Hogan Lovells

Strengthening of the French anti-benefits regulations: the wait is over! (almost)

17 June 2020

2020 marks a further milestone in stricter controls on HCPs interactions in France. French government has laid the remaining bricks for the new (and stricter) regulatory framework for interactions between the industry and healthcare professionals: **a decree was published on 17 June 2020** and ministerial orders implementing this decree are imminent to enact this new framework.

As a reminder, on 19 January 2017, major modifications were adopted in France to the regulations governing these interactions. Since this date, the healthcare sector was waiting for the adoption of the "implementing regulations" (*i.e.*, the decree and orders) which provide the key practical details on how the new framework operates.

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 HCPs and other stakeholders.

The key takeaway points of these new rules and their draft implementing regulations are:

- **extension of the types of companies concerned:** the regulations will now apply to any entity manufacturing or marketing healthcare products (regardless of whether they are reimbursed by French Social Security schemes) or providing health services;
- **extension of the range of stakeholders concerned** by the prohibition to receive benefits;
- **introduction of a declaration and an authorization process** involving French health authorities or professional bodies depending on the amounts involved;
- **introduction of a mandatory dedicated online application system** for declarations and authorizations;
- **stronger control on compliance and enforcement.**

We have set out further details on the new regulatory framework below.

What is prohibited?

As a reminder, the anti-benefits regulations prohibit any entity manufacturing or marketing healthcare products or providing health services from **granting, or offering,** 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 granting or offering 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 limited exceptions. Both French and foreign entities are concerned.

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 national health insurance. 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 in the product manufacturing chain without manufacturing the final product (*e.g.*, API suppliers), may now be targeted by these regulations.

The new regulations also encompass providers of "health services", which mostly target regulated entities such as health institutions or providers of services reimbursed by the French national health insurance.

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 explicitly 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 not concerned by the regulations?

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

- remuneration paid in the course of the employment contract with 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 negligible value which are related to the stakeholder's activity (see below).

What is considered to be of negligible value under the new regulations?

Up until now, the criteria used to determine whether a benefit is of negligible value were set by practice and case law, which were applied indifferently to all types of benefits. It was generally accepted by case-law that a benefit of a value remaining less than or equal to EUR 30, per year and per HCP, was a benefit of negligible value, and not prohibited.

In contrast, the new regulations set out a variety of thresholds below which the benefit will be considered to be of negligible value, and therefore allowed. The publication of the ministerial orders setting out the new thresholds is imminent. The last version of the draft orders which were circulated have indicated, for example, that meals and snacks with an HCP will be considered as of negligible value if they are unexpected, if they relate to the HCP's activities and do not exceed EUR 30 (incl. tax) per HCP with a maximum of two per year. Other thresholds relate to the offering of educational material, samples of products, office supplies or other products/services relating to the HCP's activities.

What exceptions are permitted under the regulations?

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

- remuneration, compensation and payment for research activities, research promotion, scientific evaluation, advice, provision of services or trade promotion. The amounts at stake must be proportionate to the services provided. Any additional payments or reimbursements must be limited to the costs actually incurred;
- hospitality offered, directly or indirectly, during professional, scientific or promotional events. Such hospitality must be reasonable, strictly limited to the main objective of the event and not extended to persons other than the stakeholder directly concerned by the event;
- educational grants (*e.g.*, in the context of continued medical education) and research grants;
- grants made to associations composed of HCPs and/or HCP students, provided that the purpose of the association is related to their professional activity.

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. The requirements on the content of

such agreement are precisely listed in the new regulations. This means that companies will need to review relevant template agreements to make sure such requirements are met. A ministerial order will further specify the scope of some of these requirements.

These requirements are not necessarily complicated to meet, but there are items which will need analysis based on the company's practices and the context in which the agreements will be used. For instance, the agreement must include:

- information enabling the identification of indirect and final beneficiaries: the scope of this concept leaves room for interpretation on what indirect and final beneficiaries are assessed, especially where third party vendors are used to streamline contracting with HCPs in global projects, or where all potential beneficiaries are unknown (*e.g.*, double-blinded research);
- the individual amount of each benefit and, where appropriate, the cumulative amount of such benefits: companies will need to assess what benefits in kind will be provided, and how these are identified in the agreement;
- if a public official is concerned, the authorization by the HCPs employer to carry out private practice: this requirement has been subject to important debate, as such authorizations may take time to obtain (see more details on this below).

Permitted benefits must be subject to prior declaration or authorization

The industry will have to submit agreements on permitted benefits to the national or central (for pharmacists) professional bodies or competent administrative authorities. This significantly differs from the current regulations which require only a prior opinion to be sought from professional bodies.

