MARCH 10, 2022

France - A Charter for the Promotion of Medical Devices (Including IVD)

For more information, contact:

Geneviève Michaux
+32 2 898 0202
gmichaux@kslaw.com

Vanessa Benichou
+33 1 7300 3919
vbenichou@kslaw.com

Lisa Dwyer
+1 202 626 2393
ldwyer@kslaw.com

Jessica Ringel
+1 202 626 9259
jringel@kslaw.com

Elaine Tseng
+1 415 318 1240
etseng@kslaw.com

King & Spalding

Brussels
Bastion Tower
5 Place du Champ de Mars
1050 Brussels
Belgium
Tel: +32 2 898 0200

Washington, D.C.
1700 Pennsylvania Avenue, NW
Suite 900
Washington, D.C. 20006
Tel: +1 202 737 0500

An ordinance (« *arrêté* ») was published in the French Official Gazette of 8 March 2022 that sets out a quality charter overseeing the professional practices of individuals responsible for the presentation of educational information about, or marketing or promotion of, medical devices for individual use and health products other than medicinal products ("Products") and associated services reimbursed by social security ("Charter").

The Charter results from negotiations between the Economic Committee for Health Products (*Comité économique des produits de santé* or "CEPS") and trade associations representing companies producing and distributing Products and associated services, most of which accepted the Charter.

It seeks to provide a framework for the commercial, promotional, presentational, or informational practices relating to the Products and associated services listed in Article L. 165-1 of the Social Security Code in order to prevent such practices from harming the quality of care or leading to unjustified social security expenditures. It also intends to ensure the quality and proper use of Products, the accuracy of information about them, and appropriate prescription by professionals who are authorized to prescribe, purchase, or use those Products or associated services.

The Charter sets out rules governing the content of informational and promotional documents, visits to healthcare professionals, ethics, traceability, etc. A free English translation of the Charter is attached for your convenience.

It will be supplemented by a (mandatory) certification system to be developed and implemented by the High Health Authority (*Haute Autorité de Santé* or "HAS") within a 12-month period. During the transitional period, companies will apply the Charter on a voluntary basis. A similar system - charter with certification - already exists for medicinal products (*Charte de l'information par démarchage ou prospection visant à la promotion des médicaments*) that will undoubtedly be used as a model for medical devices.

The Charter will apply to companies manufacturing and distributing Products, or providing services, which are reimbursed under the French national health insurance system. They will have to implement a quality

system for their presentational, informational, and promotional activities and to be certified for compliance with the Charter.

The Charter will bring significant changes in the promotion of medical devices, including IVDs, in France. K&S regulatory lawyers from our Brussels/Paris Office may help you better understand and implement the changes and anticipate requirements for the upcoming certification.

1. Scope of Application

The scope of the Charter is broad, covering almost any form of communication made by companies or actors relating to Products and related services.

Products and services. -- The Charter applies to all products and services mentioned on the list of Products and services provided for in Article L. 165-1 of the Social Security Code that are used in healthcare or medico-social institutions, as well as at home or in public settings. The requirements apply to these Products and services, whether or not they are subject to rules on medical devices (i.e., CE marking).

Article L. 165-1 of the Social Security Code refers to medical devices for individual use, human tissues and cells (whatever the transformation level) and their derivatives, health products other than medicinal products with reference to Article L. 162-17 of the Social Security Code, as well as the services associated to those Products.

Actors. – The Charter applies to:

- All persons responsible for promotional, presentational, or informational activities of operators and retail distributors of Products and services in the context of their practices (or during transfers) ("actors"). The requirements apply to the actors' own activities and responsibilities (as well as those that they control), but the Charter does not address the relationships between actors.
- All "companies" employing actors, whether they are operators or distributors of Products or service providers.

"Beneficiaries" are all professionals, whether healthcare professionals or not, who are authorized to prescribe, use (free of charge or for a fee) or purchase Products and services, regardless of the type of organization in which they practice (e.g., institutions, healthcare facilities, pharmacies, etc.).

Activities. — The Charter covers all forms of promotion, presentation, and information regarding Products and related services, at the initiative of an actor and to the beneficiaries, irrespective the method of conveyance or relationship to any visits. The term "visit" covers both physical meetings at the beneficiary's place of practice and remote contacts (such as videoconferencing or teleconferencing but excluding one-off contacts).

The activities fall into three broad categories: (1) presentation of products and services; (2) technical, regulatory, or therapeutic information on products and services; and (3) promotional activities for products and services.

2. Visits to Professionals

The Charter establishes rules on visits to professionals. The key rule is that all actor-initiated visits must be recorded and documented, on an annual basis, on an online platform to be made available by CEPS. Companies will have to provide detailed information: nature of every visit; name of the beneficiary and institution; date of visit; visit condition; therapeutic area; and list of documents and samples handed out to the beneficiary. Certain visits exempted from the reporting obligation (but not from the traceability system) are listed in the Appendix to the Charter. The aggregate data from the platform will be presented annually to the Monitoring Committee.

Additional rules apply to visits to healthcare or medico-social institutions. For example, actors may not make visits during a period of public tender (except for trial, testing, or clinical assessment periods requesting a user training) and may not organize a survey to collect specific data on the institution.

Importantly, there is a limit of four visits per year for companies until such time as there is better understanding of current practices. This benchmark threshold:

- is set by professional or, for institutions, by service;

- does not include visits linked to training, vigilance, or public tenders.

3. Quality Control

Each company is expected to set up a system ensuring compliance with the Charter. This includes implementing quality controls to guarantee that the content of presentations, informational sessions, and promotional activities comply with the Charter, and keeping an updated list of the media to be handed out by the actors.

The company is responsible for the content of messages by, and delivery conditions of, all its actors, including in the case of outsourcing to a third party. It is also responsible for its actors' training.

Documents used for presentational, informational, and promotional activities must be kept for five years.

4. Certification

A certification system will be developed and implemented by the HAS in order to ensure that the companies' presentational, informational, and promotional activities comply with the Charter. The first step will be the drawing up of a certification reference document by the HAS. The HAS will also determine the certification procedure.

In line with the Charter for medicinal products, it is expected that the certification will involve the review of the quality management system implemented by companies. Certification will be granted following an audit which will likely be conducted by the French Accreditation Committee (*Comité français d'accréditation* or COFRAC). Audits will be performed both prior certification and then periodically.

Certification will most probably be mandatory for all manufacturers and distributors of Products and providers of associated services that enter into an agreement with the CEPS (for pricing and reimbursement purposes) and have promotional activities relating to at least one reimbursed Product or service. The certification system is expected to be implemented within the next 12 months. In the meantime, compliance with the Charter will be on a voluntary basis.

5. Monitoring Committee

A Monitoring Committee will be set up to oversee implementation of the Charter and the achievement of its objectives. The committee will meet at least once a year to analyze reports received from professional associations and the regional health agencies and to receive aggregated data from the reporting platform.

The Monitoring Committee may adjust, in particular during the first year of application of the Charter, the frequency of visits.