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Healthcare & Life Sciences Update: The Netherlands

Companies active in the Dutch healthcare and life sciences sector are facing continuous regulatory changes. Recent changes include: an updated policy regarding the use of biosimilars, new policy rules on healthcare related administrative fines and a clarification on mandatory notifications when making use of Google Ads. This Healthcare & Life Sciences Update highlights some of the latest developments in regulations and enforcement which may impact your business.

Medical Devices Decree now prohibits permanent dermal fillers

As of 1 January 2015, the Medical Devices Decree (*Besluit medische hulpmiddelen*) has been amended. A new Article 16(a) has been added, pursuant to which the application of permanent dermal fillers, which are fillers that remain in the body for all of one's life, is prohibited *unless* the dermal fillers are applied for reconstructive purposes. This means that permanent dermal fillers can only be used for treatments where clear medical grounds exist.

Information requests by Dutch Healthcare Inspectorate

On 16 February 2015, the Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*; 'IGZ') has requested information from producers, authorised representatives and retailers of in vitro diagnostic medical devices to fill out a web based survey. Furthermore, businesses established in the Netherlands that market class I medical devices are requested to fill out the web based survey on their business and products.

Businesses are obliged to cooperate and provide the requested information. The request qualifies as a regulatory information request under the Dutch General Administrative Law Act (*Algemene Wet Bestuursrecht, Awb*). The Healthcare Inspectorate has indicated that the requested information will be used to monitor businesses and may lead to further investigations. For more information and guidance on dealing with regulatory information requests, please refer to our checklist on regulatory information requests.

Updated CBG policy on interchangeability of biosimilars

The Dutch Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, 'CBG'), the authority responsible for registration of medicinal products, has updated its policy on similar biological or 'biosimilar' medicines.

The CBG considers its previous policy, ie to provide patients with biological medicines as much as possible (as opposed to biosimilars) if they show a good clinical response, to be outdated. Given the most recent literature and experiences with biosimilars, there is sufficient ground to make careful use of biosimilars, subject to certain essential conditions. According to the CBG:

- new patients can be treated with biosimilars right away;
- the unverified exchange between biological medicines (regardless of whether it concerns innovator products or biosimilar medicines) should be avoided;
- if a patient is treated with a biological medicine, the patient's file should record in detail product and batch information to be able to trace the product if issues arise.

Launch of National Implants Register

On 30 January 2015 the National Implants Register (*landelijk implantatenregister*) was launched. The goal of

this register is to enhance the traceability of medical implants. The current register links together the existing registrations of cardiologists, orthopedic surgeons and the recently started registrations of plastic surgeons. In the course of 2015 the registrations of gynecologists will be added to the register. The register will be gradually expanded over time to eventually establish a complete, nationwide register. The Dutch Minister of Health, Welfare and Sport (*Minister van Volksgezondheid, Welzijn en Sport*) is drafting a law obliging healthcare professionals to register implants.

Amended Code of Conduct concerning advertising

As of 1 January 2015 the amended 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') entered into force. The relevant amendments have been discussed in our November 2014 newsletter.

As of 1 January 2015 a new review framework for non-interventional study has entered into force (*Toetsingskader niet-WMO-plichtig onderzoek*). Whereas previously the CGR performed a preventative assessment, the review of non-interventional studies will henceforth be carried out by an independent expert committee. As of 1 July 2015 the non-interventional studies will no longer fall within the scope of the Code of Conduct, but will be covered by the review framework.

Introduction of levies for certain regulatory acts

As per 1 January 2015, an act amending the Dutch Medicines Act (*Geneesmiddelenwet*), the Blood Supply Act (*Wet inzake bloedvoorziening*), the Medical Devices Act (*Wet op de medische hulpmiddelen*) and the Body Material (Safety and Quality) Act (*Wet veiligheid en kwaliteit lichaamsmateriaal*) has entered into force. The amendments procure that the tariffs charged for certain services provided by the competent authorities can be increased to an extent that the tariff covers the costs for such regulatory acts. Such services include inter alia assessment of compliance with legal requirements, providing statements, dealing with requests for permits or exemptions, processing notifications or providing advice.

