CLIFFORD
CHANCE

Briefing note 15 February 2012

Law n°2011-2012 of 29 December 2011 improving the safety of medicines and health products

A new law aimed at improving the safety of medicines and health products was published in the Official Journal dated 30 December 2011 (the "Ethics law").

The Ethics law aims at restoring public confidence in medicine approval processes and reforming the prescription system after the controversy caused by the prescription of Servier's diabetes drug *Mediator*®.

The reform of the French health system is based on three main principles i.e. (i) the prevention of conflicts of interest and transparency of decisions, (ii) the monitoring of health products and (iii) the improvement of training and information of health professionals and patients. Following to the case of the "PIP®" breast implants, medical devices ("*dispositifs médicaux*") will probably be subject to closer scrutiny (iv).

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(i) Prevention of conflicts of interests and transparency of decisions

a) Declaration of conflicts of interest

In order to prevent conflicts of interests, the Ethics law requires to all members of national health commissions (members of councils and commissions, experts, and, when justified by their functions staff of authorities and agencies) the requirement to systematically disclose any relevant relation of interest before their appointment.

The declaration must set out every direct or indirect relation of interest such members may have had with any company or agency in their area of competence within five years period before they took on their functions into the said national health commission (the exact content of the declaration as well as the conditions for its publication will be defined by decree which has not yet been

Key issues

- Obligation of declaration of conflict of interest
- Implementation of "Sunshine Act" *à la française*
- Anti-gift legislation becomes tougher
- Closer scrutiny for medical devices

published). If a member of a national health commission has or has had a relationship with a health company or agency over the past five years, this shall prevent him from taking part in any discussions or decisions of the relevant national health commission regarding the said company's products. An ethics committee will be set up in every agency in order to control the accuracy and veracity of the information provided in the aforementioned declaration of interests.

b) The "Sunshine act" à la française

The Ethics law sets out transparency requirements for healthcare and cosmetics companies that are comparable to those provided by the US 'Sunshine Act'. The Ethics law extends the obligation to make public every agreements entered into with and benefit in kind or in cash granted directly or indirectly by companies that manufacture or market, health products for human use, medical devices, cosmetic products or provide any related services. This obligation now concerns the existence of all agreements such companies may have with healthcare professionals, students of medicine and dentistry, clinics and hospitals, foundations, press and communication agencies, drug prescription software editors, as well as educational companies in the healthcare area. The threshold amount triggering this disclosure obligation is to be set by decree, which shall be published no later than 1 August 2012. These provisions are applicable to agreements concluded or in effect, and to advantages and remunerations paid or granted, as of 1 January 2012. These provisions raise numerous questions as to how they will apply as the relevant decree has not yet been published (e.g. nature of the information to be disclosed, timing and content of the publication, updating of the information disclosed...).

In the event that disclosure of relations of interest or agreements and benefits is not made in compliance with the above-mentioned requirements, those concerned could be exposed to significant penalties pursuant to articles L. 1454-2. et seq. of the French public health code ("PHC") as modified by the Ethics law (including criminal sanctions).

c) Anti-gift regulation

The Ethics law extends the existing principle of prohibition. New categories of persons cannot receive any advantage from the industry:

- Students intending to practice professions as referred to under Part IV of the PHC with the exception of the funding of research and hospitality.

- Associations representing the members of medical professions and the aforementioned students.

It is debated whether "the normal working relationship" system which requires a mere notification instead of a prior opinion from the relevant board, will survive. Indeed, the new article L. 4113-6 of the PHC specifies that "all agreements concluded between members of the medical professions or students intending to practice professions referred to in Part IV of the PHC and companies producing products or offering services reimbursed by the health insurance scheme are before their implementation, submitted to the relevant medical board."

d) Transparency of decisions

Greater transparency of the decision taken by agencies and public bodies will be guaranteed by video recording of debates and decisions of the commissions and councils and by improving of the legibility and clarity of minutes and agendas.

To ensure there is as much neutrality, impartiality and independence as possible in the evaluations made by experts, their activity will be governed by a charter (*charte de l'expertise*) approved by decree which has not yet been published.

