FAQs about inducements (Medical Devices Act)

What is meant by inducements?
Inducements are about offering or accepting money or (normally paid for) services or goods, with the aim of promoting the sale of a medical device. Examples include giving gifts, paying a professional to give a presentation on behalf of the industry, or reimbursing trips, participation costs, or dinners at refresher courses and conferences.

From what date will the ban on inducements be in force?
The new act has been in effect since 1 January 2018. From that moment on, relevant parties are expected to act in line with the new regulations.

Which parties are covered by the ban on inducements?
Inducements may not be given by any party (the providers) that has a commercial interest in the use of a medical device. Those parties can be at various places in the chain, which starts with marketing a medical device and ends when the device is actually used. This therefore concerns not only manufacturers and suppliers but also retailers or distributors.

Inducement is about influencing people whose professional role affects the choice to use a certain medical device (the recipient). That may, for example, be a doctor, nurse or a purchaser of care institution healthcare insurer.

Our company is an international company that does not have a branch in the Netherlands. Does this ban on inducements also apply to us?
It does not matter where the (statutory) registered office of a company is located. It is, however, important whether the consequences of any improper influencing (on the end use application of a medical device) are manifest in the Netherlands.

It is therefore not important whether the participation costs funded by a medical device company are for meetings or events on Dutch territory, or whether they apply to Dutch doctors or healthcare purchasers attending meetings or events abroad.

Which regulations apply to me as a care provider or purchaser?
The prohibition is aimed at stopping inducements being offered and accepted: a recipient must neither ask for nor accept anything that a provider is not allowed to offer or give. This means that both parties must consider whether their actions are in line with the rules. The Inspectorate can also take suitable measures against the recipients of inducements.

Why has this legislation been implemented?
Inducements must not create a situation in which the choice for a certain medical device is based on any interest other than the patient's medical needs. That is why rules have been drawn up about inducements. There has been self-regulation regarding inducements since 2012 (Code of Conduct for Medical Devices). A large number of umbrella organisations for manufacturers and importers of medical devices, and the umbrella organisations for doctors and hospitals are now self-regulating in this way.

The new legislation also provides a basis on which the Inspectorate can act.

Are there any differences from the regulations about inducements that were already in force for the pharmaceutical sector?
The structure and content of both regulations are the same. There is a ban on inducements, to which four exceptions have been listed. These exceptions are explained in detail in the sector's own policy rules which are largely in line with each other. Special characteristics of the medical devices sector have been taken into account in a number of areas.
The regulations about inducements with respect to medical devices apply to a wider group of recipients than in the pharmaceutical sector. In the pharmaceutical sector, this ban covers professionals who have the authority to prescribe medicines. In the case of medical devices it involves anyone who influences the device's use. These may, for example, be doctors, as well as the management, procurement or healthcare insurance employees.

Is sponsoring allowed?
Sponsoring is not considered to be inducement and is allowed as long as it does not have the apparent purpose to promote sales. This has to be assessed case by case. It is assumed that the purpose is not directly to promote sales if the sponsorship meets the five conditions defined in Section 3.1 of the policy rules.

As a supplier/customer, I am planning to organise a meeting for healthcare providers and/or purchasers. What should I be aware of?
Transfer of knowledge must be the key element in educational meetings and procedure training events. Product-related meetings after the purchase of a medical device are also allowed as long as they are required for the proper use and maintenance of the medical devices.
Meetings that focus on the potential purchases of medical devices are classed as 'events' and not 'meetings'.

Among other things, the balance between scientific and non-scientific parts of the programme, the chosen location and transparency at the event about the relationships between those present (including the speakers) and the industry are also relevant when assessing the meetings. Additionally, the remunerations for participation costs may not exceed what is strictly necessary. These exceptions are explained in detail in the policy rules.

Companies which are affiliated with the Foundation for the Code of Conduct for Medical Devices (Stichting Gedragscode Medische Hulpmiddelen-GMH) can arrange to have their activities assessed in advance via the foundation's website.

Given the regulations for inducements, is it important to know who is organising a meeting or event?
No. The potential influence of the relevant parties is central; it is therefore not important whether a third party is the organiser.

As a recipient (e.g. a doctor), am I allowed to perform any services for a manufacturer or supplier?
Yes. Consulting arrangements between providers and recipients are part of the usual engagements of medical professionals with commercial companies. A supplier can for example ask doctors or other healthcare professionals to speak at a meeting or become a member of an advisory board. The law explicitly states that these relationships are still allowed.

However, the parties have to ensure that the consulting arrangement complies with the regulations. This means (i) that the arrangement must have been laid down in a written service agreement and (ii) that the remuneration must be proportionate to the work done. The policy rules also state in detail (in subsection 3.2.2) which elements must be included in the service agreement. The standard hourly rates from the Code of Conduct for Medical Devices are used to determine whether the remuneration is appropriate.

What are the rules on giving or accepting gifts?
Giving and accepting gifts is exempted from the prohibition as long as the costs of the gift do not exceed €50 (market value) and the gift is relevant to professional practice. Gifts up to a maximum value of €150 can be given on an annual basis to an individual professional or purchaser.

What supervision does the Inspectorate exercise?
The Medical Devices Act gives the Inspectorate a legal basis to act against inducement. The general public and businesses can notify the Inspectorate if they suspect a violation of the inducement regulations. The Inspectorate investigates these complaints and can take appropriate measures if applicable. The Inspectorate will also carry out unannounced inspections at conferences, educational meetings and other events where there is a risk of improper influencing.

In the first six months of 2018, the Inspectorate's focus is on implementing the new regulations, on working out its supervisory task in detail and on the communication to those affected by the new regulations.

How are the tasks divided between Stichting GMH and the Inspectorate with respect to inducements?
Upon request the Stichting GMH can give advice on envisaged actions by companies and can act upon formal complaints received. Their assessment is based on the self-regulation rules (the Code). The Inspectorate carries out a supervisory task based on complaints and notifications. It will also perform (unannounced) inspections. The selection for these visits will be made based on an initial risk assessment. The Inspectorate will assess the compliance with the legal requirements. The law is applicable to everyone covered by the scope of application of the Act.The Code only applies to the parties that are affiliated to Stichting GMH. Stichting GMH and the Inspectorate can refer complaints received to one another in accordance with the working arrangements that have been drawn up. The Inspectorate will retain the authority to act at all times, irrespective of any previous statements or recommendations from Stichting GMH.

What are the consequences of violating the ban on inducements?
Anyone violating the ban on inducements can expect to receive an immediate fine. Such fines can be imposed on the supplier of the medical device as well as on the medical professional or institution that accepts an unacceptable form of inducement. The amount of the fine and the rules which apply to issuing it are laid down in the Policy Rules for Administrative Penalties of the Ministry of Health, Welfare and Sport (VWS). The amount of the fine will probably be approximately the same as the amounts which apply to violations in the pharmaceutical sector where the standard amount for a fine is € 150,000 for a violation of the ban on inducements. (Parliamentary Papers 2015/16, 34 330, no. 5).

I am a manufacturer, supplier, healthcare provider or purchaser, and I have a question about the ban on inducements for medical devices. Who can I contact?
If you have any questions regarding the new legislation and regulations, we advise you to contact your umbrella organisation.