PROHIBITION CONCERNING INDUCEMENTS FOR MEDICAL DEVICES SUPPLIERS IMMINENT!

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Introduction

In 2013, the Dutch Minister of Health, Welfare and Sports ventilated her opinion that in case of excesses in the mutual relations between health care providers and suppliers of medical devices, the Inspectorate for Healthcare (hereinafter: "***IGZ***") should be authorized to intervene. The current Act on Medical devices (in Dutch: "*Wet op de medische hulpmiddelen*") does not provide such legal basis for supervision and enforcement with respect to inducements (in Dutch: "*gunstbetoon*"). That basis is being created by means of this legislative proposal.

In the medical devices sector, the same marketing methods are being employed as in the pharmaceutical sector. Therefore, the choice has been made to draw a parallel with the rules on inducements as laid down in the Medicines Act. This choice was made in consultation with the Inspectorate for Healthcare, with a view to practicability and enforceability.

Below, the legislative proposal, as far as pertaining to inducements, will be explained. Please note that the legislative proposal furthermore creates a legal basis for the use of the BIG[1] registration number of health care practitioners for transparency purposes. This topic will not be discussed here.

The proposal prohibiting inducements concerning medical devices

The term inducements is being defined as the supplier offering, granting or giving the prospect of money or money's worth services or goods to (1) a natural person who is involved in the application of a medical device or, to an (2) institution or (3) healthcare insurer with the apparent aim of promoting the sale of a medical device (article 10h(1) of the proposal).

The legislative proposal essentially consists of a prohibition concerning inducements with respect to medical devices. However, four exceptions have been formulated.

1. *Meetings aimed at the stimulation of knowledge and skills, patient care or the application of medical devices and/or events*

This exception concerns organised gatherings for natural persons who are involved with the application of medical devices[2], which are apparently solely aimed at the stimulation of (1) knowledge and skills in the field of the practice, (2) patient care or (3) the application of medical devices. Such meetings are allowed, as long as the hospitality, *i.e.* the reimbursement or not charging the participation, travel and accommodation fees, remains subordinate to the goal of the meeting and stays within reasonable boundaries. By way of

[1] The abbreviation BIG stands for: Professions in the Individual Healthcare (In Dutch: "*Beroepen in de Individuele Gezondheidszorg*")

[2] It should be stressed that the persons referred to here are definitely not only doctors and nurses, *i.e.* health care practitioners (*beroepsbeoefenaren*), also caregivers (*verzorgenden*) are meant here. Some caregivers are specialized in woundcare or the application of devices for specific diseases.

example, this may concern meetings in which specific skills are being learnt with a view to the correct application of a medical device.

Furthermore, the exception also pertains to so-called events, *i.e.* organised assemblies for natural persons who are involved in the application of a medical device, which events have the apparent purpose of stimulating the application of medical devices. Again, the hospitality should remain subordinate to the goal of the meeting and stay within reasonable boundaries. The explanation of the proposal states that this implies that such reimbursement may not amount to more than strictly needed to attend the manifestation. The explanation to the legislative proposal furthermore mentions that policy rules will be developed establishing what is to be considered as permissible.

2. *Service agreements between suppliers and medical professionals*

Service agreements between a natural person who is involved in the application of medical devices and a supplier, are also exempted from the prohibition, on the condition that there is a reasonable relation between the performance delivered and the remuneration received from the supplier. The services concerned may for instance consist of giving lectures and training aimed at the correct use of a medical device, or taking part in a trial with medical devices. Such service agreements serve a public health interest and therefore these are exempted from the prohibition[3].

For the sake of transparency and in order to be able to assess whether there is a reasonable relation between the performance and the remuneration, such service agreements should always be laid down in writing.

The Code of Conduct Medical devices[4] already contains maximum hourly rates for *e.g.* physicians, professors and nurses.

3. *Bagatelle-provision*

The prohibition is not applicable on a supplier providing money or money's worth services to a natural person involved in the decision to apply medical devices, as long as (1) the value is low and (2) an interest is served for the professional practice of the receiving party. This may concern matters with an education function. What amounts are being considered as having a low value and what can be regarded as "relevant for the professional practice of the receiving party", will be set out in Policy rules (*Beleidsregels*).

4. *Discounts relating to the purchase of medical devices*

Finally, the prohibition does not apply to discounts relating to the purchase of medical devices. It concerns all purchase advantages which are valuable in money.

