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Newsletter October 2016

Healthcare & Life Sciences Update: The Netherlands

The legal landscape for companies active in the Dutch healthcare and life sciences sector continues to change. This Healthcare & Life Sciences Update sets out some of the latest regulatory developments which may impact your business: the new circular regarding pharmacy-to-pharmacy supply, the amendment of the rules on disclosure of financial relationships and the increase of the maximum fine for culpable medicines shortage.

Bill on disclosure of inspection data and enforcement decisions

On 11 October 2016, the Dutch House of Representatives (*Tweede Kamer*) adopted a Bill amending the Health Act (*Gezondheidswet*) to introduce further possibilities for the Dutch Healthcare Inspectorate (*Inspectie voor de Gezondheidszorg*; 'IGZ') to disclose information. This includes: (i) the results of inspections; (ii) classification of supervisees in compliance categories; (iii) information provided by supervisees to IGZ; (iv) notices regarding the beginning or end of intensive supervision; (v) opinions provided to IGZ regarding supervision; (vi) information received from third parties provided that such information is the basis for supervision; (vii) enforcement actions such as warnings, orders, instructions and administrative sanctions such as fines.

In most cases the information will be disclosed two weeks after the decision to disclose has been taken. Confidential information, company-sensitive information and personal details (to a certain extent) will be deleted from the information before it is disclosed. The date of the entry into force is still uncertain; a Bill is currently pending in the Dutch Senate (*Eerste Kamer*).

Healthcare Inspectorate's Annual review 2015

The key figures of the IGZ annual review 2015 show that the number of inspection visits is declining. IGZ explains this decline by pointing to its recent reorganisation, the development of new forms of supervision, which deploy the available instruments differently. Since 2014 IGZ is focusing on good governance within the healthcare sector. As part of this new focus IGZ has conducted interviews with the management boards and supervisory board members of healthcare facilities to clarify what it expects of these boards with regard to controlling quality and safety within a healthcare facility.

With regard to enforcement measures it is noticeable that the number of more severe enforcement measures, such as penalty payments, administrative fines and recovery decisions has increased significantly in the last year(s). In contrast, the number of softer measures imposed by IGZ such as intensive supervision orders and instructions has significantly decreased in the same period. Healthcare companies must take into account more severe enforcement measures in case of violations.

New circular regarding pharmacy-to-pharmacy supply

As of 22 August 2016, a new IGZ Circular on 'Enforcement in case of pharmacy-to-pharmacy supply to other pharmacies' has entered into force and has replaced the old Circular regarding this topic. Although large scale delivery of medicinal products by preparing pharmacies to other pharmacies is contradictory to the Dutch Medicines Act, IGZ will under certain conditions not initiate enforcement measures. Only when the following conditions are met, the pharmacy-to-pharmacy supply will be allowed: (i) adequate alternatives registered in the Netherlands are not available; (ii) every 'in-house' pharmaceutical product must be registered with G-standard of Z-Index; (iii) a product file has been prepared for every 'in-house' pharmaceutical product; (iv) the products are prepared under GMP-conditions; (v) the pharmacovigilance system is operational and Lareb is notified of any side effects that occurred and (vi) no promotion is done for the 'in-house' pharmaceutical product. The new Circular will apply until 21 August 2019.

Expiration date after opening on OTC medicinal products packaging

The Dutch Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, CBG) has published a new policy with regard to the expiration date after opening of OTC products. CBG wants manufacturers of OTC medicinal products to specify the expiration date after opening on the packages of their OTC medicinal products. CBG has made this decision based on research done by the Dutch Consumer Association which shows that the expiration date after opening is often missing on sealable packages.

When the expiration date after opening is not yet specified on the current packaging of OTC medical products, manufacturers have a period of six months ending on 30 March 2017 to alter the packaging via either a notification or new packaging. The specification of the expiration date after opening on the packaging of OTC medicinal products will be part of the application process for new marketing authorisations.

Amendment of the rules on disclosure of financial relationships

The self-regulating body Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame*; 'CGR') has announced that the rules on the disclosure of financial relationships, included in the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*), will be amended. Pursuant to the amendment indirect financial relationships between pharmaceutical companies and healthcare professionals will also need to be notified to the Healthcare Transparency Register, whereas under the current rules only direct financial relationships need to be disclosed.

