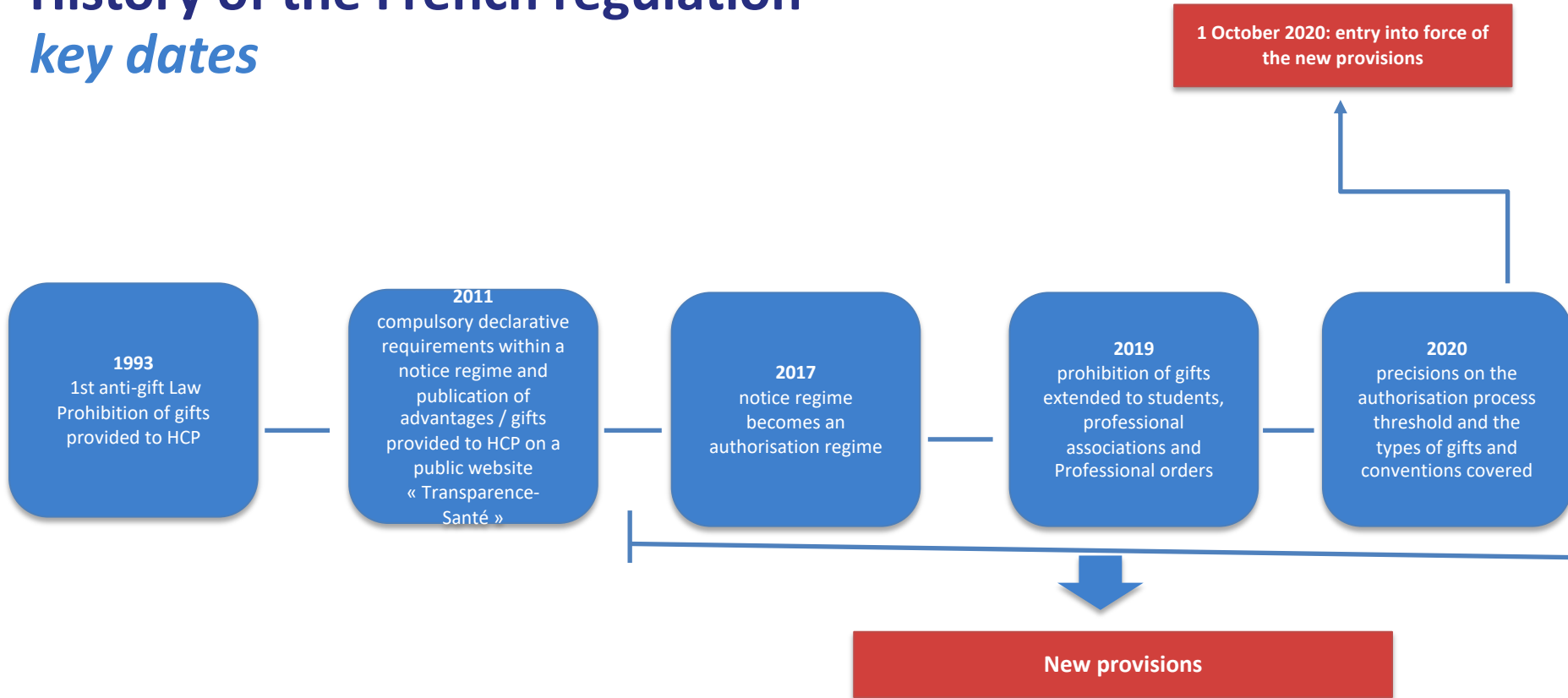

Anti gift mechanism in France: new provisions

Christelle Maréchal
Ethics Director - Leem

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History of the French regulation

key dates



Overview of the new provisions

- **Core principle:** prohibition of all sorts of advantages, originally to HCP and now expended to students, professional associations and professional orders

- **Exception to the principle :** advantages of negligible value can be permitted below a determined threshold and subject to the following requirements:
 - A contract is compulsory
 - The contract is subject to a declaration/authorization procedure depending of the threshold
 - Criminal prosecution in case of non respect of the procedure

Who's concerned?

By the prohibition to receive advantages:

- HCP, chiropractors, osteopaths, psychotherapists
- Students
- Associations comprising HCP and students
- Certain category of public servants

By the prohibition to provide advantages:

- Persons manufacturing and selling health products in France
- Persons providing healthcare services

Are not considered as advantages:

