Medicinal product regulation and product liability in The Netherlands: overview

John Lisman
Lisman Legal Life sciences

Erik Vollebregt, Carine van den Brink, Arber Gjunkshi and Annemiek Kooy
Axon Lawyers

global.practicallaw.com/3-500-7575

REGULATORY OVERVIEW

1. What are the main legislation and regulatory authorities for pharmaceuticals in your jurisdiction?

Legislation
The main legislation for pharmaceuticals is the:
- Medicines Act (Geneesmiddelenwet).
- Act on Medicine Pricing (Wet geneesmiddelenprijzen).
- Healthcare Insur-ance Act (Zorgverzekeringswet).
- Exceptional Medical Expenses Act (AWBZ).
- Act on Medical Scientific Research Involving Human Subjects (WMO).
- Code of Conduct for the Advertising of Medicinal Products, a self-regulatory code based on the Medicines Act (Gedragscode Geneesmiddelenreclame).

Regulatory authorities
The Medicines Evaluation Board (College ter beoordeling van Geneesmiddelen) (www.cbg-meb.nl/CBG/en/about/organisation/MEB) is an independent administrative body responsible for:
- Granting, rejecting, varying and revoking marketing authorisations for medicinal products for human use, including the summary of product characteristics, labelling and patient information leaflets.
- Granting parallel import authorisations.
- Pharmacovigilance.
- Determining the supply status of medicines (prescription only, pharmacy-only, pharmacy or drugstore only, and general sale).

Other main regulatory authorities include:
- The Ministry of Public Health, Welfare and Sport (VWS). This is responsible for healthcare regulation and policy, granting applications for manufacturing and wholesale distribution licences, setting rules on reimbursement and setting maximum prices for medicinal products.
- Farmatec, which is a department of the Ministry of Public Health, Welfare and Sport, dealing with applications for manufacturing and wholesale distribution authorisations. It is also involved in the decision-making for pricing and reimbursement.
- The Healthcare Inspectorate (IGZ). The Pharmaceutical and Medical Technology Division is responsible for enforcing all pharmaceutical and medical devices legislation.

2. Briefly outline how biologics and combination products are regulated in your jurisdiction.


The same applies to EU legislation on combination products (medicinal products containing two or more active ingredients). If marketing authorisations have been granted in the EU/European Economic Area (EEA) for medicinal products containing the separate ingredients, but not containing this particular combination, applicants must submit results of new preclinical or clinical tests for the combination, but not for each active ingredient separately.

Medical devices in which a medicinal product is incorporated need to comply with some of the provisions on medicinal products. The Medicines Act will apply to a product that, in relation to its characteristics, meets both the definition of a medicinal product and of a product in other legislation (Article 16(5), Medicines Act). The Dutch courts comply with EU case law on such borderline products.

3. Briefly outline how medical devices and diagnostics are regulated in your jurisdiction. Is there any specific regulation of health IT issues and mobile medical applications?

Medical devices are classified in accordance with EU directives concerning medical devices, that is:

The definition of medical device from these directives has been implemented into the Act on Medical Devices.
The risk classification of medical devices and in vitro diagnostics (IVDs) is based on the relevant annexes of the Medical Devices Directive and the IVD Directive. Non-invasive devices are generally classified as Class I, as well as invasive devices intended for transient use. Invasive devices are generally in Class IIa if they are intended for short term use and in Class IIb in case of long term use. Surgical instruments intended in respect of the heart of the circulation or in direct contact with the central nervous system are classified in Class III.

The medical devices legislation considers software, linked to a medical device or stand-alone, as a medical device if its intended purpose falls within the scope of medical devices.

PRICING, STATE FUNDING AND REIMBURSEMENT

4. What is the structure of the national healthcare system, and how is it funded?

The Netherlands has a private system of health insurance. A distinction is made between ordinary and extraordinary medical expenses.

Ordinary medical expenses

Under the Health Insurance Act, a standard package of basic insurance is mandatory for all citizens. Insurance companies must accept all citizens, irrespective of age or health condition. Insured people pay a premium to the health insurer. Insurance policies can:

- Be restitution policies, where healthcare invoices are reimbursed.
- Provide benefits in kind, where healthcare providers are contracted by the insurance company to provide services to the insured.

The Health Insurance Act was implemented to increase competition between insurance companies and healthcare providers, while safeguarding the public interest by providing a standard package of insured services. Funding comes from a fixed percentage of income tax and a nominal premium paid by the insured to their insurance company.

