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France's New Anti-Benefits Regime: Core Framework and Key Takeaways

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On October 1, 2020, France's new Anti-Benefits Regime entered into force. The new framework governs transfers of value to healthcare professionals by pharmaceutical, medical device, and other healthcare companies. France began to lay the groundwork for this Regime in January 2017, when the French legislature adopted Ordinance No. 2017-49 and thereby expanded the scope and requirements of France's Anti-Benefits Law (the "Law"), enacted in 1993. This past summer and fall, France completed the Regime with the issuance of implementing regulations. Taken together, France's amended Anti-Benefits Law and its implementing regulations create a detailed and demanding Regime governing the circumstances under which French and foreign life sciences companies may provide transfers of value to French healthcare professionals ("HCPs"). With the implementing regulations now in effect, life sciences companies must evaluate their policies, processes, and systems applicable to interactions with HCPs to ensure compliance.

Background

France's Anti-Benefits Law generally prohibits the granting or offering of benefits, in cash or in kind ("Benefits"), to HCPs by healthcare companies ("HCCs"). Prior to 2017, the Law applied to HCCs that manufacture or market products reimbursed under the French social security system. Ordinance No. 2017-49 expands the applicability of the Law to manufacturers and marketers of healthcare products without regard to reimbursement status. The previous version of the Law also created a prior opinion system whereby HCCs were required to seek opinions from relevant professional organizations on certain proposed Benefits, which were not binding. The new Regime replaces the "prior opinion system" with a novel framework requiring prior notice ("Declarations") or prior authorization ("Authorizations") for Benefits above certain thresholds. The Regime has also made other notable modifications, including imposing tough criminal sanctions and requiring that HCCs use an online system for Declaration and Authorization submissions.

The 2017 Ordinance took effect in June 2018 without implementing regulations to define the key details, including the applicable thresholds, needed to fully implement the Law. It was only recently, in June of 2020, that the French legislature began to release the implementing regulations, beginning with a June 15, 2020 Decree. The Decree was followed by two ministerial *Arrêtés* ("Orders") on August 7, 2020 and another Order on September 24, 2020.

Core Framework and Requirements

Taken together, the Law and its implementing regulations (i.e., the Decree and Orders) create a detailed and demanding set of regulations governing HCP transfers of value by HCCs. The core framework and requirements of the Regime are as follows:

I. Scope and Applicability

The Regime broadly applies to French or foreign HCCs manufacturing or marketing human health products, with some limited exceptions, or providing health services. This includes pharmaceutical and medical device companies manufacturing or marketing products in France, as well as hospitals and biomedical laboratories (i.e., both French and multinational companies).

HCPs is similarly broadly defined and includes, *inter alia*: (1) individuals working in the regulated health sector (e.g., physicians, pharmacists, paramedics, osteopaths, chiropractors and psychotherapists); (2) medical students; (3) HCP or student associations; and (4) civil servants and public officials who participate in public health or social security policies, or who have health-related administrative police powers.

Benefits include almost *any* transfer of value, similar to France's Sunshine law, including fee-for-service, grants and donations, and hospitality, whether provided directly or indirectly. Certain types of transfers of value, such as intellectual property rights and remuneration pursuant to an employment contract, are not considered Benefits.

II. New Governance System

The most notable aspect of the new Regime is that it creates a detailed system governing whether and under what circumstances HCCs may provide Benefits notwithstanding the Law's general prohibition. Benefits of "negligible value" are automatically exempted from the Law's prohibition. The August 2020 Order defines "negligible benefits" as, *inter alia*: (1) books and other publications valued at up to 30 euros per book or publication and a cumulative value of up to 150 euros per calendar year; and (2) meals valued at 30 euros per meal, up to two meals with the same HCP per calendar year.

