

France's New Anti-Benefits Regulations: Using Technology to Manage HCP Engagements

New regulations implementing France's Anti-Benefits Law entered into force on October 1, 2020, imposing rigorous requirements on French and foreign life sciences companies providing benefits to French healthcare professionals (HCPs). Companies need to ensure internal policies, procedures and systems related to HCP engagements, meals and hospitality are updated to comply with the new regime.

The Anti-Benefits Law **GENERALLY PROHIBITS** manufacturers and marketers of healthcare products from granting or offering transfers of value, directly or indirectly, to:

- Various types of HCPs (e.g., doctors, pharmacists, paramedics, chiropractors)
- Medical students
- HCP or student associations
- Civil servants and public officials who participate in public health or social security policies, or who have health-related administrative police powers

Certain benefits are **EXCLUDED** from the regulations, including:

- Remuneration paid in connection with an employment contract
- Benefits from intellectual property rights
- Commercial benefits granted in connection with commercial agreements
- Benefits of **NEGLIGIBLE VALUE**, for example:



IMPROMPTU MEALS AND SNACKS UNDER **30 EUROS PER MEAL**, WITH A MAX OF **TWO MEALS PER YEAR**



EDUCATIONAL MATERIAL (E.G., BOOKS AND MAGAZINES), INCLUDING SUBSCRIPTIONS, UP TO **30 EUROS PER MATERIAL** AND UP TO **150 EUROS TOTAL PER YEAR**



OFFICE SUPPLIES UNDER **20 EUROS TOTAL PER YEAR**



OTHER PRODUCTS AND SERVICES RELATED TO THE BENEFICIARY'S PRACTICE UNDER **20 EUROS TOTAL PER YEAR**

Benefits above the negligible value thresholds and below the following thresholds are subject to a prior **DECLARATION** requirement. Benefits above these thresholds require prior **AUTHORIZATION**.

	Healthcare Professionals	Students	Associations
Net remuneration, compensation and reimbursement for research activities, promotion of research, scientific evaluation, advice, services or commercial promotion	€200/hour, with a limit of €800/half-day & €2,000 for entire agreement	€80/hour, with a limit of €320/half-day & €800 for entire agreement	€200/hour, with a limit of €800/half-day & €2,000 for entire agreement
Donations for research, promotion of research activities, or scientific evaluation	€5,000	€1,000	€8,000
Hospitality during professional, scientific or promotional events	€150/night, €50/meal & €15/snack, and €2,000/event, including travel cost €1,000 for registration fees		
Educational grants for professional trainings or continued professional education	€1,000		
Donations and grants for other health-related purposes			€1,000
Donations and grants to associations of public interest			€10,000



COMPANIES SEEKING DECLARATIONS & AUTHORIZATIONS MUST SUBMIT AN **AGREEMENT** WITH THE HCP RECIPIENT TO THE **APPROPRIATE AUTHORITY**.



DECLARATIONS MUST BE FILED NO LATER THAN **EIGHT DAYS** BEFORE THE BENEFIT WILL BE GRANTED. AUTHORITIES REVIEWING AUTHORIZATIONS HAVE **TWO MONTHS** FROM RECEIPT OF THE FILE TO AUTHORIZE OR REJECT IT.

PLAN AHEAD WITH PRE-APPROVAL SOFTWARE DESIGNED FOR LIFE SCIENCES COMPANIES

The Gateway Pre-Approval Application:

- ✓ HCP/HCO WORKFLOWS IN A SINGLE PLATFORM (E.G., HCP ENGAGEMENTS; GRANTS, SPONSORSHIPS & DONATIONS; MEETING SUPPORT)
- ✓ AGGREGATE SPEND AND FREQUENCY FLAGGING TO ENSURE COMPLIANCE WITH DISCLOSURE REQUIREMENTS
- ✓ SOPHISTICATED LOGIC TO ALLOW SEPARATE ESCALATION OF REQUESTS WITH FRENCH HCPS & HCOs
- ✓ ABILITY TO CAPTURE RATIONALE, VALUE & CONTRACTS IN A CENTRAL REPOSITORY

