milek](#).



IPEC Europe Calendar

Board	19 Jan - Brussels
GDP	27 Jan - Cannes
Harmonisation	27 Jan - Cannes
Quality/RA	27 Jan - Cannes



Eye on Europe

European Commission

EU Health Commissioner takes over pharmaceutical policy

Responsibility for the development of pharmaceutical and biotechnology policy has been taken out of the hands of the Enterprise and Industry Commissioner and transferred to the Health and Consumer Policy directorate, DG Sanco, under Commissioner-in-waiting John Dalli.

The shift means that DG Sanco takes over responsibility for the European Medicines Agency (henceforth to be known as the EMA rather than the EMEA).

The reshuffle by Commission President Jose Manuel Barroso has been welcomed by consumer advocacy groups and non-governmental organisations (NGOs), including the European Public Health Alliance (EPHA), which noted that in most EU member states pharmaceuticals comes under the health ministry jurisdiction, not industry.

Meanwhile, Belgian premier Herman Van Rompuy was elected President of the European Council on 19 November as the EU's first permanent president. He will serve for 2½ years. Catherine Ashton from the UK is named the EU's high representative for foreign affairs and security policy, as well as a vice-president of the new Commission.

For further information: see this [press release](#) and the [Commission website](#).

Consultation on GMP guidelines

A public consultation has been launched on part I [chapter 1](#) of GMP guidelines on Quality Management System and on part [chapter 2](#) of the GMP guidelines on Personnel.

Both chapters are have been amended in order to integrate the principles of ICH Q10 on Pharmaceutical Quality Systems. Comments and suggestions are invited by 18 February 2010 and should be sent by email to: gmp@emea.europa.eu and ENTR-GMP@ec.europa.eu.

Tackling administrative burdens

DG Enterprise and Industry has prepared an [online questionnaire](#) to register problems and suggestions on administrative burdens. Contributions and feedback will be summarised in periodic reports published on the DG Enterprise website.



European Paediatric Formulation Initiative (EuPFI) meeting

The EuPFI consortium/steering committee, met on 8 December for their 8th meeting. Johann Philipp Hebestreit of BASF attended for IPEC Europe. The agenda included:

- [Updates on workstreams](#), including: excipients; taste masking and testing; administration devices; extemporaneous/industry-verified preparations; and a new workstream on age appropriateness of formulation;

- [Introduction of PDCO Formulation Working group](#): medicines developed for adults are generally adjusted for use in children which often is found to be insufficient. Timing plays a big role when PIPs (paediatric investigation plans) are considered at a very late/too late stage. Guidance is needed on "safe" and good quality excipients. A QWP guideline on the development of medicines for paediatric use is expected to be open for consultation by Q2 2010;

- [Database on safety of excipients used for paediatric formulations](#): A strategy for the development of this database based on a literature search strategy was discussed;

- The [2nd EuPFI Conference](#) will be held in Berlin, Germany, 21-22 September 2010;

- An official [website](#) has been set up at www.eupfi.org and will soon be updated to include additional information on the project.

Michael Thompson (GSK) is the main IPEC Europe board contact for EuPFI.



EDQM: glycans, monographs and the observer meeting

In its [135th session](#), the European Pharmacopoeia Commission adopted a new general chapter on glycan mapping (2.2.59) and 13 new monographs.

Of particular note is that, for the first time, the EDQM organised a specific meeting for observers to the Convention on the elaboration of a European Pharmacopoeia.

Observers were able to participate in the scientific work of the Commission, benefit from European experience in this area and to gain access to work on the quality control of medicines and the methods of analysis used and other activities of the EDQM.



The objective of this meeting was to provide a forum for discussion, to exchange experiences and views and to identify areas of common interest.

At the end of the meeting, participants agreed on a number of possibilities for a strengthened collaboration, for example in the elaboration of monographs, participation in PTS studies and other laboratory activities.

Download your IPEC Guides here...

2009 IPEC Quality Agreement Guide & Template

- Download PDF format

2009 IPEC Excipient Information Package (EIP): Template & User guide

- Download PDF format

2008 Qualification of Excipients for Pharmaceutical Use

- Download Word format
- Download PDF format

2008 The IPEC-PQG GMP Audit Guideline

- Download Word format
- Download PDF format

2008 The IPEC GDP Audit Guideline

- Download Word format
- Download PDF format

2006 The IPEC-PQG GMP Guideline

- Download PDF format

2006 The IPEC GDP Guideline

- Download PDF format



Eye on the World



Guidance for industry - residual solvents

The Food and Drug Administration has published guidance to assist manufacturers in responding to US Pharmacopeia requirements for the control of residual solvents in drug products.

The final guidance, unlike the draft version, permits manufacturers to submit test data or statements on the solvents from qualified suppliers of drug components to show control of residual solvents in finished drug products. Specifically, the guidance makes recommendations on the following:

1. How new drug application (NDA) and abbreviated new drug application (ANDA) applicants for non-compendial

drug products should limit residual solvents as described in ICH Q3C. This contains recommendations on solvent classification and permitted daily exposure.

2. How manufacturers of compendial drug products that are not marketed under an approved NDA or ANDA can comply with USP General Chapter <467> "Residual Solvents" and the Federal Food, Drug, and Cosmetic Act (the Act).

3. How holders of NDAs or ANDAs for compendial drug products should report changes in chemistry, manufacturing, and controls (CMC) specifications to FDA to comply with General Chapter <467> and 21 CFR 314.70.

IPEC Europe

Supporting the interests of pharmaceutical excipient developers, producers, distributors and users

IPEC Europe
9, Avenue des Gaulois
B-1040 Brussels
Belgium

Secretariat officers:

Elena Miceli
Carole Capitaine

Tel: +32 2 736 53 54
Fax: +32 2 732 34 27
Email: info@ipec-europe.org

Editor:

Phil Taylor

Tel: +44 1527 835 437
Email: pjtcomms@online.rednet.co.uk

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IPEC Federation General Assembly

The IPEC sister associations will meet in Cannes in the framework of the IPEC Europe annual seminar to held the first General Assembly on 27 January with the aim to finalise and sign off the by-laws.



[Rx-360 concept finds favour with European audience](#)

SecuringPharma.com's take on the Rx-360 consortium's European launch can be read [here](#).

[MEP questions figure used to justify not having mandatory inspections of API plants](#)

An MEP has questioned the EC's estimate that 20,000 API producers supply the EU, used to justify not mandating inspections, says *in-PharmaTechnologist.com* [here](#).

[Europeans Inspect Fewer Than 19 Chinese Drug Factories a Year](#)

EU authorities only inspect pharma factories in China that make medicines for Western patients after something bad has happened, according to a paper reported on BNET [here](#).

Events Calendar



IPEC Europe seminar
Cannes, France
28 January, 2010
More information [here](#).

Informex USA
San Francisco, USA
18-19 February, 2010
More information [here](#).

7th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology
Valeta, Malta
8-11 March, 2010
More information on this [website](#).
Download the flyer [here](#).

CPhI Japan
Tokyo, Japan
21-23 April, 2010
More information [here](#).

IPEC Stability Guide draft open for comment

The final draft of the IPEC Europe/IPEC Americas Stability Guide is being circulated to members for final comments by 4 January 2010. The review is limited to a verification of the content. Pending board approval from both sides of the Atlantic, the guide will be hopefully published early 2010. Should you need further information please contact Iain Moore.

This document offers best practice and guidance in the establishment of an excipient stability programme. The excipient supplier may be a manufacturer or a distributor (or both). The Guide highlights the factors to consider when planning and executing a scientific study that will determine the stability of an excipient.