Insurance companies must purchase enough healthcare services from healthcare organisations and professionals (general practitioners, pharmacies, hospitals, and so on). Most fees and tariffs for healthcare are negotiable under a legal fixed cap. Special rules apply to pharmacies and hospitals in respect of medicinal products. Medicinal products dispensed in public pharmacies are reimbursed under the Therapeutic Reference Reimbursement System (GVS). Medicinal products used in hospitals are deemed to be included in the cost of the hospital treatment.

Orphan medicinal products and other very expensive medicinal products, used in or outside a hospital, are covered from the hospital budget, but the hospital is compensated through an additional fee.

Extraordinary medical expenses

Extraordinary expenses are included in the compulsory national health insurance, under the Exceptional Medical Expenses Act (Algemene wet bijzondere ziektekosten (AWBZ)). The funding comes from premiums, personal income based contributions and government contributions.

5. How are the prices of medicinal products regulated?

Similar medicinal products used to calculate the maximum prices are medicinal products that contain the same active substance in the same pharmaceutical form. This means that the prices of generic medicinal products and biosimilars in the reference countries are used to calculate the maximum price of all variants of a medicinal product in The Netherlands.

6. When is the cost of a medicinal product funded by the state or reimbursed? How is the pharmacist compensated for his dispensing services?

The Health Insurance Decree sets out a system of reimbursement for authorised medicinal products for use outside a hospital, based on the Therapeutic Reference Reimbursement System, which is a positive list of reimbursed medicinal products.

A medicinal product can be considered a unique product or a product similar to other medicinal products. For similar products, an average of the prices of the similar products is the maximum reimbursement price. A third category of medicinal products is not reimbursed.

The patient has to make a co-payment if the reimbursement is lower than the actual price of a medicinal product.

Farmacie places medicinal products on the positive reimbursement list and sets the prices for each group of interchangeable medicinal products (cluster). It obtains advice from the Healthcare Insurance Board and the Scientific Advisory Council, which results in a list of reimbursable products.

Under the Therapeutic Reference Reimbursement System, a medicinal product is reimbursable if it is interchangeable (in other words, has equivalent therapeutic value) with one or more other medicinal products on the list with a similar indication, or has a unique therapeutic value.

A cluster can include a brand product, leader product, generic versions, parallel imported products and products with a different active substance, intended for the same therapeutic use by, in general, the same population. A maximum reimbursement will be allocated to each cluster. Patients receiving a medicinal product included in a cluster priced above the maximum reimbursement have to pay the difference (co-payment).

Non-interchangeable medicinal products are fully reimbursed if they have added therapeutic value and are cost-effective compared to products already on the reimbursement list. Applicants wishing to have their products fully reimbursed must provide the results of pharmaco-economic research and forecast budgetary implications.

Health insurers can impose additional conditions for the medicinal product to be reimbursed, for example limited to prescriptions from hospital consultants or only for limited indications or populations.

CLINICAL TRIALS

7. Outline the regulation of clinical trials.

Legislation and regulatory authorities


Authorisations

Clinical trials must be conducted in line with an approved investigational protocol. Depending on the type of research, the product to be investigated and the trial subjects, the
investigational protocol must be approved by either the Central Ethics Committee or a local ethics committee.

The competent ethics committee must give its approval or rejection within 60 days of receipt of the research file, during which period the ethics committee can ask once for supplementary information.

This term can be extended for research into medicinal products for gene therapy and somatic cell therapy, and all medicinal products containing genetically modified organisms. Scientific research into medicinal products for xenogeneic cell therapy is not allowed in The Netherlands.

Even if the assessment is carried out by a local ethics committee, the Central Ethics Committee must be notified by the researcher. If the Central Ethics Committee does not raise an objection within 14 days, the clinical trial can be started.

Consent
Informal consent by subjects is required, under the Clinical Trials Directive.

If the subjects of the trial are children under 12 years of age or incapacitated adults, they must be represented by their legal representatives. Children over the age of 12 have to consent to participation together with their legal representative.

If subjects are at least 12 years of age but cannot be deemed capable of giving informed consent, the following is required:
- Written consent of the subject's parents (if they exercise parental responsibility) or legal guardian.
- If the subject is not a minor, his or her legal representative. If no legal representative has been appointed, written consent from the person authorised in writing by the subject to act on his or her behalf or, if no such person is available, the subject's family member (of age) or registered partner or other life companion.

In these cases, extra conditions apply for authorisation of the trial, such as a lack of alternative methods to investigate the medicinal product or low risk and discomfort for the trial subject associated with participation.

In contrast to many other EU member states, The Netherlands does not allow non-therapeutic clinical trials with children.

