



AUGUST 24, 2020

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France – Thresholds for Prior Authorization of Agreements with Healthcare Professionals and for Benefits of Low Value are Finally Out

The two *arrêtés* [orders] setting thresholds for transfers of value from pharmaceutical and medical devices companies to healthcare professionals, institutions, and other actors of the healthcare sectors (Healthcare Professionals), have finally been published. They will implement the new Gift Ban legislation that was passed in January 2017, as well as the Decree of June 2020. See our previous [alert](#). Both *arrêtés* will become effective on October 1, 2020.

One *arrêté* sets the value threshold above which an agreement with a Healthcare Professional is subject to prior authorization rather than notification. See chart 1 below.

The other *arrêté* sets the amounts below which benefits are considered of low value and, as such, are permitted without any formality - see chart 2 below.

As stated above, both *arrêtés* will enter into force on 1 October. By then, companies must register with the French Medical Association (and other relevant Association) so that they can carry out the required formality online. They also have to adapt their internal procedures and train their employees and contractors on the new procedures and thresholds.

CHART 1 – THRESHOLDS FOR PRIOR AUTHORIZATION VS. NOTIFICATION

The threshold amounts for prior authorization and notification requirements vary depending on the category of Healthcare Professionals (see Art. L. 1453-3 of the Public Health Code) and the nature of the transfer of value.



They apply for total value transferred, but it is unclear whether the amounts include taxes except for those related to hospitality (taxes included).

Thresholds for Prior Authorization			
	Healthcare professionals	Students	Associations
Net remuneration, compensation and reimbursement for research, research promotion, scientific assessment, advice, services, or trade promotion activities	200 €/hour with maximum 800 €/half-day and 2,000 € for the entire agreement	80 €/hour with maximum 320 €/half-day and 800 € for the entire agreement	200 €/hour with maximum 800 €/half-day and 2,000 € for the entire agreement
Donations intended exclusively to finance research, research promotion or scientific assessment activities	5,000 €	1,000 €	8,000 €
Hospitality during professional, scientific or promotional events	150 €/hotel night, 50€/meal and 15€/snack with maximum 2,000 €/event, including travel cost + 1,000 € for registration fee		
Grants to finance professional trainings or continued professional education	1,000 €		
Donations and grants for health-related purposes other than research, research promotion and scientific assessment			1,000 €
Donations and grants to associations of public interest			10,000 €



CHART 2 – THRESHOLDS FOR BENEFITS OF LOW VALUE

The amounts and periods must be determined per beneficiary and per company. They include taxes.

Thresholds for Benefits of Low Value	
Unexpected meals and snacks related to the beneficiary’s activity	30 € and maximum 2/year
Books, magazines, journals, including subscriptions, related to the beneficiary’s activity	30 € per educational material with maximum 150 €/year
Samples of health products for health or demonstration purposes <u>Exceptions:</u> No restrictions for - samples of medicinal products - samples and demonstration samples provided for the beneficiary’s education or training and that cannot be used for patient care - samples and demonstration samples used by the beneficiary for patient’s education or given to the patient for testing or adapting purposes and for temporary use	20 € and maximum 3/year
Office supplies	20 €/year
Other product or service that relate to the exercise of the beneficiary’s profession <u>Exception:</u> No restriction for products supplied on a public authority’s order	20 €/year

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