France tightens grip on industry payments to HCPs (again)

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On 19 January 2017, major modifications were adopted in France to the regulations on interactions between the industry and healthcare professionals (and other stakeholders). These new regulations, a.k.a. "anti-benefits regulations", will entail major changes in the industry's compliance procedures relating to payments and other transfers of value to those stakeholders.

The new rules are still subject to several implementing regulations, but they will become effective at the latest on 1 July 2018.

The most notable modifications are:

- **extension of the types of companies concerned**: the regulations will now apply to any entity manufacturing or marketing healthcare products or providing health services;
- **extension of the range of stakeholders** concerned by the prohibition to receive benefits;
- **introduction of an authorization process** involving the French administration or professional bodies;
- **stronger control on compliance and enforcement**.

The new regulations are accessible here (in French) and we have set out further details on the new regulatory framework below.

What is prohibited?

The anti-benefits regulations prohibit any entity manufacturing or marketing healthcare products or healthcare services from **offering, or proposing**, direct or indirect benefits of any kind to a large scope of stakeholders in the health sector. These regulations also prohibit the stakeholders from **receiving** said benefits.

Which entities are prohibited from offering or proposing benefits?

The new regulations apply to any entity manufacturing or marketing healthcare

products or providing health services. The definition of healthcare products is particularly wide as it encompasses products having a health related purpose (for human health), save for some exceptions.

This is a major change in the scope of the regulations, which until now was limited to companies manufacturing or marketing products/services that are reimbursed by the French healthcare system. This change reflects the French authorities' objective of harmonizing certain concepts used both under the French anti-benefits regulations and Sunshine regulations.

This means that companies that manufacture healthcare products which are not yet marketed, or certain companies which only participate to the product manufacturing chain without manufacturing the final product (e.g. API suppliers), may now be concerned by these regulations.

There are still uncertainties on the potential scope of these regulations. For instance, for service providers, the concept of provision of "healthcare services" in the regulations still needs to be defined by governmental decree. The service providers concerned by this new regulatory framework (i.e. "companies providing healthcare services") may therefore not be the same as the ones concerned by the French Sunshine regulations (i.e. "companies providing services linked to health products").

Not all foreign companies

manufacturing or marketing health products should be captured by these regulations. A closer analysis of each company's situation, with regards to its activities connected to France, will be necessary.

Which stakeholders are prohibited from receiving benefits?

The regulations apply to a wide scope of stakeholders:

- various types of healthcare professionals (HCPs), such as persons working in regulated professions in the health sector (e.g. medical professions, pharmacists, paramedics), osteopaths, chiropractors and psychotherapists;
- students and persons following trainings in the medical sector;
- associations of HCPs or students, including associations which interfere in their training; and

- civil servants and public officials who participate in public health or social security policies, or who have administrative police powers in health related matters.The above scope is, however, narrower than the stakeholders covered by the Sunshine regulations.

What are the benefits targeted by the regulations?

The concept of "benefit" is not defined in the regulations. But in light of other French regulations (e.g. Sunshine regulations) and case law, this concept should be understood very widely, covering transfers of value in kind or in cash (e.g. savings that an HCP may make thanks to the benefits granted).

What benefits are <u>not</u> concerned by the regulations?

The following are <u>not</u> considered as benefits and are therefore not subject to the anti-benefits regulations:

- remuneration paid in the course of the employment contract of the HCPs;
- benefits resulting from the exploitation or assignment of IP rights (e.g. royalties);
- commercial advantages granted within the framework of commercial agreements (e.g. discounts granted to pharmacists as part of purchase of products for resale);
- benefits of modest value (to be set by a forthcoming ministerial order) which are related to the stakeholder's activity.

What exceptions are permitted under the regulations?

The following benefits can be granted to the stakeholders, under certain conditions (described below):

- various professional services fees and reimbursement of expenses (e.g. for consultancy, research or promotional services) provided they are fair market value;
- hospitality for professional/scientific events, or promotional events. Such hospitality must be reasonable, limited to the main purpose of the event and not extended to other persons than the stakeholders defined above;
- educational or research grants;
- grants to the associations mentioned above; and
- financing of professional training (e.g. in the context of continued medical education).The above benefits are not, however, permitted to civil servants and public officials who are not HCPs (though other conditions may apply in relation to research projects).

