EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Public Health and Risk Assessment
Pharmaceuticals
Head of Unit

Brussels, 29 July 2011

PHARM 588

PHARMACEUTICAL COMMITTEE - HUMAN

SUMMARY RECORD

14th February 2011

66th meeting

OPENING

Ms. Patricia Brunko, Head of Unit SANCO C8 – Pharmaceuticals opened and chaired the meeting.

AGENDA

The draft agenda of the 66th meeting (PHARM 573) was adopted with additional items under AOB.

1. LEGISLATIVE ISSUES

a) Pharmaceutical Package

The Commission representative informed the participants about state of play of the Pharmaceutical package (legal proposals adopted in December 2008).

The new pharmacovigilance legislation (Directive 2010/84/EU and Regulation (EU) No 1235/2010) was adopted and published (OJ No L 348 of 31 December 2010) and will apply from July 2012.

A political agreement in first reading on the legal proposal on falsified medicines was achieved in December 2010. Adoption by the European Parliament and the Council is expected by late spring 2011. The key issues are: introduction of harmonised safety features, quality requirements for API's imported from 3rd countries and identification of legally operating pharmacies. 18 months implementation period is foreseen.

Progress of the legal proposal on information to patients: the European Parliament completed its first reading while little progress was achieved in the Council. The Commission is preparing modified proposals adopting a majority of the EP amendments as announced by Commissioner Dalli in the the European Parliament plenary.

In the discussion Member States pointed out that there would be a lot of work to be done through delegated acts in the implementation of the legislation on falsified medicines. In this respect the Commission representatives announced a comprehensive presentation of the new procedures for adoption of implementing and delegated acts under agenda item 2A.

b) Review of the clinical trials directive 2001/20/EC

The Commission representatives updated the Committee on progress with this project. The Commission has scheduled adoption of a legislative proposal for a revision of the 'Clinical Trials Directive' 2001/20/EC for 2012. In the framework of the impact assessment, an initial public consultation was held from October 2009 to January 2010. The responses, as well as a summary document of the responses have been published on the 'clinical trials website' of DG SANCO.

A public consultation on a concept paper on the revision of the 'Clinical Trials Directive' has been launched on 9 February 2011. In this paper the Commission presents for discussion a preliminary appraisal, on the basis of the current state of the impact assessment, of options to address some of the key concerns of the Clinical Trials Directive.

In the subsequent discussion certain Member States pointed out that procedural adjustment may not tackle divergent views between Member States. It was also acknowledged that ethical aspects would not be harmonised. Some Member States expressed their concerns that a centralised assessment could not duly take into account national specifics. The Commission reminded the participants that the public consultation was still open in order to collect the views of all stakeholders.

a) Review of Council Regulation (EC) No 297/95 on fees payable to the European Medicines

The Commission informed the Committee that the new pharmacovigilance legislation[1], which will become applicable in July 2012, provides that pharmacovigilance activities of EMA will be financed from fees. In order to enable EMA to charge such fees when this legislation becomes applicable, the Commission intends to prepare a legal proposal, accompanied with an impact assessment, to amend the Fees Regulation (Council Regulation (EC) No 297/95) in respect of pharmacovigilance. As to the timing, the aim is to put forward the proposal by the end of 2011 or early 2012.

Once this proposal is adopted, the Commission would proceed with a broader exercise to review the Fee Regulation globally, as recommended also in the evaluation of EMA and in the subsequent discussions at the conference presenting the outcome of the evaluation in June 2010.

The Member States were interested to know how the national competent authorities would be involved in the process. The Commission emphasised that standard rules for legislative proposals would be applied:

- The legal proposal will be accompanied by an impact assessment
- Public consultation of at least 12 weeks is foreseen
- As nationally authorised products will be subject to the new EU pharmacovigilance procedures, information from the Member States was necessary and was being collected by EMA.

The Commission representative also explained that since the fee related provisions in the new pharmacovigilance legislation are very general, it is necessary to identify the activities which are to be subject to fees as well as the type of fee. The Commission clarified that a separate impact assessment will be carried out for the overall revision of the fee regulation in the second step and that the Members States will be regularly informed on the progress of the procedure.

2. IMPLEMENTATION OF PHARMACEUTICAL LEGISLATION

a) Implementation of the new pharmacovigilance legislation

[1] Directive 2010/84/EU and Regulation (EU) No 1235/2010 of 15 December, OJ L 348 of 31.12.2010.

The Commission representative provided the participants with an explanation of the new procedures for adoption of implementing and delegated acts following the Lisbon Treaty. Seven implementing and one delegated acts are foreseen in the pharmacovigilance legislation and two implementing acts and three delegated acts in the legislation on falsified medicines.

