GETTING THE DEAL THROUGH

Pharmaceutical Antitrust

The application of competition regulation in 29 jurisdictions worldwide

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GLOBAL COMPETITION REVIEW

Netherlands

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products?

The Dutch rules on the authorisation and marketing of medicinal products are set down in the Medicinal Products Act (MPA), which contains, inter alia, the implementation of the review of the Community Code:

- Regulation EC/726/2004 on the authorisation and supervision of medicinal products, establishing a European Medicines Agency;
- Directive 2004/27/EC on the Community Code relating to medicinal products for human use; and
- Directive 2004/24/EC on traditional herbal medicinal products.

Under this Act, all medicinal products (except for pharmacists' preparations, investigational medicinal products and products for compassionate use) must obtain a marketing authorisation before they can be marketed in the Netherlands and all manufacturing (except for pharmacist's preparations) and distribution of such products must be based on a valid licence.

The rules on the setting of maximum prices are set out in the Medicine Pricing Act.

The rules on reimbursement of medicinal products, maximum reimbursement rates, the conditions for reimbursement and the Medicinal Product Reimbursement System, are set out in the Health Care Insurance Act.

2 Which body or bodies are entrusted with enforcing these regulatory rules?

A variety of regulators is entrusted with applying and enforcing these rules:

- the Medicines Evaluation Board is an independent administrative body that is responsible for granting, rejecting and revoking Dutch marketing authorisations for medicinal products for human use, and for approval of the SmPC, labelling and patient information leaflet. It is also responsible for pharmacovigilance and determining the supply status of medicinal products. (Under the centralised EU market authorisation system, these powers are exercised by the Committee for Medicinal Products for Human Use (CHMP) of the European Agency for the Evaluation of Medical Products (EMEA));
- the minister of public health, welfare and sports is responsible for setting maximum prices and reimbursement rates;
- Farmatec, an agency of the Ministry of Public Health, Welfare and Sports, is responsible for granting manufacturing and wholesale licences; and
- the Health Care Inspectorate is responsible for enforcing compliance with the licensing system referred to in question 1.

3 Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

The legislation referred to above does not relate to the application of competition law. Sector-specific competition rules for the health-care sector are set out in the Health Care Market Regulation Act (HMRA). The regulator entrusted with the enforcement of these rules is the Dutch Health Care Authority (NZa).

4 Which laws govern the entry or approval of generic drugs?

The approval of generic drugs is governed by the Medicinal Products Act, which implements Directive 2001/83/EC, as amended.

Generic drugs can enter the market when the intellectual property rights owned by the innovator as well as the regulatory data protection provided for in the MPA have lapsed and when they have received a Netherlands or EU marketing authorisation.

Competition legislation

5 Which legislation sets out competition law?

Dutch competition law is set out in the Competition Act (DCA), which entered into force on 1 January 1998 and is closely modelled after EC competition law rules. The Dutch competition regulator is the Dutch Competition Authority (NMa), which is an autonomous administrative body.

The DCA contains provisions that are the domestic equivalents of the EC competition rules:

- article 6 of the DCA contains the equivalent of the cartel prohibition provided for in article 81 of the EC Treaty, with the difference that no impact on interstate trade is required and that reference is made to the national market and not to the EC market. Article 6(3) of the DCA provides for a legal exception with direct effect identical to that found in article 81(3) of the EC Treaty; there is no provision for requesting an administrative exemption in individual cases;
- articles 12 and 13 of the DCA provide that all EC Block Exemption Regulations apply by operation of law to situations which are governed by article 6 of the DCA;
- article 24 of the DCA contains the equivalent of the abuse prohibition set out in article 82 of the EC Treaty, again with the difference that no impact on interstate trade is required

and that reference is made to the national market and not to the EC market; and
- articles 27ff of the DCA contain a merger control system akin to that provided for in the EC Merger Regulation.

Pursuant to settled case law, the interpretation given by the EC courts of concepts of EC competition law is leading for the application of the concomitant concepts of Dutch competition law.

The powers of the NMa in respect of behavioural control (cartel prohibition and dominant abuse prohibition) are limited to ex-post action.

