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France - New notification and authorization regime for exemptions from benefits/payments to the healthcare sector will enter into force in October 2020

In France, Ordinance No 2017-49 of 19 January 2017 significantly modified the rules governing payments from life sciences companies to the healthcare sector. After more than three years, on June 15, 2020, Decree No 2020-730 ('Decree') was issued to implement the Ordinance. The Decree will enter into force in October 2020.

While French law generally bans pharmaceutical and medical device companies from providing payments or benefits to covered recipients (primarily healthcare providers and trainees), there are some categories of payments or other value that are either out of the scope of the prohibition or exempt from the prohibition.

Companies that transfer value to the healthcare sector that is exempt from the general prohibition (including donations, service fees, and hospitality) must document those transfers of value with a written agreement between the parties. Depending upon the amount, type, and recipient of the transferred value, the company will also be required to either provide notification of the payment or benefit, or to seek authorization from the relevant healthcare association.

In addition, an Order (*arrêté*) will likely be issued to set the threshold amounts for notifications and for authorizations.

A. GENERAL BACKGROUND

Payments and other benefits of value from pharmaceutical and medical devices companies to the healthcare sector are governed by:



- Articles L. 1453-1 and L. 1453-2 as well as Article D 1453-1 and Articles R 1453-2 to R 1453-12 of the Public Health Code (*Code de la santé publique* or CSP) that relate to transparency, i.e. public disclosure of (authorized) benefits/payments to the healthcare sector; and
- Articles L. 1453-3 to L. 1453-14 CSP that set out the general prohibition of benefits/payments and the exceptions thereto.
- Ordinance No 2017-49, which created new sections in the *Code de la santé publique* (Public Health Code), amended the existing provisions by extending the list of covered beneficiaries, specified which forms of payments and other benefits are not covered by the Gift Ban, harmonized the criminal provisions, and adapted the public enforcement officers' powers.
- Decree No 2020-730, which implements the provisions of Ordinance No 2017-49 and which provides specifications for the required agreements between parties transferring value that falls under an exception to the prohibition.

The current rules are as follows:

- **General principle:** In general, companies that manufacture or market pharmaceuticals or medical devices or that provide health services may not provide payments or other benefits to the covered recipients (e.g., healthcare professionals, students in healthcare professions, associations of healthcare professionals, associations of students, etc.). The prohibition is also extended to certain public officers and to those who occasionally collaborate on the Commissions' activities.
- **Out of scope of the prohibition:** Certain benefits and payments are out of the scope of the prohibition. They include standard benefits in commercial contracts, benefits of low value, payments made in relation to employment agreements, and intellectual property revenues.
- **Exceptions:** Certain benefits and payments are exempted from the prohibition, subject to certain conditions. They include service agreements, donations and gifts, and hospitality. Every transfer of value that falls within this exception must be documented by a written agreement between the parties. The exceptions, however, do not apply to public officers.
- **Formality:** Previously, transferring certain items of value required seeking a non-binding prior 'opinion' from the relevant healthcare association (medical association, pharmacists' association, etc.). The new decree instead requires companies to seek authorization from that healthcare association or the competent public authority for payments and benefits with a value above a certain threshold, and to provide notification of transfers below that threshold. This requirement does not apply to the '*convention unique*' for clinical trials.

B. DECREE No 2020-730

The Decree implements the procedural rules for the exceptions to the general prohibition. The Decree adds the following implementing sections to the Public Health Code regulations:

1. Definition of Healthcare Service Providers

This section gives a legal definition of healthcare service providers and other covered recipients under the Gift Ban. Those persons are the natural and legal persons:



- who have an activity subject to an authorization, approval, accreditation or declaration regime set forth in the Sixth Part of the Public Health Code, such as those who provide health transport or conduct biological testing;
- who have an activity subject to an authorization or accreditation by the regional health agency set forth in Book III of the Code of Family and Society Action, such as those who provide home healthcare to senior citizens;
- who provide services which are covered either by the national healthcare insurance system (sickness, invalidity or maternity insurance), the State medical assistance or the State (Titles I and II of Book II of the Invalidity or War Victims Military Retirement Benefits).

2. Exceptions to the General Prohibition of Benefits/Payments

Every payment or transferred benefit which falls under an exception to general prohibition must be documented by a written agreement between the parties. The Decree defines the basic content of the agreement (explained in more detail below).