Benefits that are greater than negligible value, but less than certain thresholds identified in the August 2020 Order, are subject to a prior notice, or Declaration, requirement. The thresholds vary, depending on the nature of the Benefit and whether the recipient is an HCP, medical student, or professional association. For instance, the threshold for fee-for-service compensation to HCPs and associations is 200 euros per hour, 800 euros per half day, or 2,000 euros per agreement. For medical students, the threshold for compensation is 80 euros per hour, 320 euros per half day, or 800 euros per agreement. The Order also provides thresholds for hospitality and various types of grants, and donations, and funding. Companies seeking to provide these Benefits will need to plan ahead, as the companies must first pursue a *Convention* ("Agreement") with the HCP, and then provide notice to the competent authority, via a Declaration, no later than eight working days before the date on which the Benefit is due to be granted. The September 2020 order identifies the various typologies of Agreements that must be used.

Benefits that are greater than the thresholds identified above are subject to an even more significant Authorization requirement. Here, companies must also obtain an Agreement, and then obtain Authorization from the competent authority pursuant to a process detailed in the August 2020 order. The Authorization requires even more advanced planning, as the competent authority has a lengthy two months from the date or receipt of the complete file to authorize or reject the Benefit. If the authority does not provide a response within this timeline, the Authorization is deemed granted. The regulations provide for an emergency procedure with reduced timelines in urgent cases, but what constitutes an "urgent" situation is still unclear.

The competent authority depends on the recipient. When the recipient is a professional or legal entity covered by a National Professional Board, or a student intending to join a profession covered by National Professional Board, the competent authority is the recipient's Board. When the recipient is any other professional, legal entity, or student, the competent authority is the Local Health Agency

(ARS) within the jurisdiction in which the Agreement was signed. Pursuant to the June Decree, requests for Declarations or Authorizations must be made electronically via a dedicated online system.

It should be noted that providing Benefits to public officials (e.g., an HCP employed by a public hospital) requires further advanced planning, as the Declaration or Authorization application file must also include an Authorization from the HCP's employer.

III. Sanctions

Finally, and importantly, the new Regime provides for tough criminal sanctions for violations of the Law. Individuals face up to two years of imprisonment for having offered or procured Benefits in violation of the law. Companies may incur a criminal fine of up to 750,000 euros, or 50% of the expenses incurred for providing the Benefit (e.g., 50% of the cost of a promotional event or marketing program constituting the offense). It also remains to be seen how, in some cases, violations of the Anti-Benefits Law will impact prosecutor decisions under the *Sapin II* law and other global anti-corruption laws, like the Foreign Corrupt Practices Act.

Key Takeaways for Your Compliance Program

The new Regime's detailed standards and parameters place companies on clear notice of the circumstances under which prior notice (i.e., a Declaration) and prior Authorization are required—which, it is worth bearing in mind, apply to almost any transfer of value and not merely gifts and business courtesies (as the name of the statute might suggest). Accordingly, life sciences companies that may engage or interact with French HCPs, whether in the commercial, clinical, or medical arenas, should assess and update, as necessary, compliance policies, procedures, and systems applicable to hospitality, engagements, grants, and donations. Many multinational life sciences companies already have policies governing topics such as de minimis gifts, and situations where transfers of value require internal pre-approval. These policies should be updated to support compliance with the new Regime, which could involve updating global policies to align with the Regime's requirements or direct colleagues to local procedures.

Likewise, many multinationals already have internal pre-approval processes and systems in place, which might define the minimum lead time for seeking approval, the necessary approvers, and applicable thresholds. These processes and systems may exist at a global, regional, and/or local level. Local processes and systems should, of course, be updated to operate under the new governance system, and companies should also reevaluate their global or regional systems and processes. Global and regional systems built to support global/regional standards might undermine compliance with the Regime's strict and detailed Declaration and Authorization requirements. These systems should be recalibrated to support local efforts to comply with the new law, particularly when colleagues outside of France pursue cross-border engagements of French HCPs. For instance, if an employee outside of France decides to engage French HCPs for a speaking engagement, s/he may not know to provide sufficient lead time to permit local colleagues to obtain the necessary Declaration or Authorization. There will need to be a training and awareness effort around these new, special rules associated with business in France.

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If you have any questions concerning these developing issues, please do not hesitate to contact either of the following Paul Hastings lawyers:

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