



ESC

European Society
of Cardiology

Information Note for Application

Agreements ESC & Healthcare Industry Partners in respect of the French Anti-Gift Regime

The French anti-gift regime, which governs benefits provided by health care companies ("HCC") to health care professionals ("HCP"), was modified by the Ordinance 2017-49 of January 19, 2017. The adoption of implementing decrees was completed by a Decree dated June 15, 2020, as well as two ministerial orders dated August 7, 2020. The application of the new regime is effective as of October 1, 2020.

The definition of "HCC" under the anti-gift regime includes providers such as hospitals or biomedical laboratories, as well as manufacturers and marketers of health products such as pharmaceuticals or medical devices. The definition of HCPs includes a wide range of doctors or nurses, medical students, medical associations and civil servants participating to the development of public health policy.

The regime provides for exceptions to the general prohibition for HCCs to provide benefits to HCPs. The system resides in a three category process for exceptions. Category 1 comprises "negligible" benefits, which may be offered freely, subject to specific cost and amount constraints defined by a first Order of August 7, 2020. Category 2 includes "non-negligible" benefits which are subject to a declaration system and whose value is higher than category 1 benefits and lower than category 3 benefits. Category 3 comprises more significant benefits, which are subject to a prior authorisation. Declarations and applications for authorisation must be filed by the concerned HCC with the Professional Board of Professionals (CNOM) or the Regional Health Agency (ARS) that are competent to oversee the activities of the HCP. The timeline for the authorisation process is recorded as two months, though it may be reduced to three weeks in urgent cases. Delays may be lengthened in cases where the competent authority requires additional information.

In view of the proposed agreement between the ESC (a French based medical association) and your organisation, you are therefore required to submit the details of our proposed agreement and project details to the ARS for authorisation, respecting the delay of two months and three weeks in urgent cases.

Process for authorisation of proposed agreement:

- Submit proposed signed agreement (order form/contract) along with a project outline in French language to the competent authority (ARS) within 15 days of the signature and a copy of the submission acknowledgement to the ESC.
- Provide the ESC without delay either a copy of the authorisation or refusal (as the case may be) issued by the Competent Authority upon receipt or written confirmation of the absence of an express response from the Competent Authority as soon as the 2-month period for the Competent Authority to review the application is over.
- The Agreement will take effect and services provisioned only on proof of approval by the Competent Authority.

Our mission: to reduce the burden of cardiovascular disease.

Headquarters: The European Heart House - Les Templiers - 2035, Route des Colles - CS 80179 BIOT - 06903 Sophia Antipolis Cedex - France
Tel. +33 (0)4 92 94 76 00 - Fax. +33 (0)4 92 94 76 01 - www.escardio.org

European Heart Agency: 29, Square de Meeus - 4th floor - B-1000 Brussels - Belgium - Tel. +32 (0)2 274 10 70

SOCIETE EUROPEENNE DE CARDIOLOGIE Association loi 1901 - Déclaration du 08/04/1992 N° 1/10006 J.O. N° 18 du 29/04/1992 - SIREN 403 299 480
Association immatriculée au registre des opérateurs de voyages n° IM006110075