CONFINDUSTRIA DISPOSITIVI MEDICI – THE NEW CODE OF ETHICS INTRODUCES NEW TRANSPARENCY REQUIREMENTS IN THE MARKET

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Confindustria Dispositivi Medici

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In December 2019 "*Confindustria Dispositivi Medici*" introduced a new set of principles of conduct by issuing a new *Code of Ethics*, which will have a significant impact in terms of transparency duties to be complied with by the operators in this sector. The Code of Ethics is in fact a self-regulatory body of rules ("soft law"), providing for best practices in the industry of the medical devices sector and its rules are binding on members of the association.

In particular, Article 4 of the Code of Ethics, titled "*Transparency of transfers of value between members, healthcare professionals, healthcare organizations and other third parties*", requires - effective from 2021 - the association's members to document and publish (on a yearly basis) details relating to any and all "transfers of value" carried out in the course of their business.

The requirement in question needs to be satisfied by way of publishing on the members' respective websites - using a template attached to the Code of Ethics - particulars concerning any direct and indirect payment (or, more generally, transfers of value) made by the concerned member to (i) healthcare professionals; (ii) healthcare organizations; and (iii) third parties.

Publication needs to be made every year in respect of the transactions carried out in the immediately preceding year; therefore, starting from January 1, 2021, members will be required to publish their 2020 data within the first semester of 2021. Information must remain publicly available for a period of at least 3 years from the time of publication.
As a consequence of the above obligation, medical device companies will have to start collecting data *from the beginning of 2020*, in order to be ready to publish them at the beginning of next year.

Data may be published either on an individual basis or in aggregate form, to the extent beneficiaries of the payments/value transfers in question have not given their consent to the processing of their personal data.

In order for the data relating to healthcare professionals to be published individually, the relevant companies shall have obtained the authorization of their counterparts and, to avoid any delay in the process, it would be highly advisable that consent to data publication is obtained in advance, by introducing an express provision to that effect in each contract entered into by the association members with said third parties.

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