Furthermore, the company providing the payment or benefit must either provide notification of the payment or benefit, or must seek prior authorization from the relevant healthcare association. Note that the new requirement for prior authorizations is a significant change from the previous system, under which companies were expected to seek a non-binding prior opinion from the relevant healthcare association before providing payments or benefits.

Whether a payment or benefit is subject to the notification requirement or to the prior authorization requirement depends upon the value, category of value, and recipient. Further details on this distinction, including the threshold value that determines whether notification or prior authorization is required, will most likely be stated in a future order (*arrêté*).

The Decree sets out the notification and authorization regimes:

Mandatory Content of the Agreement. – Parties to a payment or benefit that falls under an exception to the general prohibition must document the transfer of value through a framework agreement. The agreement must be communicated electronically. The agreement must contain at a minimum the following information:

- The detailed identities of the parties.
- The precise subject-matter of the agreement (linked to a category to be specified by a future order (*arrêté*)), subject to compliance with secrets, including industrial and commercial secrets, protected by law.
- If relevant, the information allowing identification of the indirect and final beneficiaries who did not sign the agreement.
- For payments or benefits in cash or in kind:
 - the type of payments/benefits and the information to be provided for that type of benefits/payments (still to be specified);
 - the individual amount of each benefit/payment and, as the case may be, the aggregate amount of these payments/benefits, including taxes, rounded up to the nearest euro;
- The date of signature of the agreement as well as its date of expiration and, if relevant, the period during which the benefits/payments will be given. This information however is not required for agreements subject to declaration.



- If relevant: the event program; the authorization for extra activities from the authority of which the public officer concerned is a member; a French summary of the research or evaluation; and a the draft observation notebook or, for scientific activities not covered by Article L. 1121-6, the data collection document set forth by the protocol.

Notification Regime. — When the agreement provides for a payment or benefit where the value is below certain threshold amounts, the company must forward the agreement electronically to the relevant healthcare association at least eight working days before the actual payment/benefit is transferred. If the beneficiary is not a healthcare professional, the agreement should be sent to the regional health agency in the territory in which the agreement has been signed.

Authorization Regime. — For payments or benefits that fall above a certain threshold of value, the company must submit the draft agreement and authorization dossier to the relevant healthcare association (or competent regional health agency) for prior authorization.

The healthcare association must accept or refuse the authorization within two months of acknowledging receipt of a complete dossier; otherwise, the agreement is deemed accepted. In the case of a refusal, the company may propose amendments to the agreement within 15 days of the notification of the refusal. The healthcare association must decide on the amended agreement within 15 days.

In the case of a justified emergency, the health association decides within three weeks (instead of two months) and, in the case of a refusal followed by a request for amendment, within one week (instead of 15 days).

The company must inform the beneficiary of whether the authorization has been granted.

C. FUTURE THRESHOLDS FOR NOTIFICATION VS AUTHORIZATION ?

A future *arrêté* will set the amounts above which the exceptions are subject to authorization rather than notification. Those amounts will vary, depending on the category of beneficiaries (healthcare professionals, students in healthcare professions, and associations) and payments/benefits.

See below the thresholds in the current version of the draft arrêté. Note that these values are subject to change if and when the final *arrêté* is issued.

	Healthcare professionals (Art. L. 1453-4 (1°))	Students (Art. L. 1453-4 (2°))	Associations (Art. L. 1453-4 (3°))
Net remuneration, compensation and reimbursement for activities of research, research valorization, scientific evaluation, consultancy, services or commercial promotion	200 € / hour with a maximum of 800 € / half-day and globally lower than 2,000 €	80 € / hour with a maximum of 320 € / half-day and globally less than 800 €	



Hospitality given for exclusively professional or scientific events or for promotional events	<p>150 € per hotel night</p> <p>50 € per meal</p> <p>15 € per snack</p> <p>These aggregate amounts and transportation costs may not exceed a total of 2,000 €.</p> <p>Registration fees may be added but must be authorized if 1,000 € or above.</p>		
Financing or participation in financing of professional training or continuing professional development actions	1,000 €	1,000 €	
Donations/gifts intended exclusively to finance research, research valorization or scientific evaluation activities	5,000 €	5,000 €	8,000 €
Donations/gifts destined for another purpose linked to health			1,000 €
Donations/gifts to public utility associations, including those destined to finance exclusively research, research valorization or scientific evaluation			10,000 €



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