Trial pre-conditions
A clinical trial cannot start without liability insurance covering injury or death resulting from the trial, as set out in the Mandatory Insurance for Clinical Studies with Humans Decree, and this liability cannot be excluded or limited. Further, each clinical trial site must decide that it is appropriate for the clinical trial.

A clinical trial with a medicinal product must be registered in the EudraCT (https://eudract.ema.europa.eu) database before the trial starts. This was set up to offer the relevant authorities more insight into research carried out in the EU.

Procedural requirements
The sponsor must report to the reviewing committee (recognised medical-ethical committee or central committee of scientific research with humans) and to the competent authority (central committee of scientific research or Ministry of Health, Welfare and Sport) both during and after the study about, among other things:
- Changes to the research file (amendment).
- Unexpected adverse reactions and progress.

It must also submit annually development safety update reports and a clinical trial report after finalisation.

MANUFACTURING

8. What is the authorisation process for manufacturing medicinal products?

Application
The preparation, importing and wholesale distribution of medicinal products requires authorisation according to the Code for Human Medicines Directive. The Ministry of Health, Welfare and Sport grants such licences to manufacturers and wholesalers. The application is assessed by Farmatec on the advice of the Healthcare Inspectorate.

If a laboratory checks the medicinal products on behalf of an authorisation holder, it must be appointed by Farmatec.

Conditions
The manufacturer must show it complies with Good Manufacturing Guidelines and other legal regulations. The applicant must set out on the application form, downloaded from Farmatec's website (www.farmatec.nl) details relating to, among other things, the:
- Products to be manufactured and the manufacturing process.
- Site floor plan.
- Qualified persons appointed to supervise.
- Quality controls to be used.

If the manufacturer delegates the analyses of the medicinal products or parts of the manufacturing process to third parties, the relevant agreements must be described.

Restrictions on foreign applicants
Only manufacturers with premises in The Netherlands can apply for manufacturing authorisations. There is no restriction on foreign entities owning premises in The Netherlands. A manufacturing authorisation is recognised throughout the EEA.

Key stages and timing
Farmatec must decide on new applications within 90 days of receiving the application. A request to change the authorisation holder's qualified person responsible for the authorisation is decided within 30 days. Other requested amendments are decided within 90 days. If Farmatec is not able to meet the time limit, it will inform the applicant. The decision period is suspended if Farmatec or the Healthcare Inspectorate cannot proceed with the application and this is caused by the applicant. The decision period starts again as soon as Farmatec or the Healthcare Inspectorate can proceed with the application.

Fee
The fees for manufacturing licences are listed on Farmatec's website (www.farmatec.nl).

Period of authorisation and renewals
Manufacturing licences are in principle valid indefinitely, but have to be verified regularly by inspections leading to a good manufacturing practices (GMP) certificate.

Monitoring compliance and imposing penalties
The Healthcare Inspectorate monitors compliance with manufacturing licences and can carry out inspections before or after the grant of a GMP certificate. It can impose administrative fines for breaches of the licence, possibly after giving instructions to take corrective measures.
MARKETING
Authorisation and abridged procedure

9. What is the authorisation process for marketing medicinal products?

Application
Applications for marketing authorisation are made either to:

- Medicines Evaluation Board (national, mutual recognition or decentralised procedure).
- European Commission through the European Medicines Agency (EMA) (www.ema.europa.eu/ema/) under the centralised EU system.

In The Netherlands, the term registered is used to describe authorised medicinal products.

Authorisation conditions
Chapter 4 of the Medicines Act implements the articles of the Code for Human Medicines Directive regarding marketing authorisations. Medicinal products that are industrially manufactured can only be manufactured, imported, stored, sold, supplied or marketed with a valid marketing authorisation from the Medicines Evaluation Board or from the European Commission through the EMA. A marketing authorisation is granted if the medicinal product meets the requirements for quality and if the competent authorities find that the risk/benefit balance for the proposed indication is favourable.

Key stages and timing
A marketing authorisation can be applied for at the Medicines Evaluation Board if it does not fall under the scope of the EMA Regulation. The decision of the Medicines Evaluation Board has to be taken within 210 days after the submission. If the Medicines Evaluation Board requires additional information from the applicant the clock will stop until the applicant answers the request.

If an application is made in more than one EEA member state for the medicinal product the decentralised procedure applies. If the medicinal product has been authorised in another EEA member state the Medicines Evaluation Board, in accordance with the mutual recognition procedure, has to grant the marketing authorisation within 90 days, recognising the earlier marketing authorisation. In case of different opinions between the national authorities a referral to the Co-ordination group for Mutual recognition and Decentralised procedures human (CMDh) takes place. If the issue is not resolved, the Committee for Medicinal Products for Human Use (CHMP) has to be consulted.