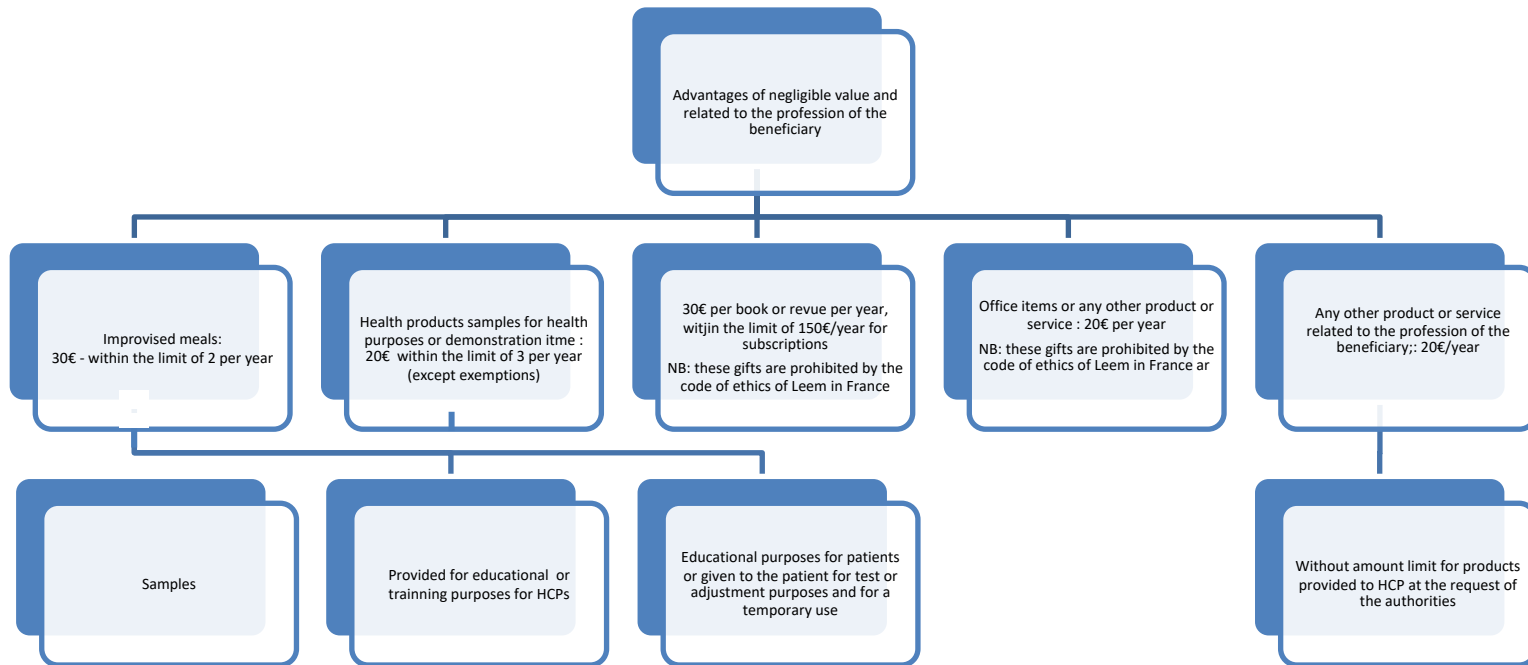
The following items **are not considered as advantages** (*and therefore permitted under specific conditions*):

- **Remuneration, compensation and payment** for expenses provided for in an agreement
- **Incomes from patent exploitation** related to a health product
- **Commercial benefits provided in an agreement and subject** to the purchase of goods or services within conditions set up by the French Public Health code
- **Advantages in cash or in kind regarding the practice of the beneficiary** and of negligible value, without exceeding the required threshold

Advantages are therefore permitted if they are:

- **Remuneration, compensation and payment of expenses for activities of research, research enhancement, scientific evaluation, advice, services, or commercial promotion**, as long as the remuneration is proportionate to the fair market value and does not exceed what the recipients would normally be willing to pay for themselves.
- **Donations to associations** comprising HCP and students
- **Hospitality offered, whether directly or indirectly**, during exclusively scientific or professional events, or during promotional events, as long as this hospitality is reasonable, limited to the main objective of the event
- **Funding or participation in the funding** of professional training or professional development actions
 - ➔ **Subject to the following prerequisites :**
 - A contract is compulsory
 - The contract is subject to a declaration/authorization procedure depending of the threshold

List of advantages of negligible value permitted



Declaration/authorization regime: threshold (1)

GENERAL RULE:

- Declaration procedure is applicable to contracts providing for an advantage which value is lower or equal to the threshold
- Authorization regime is applicable to contracts providing for an advantage which value is strictly higher to the threshold

Declaration/authorization regime: timing for submission (3)

GENERAL RULE:

- **Declaration: 8 days prior the day the remuneration is transferred to the HCP**
- **Authorization: 2 months prior the day the remuneration is transferred to the HCP**
 - **Autorities have 2 months to reply**
 - **If the file is incomplete, authorities have 1 month to request additional information and then 2 months to reply**

Consequently, in practice, 3 to 5 months prior are necessary to get an autorisation

Declaration/authorization regime: threshold (2)

Amount above which a convention is subject to authorization:

	Net remuneration, compensation, et payment of expenses for activities of research, research enhancement, scientific evaluation, advice, services or commercial promotion	Donations exclusively aimed at the funding of activities of research, research enhancement or scientific evaluation	Hospitality offered during exclusively professional or scientific events, or during promotional events or service provision (inclusive of VAT)	Funding or participation in the funding of professional training or professional development actions	Donations intended for another purpose related to health	Donations benefiting to associations registered for public purposes, including the ones aimed at funding activities of research, research enhancement or scientific evaluation exclusively
HCP, medical assistant, osteopaths, chiropractors and psychotherapists	200€/hour Within the limit of: - 800€/mid-day - 2 000€/total convention	5 000€	150€/night 50€/meal 15€/snack 2 000€/convention (transportation compris) + subscription fees : 1 000€	1 000 €	-	-
Students on initial training, persons benefiting for continuing education	80€/hour Within the limit of: - 320€/mid-day - 800€/total convention	1 000€	-	-	-	-
Associations comprising HCPs or students	200€/hour Within the limit of: - 800€ / mid-day - 2 000 € / total convention	8 000€	-	-	1 000€	10 000€