

Industrial pharmacists

TAKING ACTION TO TAKE CONTROL



French National Order of Pharmacists

The Central Council of Section B of the Order of Pharmacists has drafted a White Paper with the aim of analysing changes within the profession of industrial pharmacists and to identify actions to be taken so that they can better play their role in the future.

Globalization of corporations, development of outsourcing (including within groups), regulatory inflation to meet the demands of society at large, impact of therapeutic and technological innovation, role of the media and public opinion....today many factors come together to accelerate change within the pharmaceutical industry. In this constantly changing environment, what must be the place and role of industrial pharmacists? Do they have sufficient resources to carry out their tasks as defined in the Public Health Code? Is the French model of Chief Pharmaceutical Officer such that it favours the expertise of these professionals at a time when quality and security issues in the medicines chain were never so vital? Section B of the National Order of Pharmacists has decided to address these issues. Under the aegis of its president, Frédéric Bassi, the Section has undertaken an in-depth study with the assistance of the CMI consulting company, a firm which specialises in accompanying changes in companies and organisations. Frédéric Bassi explains that “We wanted to carry out this in-depth study with the help of CMI in order to precisely identify how significant changes in the pharmaceutical industry call our professions into question. The aim was to construct together an action plan so that the industrial pharmacist would be more than ever the reference point in the quality of procedures, from manufacturing to marketing, both in respect of companies and health authorities.”

ONE WHITE PAPER, THREE SCENARIOS

Fortified by these ambitions, Section B mobilised more widely to draft a White Paper. This was an unprecedented exercise for the Order’s elected representatives

and the document is based on an analysis of documentation, interviews with 14 leaders representing public institutions and work sessions of the project's Pilot Committee. The methodology used highlighted six priority subjects: sector trends; regulatory issues and interaction with the authorities; demarcation of responsibilities; place and influence within organisations; training, skills and attractiveness; scientific and technological advancements. Within these subjects, 22 variants were identified including 10 “key variants” which are believed to have a greater impact on the profession of industrial pharmacist. On the basis of this inventory, three scenarios were drafted: two “trend” scenarios and one “wish-list” scenario. Finally, it was possible to identify three “quick wins” and the Pilot Committee also selected three subjects for more in-depth study. In the end, thanks to this approach, the White Paper enables a strategy to be drawn up which can be applied to all industrial pharmacists.

WHAT IS THE CENTRAL COUNCIL OF SECTION B?

Within the National Order of Pharmacists, Central Council B is responsible for the section of pharmacists holding, in companies with at least one establishment involved in the manufacture, “exploitation” and import of medicines, the posts of Chief Pharmaceutical Officer, Acting Chief Pharmaceutical Officer, Delegate Pharmacist, Acting Delegate Pharmacist or Assistant Pharmacist.

FIGURES

- 3,927 industrial pharmacists were registered with the Order in 2018
- 41.9 years is the average age of industrial pharmacists
- 64% of industrial pharmacists are women
- 459 pharmaceutical companies employ industrial pharmacists in 764 establishments
- 200 is the average number of movements recorded every month - registrations, removals from registration, job changes linked to a change in activity (establishment/company).

Method

Defining the future using “key variants”

The methodology used enabled the forecasting of the future of the industrial pharmacist's profession using ten key variants

During its meetings, the Pilot Committee, with the help of CMI, endeavoured to determine among the 22 identified variants those which shall have the greatest influence on the future of the industrial pharmacist's profession. Two of them relate to the globalisation of enterprises with a double impact on production and

R&D activities. Changes in outsourcing also impact the responsibility of the Chief Pharmaceutical Officer, as does the increased attention the media and public opinion pay to the pharmaceutical industry. In addition, the authorities' regulatory requirements are increasing in respect of quality practices while the status of the Chief Pharmaceutical Officer is increasingly supervised, both on a European and French level. Finally, the development of innovating therapies "challenges" the tasks and skills of the industrial pharmacist. Furthermore, the methods used for control and batch release, a core task in the profession, are more and more demanding from year to year. On the basis of these variants, the seminar was able to work on two trend scenarios (the most likely) and a "wish-list" scenario (involving a specific action plan) identified upstream in a working session. The outcome of the seminar has highlighted three "quick wins" which, furthermore, shall be implemented: the development of training tools in English to explain the concept of Chief Pharmaceutical Officer; identification of all pharmaceutical tasks, the role and the responsibilities of the industrial pharmacist; improvement of the system whereby the Order's counsellors sponsor newly-appointed Chief Pharmaceutical Officers. Finally, three subjects for further study were selected among the eleven proposals for issues or actions which the Pilot Committee studied after the seminar.