Fee
The fees for marketing authorisations are published on the Medicines Evaluation Board's website (www.cbg-meb.nl) under Human medicines/Regulatory affairs/Products and fees.

Period of authorisation and renewals
All marketing authorisations (including national authorisations) must be renewed five years after the initial authorisation. After then, they remain valid until suspended or revoked. In some cases, for instance if too few patients have been exposed to the medicinal product before authorisation, the authorisation will only be extended for another five years.

An authorisation will lose its validity if it has not been used for three consecutive years, although exemptions are possible.

Monitoring compliance and imposing penalties
The Medicines Evaluation Board can suspend, revoke, amend or withdraw marketing authorisations. Monitoring compliance with the marketing authorisations is done by the Healthcare Inspectorate, which can impose an administrative fine for marketing a medicinal product without a valid authorisation.

Regulation (EC) 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) 726/2004 contains extra enforcement tools at EU level for products authorised under the centralised procedure. The EU and EEA member state authorities collaborate in this respect.

10. What commitments and pharmacovigilance obligations apply after a company has obtained marketing authorisation? Are there further conditions concerning how the drug is distributed and accessible to patients?

In accordance with EU legislation, the holder of a marketing authorisation must:

- Maintain a pharmacovigilance system, including a qualified person for pharmacovigilance.
- Comply with post-marketing obligations, from the risk management plan or as determined by the competent authorities.

The Medicines Evaluation Board has adopted all EU guidance in the area of spontaneous adverse drug reaction reporting. Marketing authorisation holders must report any suspected adverse drug reaction reports directly to the EMA in the EudraVigilance database (https://eudravigilance.ema.europa.eu/human/index.asp). Period safety update reports (PSURs) must be submitted to the competent authorities. Amendments to EU pharmacovigilance legislation mean that holders of national marketing authorisations must notify the EMA, in addition to the member state in which the medicine is authorised.

No specific national obligations apply. The channel for dispensing medicinal products to the patient is decided by the Medicines Evaluation Board (pharmacy only, pharmacy or drugstore only or general sales).

11. Which medicinal products can benefit from the abridged procedure for marketing authorisation and what conditions and procedure apply? What information can the applicant rely on?

The Medicines Act implements the articles of the Code for Human Medicines Directive regarding marketing authorisations, so that the EU’s conditions and procedures apply for generic medicinal products.

Generic medicinal products are medicinal products containing the same active substance(s) in the same strength and pharmaceutical form and for which bioequivalence to a reference medicinal product has been demonstrated.

The EU “8+2+1” rule applies:

- Generics cannot be authorised until after eight years from authorisation of the reference medicinal product (data exclusivity period). A generic marketing authorisation is based on the clinical and preclinical data submitted for the reference medicinal product.
- Generics cannot be marketed before a marketing exclusivity period of ten years has expired from authorisation of the reference medicinal product. This is extendable by one extra year, due to the addition of a significant new indication.
If a medicinal product contains an active substance(s) with a well-established medicinal use, and the use has been well-documented in a peer reviewed journal, a bibliographical application can be submitted referring to published data.

Fixed dose combinations can be authorised on the basis of preclinical and clinical data available for the active substances in the combination. In that case, only the combination of the active substances in one medicinal product has to be investigated.

If the holder of the marketing authorisation consents, a second medicinal product can be authorised on the basis of the dossier of a reference medicinal product.

12. Are foreign marketing authorisations recognised in your jurisdiction?

Marketing authorisations from countries outside the EEA are not recognised.

The Medicines Evaluation Board recognises an authorisation granted by the EMA or in another EEA member state, following the mutual recognition procedure in the Code for Human Medicines Directive, unless the competent authority finds that recognition would establish a potential serious risk to public health.

Differences of opinion between member states can be settled by arbitration before the EMA’s Co-ordination Group for Mutual Recognition and Decentralised Procedures (CMD(h)) or, if no solution is found in the CMD(h), before the Committee on Human Medicinal Products (CHMP).

Parallel imports

13. Are parallel imports of medicinal products into your jurisdiction allowed?

Parallel imported medicinal products must be covered by a parallel import authorisation. The authorisation is granted within 60 days of receipt if the product is authorised both in the exporting member state and The Netherlands.

The only reason for the competent authority to refuse parallel import authorisation is if authorisation would create a serious risk to public health. The parallel importer must notify the patent holder or licensee and/or the company responsible for the dossier of his intent. Parallel importers repacking the product must hold a manufacturing authorisation and comply with case law concerning repackaging of the Court of Justice of the European Union.

