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Healthcare & Life Sciences Update: The Netherlands

Companies active in the Dutch healthcare and life sciences sector must adapt to a continuously changing environment due to ever changing regulations. This Healthcare & Life Sciences Update sets out some of the latest regulatory developments which may impact your business, such as the new framework on instructions regarding the use of administration devices, the new Healthcare Quality, Complaints and Disputes Act and the European approach towards antibiotic resistance.

Code of Conduct no longer applies to all specialist nurses

For some years now specialist nurses such as respiratory, diabetes and oncology nurses have qualified as 'healthcare professionals' within the meaning of the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*) established by the self-regulating body Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*; 'CGR'). As of 1 March 2016, the Code of Conduct no longer applies to all specialist nurses. It now only applies to specialist nurses that have their individual prescription authority registered with the healthcare professional registry (*BIG-register*). Specialist nurses with such registration will qualify as a 'healthcare professionals' within the meaning of the Code of Conduct.

Due to this amendment promotional activities with regard to medicinal products can no longer relate to the entire group of, for example, oncology nurses, but they need to be limited to oncology nurses that have their individual prescription authority registered with the BIG-register. This limitation carries further compliance risks.

Framework on user instructions for administration devices

Some medicinal products need to be administered by means of an administration device. When information or instructions on the use of such devices are given and, at the same time, the device is promoted, there is a risk that the medicinal products are also (in)directly promoted. In order to provide clarity on which instructions and information sharing is allowed under the Code of Conduct, the CGR, in consultation with the Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*; 'IGZ'), has established a Framework which sets out the rules and limitations with regard to the instructions for use of administration devices.

The Framework introduces guidelines that enable pharmaceutical companies and healthcare professionals to assess whether the instructions merely contain information or whether the instructions also contain 'promotion' (step 1). In case the instructions would qualify as promotion, there is guidance to assess whether a prescription medicine is (in)directly promoted (step 2). The Code Commission and Commission of Appeal of the CGR have determined in previous rulings that promotion of an administration device may qualify as indirect promotion of a prescription medicine when the device is intended to be used in combination with one or more prescription medicines of the same supplier.

When a device can be used in combination with multiple prescription medicines of various suppliers, promotion of the device will less likely qualify as '(in)direct promotion of a prescription medicine'.

Healthcare Inspectorate presents its Work Plan 2016

In its Work Plan 2016 the Dutch Healthcare Inspectorate has described the activities which it plans to undertake during this year and the risk themes it will focus on. One of the focus areas is medical technology and more specifically medical devices. The Work Plan 2016 states that supervision with regard to medical devices will be strengthened in several ways. For example, IGZ is involved in the set-up of a register in which the side effects of medical devices will be recorded. To ensure the safety of Class I medical devices, IGZ will enhance its risk-based supervision with respect to these devices by closely monitoring the NOTIS-notification system and by imposing enforcement measures if the safety or application of such device is at risk. As a result, it is expected that the number of enforcement measures in 2016 will increase compared to 2015. IGZ also intends to publish more of its decisions to impose administrative fines.

In addition, IGZ will adopt and implement a new enforcement framework in 2016. This new framework is, amongst others, based on a project to improve the collaboration between the Inspectorate and the Dutch public prosecutor. The framework will strengthen the coherence between the use of administrative, disciplinary and criminal enforcement measures. Besides the focus on medical devices and the collaboration with the public prosecutor, the work plan also focuses on the broadening of the supervising duties of IGZ due to regulatory changes. The current medical devices regulations are amended making IGZ responsible for the supervision of the transparency of financial relationships in the medical devices sector. IGZ is also preparing for its new duties under the upcoming EU regulation regarding medical devices and in-vitro diagnostic which is expected to enter into force in 2019.

New Healthcare Quality, Complaints and Disputes Act

As of 1 January 2016 the new Healthcare Quality, Complaints and Disputes Act (*Wet kwaliteit, klachten en geschillen zorg, 'Wkkgz'*) has entered into force. This act applies to all healthcare providers including the (management) boards of institutions and individual practitioners. It is aimed at ensuring that everybody receives proper care. To make sure that proper care is provided, the act introduces a number of obligations healthcare providers need to comply with. Amongst others; (i) the appointment of an independent complaints officer who must be easily accessible and free of charge, (ii) the recording and notification of mistakes and incidents, (iii) the introduction of an independent dispute settlement authority and (iv) the dismissal of a healthcare provider due to serious poor performance must be reported to the IGZ. The new act also applies to alternative care and cosmetic care.

To offer healthcare providers the opportunity to implement the required measures, the act includes a number of transitional periods until 1 July 2016 (for incident reporting) and 1 January 2017 (for written agreements between healthcare providers and professionals and the compliance procedure). IGZ will supervise compliance with the rules and obligations set out in the act. Part of this supervision is to assess whether, for example, the correct treatments are provided. This seems to imply that, indirectly, IGZ will also look at the use of medical devices and medicinal products. There is a risk that a negative assessment of a certain treatment or healthcare professional may also negatively affect (the reputation of) the devices and products used.

Focus on gender specific healthcare

During a March 2016 Women Inc. convention regarding gender (female) specific healthcare the Dutch Minister of Healthcare, Welfare and Sport announced that EUR 12 million will be made available for research focusing on gender specific healthcare. The money will be used to implement the knowledge agenda Gender and Health (*kennisagenda Gender en Gezondheid*). The agenda sets out which healthcare differences between men and women are already known and which information regarding these differences is still missing. New research will focus on obtaining such missing information and improving

healthcare for women. The implications for the healthcare sector are potentially far-reaching, as it may point out that treatments and medicines currently provided to men and women may not be the most suitable option for women. This could mean that new treatments and products are needed, new regulations are required and potentially also affect the position of medicinal products and medical devices currently used.

European approach towards antibiotic resistance

During a ministerial conference held on 10 February 2016 the Ministers of Health and healthcare experts from 28 EU Member States committed to fight antibiotic resistance together. This spring formal and informal European Councils will be organised to talk in more detail about the steps to be taken and the required decision-making. Currently, no informal or formal decision-making processes have been initiated, but it is expected that such decision-making processes will be initiated later this year.
If European legislation regarding antibiotic resistance is put into place, then this may have a significant effect on the healthcare, and more specifically the pharmaceutical sector, as new regulations will become applicable within a sector that is already highly regulated.

Contacts

Simone Peek
+31 20 711 9182
simone.peek@cliffordchance.com

Sabien Schipper
+31 20 711 9498
sabien.schipper@cliffordchance.com