

COMPLETION OF REINFORCED "ANTI-GIFT" RESTRICTIONS: PUBLICATION OF THE TWO LONG-ANNOUNCED *ARRETES*

Further to the publication of the Decree of 15 June 2020 (on 17 June 2020), reinforced French "anti-gift" restrictions should be implemented from 1 October 2020 onwards. Several significant subjects have been clarified (see our previous client briefing: [link](#)). On 14 August 2020, two additional *Arrêtés* ("Ministerial Orders") of 7 August 2020 have been published to ensure the actual implementation of these strengthened "anti-gift" restrictions. Operators in the healthcare & life sciences sector must soon be ready to comply with them.

WHAT DOES THE PUBLICATION OF THESE MINISTERIAL ORDERS MEAN FOR THE HEALTHCARE & LIFE SCIENCE INDUSTRY?

The Decree published on 17 June 2020 represented the penultimate step for the entry into force on 1 October 2020 of reinforced "anti-gift" restrictions. 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.

The two Ministerial Orders provide the clarifications which should have been published in ...July 2018 : (i) the amount beyond which contracts on derogatory benefits are subject to prior authorization and (ii) the amount below which benefits are considered as negligible.

THE FIRST MINISTERIAL ORDER SETS THE AMOUNTS BEYOND WHICH CONTRACTS ON DEROGATORY BENEFITS ARE SUBJECT TO PRIOR AUTHORIZATION

The Ministerial Order sets, for each category of agreement and beneficiary, thresholds above which these agreements must be subject to prior authorization.

Key issues:

- On 14 August 2020, two additional *Arrêtés* ("Ministerial Orders") of 7 August 2020 have been published to ensure the actual implementation of these strengthened "anti-gift" restrictions.
- The first Ministerial Order sets the amount beyond which contracts on derogatory benefits are subject to prior authorization.
- The second Ministerial Order sets the amounts beyond below which benefits are considered as being of a negligible value.
- These two Ministerial Orders will come into force on 1 October 2020. This leaves two months to operators in the healthcare & life sciences sector to implement new compliance procedures.

These are:

a) Net remuneration, compensation and expenses for research activities, promotion of research activities, scientific evaluation, consultancy, provision of services or commercial promotion:

- for healthcare professionals: 200 € per hour, up to a limit of 800 € per half-day and 2,000 € for the whole agreement;
- for students: 80 € per hour, up to a limit of 320 € per half-day and 800 € for the whole agreement;
- for associations of healthcare professionals or of students: 200 € per hour, up to a limit of 800 € per half-day and 2,000 € for the whole agreement.

b) Donations and gifts (intended to exclusively finance research activities, the promotion of research activities or scientific evaluation activities):

- for healthcare professionals: 5,000 €;
- for students: 1,000 €;
- for associations of healthcare professionals or of students: 8,000 €.

Associations of healthcare professionals or of students may receive donations and gifts intended for other health-related purposes but, in that case, the threshold is lowered to 1,000 €.

If these associations are declared to be of public utility, the threshold is increased to 10,000 €, including for donations and gifts intended to finance research activities, promotion of research activities or scientific evaluation activities.

c) Hospitality offered during events of an exclusively professional or scientific nature, or during events aiming to promote products or services:

- for healthcare professionals: 150 € per night, 50 € per meal and 15 € per snack, and 2,000 € for the entire convention including the cost of transport to the venue. In addition to these amounts, registration fees can be borne but an authorization shall be requested above 1,000 €. Those amounts are set VAT included.

d) Financing or participation in the financing of vocational training or continuing professional development measures:

- for healthcare professionals: 1,000 €.

THE SECOND MINISTERIAL ORDER SETS THE AMOUNTS BELOW WHICH BENEFITS ARE CONSIDERED AS BEING OF A NEGLIGIBLE VALUE.

Benefits in kind or in cash are considered to be of negligible value when their market value, including tax, is less than or equal to the amounts per beneficiary mentioned below, within the limit of the determined frequencies. These amounts are:

- impromptu meals and snacks (*à caractère impromptu*) and relating to the beneficiary's profession: 30 € within the limit of two per year;

- books or magazines: 30 € per item and within a total limit of 150 € per year;
- sample of health products for health purposes or demonstration copy: 20 € within the limit of three per year (as an exception to this rule, some samples of health products for health purposes and demonstration copies are authorized without limit of amount);
- office supplies: 20 € in total per year;
- other products or services related to the beneficiary's professional practice: 20 € in total per year.

WHAT ABOUT NEXT STEPS?

These two Ministerial Orders will come into force on 1 October 2020. This leaves two months to implement new compliance procedures: 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.

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