If parallel importers meet all the requirements, intellectual property right holders cannot rely on these rights to oppose parallel imports within the European Community, due to legislation on the exhaustion doctrine and the principle of free movement of goods in the European Community.

RESTRICTIONS ON DEALINGS WITH HEALTHCARE PROFESSIONALS

14. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for healthcare establishments or individual medical practitioners?

Bribery or fraud provisions relating to inducement are in the Medicines Act and the Policy Rules Administrative Fine Medicines Act. Non-specific provisions can be found in criminal legislation.

The Medicines Act provides that the Healthcare Inspectorate will advise the Minister of Health to penalise violations of advertising regulations by an administrative fine up to EUR450,000. This does not exclude criminal proceedings, but they are exceptional in cases of inducement.

There are no disclosure obligations in The Netherlands equivalent to the US Sunshine Act registration requirements. However, the Minister of Health intends to include Sunshine Act-type transparency, similar to that in the US medicinal products industry, in the Dutch Code of Conduct on Medical Devices from 2015. For medicinal products, this type of transparency has applied since 2013.

Transparency plays a role in the self-regulating Code of Conduct for the Advertising of Medicinal Products (CCAMP). The CCAMP is based on the principle that sponsoring and inducement are permitted, as long as several requirements are met. These requirements are built around the goals of support, transparency and integrity.

The inducement codes of conduct on elaborate on Articles 12 and 13 (hospitality), and 16 to 22 (among others gifts, bonuses and other benefits) of the CCAMP. Hospitality must relate to scientific conferences. It is generally considered to be within reasonable limits if its value is limited or if the healthcare professional pays a relevant part of the costs at his own expense.

Hospitality relating to non-scientific meetings can amount to up to EUR50 per healthcare professional per year. Gifts can be given to healthcare professionals, provided they are useful for the professional’s practice and have a maximum value of EUR50, up to a maximum amount per year.

Any hospitality provided outside The Netherlands should usually be approved in advance by the Foundation for the Code for Advertising of Medicinal Products.

The sponsorship codes of conduct (like the codes relating to inducement) are based on the principle that sponsorship is permitted as long as several requirements are met. These requirements are built around the goals of support, transparency and integrity. All forms of support could amount to sponsorship, irrespective of whether there is consideration by the healthcare professional or the manner in which the parties qualify the support.

Importantly, the sponsorship codes of conduct do not apply to the sponsoring of symposia, congresses, events, gatherings and so on by healthcare professionals. Also, granting or receiving gifts or advantages that are of limited financial value and are of importance to healthcare do not fall under the sponsorship codes of conduct. They fall under the inducement codes of conduct.

SALES AND MARKETING

15. What are the restrictions on selling medicinal products? Are there specific regulations for the sale of medicinal products on the internet, by e-mail and by mail order?

Importing and wholesale distribution of medicinal products requires authorisation. The Minister of Health grants such licences to manufacturers and wholesalers (see Question 9).

Obligations concerning import, distribution and use of raw materials are set out in the Medicines Act. The implementation of Directive 2011/62/EC (falsified medicines) entered into force on 10 December 2013. Brokers of medicinal products and companies manufacturing or dealing in raw materials now need to obtain a registration certificate. The ICZ will monitor the registrations and can carry out inspections before or after granting a certificate.

The Medicines Evaluation Board decides the supply status of medicines (prescription only, pharmacy only, pharmacy or drugstore only, and general sale). The Medicines Act also contains restrictions on internet sales or other distance selling. For instance, it is prohibited to prescribe
medicinal products through the internet to a person whom the prescriber has never met in person or does not know. Websites must also contain a hyperlink to the EMA and a link to the website that lists entities authorised to sell medicinal products online (www.internetpillen.nl).

**ADVERTISING**

16. What are the restrictions on advertising medicinal products?

**Legislation and regulatory authority**

Advertising of medicinal products is based on self-regulation in The Netherlands, which is in turn based on Articles 94 and 95 of the Code for Human Medicines Directive and Chapter 9 of the Medicines Act.

The starting principle is that the patient or consumer should be able to rely on an unbiased choice for a specific medicinal product. The Foundation for the Code for Advertising of Medicinal Products created the Code of Conduct for the Advertising of Medicinal Products (CCAMP). This is elaborated in several documents, including explanatory codes.