Marc Lefrançois, Partner at CMI, responsible for healthcare industry practices

"A hands-on Pilot Committee"

How did you perform this mission?

CMI is a consulting firm specialising in strategy which aims to solve complex problems, especially in the healthcare industry. The challenge raised by Section B was motivating and matched our firm's DNA profile. Of course, the objective was to define developments in the role of industrial pharmacist within the health system. Consequently, with the Pilot Committee we instituted an approach of exploratory reflection: on the basis of an in-depth analysis of the environment, interviews with leaders in the sector and the identification of factors impacting the environment we drafted three scenarios. Two of these scenarios, known as "trend scenarios", forecast a future made up of the currently-identified trends. The third scenario, known as the "wish-list" scenario, describes the situation considered to be the most favourable for the environment and for industrial pharmacists performing their role fully. The Pilot Committee's and then the Central Council's support for this approach was remarkable.

How can this type of approach support Section B's action programme?

It was vital not to limit ourselves to a diagnosis and to identifying actions to be implemented. Further to intense discussion at the seminar we identified three “quick wins” and carried out three in-depth studies. They contribute to finding an answer to the question which is at the centre of the project: how can the industrial pharmacist be positioned in respect of his company's legal status in terms of skills, and his relationship with the authorities, to best meet future challenges, both within his company and in respect of public health? This work required the close involvement of Section B's Central Council and this involvement must continue to make the results known and to engage in dialogue with the stakeholders in the industrial pharmacist's future. I feel confident as to the follow-up to the White Paper: I was in a position to measure the involvement of the members of Section B, their ability to undertake an original approach and to ask questions about their profession, and their willingness to build.

Scenarios

Building a desirable future for industrial pharmacists

When faced with the probable trend of change in medicine production, it is possible to act to include the role and tasks of the industrial pharmacist

Two scenarios were drafted within the framework of the White Paper on the basis of an analysis of the current situation and probable trends in the future. Both are based on a premise: the trend towards globalisation should continue, or even increase, with a possible rise in the delocalisation of production, a reduced role for local authorities and wider use of outsourcing and transfers of activities, under the responsibility of the Chief Pharmaceutical Officer, towards contracting companies. In addition, both media attention and regulatory requirements should increase in intensity. Within this framework of increased pressure, the first scenario is based on a “status quo” hypothesis: the Chief Pharmaceutical Officer would keep all his prerogatives but would have to face an increased level of requirements in respect of regulatory, organisational or society aspects. In the second scenario, more liberal in its inspiration, the Chief Pharmaceutical Officer would lose some of his prerogatives. The companies themselves would entrust the new responsibilities linked to regulatory changes to the professionals of their choice while the status of the Chief Pharmaceutical Officer would be called into question on a European level, to the advantage of other professionals.

When faced with these forecasts, Section B worked on an alternative, “wish-list” scenario based on a control of the production chain at the current level without increased delocalisation, a limited transfer of responsibility but no transfer of responsibility towards outsourcers, a stabilisation of media attention and regulatory requirements and, finally, the preservation of the regulatory responsibilities entrusted to industrial pharmacists. In this scenario, the industrial pharmacists should come together to promote, on a European level, a harmonisation of control and mastery practices in the fields currently coming under the responsibility of the French Chief Pharmaceutical Officer.

Frédéric Bassi, President of Section B, National Order of Pharmacists

“Promoting the French model of Chief Pharmaceutical Officer”

Why did you draft a “wish-list” scenario for the future of industrial pharmacists?

As we can see, an analysis of current trends in the medicines manufacturing chain clearly challenges the future of the profession of industrial pharmacist. Firstly, we should look ahead to these developments in order to prepare for the probable changes in our tasks and take action to preserve our professional independence. When drafting a “wish-list” scenario, we aim principally to come together on a concrete action plan, for example, the need to clarify the “Exploitant” entity and “Local Representative” concepts, the redefinition of the career path validating the obtention of the status of Chief Pharmaceutical Officer or the correct level of interaction required with the health authorities. Whatever the scenario, we shall not remain inactive. Section B shall continue to actively promote the French model of Chief Pharmaceutical Officer.