As regards pharmacovigilance, as a delay of 18 months is foreseen before the new legislation becomes applicable, it is important that the implementing elements necessary for the proper application of the legislation are put in place by July 2012. In order to respect the hierarchy of norms, the Commission representatives emphasised that priority needs to be given to the implementing acts specified in the legislation, more specifically Article 87a of the Regulation and Article 108 of the Directive.

b) Variations regulations – extension to 'purely national' products

The Commission representative informed the participants on the status of transposition of Directive 2009/53/EC of the European Parliament and of the Council amending Directive 2001/82/EC and Directive 2001/83/EC adopted on 18 June 2009. Members States were reminded to notify the Commission of their national transposition measures.

The final step to conclude the adoption of the variations' initiative announced by the Commission in 2006 will be the amendment of Regulation (EC) No 1234/2008 to enlarge its scope to include so called "purely national authorisations".

c) Revision of Annex 14 on good manufacturing practices for the Medicinal Products derived from Human Blood or Plasma

The Commission representatives informed the participants that Annex 14 of the GMP guide is currently under revision. This guideline covers the good manufacturing practices for the preparation of medicines based on blood or plasma.

The revised guideline proposes:

1) a solution to define the responsibility of the responsible person present in the blood establishments and the qualified person present in the manufacturers.
2) a reference to the quality practices for blood establishments. These good practices will be the quality standards in the blood establishments
3) clear rules for the quality of imported blood used for fractionation

Further reflections are ongoing as regards the requirements for imported plasma used in fractionation programs for third countries. In that case, the plasma components sourced in the third countries are fractionated in the EU but the manufacturing products are not brought onto the EU/EEA market.

The Commission representative announced that would distribute the revised text after the meeting. It would be discussed on 22 February with GMP inspectors with a view of publication by the end of March.

d) Implementation of the herbal directive

The Commission representative informed the participants of certain aspects of the application of Directive 2004/24/EC. The deadline for its transposition ended on 30 October 2005 with a transitional period of seven years for traditional herbal medicinal products that were already on the market, which expires on 30 April 2011. The Commission is receiving numerous questions on the implications of this date. To address questions received, a Q&A document has been published.

Currently, the Directive has been transposed in all Member States. However, the number of applications under the simplified procedure is unevenly distributed among Member States. The Committee for Herbal Medicinal Products (HMPC) is collecting concrete figures on the basis of a questionnaire. In addition the Commission invited the Member States to inform the Committee of their national experience with this Directive.

Finally, the HMPC has raised with the Commission the issue of the borderline between medicinal products and food. The Commission representatives reminded the Committee that according to the case-law of the ECJ the certification of products as medicinal products is to be done by national competent authorities on a case by case basis.

e) Use of the EudraCT database

The Commission representative informed the participants about the progress of inclusion of data on clinical trials contained in EudraCT in EudraPharm, in line with Guideline 2008/C168/02 and Guideline 2009/C28/01 setting out the principles, responsibilities, and procedural aspects. In addition further detailed guidance has been published in chapter V of EudraLex, Volume 10.

With regard to protocol-related information, programming has been finalised and the public launch is expected soon. However result-related information is presently not contained in EudraCT and therefore, prior to making anything public, work has to focus on the format and procedure to submit this information by the sponsor in the first place. This has to be subsequently programmed. A public consultation on the format was held in 2010 and the results are currently being analysed.

3. INTERPRETATION OF PHARMACEUTICAL LEGISLATION

a) Recent European Court of Justice judgments

The Commission called the Committee attention to the recent rulings and to the court's conclusions:

- In its rulings of 28 October 2010 (Case C-350/08, "Commission v. Lithuania") and of 22 December 2010 (Case C-385/08, "Commission v. Poland) the Court addressed accession related questions, in particular the situation of marketing authorisations for medicinal products granted in accession countries prior to accession.

  The Court ruled that new Member States are required (under Article 6(1) of Directive 2001/83/EC) to examine whether national marketing authorisations issued prior to accession comply with the requirements of EU legislation on pharmaceutical products in force at the time of accession and, as from the date of accession, to ensure that only medicinal products for which the authorisations comply with EU requirements are placed on the market. The term marketing authorisation has to be interpreted according to EU law, i.e. as acts conferring an unconditional right to immediately place the product on the market.
- In its ruling of 22 April 2010 (Case C-62/09, "ABPI") the Court considered whether financial incentive schemes introduced by a public body would fall in the scope of advertising pursuant to Directive 2001/83/EC. According to the Court, the health policy defined by a Member State and the public expenditure in that field do not pursue any profit-making or commercial aim; therefore, a financial incentive scheme, which forms part of such a policy, cannot be regarded as seeking the commercial promotion of medicinal products. Member States have nevertheless to comply with Directive 89/105/EC relating to the transparency of measures regulating the pricing and reimbursement of medicinal products.

