

Signing of the new "Promotional Information Charter"
**Improved quality and transparency of the information provided to doctors
about medicines**

Leem and the Economic Committee for Health Products (CEPS) have today signed a new "Promotional Information Charter". This latest text replaces the 2004 "Medical Representative Charter" and introduces reforms to promotional information practices by guaranteeing the quality of the information provided to doctors and by improving the proper use of medicinal products.

This revision incorporates the changes introduced by the law of 29 December 2011 aimed at strengthening health protection for medicinal and health products.

The new charter also includes a series of improvements suggested by the industry as part of the national conference on medicines policy (Assises du Médicament) in 2011.

The text has also taken into account in its drafting the new rules of professional conduct adopted by Leem together with the code of practice introduced by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

New guarantees for high quality information and the safe use of medicines

Applicable to all professionals engaged in the promotion of medicines through prospecting and canvassing, the new charter sets out a number of new provisions relating to the quality of information provided, the proper use of medicines and the independence of healthcare professionals.

- Thus, in compliance with the law of 29 December 2011, the charter provides that where a company finds that a prescription fails to conform to the proper use of a medicinal product - off-label use in particular - it will take all appropriate measures to inform healthcare professionals, at the request of the public authorities, and to notify the National Agency for Medicines Safety (ANSM).
- The pharmacovigilance tasks and responsibilities of companies in respect of promotional information are further enhanced for medicines subject to the Risk Minimisation Plan or to the Risk Management Plan.
- In an effort to enhance proper use of medicinal products and to prevent any confusion, the new charter has introduced new rules of professional conduct for the industry in respect of samples. Accordingly, the ban in 2004 on the distribution of medicinal product samples by medical sales representatives is extended to cosmetics, dietary supplements and medical devices.
- Similarly, gift-giving to healthcare professionals is banned and severe restrictions are imposed on the conditions under which invitations to meals are permitted.

- The charter also defines the conditions for access by company representatives to doctors' surgeries and health facilities in order to avoid disrupting their operations and to comply with their organisational rules.
- Continuing training has been stepped up for persons in charge of promotional information, and their scientific and regulatory knowledge is subject to a mandatory annual assessment.

A monitoring scheme to ensure high quality practice

Another major innovation of the new charter is the decision by Leem and CEPS to set up a national monitoring scheme for promotional information, responsible for measuring the quality of promotional practices based on objective, verifiable and transparent criteria.

This scheme will make it possible to track the practices of each company, and to notify Leem and CEPS, via a trusted third party, of any deviations that may occur. CEPS may use this as a basis for penalising companies whose practices would not be in accordance with the principles of the charter.

The monitoring scheme will not replace the control and certification audit processes already implemented by HAS (French National Authority for Health). Instead, it will complement them.

"Proactively developed by our industry through ongoing dialogue with the authorities, this text reaffirms the very principle of our mission to provide healthcare professionals with information and promotional materials, according to Patrick ERRARD, Chairman of Leem. This new charter will hopefully ensure that medical sales visits are truly associated in the minds of everyone with the promotion of the proper use of medicinal products among healthcare providers, based on high quality medical information".

The text of the charter is available on request from the Press Office

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