The agreements will be submitted for **prior authorization**, if the amount provided in the agreement **exceeds certain thresholds**. The thresholds depend on the beneficiary of the benefit (HCP, HCPs student or association) and the type of benefit. A ministerial order will set out such thresholds. For instance, the draft orders set out the following amounts:

- consultancy services contracted with HCPs will require prior authorization if the hourly fees agreed exceed EUR 200 and/or if the overall fees under the contract exceed EUR 2,000;
- hospitality provided to HCPs will require prior authorization if the applicable values exceed EUR 150/night for accommodation, EUR 50 per meal, or EUR 15 per snack;
- a research grant for an HCPs association will require prior authorization if the grant exceeds EUR 8,000.

The regulations will set out several other figures for other types of benefits such as educational grants and registration fees for professional events.

The new authorization process is detailed under the new regulations and will require advance planning. The competent authority has:

- two months from the date of receipt of the complete file to authorize or refuse. If the authority does not provide a response within this timeline, the authorization is deemed granted.

- one month from the date of receipt of the file to indicate if the file is incomplete. In such case, the competent authority has two months from the date of receipt of the completed file to make a decision.

If the authorization is not granted, a revised agreement can be submitted with shorter timelines for the new review.

The regulations provide for an emergency procedure with shortened timelines, but we suspect this will apply under exceptional circumstances only (*e.g.*, lack of anticipation by the company will probably not, in most cases, allow using the emergency procedure).

The approval procedure is a major change which will impact the industry's practice. For instance:

- until now, competent professional bodies only issued opinions. In practice, companies could still decide to proceed with the prospective project despite a negative opinion, in particular, after ensuring that payments were of fair market value. However, under the new regulations, the failure to obtain an authorization will mean that the project cannot be implemented. In such case, the only recourse will be to bring a claim challenging the rejection of the authorization;

- for agreements with HCPs that are public officials (*e.g.*, HCPs employed by public hospitals), the application file must include the authorization for the HCP to carry out private practice. This authorization is granted by the HCPs employer (*e.g.*, director of the public hospital). This was already required in practice by French professional boards under the current prior opinion procedure. From a practical standpoint, obtaining such authorization is often delayed and some companies have implemented projects with HCPs without waiting for obtaining such authorization. One of the reasons is that obtaining such authorization is essentially an obligation for the HCP (the company relying then on representations and warranties that the HCP has appropriate approvals in place at the time it starts the work). With the new regulations, the industry will have to make sure the authorization is obtained at the time the relevant agreement with the HCP is submitted for approval.

If the transfer of value is **below the thresholds** mentioned above, **the agreement must be notified to the competent authority 8 working days** before the day the relevant benefit is granted. This notification will also include items that need to be anticipated, such as the above mentioned employer authorization. Further to the notification, the competent professional body or administrative authority may issue recommendations. These recommendations are addressed individually, as appropriate, to the entities which are granting or offering benefits, HCPs or directors of the concerned health institutions. The recommendations may relate in particular to the content of the agreement. These recommendations will not be binding upon the company, but may be an indication that the relevant body or authority has concerns or is in disagreement with the projected interaction.

Companies will carry out the notification and authorization procedure through a dedicated online application system.

From a practical standpoint, under the new regulations, **any agreement entered into with a stakeholder, which contains a transfer of value to such stakeholder, will need to be submitted in advance to the competent professional bodies or to the competent regional health agency**. Companies will therefore need to take into account this prior submission system in their project timeline.

A major exception to the above rule relates to agreements on interventional studies entered under the 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 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. **Clinical study agreements are not subject to the authorization/declaration procedure but must be transmitted for information to professional bodies under a separate procedure.**

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;
- a 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 program which would breach the anti-benefits regulations).

If the breach has been committed by a company which markets products or services that are reimbursed by the French national health insurance, 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 potential breaches of the anti-benefits regulations. In particular, the ANSM will be able to carry out investigations on such potential breaches, and has been granted investigative powers to this end.

How to get ready to what is next

The decree will become effective on 1 October 2020, hence providing a transition period of a few months to the declaration and authorization procedures. It is unclear whether this period applies to files submitted in relation with interactions taking place as from that date or to files submitted for review as from that date.

Many industry players have already started anticipating the regulations, and companies should in any event:

- continue complying (to the extent applicable) with the current anti-benefits regulations until entry into force of the implementing regulations ;
- prepare a compliance map to identify interactions that may fall under the new regulations and in particular the activities that will require the submission of authorization requests to competent authorities based on the amounts provided above;

- assess to what extent group companies or joint-venture partners may now fall under the regulations;
- evaluate changes that are required to all template agreements used in interactions with the relevant stakeholders (such as HCPs and HCP associations);
- assess 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 studying any changes that may be required for project planning due to the new submission system that will be implemented by the professional bodies and administrative authorities;
- assess how this fits with existing industry codes (*e.g.*, EFPIA Code for pharmaceutical companies, Medtech Code for medical device companies) or general policies, such as anti-bribery policies;
- inform and train business teams working with relevant stakeholders;
- monitor the imminent publication of remaining ministerial orders.

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