

## Summarized new legal framework of exceptions to the anti-gift principle

<b>THRESHOLDS ABOVE WHICH THE AGREEMENT IS SUBJECT TO <u>PRIOR APPROVAL</u></b>			
	<b>Healthcare professionals</b>	<b>Students</b>	<b>Associations</b>
<b>Net remuneration, compensation and expenses for research, research valorization, scientific evaluation, consultancy, provision of services or commercial promotion activities</b>	€200 per hour, and exceeding the limit of: <ul style="list-style-type: none"> <li>• €800 per half day; and</li> <li>• €2,000 for the whole agreement</li> </ul>	€80 per hour, and exceeding the limit of: <ul style="list-style-type: none"> <li>• €320 per half day; and</li> <li>• €800 for the whole agreement</li> </ul>	€200 per hour, and exceeding the limit of: <ul style="list-style-type: none"> <li>• €800 per half day; and</li> <li>• €2,000 for the whole agreement</li> </ul>
<b>Hospitality offered during events of an exclusively professional or scientific nature, or during events promoting products or services (amounts include all taxes)</b>	<ul style="list-style-type: none"> <li>• €150 per night;</li> <li>• €50 per meal;</li> <li>• €15 per snack; and</li> <li>• €2,000 for the whole agreement (including transportation costs to the event)</li> </ul> Registration fees can be paid in addition to these amounts and must be subject to request for approval from €1,000	Prohibited	N/A
<b>Financing or participation in the financing of vocational training or continuing professional development measures</b>	€1,000	N/A	N/A
<b>Donations and gifts exclusively intended to finance research, research valorization or scientific evaluation activities</b>	€5,000	€1,000	€8,000
<b>Gifts and donations for other health-related purposes</b>	N/A	N/A	€1,000
<b>Donations and gifts to associations</b>	N/A	N/A	€10,000

declared to be of public utility (including those intended exclusively to finance research activities, the promotion of research or scientific evaluation abovementioned).			
--	--	--	--

SUBMISSION REQUIREMENTS		
	Prior Approval system	Declaration system
<b>Timeline for the submission</b>	<p>In an ordinary case: <u>At the latest:</u> Two months prior to the planned date of implementation of the agreement. Absence of response within the abovementioned timeline is deemed an authorization</p> <p>In case of emergency: <u>At the latest:</u> Three weeks prior to the planned date of implementation of the agreement. Absence of response within the abovementioned timeline is deemed an authorization</p>	Eight business days prior to the day on which the benefit is granted
<b>Consequences</b>	<p><u>Approval:</u> Implementation of the agreement</p> <p><u>Refusal (with reasons for such refusal):</u></p> <ul style="list-style-type: none"> <li>• It is not possible to implement the agreement;</li> <li>• It is possible to contest the refusal before the administrative courts</li> </ul>	At the discretion of the healthcare company and professional, amendment, implementation or non-implementation of the agreement
<b>Content of the agreement and dossier</b>	<p>Minimum content of the agreement:</p> <ul style="list-style-type: none"> <li>• Identity of the parties;</li> <li>• Precise purpose of the agreement according to the thematic typology provided for in the ministerial order;</li> <li>• If applicable, information to identify indirect and final beneficiaries who are not signatories to the agreement;</li> <li>• With respect to the benefits: (i) the benefits and information specified depending on the thematic typology (ii) the individual amount of each benefit and, where appropriate, the cumulative amount of such benefits, all taxes included, rounded to the nearest euro;</li> </ul>	

	<ul style="list-style-type: none"> <li>• The signing date of the agreement and, where applicable, the period during which the benefits are granted and its expiry date; and</li> <li>• If applicable, depending on the purpose of the agreement, the following attachments: <ul style="list-style-type: none"> <li>■ Program of the event;</li> <li>■ Authorization for <i>cumul d'activités</i> for public servants;</li> <li>■ Summary, in French, of the research or evaluation protocol; and</li> <li>■ Draft observation notebook or data collection document provided for in the protocol for other research or scientific evaluation activities, excluding interventional research</li> </ul> </li> </ul>
<p><b>Modalities and recipient of the transmission</b></p>	<p>Transmission of the agreement with attachments, if any, by tele-procedure, to:</p> <ul style="list-style-type: none"> <li>• The professional board of the beneficiary if any; or</li> <li>• The Regional Health Agency where the agreement is executed</li> </ul>