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Healthcare & Life Sciences Update: The Netherlands

Companies active in the Dutch healthcare & life sciences sector are facing increasing compliance challenges: from ongoing changes to advertising rules and broadened enforcement of healthcare laws to increased attention for product classification and upcoming transparency requirements for medical devices. Pharmaceutical and medical devices companies in the Netherlands need to make sure that compliance with laws and regulations is at the forefront of their business planning. This Healthcare & Life Sciences Update highlights certain recent healthcare regulatory developments.

Preliminary CE check for class I medical devices

Since 1 April 2014 the plausibility of the qualification and classification of newly introduced class I medical devices is checked as part of the review of public advertisements for these products. From 1 January 2015 the check will apply to all medical devices advertising to the general public (both new and existing).

The CE-check is an initiative of the self-regulatory Inspection Board for the Public Promotion of Medicines (*Keuringsraad Openlijke Aanprijzing Geneesmiddelen;* 'KOAG') and Inspection Board for the Promotion of Health Products (*Keuringsraad Aanprijzing Gezondheidsproducten;* 'KAG'). On the basis of a checklist that the manufacturer or wholesaler needs to complete, an independent expert appointed by the KOAG/KAG assesses the correct use of the CE-marking.

Amended rules governing pharmaceutical advertising

The self-regulating Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*; 'CGR') has published a draft of an integrated Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*) for consultation. The draft code integrates the different regulations for pharmaceutical companies and healthcare professionals that have developed over the years into one single code. It is expected that the new Code of Conduct will enter into force on 1 January 2015.

In addition, the CGR has set hourly rates that are considered reasonable for services that healthcare professionals provide to pharmaceutical companies, for seven different disciplines. Furthermore, the CGR has developed an instrument to assess whether educational meetings (*nascholingsbijeenkomsten*) that are (partly) funded by suppliers of medicinal products, medical devices and other medical products meet the criteria for inducement. This instrument will become an obligatory component within the Common accreditation internet application (*Gemeenschappelijke accreditatie internet applicatie*). It is expected to be implemented in the course of 2014.

On 1 May 2014 the amended Policy Rules Inducement Medicines Act (*Beleidsregels gunstbetoon Geneesmiddelenwet*) will enter into force (Stcrt. 2014, 9496). The Policy Rules have been amended in order to clarify the present framework. The assessment criteria on hospitality (*gastvrijheid*) have been aligned with the terminology of the Dutch Medicines Act (*Geneesmiddelenwet*). This means that hospitality arrangements should be secondary to the main goal of the event and kept within reasonable limits.

Interactions with medical devices industry under scrutiny

In a recent policy letter the Dutch Minister of Health, Welfare and Sport has emphasized the importance of both industry and other parties involved in the healthcare sector subscribing to the Code of Conduct for Medical Devices (*Gedragscode Medische Hulpmiddelen*). To that end, a register has been set up (*Register Naleving Gedragscode Medische Hulpmiddelen*). In this register institutions, suppliers, wholesalers and healthcare professionals that endorse the Code of Conduct can be included.

In addition, the Minister has indicated that in advance of the materialization of the new European Medical Devices Regulation a provision is to be included in the Dutch Medical Devices Act (*Wet op de medische hulpmiddelen*) that authorizes the Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*) to intervene when undue influence or inducements in the medical devices sector occur. Such provision should take effect from 1 January 2016.

Furthermore, the Minister has agreed with the Code of Conduct for Medical Devices Foundation (*Stichting Gedragscode Medische Hulpmiddelen*) that it starts working on the disclosure of relationships between healthcare professionals and the medical devices industry in 2015. Preferably, this is done in the Transparency Register (*Transparantieregister Zorg*) that has been set up for the pharmaceutical industry.

