Country Report 2013 : France

- **Mission and goals**

Through permanent contacts with health authorities such as French medicine agency (ANSM) and ministry of Health, the Conseil national de l'ordre des pharmaciens (CNOP)

- guaranties the ethics and the quality of professional exercise though deontology code
- controls the access to the professional exercise
- defends the honour and independence of the profession
- ensures competency of pharmacist by validation of professional training
- judges offences though disciplinary committee

Activities of section B of Central Council of section B of the Order of Pharmacists (industrial pharmacists)

A **strategic seminar** was hold beginning of October 2012,taking opportunity of the new council (election of half of the members in June 2012) , which led to 13 working groups and a road map for the next 3 years. The main objectives for the next 3 years were defined as follows :

- promote and develop the industrial pharmacy profession (security, responsibility..)
- reinforce efficiency of section B
- improvement of the image of the order towards industrial pharmacists
- reinforce collaboration with health authorities and other sections of the order of pharmacists
- reinforce the image of section B at international level (IEPG, Morocco...)

- Cold chain transport recommendations:
The section B of the Order of Pharmacists has published the "Recommendations concerning the transport of health care products under controlled temperatures (5°C +/- 3°C)" in French and English version. The French Order wanted to formalize for the carriers, its vision of the technical and regulatory constraints in order to improve the quality of the transport activities and the observance of these requirements in the eyes of the law. This document contains a main part with the recommendations related to the services required, indicators, responsibilities and audit, as well as six appendixes about methodologies. It is now available on the French Order of Pharmacists website and the EIPG website respectively in French and English version. Hardcopies in the French version are also available.

- **French pharmaceutical record and Medicine shortage services:**

Decree n° 2012-1096 was published on 28th of September 2012 : industrial companies have to inform health authorities of any potential or real shortages and

further actions undertaken towards retail pharmacists, hospital pharmacists and others in the supply chain .

The council of Pharmacists is developing an IT system (using the French pharmaceutical record (DP) and batch recall services) to collect the information flow between all actors of the distribution chain for any potential shortages and to arrange discussions with their National Agency. The French pharmaceutical record will allow to collect information at the national level, available within 5 mn to 100 % of the pharmacists, 24h/24, 7j/7.

The go live is planned for end of 2013.

- **International Good distribution practices :**
  This working group is drafting guidance regarding transport and distribution outside France for products which stability is not guarantee outside 15°C-25 °C, with a focus on the responsibility and duties of the responsible pharmacist.

- **Role and place of the deputy responsible pharmacist** in the pharmaceutical companies : survey on-going in order to know the expectations of the deputy responsible pharmacists , to evaluate their knowledge of their role and responsibility and to promote their status.

- **Medicinal products and Health Products Safety Reform Act in France published on 29 of December 2011 :** The law, sponsored by France's Ministry of Labor, Employment and Health to restore public confidence and enhance the safety of medicinal and health products, affects all stakeholders and healthcare professionals and impacts key points in the lifecycle of a medicinal product: marketing authorization, post marketing authorization, reimbursement, advertising, promotion, medical visit to the hospitals, French sunshine act, distribution, prescription, dispensing , off label, compassionate use authorisation, post-marketing studies, vigilance....
  ⇨ several working groups in section B are involved in establishing guidances to precise the role and responsibility of the responsible pharmacists such as Temporary Recommendation for Use , shortage of medicines

- **Good practice of OTC products**
  a guideline on good practices for pharmaceutical companies marketing self-medication products is being finalised, focusing mainly on promotion, pharmacovigilance, quality complaints, distribution, medical information , transparency in particular with HCP relationship and training of sales representatives.
  This guideline was developed as recommendations for pharmaceutical companies and their suppliers when handling OTC product and is intended to be provided to all responsible pharmacists and their management in France in an effort to drive continuous improvement and compliance on the growing self-medication pharmaceutical sector .

- **Raw material samples sampling**
  Section B of National French Order of Pharmacists and the European QP Association conducted a survey among its members in order to find out more and to reflect the diversity of practices of sampling. The results of this survey were published in STP Pharma pratiques vol 22 n°4 July-August 2012.

  The interest and the diversity of responses should prompt a move towards standardization of practices taking into account the risk analysis required.

  A concept paper for a monograph concerning sampling of pharmaceuticals substances, excipients and active substances in EUR PH. was supported and submitted to the ANSM in October 2012.

- **Generics and bio-similar**
  Recommendations for industrial pharmacists, focusing on the duties of the responsible pharmacists, are being drafted.

Members total count : 3 527 in section B (industrial pharmacists).
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