

Country Report 2016 : 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

- **Working groups within section B of the Order of Pharmacists (industrial pharmacists)**

- **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.

- A pilot project has been implemented since September 2013, involving now around 4 000 retail pharmacies, 70 industrial companies, several wholesalers and 144 hospital pharmacies.
- Next step is end 2016 : 14 000 retail pharmacies

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

- **hospital pharmacy supply** : good practices for identification / authorisation/ agreement/ shipment addresses at hospital pharmacies have been validated by the national council and are being published.
- **Role & independance of the responsible pharmacist** : letter signed by CNOP (sections B and C) and ANSM, sent to general manager and legal departments of pharmaceutical companies in order to precise the role of the responsible pharmacist in conformity with the French health code.
- 2 webcasts have been organised for all the industrial pharmacists of section B, presenting :
 - o the French pharmaceutical record (DP) and batch recall services
 - o the results of the survey on the role and place of the deputy responsible pharmacist
 - o notification to ANSM of the off label use
 - o new financial sanctions procedure from ANSM applying to pharmaceutical industry, in application of Law N°2011-2013 dated 29/12/ 2011 (loi Bertrand) , ordonnance n° 2013-1183 dated 19/12/2013 and its decree n°2014-73 dated 30/01/2014
- publication of a guideline on role and responsafor new section B members
 - **Main regulatory texts impacting industrial pharmacists and pharmaceutical products**
- Law 2015-1702 dated 21 December 2015 (2016 French Social Security Financing Law) published in the Official Journal of 22 December 2015
- Updated representative medical charters signed in september 2014 ► New guidelines published on 13/04/2016 , reinforcing the role and responsibility of the responsible pharmacist on information provided for the promotion of medicines through prospecting and canvassing.
- Public health law (57 articles) published on 26/01/2016, many decrees are awaited. Among the articles concerning pharmaceutical industry, one is related to the fight against shortages in the supply of medicinal products : a list of therapeutic classes containing medicinal products of major therapeutic significance , for which the pharmaceutical industry must have a security stock and specificmanagement plans will be established.

Members total count : 3 464 in section B (industrial pharmacists).

Secretariat name and e mail : [Nicole Cesselin : NCesselin@ordre.pharmacien.fr](mailto:NCesselin@ordre.pharmacien.fr)

www site of your association : www.ordre.pharmacien.fr