**Restrictions**

The self-regulation framework contains specific rules on advertising directed at the general public and advertising directed at healthcare professionals. For example:

- Advertising prescription-only medicinal products to the general public is not allowed.
- Advertising non-prescription medicinal products to the general public is allowed, subject to strict conditions.
- Advertising prescription-only medicinal products to healthcare professionals is permitted, subject to strict conditions (see Question 14).
- Objective general information on medicinal products can be provided to the general public and to healthcare professionals, subject to strict conditions.

Information and promotional material in respect of medicinal products must promote their rational use. The material must be completely in line with the official product information and cannot be misleading in any way. Comparative claims have to be based on scientific research. The minimal requirement is one publication reporting the outcome of clinical research in a peer reviewed journal.

**Internet advertising**

Advertising over the internet is subject to the general advertising rules (see above, Restrictions). It is not regarded as advertising directed just at healthcare professionals.

**DATA PROTECTION**

17. Do data protection laws impact on pharmaceutical regulation in your jurisdiction?

The Personal Data Protection Act (J) implements Directive 95/46/EC on data protection (Data Protection Directive). Personal data means any information relating to an identified or identifiable natural person, so that anonymous data which can be decoded and traced back to personal data will also fall under this act. In principle, all processing of personal data requires advance consent from the person whose data are under consideration.

A researcher involved in a clinical trial who processes personal data for a particular study should, in principle, report this processing to the Data Protection Authority (CBP).

According to the Data Protection Authority, self-regulation will contribute effectively to the achievement of the individual’s fundamental right to the protection of his privacy. The Data Protection Authority therefore recommends that companies appoint a data protection officer and encourages companies to formulate a code of conduct for their branch of industry or sector. The Dutch biomedical research community has adopted the Code for Healthcare Research (Centraalcode Gezondheidsonderzoek), which has been approved by the Data Protection Authority.

Research subjects must not only consent to participation in the clinical trial, but also to the processing of their personal health data for the purpose of the trial and any subsequent processing, such as use of the data in a marketing authorisation application.

**PACKAGING AND LABELLING**

18. Outline the regulation of the packaging and labelling of medicinal products.

**Legislation and regulatory authority**

The EU legislation concerning packaging, labelling and the package leaflet is implemented in The Netherlands in Chapter 7 of the Medicines Act. The Medicines Evaluation Board enforces compliance with the legislation on packaging and labelling.

**Information requirements**

The Medicines Evaluation Board has issued a policy document, Labelling of pharmaceutical products MEB 6-3-5, which is also available in English. The policy document states that the Medicines Evaluation Board follows the standards set in the European Commission’s guidelines, such as the:

- Guideline on readability.
- Notice to Applicants volume 2a chapter 7 - General Information for products registered under the Mutual Recognition Procedure.
- Notice to Applicants volume 2c Guideline on the packaging information of medicinal products for human use authorised by the Community for products registered under the centralised procedure.

The EMA’s Quality review of documents, Product Information templates and Guideline on the excipients in the label and the package leaflet of medicinal products for human use are also followed by the Medicinal Evaluation Board.

The package label must contain the:

- Name, strength, active substances and pharmaceutical form.
- Name of the marketing authorisation holder.

For non prescription medicines the label must also mention contraindications and the intended uses.

The patient information leaflet must contain among other things:

- The indication.
- Information on contraindications.
- Dosage and method and route of administrations.
- Adverse drug reactions.
- Precautions and warnings.

**Other conditions**

The text of the outer packaging and primary packaging must be worded in Dutch.
Packaging texts in several languages are permitted, provided that a declaration is made that the information provided in all languages is the same.

Products accepted through the mutual recognition procedure that are not marketed in The Netherlands can be authorised without the Dutch product information.

Additional legal requirements apply for the labelling of homeopathic products and traditional herbal medicines (Articles 73 and 74, Medicines Act).

**PRODUCT LIABILITY**

19. Outline the key regulators and their powers in relation to medicinal product liability.

The Medicines Evaluation Board can take actions such as suspending sales or even withdrawing the medicine from the market entirely.

The Healthcare Inspectorate can impose several measures to ensure compliance with legislation, professional standards and guidelines. It can impose corrective or coercive measures. In the most serious cases, it can bring disciplinary or criminal proceedings.

20. Are there any mandatory requirements relating to medicinal product safety?

Companies marketing medicinal products in The Netherlands must report occurrences of defective quality to the Healthcare Inspectorate and to the Medicines Evaluation Board. Reports can also be made by individual pharmacists. Spontaneous suspected serious unexpected adverse reactions must be reported by the marketing authorisation holders promptly, and no later than 15 days following receipt of the information, to the EMA.