Implementation of EU rules against counterfeit medicines

On 10 December 2013, the Act implementing Directive 2011/62/EU regarding the prevention of the entry into the legal supply chain of falsified medicinal products by means of an amendment to the Medicines Act (Stb. 2013, 407) entered into force. The new rules on manufacturers and wholesalers of active substances, safety features for medicinal products and sale at a distance aim to protect the supply chain.

Also the Regulation implementing Directive 2011/62/EU regarding the prevention of the entry into the legal supply chain of falsified medicinal products by means of an amendment to the Medicines Act Regulation (*Regeling Geneesmiddelenwet*) (Stcrt. 2013, 33012) entered into force. Besides a further elaboration of the statutory change, the amended regulation includes a new provision on the recognition of prescriptions issued in another Member State. Thus it also implements Directive EU 2011/24/EU on the application of patients' rights in cross-border healthcare.

Interim report on financial cost of healthcare fraud

Recently, the Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*; 'NZa'), the supervisory body for the healthcare markets, has published its interim report on fraud committed under the Healthcare Insurance Act (*Zorgverzekeringswet*) and the Exceptional Medical Expenses Act (*Algemene Wet Bijzondere Ziektekosten*).

The initial conclusion of the NZa is that insurers pay about €80 million per year in excess of what they should for general care, dental care, pharmacy and mental health (about 1% of the total amount of declarations). The NZa recommends that fraud detection measures available to insurers should be widened, for example, by allowing random samples on declarations without a suspicion of fraud. The final report is expected to be issued in July 2014.

Increased enforcement in respect of quality defects

The Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*; 'IGZ'), the regulator that oversees public health through enforcement of the quality of health services, prevention measures and medical products, has revised its Guideline for Notifications (*Leidraad Meldingen IGZ 2013*) (Stcrt. 2013, 29693). The Guideline for Notifications provides rules and procedures for filing notifications and for investigating such notifications. The new guideline entered into force on 23 October 2013.

In addition to healthcare institutions, manufacturers of medicinal products and medical devices fall under the supervision of the IGZ. Therefore, the guideline now contains an explicit definition of the term "product". Notifications can thus relate to blood products, medicinal products, medical devices, body material and opiates. Also quality issues in relation to medical research including investigational medicinal products are now explicitly included within the scope of the guideline.

Joint penalty rules for entire healthcare sector

The Policy Rules on administrative fines of the Ministry of Health Welfare and Sport (*Beleidsregels bestuurlijke boete Minister VWS*) (Stcrt. 2013, 29336) entered into force on 24 October 2013 replacing, inter alia, the Policy Rules on

administrative fines under the Medicines Act (*Beleidsregels bestuurlijke boete Geneesmiddelenwet*) and the Policy Rules on administrative fines under the Medical Devices Act (*Beleidsregels bestuurlijke boete Wet op de medische hulpmiddelen*). The new policy rules include standard amounts for each established breach, indications on whether a prior warning is given or an immediate fine is imposed and when the IGZ may refer to the Public Prosecutor.

Since 1 January 2014, the IGZ actively enforces the rules applicable to CE-marking of software products that fall within the scope of the Medical Devices Act. The enforcement is based on incident reports from manufacturers of medical devices and healthcare providers and on risk assessment. In the event of a breach of the Medical Devices Act, the Minister may impose an administrative fine.

New tasks and name for Healthcare Insurance Board

Since 1 April 2014, the Healthcare Insurance Board (*College voor zorgverzekeringen*), the administrative authority that advises the Minister of Health, Welfare and Sport on health insurance matters, operates under a new name: the National Healthcare Institute (*Zorginstituut Nederland*) (Stb. 2013, 578).

The name change is the result of an expansion of operations to two new tasks in the field of healthcare quality: promotion of improvements in the quality of healthcare and promotion of innovation in healthcare professions and training. In addition to this, the institute will continue to advise on the composition of the basic insured package of healthcare and to implement civilian insurance arrangements.

Contacts

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

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

Eva Pera
+31 20 711 9292
eva.pera@cliffordchance.com