Reciprocity

An important element of the newly proposed provision is the principle of reciprocity: what is prohibited for suppliers to offer is also prohibited for medical professionals and institutions

[3] Explanation to the legislative proposal, Lower House, proposal 34 330, No.1, p. 3.
[4] Explanation to article 13 Code of Conduct Medical Devices ("*Gedragscode Medische Hulpmiddelen"*).

to accept. Thus, the addressees of this proposal are not only the manufacturers, assemblers and suppliers of medical devices, but explicitly also the persons who or institutions which are involved with the decision concerning the application of medical devices. It concerns medical practitioners, such as doctors and nurses but also buyers with health care insurers and health care institutions.

Advertising

Furthermore, the topic of advertising medical devices has not been touched upon in this legislative proposal. The Minister is of the opinion that there are no signals of abuses with respect to advertisements for medical devices and therefore the Minister sees no trigger to adjust or sharpen the current provisions on advertising for medical products.

Enforcement

Noncompliance with the provisions concerning inducements concerning medical devices entitles the Minister[5] to impose an administrative penalty of €900.000 at maximum. It is remarkable (and somewhat frightening as well) that the amount mentioned in the Medicines Act is twice as low: €450.000.

It is anticipated that the amounts of the administrative penalty will be further specified in the Policy rules administrative penalties Minister VWS ("*Beleidsregels bestuurlijke boetes Minister VWS*[6]", hereinafter: "***Policy rules***"). The final amount of the administrative penalty will be adjusted according to several differentiation criteria, such as seriousness of the breach, culpability, size of the medical devices supplier-company and recidivism. It should be awaited how high the standard amount will be. By way of comparison, the standard amount for breach of provisions concerning inducements in the field of pharmaceuticals is €150.000.

As mentioned above, the Policy rules do differentiate according to the size of the company, *i.e.* in case of a company with more than one and less than ten employees, 1/5 of the established amount of the penalty will be imposed. Nevertheless, if the standard amount is very high, the penalty will still be high and noncompliance may thus have direct consequences for the continuity of the smaller-sized medical devices company.

As the medical devices sector is more diffuse when compared to the pharmaceutical sector – at least as to company size, it is anticipated that the proportionality of the imposition of penalties will become an important topic in the years to come.

Conclusion

In conclusion, it is striking that the Minister has decided to regulate inducements with respect to medical devices stricter in the Netherlands. In most of the EU countries, such have either been laid down in self-regulatory codes, which is also the case for the Netherlands currently. As far as we are aware, there are not many European countries (if any) in which rules pertaining to inducements in the field of medical devices have been laid down in specific statutory law and allowing for the imposition of such high financial penalties.

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[5] This capacity has been mandated to the Inspector-General of the Inspectorate for Healthcare.
[6] *Beleidsregels bestuurlijke boete Minister VWS*.

It is also remarkable that it is anticipated that this legislative proposal will not increase the regulatory burden for civilians and businesses[7]. Of course, it remains questionable whether this prohibition does not create a forbidden "obstacle to the placing of the market or the putting into service within their territory of devices bearing the CE marking", pursuant to the Medical Devices Directive[8].

Compared to the pharmaceutical field, this prohibition may be conceived as somewhat wider, as it does not only concern prescribing or dispensing health care practitioners, such as doctors, pharmacists and (some) nurses – only if they prescribe medicinal products, but also (specialised) caregivers, who are in the position to (co-)decide which medical device will be applied. Besides, the prohibition on inducements also addresses health care institutions and health care insurers.

For manufacturers and suppliers who are active in several Member States of the European Union, among which the Netherlands, this proposal may imply that local ethical codes need to be amended in order to increase awareness and to ensure strict compliance with the Dutch legislation.

Nevertheless, it should be mentioned that the proposal has not passed yet. However, taking into account that the Dutch Minister has talked about this topic for a few years, that the Dutch relevant supervising authority (***IGZ***) appears to have become more active as to imposing administrative penalties lately and, finally that the administrative penalties are likely to be very high, it seems advisable not to wait, but to anticipate on what actually seems to be coming.

[7] Explanation to the legislative proposal, Lower House, proposal 34 330, No.1, p. 7 under 5. "*Regeldruk gevolgen*".
[8] Article 4(1), of the Medical Devices Directive, Council Directive 93/42/EEC, as amended.