Permitted benefits must be subject to an agreement

For the above benefits that are permitted, the regulations require an agreement to be entered into between the recipient and the entity granting the benefit. A governmental decree will provide details on the content of such agreement. A practical question, among others, is whether the industry will still be able (and how) to continue outsourcing contracting processes with third party service providers.

Permitted benefits will be subject to prior declaration or authorization

The industry will have to submit agreements on permitted benefits to professional bodies or administrative authorities. This differs from the current regulations that require only a prior opinion to be sought from professional bodies.

Depending on the value of the benefits concerned, the agreements will either be:

- **notified**, if the transfer of value is below a threshold to be set by a future ministerial order. In such case, the competent professional bodies or competent administrative authorities may nevertheless issue recommendations. The impact of such recommendations is yet to be assessed (e.g. if and how must the industry take into account such recommendations?); or
- **submitted for prior authorization**, if the amount is above a threshold: **this is a major change which will impact the industry's practice**. Until now, competent professional bodies only issued opinions. In practice, companies could decide to proceed to the contemplated project despite a negative opinion, notably after ensuring that payments were fair market value. Under this new system, failing authorization, the relevant project will not be authorized to proceed. The only recourse would be, in such case, to bring a claim against the decision challenging such rejection of the authorization.

From a practical standpoint, under the new regulations,

any agreement entered into with a stakeholder which contains a transfer of value will, before its implementation, need to be submitted to the HCPs' competent professional bodies or to competent administrative authorities.

The competent administrative authorities are not yet defined.

Companies will therefore need to take into account this prior submission system in their project's timeline.

The practicalities surrounding the above declaration and authorization procedures will be detailed in a future governmental decree.

A major exception to the above rule is agreements on interventional studies entered under the new French single agreement system. French regulations on clinical studies were substantially amended in 2016 with the aim of simplifying and accelerating the contracting processes for clinical studies. Under these new regulations, clinical study agreements relating to

commercial interventional studies must be entered into with the French health institutions where the studies take place.These regulations impose the use of a specific form of agreement which was published in November 2016. Under this new system,

clinical study agreements will be transmitted to professional bodies under a separate process.

What are the sanctions in case of non-compliance?

Tougher criminal sanctions will be incurred in case of non-compliance with the anti-benefits regulations. In particular:

- 2 years of imprisonment for persons having offered or procured illicit benefits;
- fine of up to EUR 750,000 for companies. The total amount of the fine can amount up to 50% of the expenses incurred for carrying out the offense (e.g. 50% of the cost of a promotional event or marketing programme which would breach the above regulations).

If the breach has been committed by a company which markets products or services that are reimbursed by the French healthcare system, the applicable sanctions will be brought to the attention of the French Economic Committee for Healthcare Products (CEPS). This is similar to the French advertising regulations that require the French National Agency for Medicines and Health Products Safety (ANSM) to transmit to the CEPS decisions on withdrawal or prohibition of advertising.

The regulations also clarify the roles of the public authorities in charge of investigating the breaches to the anti-benefits regulations. In particular, the ANSM will be able to carry out investigations on breaches of anti-benefits regulations, and has been granted investigative powers to this end.

How to get ready to what is next

Companies should:

- continue complying (to the extent applicable) with the current anti-benefits regulations until entry into force of the new regulations, which will be fixed in upcoming decrees;
- start preparing a compliance map to assess those of their activities that may fall under the new regulations;
- start assessing to what extent their compliance policies need to be updated (or prepared if no such policies exist) to take into account the new regulations. This includes considering any changes that may be required for project planning due to the new submission system that will be implemented with professional bodies and administrative authorities;
- inform and train business teams working with stakeholders;
- monitor the publication of the future decrees to obtain further details (e.g. thresholds above which an authorization will be necessary, definition of "healthcare services", details on the contents of agreements).

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