The French government will also have to report to the Parliament on the funding of patient associations and on their needs, by 30 June 2012 at the latest.

(ii) Monitoring of health products

The French medical agency ("AFSSAPS") whose missions and sanctioning powers have been reinforced, will become the National Agency for Medicines Safety ("**ANSM**", *Agence Nationale de Sécurité du Médicament*). One of its missions will be to carry out an overall risk-benefit assessment of the products throughout their entire life cycle ; and it may request additional studies from the holder of the marketing authorisation ("**AMM**").

Without prejudice to its power to revoke, suspend or change the AMM, if any doubt exists, the ANSM will be entitled to withdraw a product from the market if it considers that the product is harmful, or that it lacks therapeutic efficiency, or that the risk-benefit balance is not positive under the authorised conditions of use. The ANSM will also be able to fine non-

compliant operators pursuant to articles L. 5121-23 and L. 5421-6-1 of the PHC.

Pharmacovigilance is now managed by the ANSM. Doctors, dental surgeons, midwives and chemists must report any adverse reaction to medicinal products of which they become aware. Other professionals and patients are encouraged to communicate any adverse reaction. However, this is not mandatory.

Pharmaceutical companies are under the obligation to keep record of, disclose and monitor any adverse reaction suspected of being caused by one of their products. They must inform the ANSM of any marketing, prohibition or restriction decided by any authority in any country or of any information that could influence the risk-benefit balance of the product.

Off-label prescriptions are only possible with a temporary recommendation of use issued by the ANSM or an express request from the prescriber if he/she finds it indispensable to improve or stabilise the clinical condition of the patient. The patient has to be systematically informed when the prescription is not compliant with the AMM and the reasons of the deviation from the AMM must be motivated into the patient's medical records.

The Ethics law lays down stringent conditions for temporary authorisations of use ("*autorisations temporaires d'utilisation*").

Medicinal products eligible for reimbursement by the health insurance scheme will now be determined, where possible, by comparison with therapeutic strategies of reference.

(iii) Improvement of training and information of health professionals and patients

Only pharmaceutical products in respect of which an AMM has been granted can be advertised. The Ethics law adds that thereof the risk-benefit balance of the medication is being re-evaluated, its commercial advertising is prohibited during the reassessment.

The supervision of the advertising of medicines to healthcare professionals is reinforced by way of a control system and a prior advertising authorization that must be issued by the ANSM (application to advertising made to professionals of the existing procedure for advertising of medicines made to the public).

A webpage on the website of the Ministry of Health bringing together all the administrative and scientific data (regarding treatments and the proper use of products), submitted by the French National Authority for Health (*Haute Autorité de Santé*), the ANSM and the Health Insurance Fund (*l'Assurance Maladie*) will be made available to the public and to health professionals.

Lastly, the continuing education of health professionals will also now be strictly managed. In the former system, the continuing education of professionals was mostly financed by the industry. Decree n°2011-2113 dated 30 December 2011 specifies the composition of the governing bodies of the entity in charge of continuing education, as well as the system for the funding of the said entity. It also lays down the conditions upon which the continuing training institutions are approved to provide education identified as forming part of the continuing education of professionals. These institutions, independent from the industry, will be assessed on a regular basis by an independent commission composed of professionals who shall be required to beforehand disclosed that they have no discernible previous link of any kind with these institutions.

(iv) Supervision of the medical devices sector

The Ethics law has harmonized rules applicable to the advertising of medical devices to those applicable to pharmaceutical products and those applicable to medical devices. Medical devices presenting major risk concerns will have to obtain a prior authorization issued by the ANSM for 5 years. A system of penalties for misleading advertising has also been implemented.

Following the current affair concerning "PIP® breast implants", the French Health Minister, Xavier Bertrand, declared that a change in the European regulation of medical devices is required and that traceability and the exchange of information between Member States should be improved. The European Commission answered this request by calling for tighter controls, increased surveillance and the restoring of confidence. In the coming months, it will be essential to monitor the changes that may occur in the regulations applicable to medical devices.

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