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Healthcare & Life Sciences Update: The Netherlands

The regulatory environment for companies active in the Dutch healthcare and life sciences sector continues to change. Rules regarding advertising have been amended and new supervision instruments are being introduced. On a European level, pharmacovigilance has been further harmonised, resulting in amendment of the Dutch Medicines Act. Pilots for funding of specific (more expensive) medicinal products are also being assessed and next steps are determined. This Healthcare & Life Sciences Update highlights certain recent developments in regulations and enforcement, which may impact your business.

Web-based surveys introduced as part of risk-based supervision

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, introduced web-based surveys as part of its risk-based supervision. In March 2014 the IGZ informed relevant companies about this new tool. The companies that are asked to fill out the web-based survey are legally obligated to do so within the time period set by the IGZ.

On 19 June 2014 IGZ has sent its first web-based survey to 309 companies located in the Netherlands, all of whom supply class I medical devices to the Dutch market. Out of these, 274 companies have provided the requested information to IGZ, who will use the information provided in this, and in future surveys to monitor these companies and identify any trends.

Amendments announced to rules governing pharmaceutical advertising

Amendments to the Code of Conduct for Pharmaceutical Advertising (*Gedragscode Geneesmiddelenreclame*) have been announced by the self-regulating body Foundation for the Code for Pharmaceutical Advertising (*Stichting Code Geneesmiddelenreclame;* 'CGR'). The amended Code of Conduct will enter into force on 1 January 2015. The amendments concern the implementation of maximum amounts for the reimbursement of reasonable meal expenses (as part of any hospitality), the introduction of the requirement to record the mutual financial relationships between healthcare professionals and pharmaceutical companies in writing and to disclose these agreements and the expansion of the rules regarding the disclosure of financial relationships between pharmaceutical companies and healthcare professionals.

The European Federation of Pharmaceutical Industries and Associations ('EFPIA') (in its code) has recently elaborated on the gifts that may be given to healthcare professionals by pharmaceutical companies. The only gifts that are allowed are materials that are solely informational or educational in nature and products that can be used in medical practice, but not part of the routine costs of professionals. From the perspective of European harmonisation of standards regarding gifts, the CGR has also included the EFPIA elaboration in the notes to the Elaboration on Standards for Inducements (*Uitwerking Normen Gunstbetoon*). On 1 July 2014 the revised Elaboration entered into force.

On 1 May 2014 a pilot project was launched to test the instrument developed by the CGR to self-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. The pilot project is limited to educational

meetings related to family medicine, general medicine and orthopaedics. The self-assessment instrument consists of a minimum of one question and a maximum of three questions, depending on how many questions can be answered with 'no'; if the answer to one of the questions is 'no', the self-assessment is completed.

Pharmacovigilance Directive implemented in Dutch Medicines Act

On 7 November 2014 the Amendment of the Dutch Medicines Act (*Geneesmiddelenwet*) implementing Directive 2012/26 EU regarding pharmacovigilance (*Wijziging van de Geneesmiddelenwet ter implementatie van richtlijn 2012/26/EU, wat de geneesmiddelenbewaking betreft*) entered into force. The amendment further clarifies and strengthens the Urgent Union Procedure to enable immediate action to protect public health. It also contains some technical changes to further harmonise pharmacovigilance in the EU. One example of this harmonisation is the increased number of notifications on for instance the request to withdraw a marketing authorisation or the omission of an application for renewal of a marketing authorisation.

Provisional continuation of financial arrangements for specialist medicines

An update on the financial arrangements for certain specialist medicines for serious illnesses was provided by the Dutch Minister of Health, Welfare and Sport in her letter of 11 June 2014. The instrument 'financial arrangement' can only be used by the minister (i) where there are significant financial risks (regarding costs and/or cost effectiveness) and (ii) if healthcare providers and health insurers themselves are insufficiently able to influence the price or cost of the relevant medicinal products. As costs and cost effectiveness can vary greatly between medicinal products, negotiating a financial arrangement directly with the supplier of the product may sometimes be advisable.

Since the second half of 2012 eight financial arrangements have been entered into. These arrangements are still in the pilot phase but the minister is very pleased with the results and has decided to continue the pilot in order to implement the ongoing arrangements and, if required, start new pilot arrangements. The minister will also draft procedures and processes based on the experiences gained during the pilot phase, as well as increase transparency of the selection and negotiation process and of the implementation and benefits of the arrangements. It is expected that the pilot phase will be completed by the end of this year.

Limited transfer of expensive medicines to intramural funding in 2015

In 2012 the Dutch Minister of Health, Welfare and Sport initiated the transfer of certain (expensive) specialist medicines from extramural reimbursement to intramural funding in order to have these specialist medicines completely and exclusively included in the medical specialist care in hospitals and to unambiguously determine the insured entitlement. In her letter of 15 May 2014 the minister discusses the evaluation of the transfer. This evaluation shows that especially in the field of medication reconciliation there still are some problems that need to be resolved. Due to these problems the minister has decided to scale-down the transfer scheduled for 2015. From 1 January 2015, new products that do not have a substitute within the extramural reimbursement system are no longer eligible for inclusion in this system. Manufacturers can apply for inclusion in the intramural funding system if they meet the criteria applicable to this system.

New policy for QR codes on packaging information

A policy regarding the use of QR codes on the packaging and/or leaflet of medicinal products has been laid down by the Dutch Medicines Evaluation Board (*College ter Beoordeling van Geneesmiddelen*, 'CBG'), the authority responsible for registration of medicinal products. QR codes or quick response codes are two-dimensional barcodes consisting of square dots arranged in a square grid, which can be read by an imaging device such as a smartphone and converted into an URL of a website. The policy describes the conditions companies need to meet in order to be able to use a QR code. The policy immediately enters into force and applies to all medicinal products for which a national marketing authorisation has been or will be issued.

Expansion of conditional admissions of products to insurance package

In 2012 the first admissions on a conditional basis of promising interventions to the basic health insurance package were made and since then the instrument 'conditional admission' has continued to evolve. The Dutch Minister of Health, Welfare and Sport announced in her letter of 10 June 2014 that the conditional admission

will be expanded as follows: (i) conditional admissions will be handled several times a year instead of once a year and (ii) besides the companies, institutions and professionals active in the healthcare sector (bottom-up), the Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*, 'NZa'), the supervisory body for the healthcare markets in the Netherlands, may also recommend interventions for conditional admission (top-down). Additionally, the procedure for conditional admission will become stricter. The minister will monitor the procedure on a yearly basis and an intermediate stop of the procedure is also an option.

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