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Healthcare & Life Sciences Update: The Netherlands

The continuously changing Dutch healthcare and life science environment requires companies that are active in the Netherlands to adapt quickly. This Healthcare & Life Sciences Update sets out some of the latest regulatory developments which may impact your business, such as a new legislative framework on inducement in the medical devices sector, amendment of the rules on clinical trials and the launch of a medicines shortage notification centre.

Legislative framework for inducement in the medical devices sector

On 16 May 2017 the Dutch Senate adopted a legislative bill that provides a legislative framework for inducement in the medical devices sector to be included in the Dutch Medical Devices Act (*Wet op de medische hulpmiddelen*). Similar to the legislative framework included in the Dutch Medicines Act (*Geneesmiddelenwet*, Gnw), the proposed legislative framework for inducement is an addition to the already existing self-regulation of the medical devices sector in the form of the Code of Conduct for Medical Devices (*Gedragscode Medische Hulpmiddelen*).

The legislative framework consists of a prohibition of inducement and a limited number of exceptions to this prohibition, being: (i) if the main goal of the event is to increase the knowledge of the participants and hospitality is a limited and subordinate element; (ii) if the service provided by the healthcare professional is reasonable to the remuneration paid by a medical devices company; (iii) if the funding or the services provided by a medical devices company to a healthcare professional are limited in value and is relevant to the professional conduct; and (iv) if the inducement is a discount relating to the purchase of medical devices.

The prohibition has a reciprocal basis: everything that medical devices companies may not offer to healthcare professionals may also not be accepted by the healthcare professionals. At the moment, the effective date of the bill is still unknown.

Amendment of the Medical Research Act

On 1 March 2017 the amended Dutch Medical Research (Human Subjects) Act (*Wet medisch wetenschappelijk onderzoek met mensen,* WMO) entered into force. The amendment expands the possibilities to conduct clinical trials with minor and incapacitated subjects. The changes introduced by the amendment include: (i) maximum amount of impact and risks that is allowed, which is similar to the impact and risks associated with the standard treatment of the disease; (ii) the age limit to grant autonomous approval for participating in a clinical trial is reduced from 18 to 16; (iii) a paediatrician needs to be present at the assessment of the clinical trial by the Central Committee on Research Involving Human Subjects (*Centrale Commissie Mensgebonden Onderzoek*, 'CCMO'). If a medical research ethics committee (*medisch-ethische toetsingscommissie, METC*) assesses the application and if the clinical trial has minor subjects a paediatrician is mandatory; and (iv) to provide sufficient protection METC's and CCMO set up a detailed framework for the assessment of clinical trials with minor and incapacitated subjects.

In addition to above mentioned amendment, the Dutch Senate adopted a bill to the amendment of the WMO and

the the Dutch Medicines Act (*Geneesmiddelenwet*, Gnw) to reflect the direct applicability of the EU Clinical Trial Regulation (ECTR, EU Regulation no. 536/2014) to clinical trials in the Netherlands. The bill was adopted on 21 March 2017, but will come into effect when the ECTR becomes applicable which is expected no later than October 2018. The aim of the bill is to simplify and accelerate clinical trial procedures. As part of this simplification the current dual assessment system of an assessment committee and a competent authority will cease to exist. The bill introduces a new system in which the assessment committee (CCMO or a recognized METC) is responsible for the assessment and approval of a clinical trial.

Introduction of a purchasing platform for expensive medicines

At the beginning of 2017, the Dutch Council of Ministers (*Ministerraad*) adopted a new medicines policy (*nieuwe geneesmiddelenvisie*) proposed by the Dutch Minister of Healthcare, Welfare and Sport (*Minister van Volksgezondheid, Welzijn en Sport*). The aim of the new policy is to ensure that patients have access to new, innovative medicines at acceptable prices.

To achieve this aim, the new medicines policy provides for the creation of a purchasing platform, the Purchasing Strength Expensive Medicines Platform (*Platform Inkoopkracht Dure Geneesmiddelen,* 'PIDG'). By creating the PIDG the Minister wants to establish a joint purchasing platform through which hospitals, health insurers and other healthcare providers can jointly purchase new medicines. Once the platform becomes operational, the PIDG may significantly impact the negotiation position of pharmaceutical companies that sell these types of innovative medicines.

Basic principles of hospitality in sponsored events

On 20 February 2017 the Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*, 'IGZ') published basic principles of hospitality in sponsored events to eliminate the uncertainty that there seems to be with regard to the inducement rules in the Dutch Medicines Act (*Geneesmiddelenwet*), the Policy Rules on Inducement (*Beleidsregels gunstbetoon*) and the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*).

The basic principles set out when hospitality in events sponsored by pharmaceutical companies is acceptable. The basic principles contain four cumulative criteria, being: that (i) hospitality must be subordinated to the academic program of the event. When assessing the proportionality of the hospitality IGZ takes into account the hospitality provided during the academic part of the programme as well as the other parts of the programme. IGZ accepts networking to the extent that it is necessary; (ii) hospitality is not extended to non-professionals; (iii) the hospitality may only take place at a suitable location. The location should not be the main reason for participants to join the event. The location should be suitable for the academic programme of the event; and (iv) the costs associated with the hospitality must be reasonable.

Pharmaceutical companies are not allowed to sponsor non academic parts of the programme that have a leisure element. The participants (or the organisation) should fund these parts themselves.

Launch of a medicines shortage notification centre

On 2 January 2017, the Minister launched a medicines shortages and defects notification centre; a single point of contact for shortage notifications. Pharmaceutical companies can now notify the centre through its website that: (i) a medicine is (re) introduced to the market; (ii) the trading of a medicine on the market will be paused or ceased (this includes a possible shortage); (iii) smaller quantities of a medicine will be available on the market which may result in possible shortage; or (iv) when there is a quality defect. The notification centre follows the recent increase of the maximum fine for culpable medicines shortage for EUR 45,000 to EUR 150,000.

Revised policy rules on administrative fines

On 25 March 2017 the revised Policy Rules on administrative fines of the Ministry of Health Welfare and Sport (*Beleidsregels bestuurlijke boete Minister VWS*) entered into force. The revised Policy Rules now include the higher maximum fine for medicines shortage.

With regard to medical devices the revised Policy Rules include a decrease of the severity of the offence for the specific circumstance where a manufacturer places a CE mark on a product that does not qualify as a medical device. As a result, an amount of the administrative fine might be reduced.

Furthermore, the assessment of the 'extent' of the offence was revised for Class I medical devices that qualify as a 'volume product'. The extent of the offence will qualify as 'small' when there are no more than 100 products available or delivered. The small size is seen as a mitigating factor which may result in a lower fine. If there are more than 500 products available the size qualifies as large. This is seen as an aggravating factor and may result in an increase of the fine.

Regulations on In-Vitro Diagnostics and Medical Devices will enter into force

On 5 May 2017 the new European Regulations on Medical Devices (Regulation (EU) 2017/745) and In-Vitro Diagnostics (Regulation (EU) 2017/746) were published. Both regulations will enter into force on 25 May 2017, but do not immediately apply.

The regulations provide for transitional periods. The general transition period for medical devices is three years (26 May 2020); the regulation i.a. also provides for specific transition periods for certificates, medical devices that are already on market or will be marketed during the transition period and for clinical trials.

In case of the in-vitro diagnostics a general transition period of five years (26 May 2022) applies and similar to the medical devices regulation, the in-vitro diagnostics regulation contains specific transition periods i.a. for certificates and in-vitro diagnostics that are already on the market or will be marketed during the transition period.

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