What are the next steps after this White Paper?

Firstly, we shall give wide publicity to this work which demonstrates that industrial pharmacists are capable of understanding the environment within which they operate, of drafting proposals designed to strengthen their role in the defence of public health and of defending the values of skill and independence which underly their profession. In particular, we must reinvent ways to have a constructive dialogue with health authorities on the basis of areas of common interest such as management of shortages, information imparted to patients, training or promotion of the French model at a European Union level.

Action Plan

Three issues to be studied in-depth

The Pilot Committee identified three issues to be studied in depth and which will be the guiding points for Section B's work in the coming months

On the basis of eleven subject-based proposals, three priority issues were selected to form the basis of discussion of the elected members of Section B: clarification of the concepts of an "Exploitant" entity and "Local Representative" concepts, redefinition of the experience required to obtain the status of Chief Pharmaceutical Officer and the introduction of regular interactions and meetings with the authorities.

"EXPLOITANT" ENTITY AND LOCAL REPRESENTATIVE

A special feature of France is the special "Exploitant" status which would appear to overlap with that of "Local representative" as defined on a European level. This overlapping has yet to be clarified and it creates in-house misunderstanding and confusion within international groups while outside companies there is fluctuation with the terms used and their definition in respect of the French Public Health Code. Consequently, it would appear necessary to clarify these points to the benefit of all the bodies concerned and to provide the best guarantees for the roles of the industrial pharmacists in their respective tasks.

EXPERIENCE REQUIRED

The conditions which today govern access to the function of Chief Pharmaceutical Officer would appear to be off-centre in relation to current requirements in terms of experience and skills. Consequently, section B recommends that the practical experience required to perform this function be reviewed in respect of several points: description of the finality of the Chief Pharmaceutical Officer in the Public Health Code and the establishment of an evolving reference taking into account the professional career.

RELATIONS WITH THE AUTHORITIES

All too often interactions between the health authorities and the industrial pharmacists are limited to crisis situations. And changes in regulations are often viewed as an imposition. A more regular dialogue could be established on the basis of subjects of common interest to which the Order could bring a position or a recommendation: public health, communication with patients, a charter on

promotion information, combatting counterfeiting, crisis management and promotion of the French organisation within Europe.

Laure Brenas, President of Section C and Philippe Godon, Vice-President of Section C

“Preparing the future of wholesale distribution pharmacists”

Section C was associated with the work undertaken by Section B. To what degree are wholesale distribution pharmacists interested in changes for industrial pharmacists?

Section B did indeed ask us to participate in this work as the tasks and job descriptions of both categories of pharmacist are relatively close. One of the vital issues for our professions is the value of our qualifications. At present there is a D.E.S. (Diploma in Higher Studies) for pharmacists who work in laboratories and in health establishments while the possibility of a similar qualification for dispensing pharmacists is also under discussion, whereas this is not the case for our two specific profiles. This calls into question the unique nature of the qualification and, in particular, the conditions under which a pharmacist can work in a job different from that for which he was trained. Along the same lines as Section B, we believe that a pharmacist, a dispensing pharmacist for example, who would like to work in distribution should be authorised to do so only when he has completed a six-month re-training period. For example, he must have an in-depth knowledge of Good Distribution Practice (GDP) and must have had an opportunity to apply them “in real-life situations”.

In your opinion, should Section C also discuss the future of the distribution pharmacist?

Yes, without a doubt and one of the reasons the Order of Pharmacists exists is to forecast the changes in our professions and to guarantee our public health role in the service of patients. In future years we intend to continue with the work which has already begun on themes such as the status of the Acting Pharmacist, the quality-focused initiatives in distribution or again risk analysis. The medicine environment is constantly changing and it is our duty to understand how these changes impact the chain of distribution of medicines and the positioning of distribution stakeholders.

To obtain the executive summary of the White Paper: www.ordre.pharmacien.fr

For further information: webbbc@ordre.pharmacien.fr