Quality Charter and Certification for medical representatives in France:
- A new regulative approach
- A novel experience

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Malta - April 2008

French Council of Pharmacist

A new regulative approach: main objectives

- Strengthen the role of medical reps in the rational use of drugs and in the quality of information conveyed
- Improve control of promotional practices
- Prevent the misuse of drugs and avoid unnecessary costs

Preserve French's Health Insurance System

A new regulative approach: background

- August 2004: Health Insurance Reform Law ⇨ introduction of a Quality Charter for reps before end of 2004.
- December 22, 2004: signature by Leem (French Trade Association) and CEPS (Committee for pricing of Health Products), on behalf of the government.
- July 2005: a new amendment adding a mechanism to limit the number of calls, per therapeutic area.

A new regulative approach: As defined by the law

- Medical reps Charter to be adapted to a certification audit plan by an official body: Haute Autorité de Santé (HAS).
- Certification carried out by external accredited organisms.
- Certification granted for 3 years (with intermediate annual audit).
- ? Sanctions: economic sanctions decided by CEPS.

A new regulative approach: scope

- Charter only applies:
  - to companies having signed an economic agreement with CEPS
  - to promotion of reimbursed products in non-hospital environment
  - to third party reps suppliers as of April 2009

- Further document concerning hospital calls due shortly.

A new regulative approach: 5 key points

- Reps missions: promote products in compliance with MA and rules concerning rational use.

- Quality of information provided: rules guaranteeing quality of information, promotional documents and messages, and reps training.

- Reps ethics: code of conduct defining reps relations with physicians, patients, competitors, health insurance organisations.

A new regulative approach: 5 key points

- Specific organisation and supervision fostering incremental improvement:
  - Emphasize management commitment and employee involvement.
  - Ensure customer focus.
  - Set up Quality Policy and management Quality review:
    - **Definition of objectives/ KPIs**
    - **Monitoring processes**
    - **Analysis of non-conformity**
    - **Implementing corrective actions**
- Pivotal role of the Responsible Pharmacist based on the mission defined by Public Health Code

Certification: a novel experience

1) Samples can no longer be distributed by reps.

2) Post-marketing, pharmacoeconomic and observational studies no longer part of reps missions.

3) Promotional materials must be validated and regularly updated by the RP, with a tracking system.

4) Training (initial and regular training) and the oral presentation must be validated prior to calls.

Certification: a novel experience

5) Gifts: reps are prohibited from offering gifts of any value or nature to physicians.

6) Role of the Responsible Pharmacist:

- ✓ Guarantee the scientific quality and accuracy of the messages
- ✓ Ensure reps knowledge by regular training
- ✓ Validate all documents used for reps training and for calls
- ✓ Ensure traceability of promotional documents, information feed back and monitoring of reps activities.

Certification implementation and role of the French Council of Pharmacists (industry section)

- In accordance with the law, the HAS is responsible for implementing a certification procedure

- French Council of Pharmacists (industrial professionals) actively participating in various workshops to draw up certification criteria. With a main objective: respect of the RP missions defined by the law.

- French council proposed to separate:
  - Regulatory requirements previously stated in the Public Health Code (RP's responsibilities) subject to official AFSSAPS inspection.
  - From the new requirements introduced by the Charter (company's responsibility) subject to certification.

Certification implementation: recent developments

- Certification criteria published by HAS in July 2006 and modified in July 2007 (deadline: June 2008).

- Setting out 3 key requirements:
  - The company ensures that its reps have the knowledge and skills needed to provide high quality and accurate information
  - The company makes available to reps and their managers all the resources they need to comply with ethic rules.
  - The company defines a set of policies, and procedures and is able to identify, measure, control and improve the main predefined processes that lead to improve quality.

- The RP may intervene in areas directly covered by his/her pharmaceutical expertise and legal responsibility.

CONCLUSION

- Harmonisation of existing reps practices by definition of quality standards (e.g.: GMP, GCP …).
- Reinforcement of ethical practices and of the quality of scientific information:
  - Correct and rational drug use
  - Improvement of patient care
- Illustrates a new trend towards industry self-regulation
- Further assessment is required:
  - at the company level
  - at the physician level