If the Healthcare Inspectorate is considering a recall, it will first consult the marketing authorisation holder and inform him that it will prohibit any further placing on the market, prescription and delivery of the medicinal product. The Healthcare Inspectorate does not order the recall, since this is the responsibility of the marketing authorisation holder. The recall notice must be submitted to the Healthcare Inspectorate for its approval before the recall begins. Warnings relating to medicinal products are published on the Medicines Evaluation Board’s website.

21. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.


Liability arises if a claimant shows that a pharmaceutical product or a medical device is defective and has caused damage. A product is defective when it does not provide the safety a person is entitled to expect, taking all circumstances into account such as the presentation of the product, reasonably expected use and the moment the product was brought on the market.

The Product Liability Act only applies to claims for compensation for:

- Death or personal injury.

- Damage caused to property other than the defective product itself, if that sort of property is normally intended for private use or consumption and was used as such by the claimant. Claims for such damage must exceed the minimum threshold laid down in the Product Liability Act, currently EUR500.

Liability claims based on tort are possible, if negligence occurs.

22. Who is potentially liable for defective medicinal products?

The producer of a medicinal product can be liable. In accordance with EU case law, the definition of producer is interpreted broadly, so that all the following can be liable:

- Several entities in the supply chain from the raw material to the final medicinal product.
- Companies presented as the producer by attaching, for instance, a trade mark or a trade name on the product or packaging.

If a physician, pharmacist or manufacturer causes physical injury or death by administering, prescribing or manufacturing drugs incorrectly, they can be prosecuted under criminal law. Further, it is a crime to provide medicinal products while knowing that they are mixed with unrelated ingredients, which lessen the medicinal products' efficacy or make them harmful to health or life, without notifying the buyer of this.

Non-compliance with the Medicines Act can also give rise to criminal liability.

Liability for damages only exists when there is a causal relationship between the event on which liability is based and the damage incurred.

23. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

The following defences under the Product Liability Act among others can be available:

- The product (medical device or other pharmaceutical product) is not defective because it provides the safety a person is entitled to expect.
- No causal relationship between the event on which liability is based and the damage incurred. The burden of proof is on the claimant in this respect.
- Development risk defence. Taking into account the state of scientific and technical knowledge, it was impossible to discover the defect at the moment the product was circulated.
- The defect did not exist when the producer placed the product on the market, for example because the product has been tampered with.
- The product was produced in a certain way because of mandatory government regulation.

It is sometimes possible to reduce liability if the injured person is entirely or partly at fault.

Strict liability for defective products on the basis of Article 6:185 and following of the Civil Code cannot be restricted or excluded in relation to the injured party. However, manufacturers and suppliers can agree to provide indemnities to each other.

Defences against liability claims under tort law come down to the same defences as set out above, and the argument that no negligence occurred.
24. How can a product liability claim be brought?

Limitation periods

A product liability claim is brought in a civil court against the producer, by means of a writ of summons (dagvaarding).

The injured party must submit its claim under the Civil Code within three years after it became aware or should have been aware of the fault, the injury and the identity of the manufacturer. The right to compensation expires when ten years have passed from the day after the manufacturer marketed the product causing the injury.

The limitations for claims based on tort are:

- Five years starting from the day following that on which the claimant became aware of the damage and the liable person.
- 20 years starting from the day following the day on which the event causing the damage occurred.

The limitation periods of five years and 20 years also apply to claims based on contractual liability. Consumers basing their product liability claim on an agreement should submit their claim within two years from the day they informed the seller that the product does not possess the qualities a consumer is entitled to expect.

Class actions

Class actions for product liability claims are possible under Dutch law, based on the Act on the Collective Settlement of Mass Torts (Wet Collectieve Afwikkeling Massaschade). The well-known class action initiated by the daughters of women who took DES during their pregnancy was the first one in The Netherlands. However, class actions relating to financial services are more common.

25. What remedies are available to the claimant? Are punitive damages allowed for product liability claims?

A claimant can initiate civil proceedings on the merits at the District Court. Because proceedings on the merits can take a long time before a judgment is rendered, a claimant can also start summary proceedings at the District Court and claim an advance payment of damages. The summary proceedings can run parallel with a judgment in civil proceedings on the merits.

Punitive damages are not allowed for product liability claims under Dutch law.

REFORM

26. Are there proposals for reform and when are they likely to come into force?

The Minister of Health plans to put US Sunshine Act-type transparency requirements into the Code of Conduct on Medical Devices, as from 2015.

The Healthcare Insurance Board is also considering a new procedure regarding the reimbursement of medicinal products used in hospitals.

The adoption of new EU legislation on clinical trials is expected early in 2014. The new Clinical Trial Regulation would apply from 2016.

