

## THE ENTRY INTO FORCE OF REINFORCED ANTI-GIFT RESTRICTIONS

French anti-gift restrictions were strengthened on 1<sup>st</sup> July 2018 but with little visible effect as implementing regulations were not enacted. Thanks to the publication, on 17 June 2020, of a Decree and to the incoming enactment of two Ministerial Orders, these reinforced restrictions should - finally - be implemented from 1<sup>st</sup> October 2020 onwards. Undertakings operating in the healthcare & life sciences sector must be ready to comply with them.

### THE LONG-DELAYED REFORM OF ANTI-GIFT REGULATIONS

The Ordinance n°2017-49 of 19 January 2017, ratified and amended by the Law n°2019-774 of 24 July 2019, has strengthened the so-called "*anti-gift regulations*", which prohibit numerous types of persons (including certain healthcare professionals and public officials) from receiving benefits in kind or in cash, in any form, directly or indirectly, provided by entities manufacturing or selling health products or services. Such entities are also prohibited from offering or providing benefits to these persons.

The Ordinance was meant to enter into force on 1<sup>st</sup> July 2018. As none of the necessary implementing regulations were enacted on time, the Ministry for Health stated in June 2018 that it would keep applying previous rules.

The first of these implementing regulations was, at last, published on 17 June 2020. Two additional ministerial orders, which are being discussed, should soon be published.

### WHAT DOES THE PUBLICATION OF THIS DECREE MEAN FOR THE HEALTHCARE & LIFE SCIENCE INDUSTRY?

#### **The Decree is the first step for the entry into force on 1<sup>st</sup> October 2020 of reinforced anti-gift restrictions**

The Decree published on 17 June 2020 should lead to the actual enforcement of strengthened anti-gift restrictions from 1<sup>st</sup> October 2020 onwards.

Under previous regulations, created by the Law n°93-121 of 27 January 1993, known as "DMOS", it was necessary to request the opinion ("*avis*") of competent ordinal bodies prior to implementing agreements on benefits. This should remain applicable until 1<sup>st</sup> October 2020 subject to significant amendments.

#### Key issues:

- French anti-gift restrictions should have been reinforced on 1<sup>st</sup> July 2018 but implementing regulations were not enacted.
- On 17 June 2020, a Decree was finally published and has clarified several important subjects.
- Two Ministerial Orders, which are being discussed, should soon be enacted.
- Undertakings operating in the healthcare & life sciences industry will have to comply with strengthened anti-gift restrictions from 1<sup>st</sup> October 2020 onwards.
- Anticipation is key: identifying which entities are within the scope of these rules, amending internal processes and contracts, informing and training internal teams.

Under the new regulation, procedures of declaration and authorization are implemented: the offer or provision of benefits (authorized by way of derogation) depends on the conclusion of an agreement, which must be notified to competent ordinal bodies or administrative authorities for the purpose of being declared or authorized.

Other major changes, which are, according to the Ministry for health, not applicable until the entry into force of the implementing regulations, will finally be in effect, including:

- extension of the scope of the persons who are prohibited from receiving benefits (*i.e.* numerous types of health professionals, students, certain associations and certain public officials);
- extension of the scope of the persons who are prohibited from offering or providing services (*i.e.* anyone who manufactures or markets medicinal products or who provides health services);
- definition of the benefits which are not within the scope (*e.g.* certain benefits of a negligible value and in relation to the beneficiary's profession, remuneration under an employment contract, etc.) or are subject to the conclusion of a contract and to the above-mentioned procedures (*e.g.* donations to finance research activities, donations to associations, hospitality if reasonable and limited to the purpose of the event, etc.);
- increase of the penalties incurred for receiving or providing benefits (offering or providing benefits shall be subject to a penalty of up to 2 years of imprisonment and to a fine of up to 750,000 euros).

## The Decree clarifies some of the new rules

The Decree clarifies the scope of the persons who are prohibited from offering or providing benefits by listing those who provide health services.

It also specifies the content of agreements on derogatory benefits (*e.g.* donations to finance research, hospitality, etc.). For instance, such contracts must clarify the identity of the parties, the indirect and final third-party beneficiaries (this concept is not defined by the text and may be difficult to interpret in practice), the amount of each and all benefits and, if a public official is involved, the authorization for multiple activities (the obtention of which often involves significant delays).

Finally, it contains useful clarifications regarding the new procedures. It is already clear that anticipation will become crucial, especially for contracts subject to a prior authorization, and that these new procedures will need to be taken into account in the timeline of many projects.

Regarding the procedure of declaration, the contract must be notified to the competent authority at the latest eight business days before the day on which the benefit is granted.

Regarding the procedure of authorization, the competent authority must answer within two months of the reception of the application and, if the application dossier is incomplete, must notify it within one month. Any refusal must be motivated. In the event of a refusal, a new contract may be notified within fifteen days and the competent authority must decide whether to authorize it within fifteen days. In the event of an emergency (which is not defined by the text), delays are shortened (three weeks to issue an initial decision and one week to issue a second decision if an amended contract is notified on time).

## **WHAT ARE THE NEXT STEPS?**

Two Ministerial Orders should soon be published to ensure the actual implementation of these strengthened anti-gift restrictions on 1<sup>st</sup> October 2020. Two draft Ministerial Orders were already issued and are subject to a consultation process. They will determine (i) the amount beyond which contracts on derogatory benefits are subject to a prior authorization and (ii) the amount below which benefits are considered as negligible.

The Ministry for health will also draft a briefing note to further clarify these new restrictions. We hope that this note will give some insight regarding the interpretation of the concepts of emergency and of third-party beneficiaries.

In the meantime, undertakings operating in the healthcare & life sciences sector should not only keep complying with current regulations but also anticipate this deadline by reassessing which of their legal entities are within the scope of these regulations, amending their internal processes and contracts and informing and training their teams.

Of course, we will keep you informed once these Ministerial Orders are published.

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Entry into force of reinforced anti-gift restrictions

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