For example, when a pharmaceutical company provides funds for refresher courses for healthcare professionals to a third party who organises these refresher courses, it is considered to provide indirect compensation for the refresher courses of healthcare professionals. The amendment will enter into force on 1 January 2017 and will impact companies that annually notify the Healthcare Transparency Register of their financial relationships.

New organisation responsible for review of non-interventional studies

As of 1 July 2016 the responsibility for reviewing non-interventional studies has been transferred from the CGR to the Dutch Clinical Trial Foundation (DCTF). Furthermore, a new procedure for the review of non-interventional studies initiated and/or funded by pharmaceutical companies has been introduced.

Due to the shift of responsibility and the introduction of a new review procedure, the review procedure will change as follows: (i) the review only applies to non-interventional studies initiated and/or funded by pharmaceutical companies; (ii) requests need to be made through the request form and emailed to the DCTF; (iii) applicants can indicate which advisory committee needs to review the request: advisory committee nWMO UMC Groningen,

Martini Ziekenhuis or Brabant; (iv) requests filed before 1 July 2016 will be still be reviewed by the CGR; (v) services provided must fully comply with the rules of the Code of Conduct.

Additions to the review process of event sponsoring

In response to a request for advice from an event planner regarding an event sponsored by pharmaceutical companies (A16.005), the CGR has announced several additions to the existing review process of event sponsoring. First, in cases where an event planner is organising an event which is sponsored by one or more pharmaceutical companies, the request for advice needs to include a budget (balance sheet). When the CGR asks the applicant about the implementation of the advice, it will request an explanation regarding the implementation of the advice, a motivation if deviations have been made and a final statement in which the names and contributions of the individual sponsors are set out.

Secondly, an event planner needs to inform the participating healthcare professionals about which part of the hospitality expenses are sponsored by pharmaceutical companies. As of 1 January 2017 the pharmaceutical companies need to include in the sponsoring agreements that participants will be informed about the sponsoring of hospitality expenses by the pharmaceutical companies. If the hospitality (also) includes travel and accommodation expenses (without the pharmaceutical companies being aware of this), the event planner needs to include the arrangements regarding these costs in a written agreement between the event planner and the individual healthcare professional.

Increase of the maximum fine for culpable medicines shortage

By letter of 23 juni 2016, the Dutch Minister of Healthcare, Welfare and Sport (*Minister van Volksgezondheid, Welzijn en Sport*) has announced that the maximum fine for culpably causing medicines shortage will be increased from EUR 45,000 to EUR 820,000. In order to implement this increase, the Medicines Act (*Geneesmiddelenwet*) must be amended. Until this amendment enters into force the maximum fine will be increased from EUR 45,000 to EUR 150,000. In addition to the increase of the maximum fine, the Minister also announced that wholesalers will need to keep certain stocks, so that they can provide the relevant medicinal products in case of an immediate shortage.

A single point of contact will be set up by IGZ and CBG for reporting possible shortages of medicinal products. The point of contact should be operational by the end of this year. Furthermore, the Minister is looking into the possibility to act more quickly in case of shortage, for example by making it easier to switch to (foreign) alternative medicines. The Minister has already reached an agreement with healthcare insurers with regard to the reimbursement of alternative medicines in case of a shortage.

New European regulations on medical devices and in-vitro diagnostics

On 25 May 2016 the European Council and the European Parliament have reached a tentative agreement on new regulations for medical devices and in-vitro diagnostics. The focus of these regulations will be on the safety of medical devices and quick access to innovative devices. To ensure the safety of medical devices the following amendments will be made: (i) the requirements for and the supervision of the bodies responsible for market access will become stricter (sufficient and qualified personnel); (ii) clear rules for manufacturers to ensure the quality, performance and safety of medical devices; (iii) additional responsibilities for manufacturers and other market participants on liabilities and registration of complaints; (iv) extra screening of high-risk medical devices by experts; (v) coverage of other risk products that are similar to medical devices by the regulations and (vi) an extensive database containing information regarding manufacturers, distributors, regulatory bodies, market surveillance results, clinical research and certificates which can easily be accessed by patients, healthcare professionals and the public.

The proposed regulations have been sent to the EU member states for their approval and the European Parliament will be voting on the proposed regulation in the fall of 2016. If approved the new regulation on medical devices will enter into force three years after publication and the new regulation on in-vitro diagnostics will enter into force five years after publication.

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