New policy rules on healthcare related administrative fines

The Dutch Minister of Health, Welfare and Sport has issued new policy rules on administrative fines which apply in the case of breaches of various legislation in the area of public healthcare, such as the Opium Act (*Opiumwet*), the Medical Devices Act (*Wet op de medische hulpmiddelen*), the Medicines Act (*Geneesmiddelenwet*) and the Care Institutions (Quality) Act (*Kwaliteitswet zorginstellingen*). The new policy rules have come into effect on 1 January 2015.

The new policy rules contain changes in certain elements of the previously existing policy rules. The policy rules have been integrally re-issued for the purpose of readability and accessibility. The most important changes are:

- Not only a second finding of a punishable fact is considered to be a repeated offence, but also a second breach of the same statutory provision is considered to be a repeated offence.
- As a result of changes to the Medicines Act, additional breaches can be sanctioned with administrative fines.
- Certain acts in violation of the Medicines Act are now categorised to be more severe, certain standard amounts of administrative fines have been amended and certain offences can as a starting point now immediately be sanctioned by administrative fines.
- There is further differentiation of standard amounts for administrative fines based on the size of the business committing the offence.
- Violation of the prohibition relating to permanent dermal fillers (discussed above) is sanctioned with an administrative penalty of which the standard amount is EUR 450,000.

New cooperation protocol of market authorities

The Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*, 'NZa'), the supervisory body for the healthcare markets in the Netherlands, and the Dutch Authority for Consumer and Market (*Autoriteit Consument en Markt*, 'ACM'), the supervisory body for competition, telecommunications and consumer law, have entered into a new Cooperation Protocol (*Samenwerkingsprotocol*). This cooperation protocol sets out a number of general principles promoting efficient and effective cooperation between the two authorities. The protocol also contains further details

regarding the healthcare specific merger test being performed by NZa since 1 January 2014 in case of concentrations within the healthcare sector.

Google Ads for medicinal product and medical devices

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') have received a large number of questions regarding Google Ads and the mandatory notifications for both medicinal products and medical devices. As a result thereof, the Inspection Boards have clarified in a newsletter of December 2014 which wording should be included for the various types of products in addition to a direct link to a website listing all mandatory notifications:

- Medicinal products without contraindications
  - Read patient information leaflet
- Medicinal products with contraindications
  - Read packaging
- Traditional herbal medicinal products
  - Read packaging (The notification of "traditional herbal medicinal product" and the additional mandatory text "indications are exclusively based on long-standing use" do not have to be included.)
- Medical devices
  - Read packaging (The notification "medical device" does not have to be included.)
- Healthcare products complying with the EU Claims Regulation applies
  - Read packaging*

  * Only replaces any conditions of use, but if a claim is used there should always be a link with the nutrient (unless the nutrient is already mentioned in the product name).

Broadening of the group add-on medicinal products

From 2012 up to and including 2014, funding as an "add-on" to the reimbursement of the diagnosis and treatment combination (DBC) for a disease, could be requested for combinations of substance names and indications that on average costs more than EUR 10,000 per patient per year.

The Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*, 'NZa') has indicated that as of 1 January 2015, less expensive medicinal products can also be included in the add-on list. Healthcare professionals and healthcare insurers can file a request if they find it impossible to cover a certain medicinal product with the rate of a DBC healthcare product.

Assessment and Amendment of the Transparency Register

From an assessment of the effectiveness of the Transparency Register that was launched in April 2013 for the purpose of providing insight into financial relationship between healthcare professionals and pharmaceutical companies, it follows that all pharmaceutical companies are familiar with the transparency rules and the register itself. Almost all notifications to the register are done by the compliance department of these companies. A majority of healthcare professionals (over 75%) was not aware of the transparency rules and the register.

To strengthen the rules and the register itself several measures are proposed, such as (i) a new campaign targeting healthcare professionals to increase awareness, (ii) the content of the notifications will be checked before it is published in the register and (iii) it will be discussed with the Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*; 'IGZ') whether compliance programmes of pharmaceutical companies can be part of the risk-based supervision by the IGZ.

Final report on financial cost of healthcare fraud

In December 2014 the Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*, 'NZa') published its final report regarding the financial costs of healthcare fraud (the interim report has been discussed in our April 2014 newsletter).

The final report contains a number of recommendations to prevent the irregularities that were identified. These recommendations are: (i) clarify laws and regulations so everybody knows what is allowed, (ii) patients have an important role in checking their healthcare bills, (iii) healthcare providers need to be able to clearly explain what and why they charge certain costs and (iv) insurers must properly check the charges made by the healthcare providers.

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