4. INTERNATIONAL ASPECTS

a) Combined products – international harmonisation initiatives

The Commission informed the participants about discussions held in an ad-hoc task force, composed of representatives of EU, USA, Japan, Canada and Australia in the devices and medicinal products areas, on possibilities of international convergence in the area of the regulation of combination products.

The Commission representatives requested the participants for their views and agreement before any endorsement could be given internationally to move forward.

On the request of the participants the Commission representative provided some additional clarifications with regard to the proposed project. While the Member States acknowledged that such an international harmonisation work could be an interesting exercise, the need for further harmonisation within the EU before engaging in international discussions was emphasized.

In conclusion, the international project was considered premature by most Member States before reaching an internal EU consensus and therefore the Committee did not endorse pursuing such international collaboration for the time being.

b) International Conference on Harmonisation

The Commission informed the Committee of the outcome of the last ICH Steering Committee meetings and provided an overview of the latest ICH guidelines and developments in the areas of quality, safety, efficacy and multidisciplinary topics.

Recently, an extended emphasis has been put on efforts to extend international outreach of the ICH guidelines beyond the ICH regions. The aim of the newly created Regulators Forum is to have an open, robust dialogue among regulators and to assist with the implementation of ICH guidelines, while ICH Global Cooperation Group focuses on training on ICH guidelines in non-ICH regions.

The last ICH meeting in Fukuoka marked the 20 year anniversary of this successful international harmonization initiative. The ICH Steering Committee endorsed the opening of the ICH technical working groups to the active participation of experts from qualifying members of the Global Cooperation Group (GCG). This represents a new level of involvement of the GCG and will provide an opportunity for direct technical contributions to the work of ICH, a more global perspective, and will advance implementation of ICH guidelines.

c) Other on-going international activities

The Commission representatives provided the participants with an overview of ongoing developments in the area of international regulatory collaboration. Bilateral regulatory dialogues under confidentiality arrangements with our counterparts from the USA FDA, Canada, and Japan) have been further enhanced. In particular the relationships with the US FDA have been further intensified through the placement of the EMA/FDA liaison officials in Washington and London respectively. In the last bilateral meeting, held on 29-30 September 2010 in Brussels, both parties agreed on the successful conclusion of the Transatlantic Simplification Action Plan.

At the same time, regulatory dialogue with India, China and Russia has become significantly relevant on APIs. Regulatory dialogue on pharmaceuticals with Russia is now placed under the umbrella of the general Heath Dialogue.

5. UPCOMING INITIATIVES

Antimicrobial resistance

The Commission representatives informed the participants about ongoing activities in the of antimicrobial resistance:

- The Commission five year strategy on AMR, based on the Council Conclusions and the activities following the 2009 Staff Working Paper.
- Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) aiming to identify priority cooperative activities in the areas of prudent therapeutic use of antimicrobial agents, infection control and strategies for improving the pipeline of new antimicrobial drugs. A recommendation for a framework for implementing and coordinating these activities will be prepared for the 2011 EU-US Summit.
- Action plan on incentives to develop new effective antibiotics to be included in the proposed new Strategy on AMR so as to ensure a comprehensive approach when considering the existing mechanisms and needs in terms of new antibiotics along with the promotion of the prudent of antimicrobial agents.

A number of participants reported on their national initiatives in this area and sought some additional clarifications in the subsequent discussion. In this context the Commission representatives explained that the actions listed in the Strategy document would be subject to individual impact assessments and that the outcomes of TATFAR should be regarded exclusively as technical and scientific statements or recommendations to be followed by appropriate follow-up mechanisms in both jurisdictions.

6. HANDLING OF SHORTAGES OF PERITONEAL DIALYSIS SOLUTIONS

Member States exchanged their experience with handling of shortages of certain peritoneal dialysis. Furthermore, the regulatory handling of the variations of the relevant marketing authorisations, in order to ensure the long term supply of the European market, were discussed (in particular whether to consider them under a referral procedure). In this context, pros and cons of various procedures were discussed in order to achieve the best outcome for the patients. The scientific assessment should be the same and ensure that the variations would be adopted approximately at the same time in all Member States. The Commission representatives indicated that they would come back to Member States on the option chosen.

7. AOB

Revision of QRD template

Czech Republic proposed discussion of the recent revision of the QRD template as a number of Member States were not in favour of the possibility to include a reference to a product website in the packaging of OTC medicines. The Commission took note of these concerns and invited Member States to call the attention of the Commission if they identified any cases of promotional information on product specific websites listed in PIL.

Translation of substance names

The Commission representatives raised the issue of Member States' requests for a change of the substance name during the Commission procedure. In the past it was agreed that, as this was an issue of translation, these concerns should be raised earlier in the process, otherwise the Commission needs to depart from an opinion of EMA.

Names of medicinal products

Furthermore the Commission representatives sought the view of participants on public health concerns due to very similar names of medicinal products containing different formulations of the active substance. There was consensus that any confusion should be avoided.