ONLINE RESOURCES

Dutch government website

[www.overheid.nl/ english](http://www.overheid.nl/ english)

Description. All valid legislation is available on this website in Dutch. The website is maintained by the Ministry of Justice and the information is official. There is no official source for translations of Dutch legislation.

Dutch judiciary

[www.rechtspraak.nl/ english/Pages/default.aspx](http://www.rechtspraak.nl/ english/Pages/default.aspx)

Description. This website contains all published case law in The Netherlands. Each judge and court in The Netherlands is responsible for reporting their rulings on this website.

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**Practical Law Contributor profiles**

**John Lisman**
Lisman Legal Life Sciences  
T +31 348 688687  
F +31 348 688760  
E legal@john-lisman.nl  
W www.lismanll.nl

**Professional qualifications.** Master of Pharmacy, Utrecht University 1985; (doctorandus); Master of Dutch Law, Utrecht University, 1988, admitted to the bar in The Netherlands (advocaat), 2007.

**Areas of practice.** Life sciences

**Recent transactions**
- Acting for a pharmaceutical company in litigation against a competent authority for marketing authorisation.
- Advising and representing a pharmaceutical company in respect of pricing and reimbursement.
- Advising and representing several companies in respect of tax legislation.

**Languages.** Dutch, English

**Professional associations/memberships.** Board member of the Dutch Pharmaceutical Law Association; Member of the Drug Information Association.

**Publications.** Editor of *Jurisprudentie Geneesmiddelenrecht*; Member of the Editorial Board of MedNous and *Scrip Regulatory Affairs*. Author of many publications on pharmaceutical law.

**Erik Vollebregt**
Axon Lawyers  
T +31 88 650 6500  
F +31 88 650 6555  
E Erik.Vollebregt@axonlawyers.com  
W www.axonlawyers.com

**Professional qualifications.** Groningen University, 1991 to 1996; Stockholm University 1996 to 1997; stagiair at DG Competition, European Commission, 1997 to 1998; visiting teacher Regulation of Life Sciences Products at Twente University, 2012 to present.

**Areas of practice.** Life sciences; competition law; IP

**Recent transactions**
- Acting for a pharmaceutical company in patent litigation and IP licensing matters.
- Advising several pharmaceutical companies regarding personal health data regulation.

**Languages.** Dutch, English, German, French, Swedish

**Association of Pharmaceutical Law, RAPS**

**Publications.** Editor of *Jurisprudentie Geneesmiddelenrecht* and *eHealth Law & Policy*, many publications on pharmaceutical and medical technology regulation; author of the *MedicalDevicesLegal.com* blog.

**Carine van den Brink**
Axon Lawyers  
T +31 88 650 6500  
F +31 88 650 6555  
E Carine.vandenBrink@axonlawyers.com  
W www.axonlawyers.com

**Professional qualifications.** Law, Amsterdam University, 1989; Medicine, Groningen University, 1987.

**Areas of practice.** IP licensing, research and development driven contracts; pharmaceutical contracts; corporate law; advising on the various phases of the product life cycle, including spinning out businesses from universities, obtaining financing, securing strategic partners, IP exploitation, clinical development, market approval, and commercialisation.

**Professional associations/memberships.** Frequently acts as a jury member for life sciences venture awards and grant committees; lectures at Leiden University and various Master classes in the sector; in-depth knowledge of the biotech and technology markets.

**Arber Gjunkshi**
Axon Lawyers  
T +31 88 650 6500  
F +31 88 650 6555  
E Arber.Gjunkshi@axonlawyers.com  
W www.axonlawyers.com

**Professional qualifications.** LLB, Ankara University, 2003 to 2007; LLM Hamburg University, 2008 to 2009; LLM Maastricht University, 2012 to 2013; Lector of EU law at Epoka University, 2009 to 2010.

**Areas of practice.** Life Sciences; competition law; IP; commercial contracts relating to medical technology and IP licensing

**Languages.** English, German, Italian, Turkish, Albanian, Dutch


global.practicallaw.com/lifesciences-mjg
**Annemiek Kooy**

Axon Lawyers  
**T** +31 88 650 6500  
**F** +31 88 650 6555  
**E** Annemiek.Kooy@axonlawyers.com  
**W** www.axonlawyers.com

**Professional qualifications.** Groningen University, 2002; LLM, King’s College London.

**Areas of practice.** IP, specifically patent, trade mark, trade name, domain names, design right and copyright litigation; licensing, cooperation and non-disclosure agreements in national and international matters; SPCs and regulatory proceedings regarding marketing authorisations for medicinal products.