Specific rules for the health care sector are set down in the HMRA (see questions 3, 8 and 10). This Act provides, inter alia, for ex-ante measures to be taken where the NZa finds that competition in the context of health-care provision contracts must be stimulated; or an undertaking has significant market power in a health-care market.

6 Are there guidelines on the application of competition law that are directly relevant to the pharmaceutical sector?

The NMa has published specific guidelines on the application of the DCA to the health-care sector, the 2007 Health Care Sector Guidelines. These rules do not give specific guidance to the pharmaceutical sector, but illustrate how the cartel prohibition, the abuse prohibition and the merger control system set out in the DCA are to be applied in the health-care sector. Some examples relate specifically to dealings between pharmacists, wholesalers and health care insurance companies.

The NZa has published policy guidelines on how it intends to apply its powers pursuant to the HMRA to impose ex-ante measures in case of significant market power, namely the Health Care Significant Market Power Policy Guidelines.

7 Which authorities investigate and decide upon pharmaceutical mergers and the anti-competitive effect of certain conduct in the pharmaceutical sector?

The NMa is the Dutch regulator responsible for investigating and deciding upon mergers relating to all industries, including the pharmaceutical sector.

The following transactions qualify as concentrations within the meaning of the DCA:
- two or more previously independent undertakings merge;
- one or more undertakings acquire direct or indirect control of the whole or parts of one or more other undertakings; or
- a joint venture is established that performs on a lasting basis all the functions of an autonomous economic entity.

Unless a concentration must be notified to the European Commission pursuant to the EC Merger Regulation, it must be notified to the NMa if, in the previous calendar year:
- the aggregate worldwide turnover of all undertakings concerned exceeds €113.45 million; and
- the individual turnover in the Netherlands of each of at least two of the undertakings concerned exceeds €30 million.

Notification of concentrations meeting these thresholds is mandatory and a standstill obligation applies until the NMa has given clearance or four weeks have lapsed following notification, without the NMa taking action. The DCA does not require that an agreement be signed or that a controlling interest be acquired prior to notification: a concrete intention to undertake a transaction, set out in a letter of intent, heads of agreement or memorandum of understanding is sufficient.

Similarly to the EC merger control rules, the DCA provides for a two-phase procedure. In first phase, the NMa has four weeks from the day following notification to decide whether a second phase is required or whether it can clear in first phase. To initiate the second phase, the parties concerned must submit a separate application. The NMa must then decide within 13 weeks whether it wants to block the transaction, clear it, or clear it with remedies.

Pursuant to an administrative agreement between the NMa and the NZa, the NMa shall consult the NZa when reviewing mergers that involve undertakings that are active in one or more health-care sectors.

The NMa is also the regulator for general behavioural competition law and therefore enforces the prohibitions of articles 6 (cartels) and 24 (dominance abuse) of the DCA. These powers are exercised ex post.

The NZa is the sector-specific regulator (see question 3). It can impose ex-ante remedies where it finds that competition in the context of health care provision contracts must be stimulated; or an undertaking has significant market power in a health-care market. No cartels or abuses need to be proven for these powers to apply: their aim is to ensure fair market conditions ex ante in markets that are in transition.

See question 10 for the division of powers between the NMa and the NZa.

8 What remedies can competition authorities impose for anti-competitive conduct or agreements by pharmaceutical companies?

Under its powers of enforcement under the DCA and Regulation (EC) 1/2003, the NMa can impose administrative fines for infringements of the cartel and abuse prohibitions in the DCA and in articles 81 and 82 of the EC Treaty. These fines can reach €450,000 or 10 per cent of the aggregate worldwide turnover of the undertaking concerned in the preceding calendar year, whichever is higher.

The NMa also has powers to impose personal fines of up to €450,000 on directors or de facto managers responsible for infringements of the cartel or abuse prohibitions.

The NMa can also impose orders with the threat of periodic penalty payments in case of non-compliance. Both remedies can be imposed for the same offence. Such orders cannot apply for more than two years.

Finally, the NMa can impose orders without the threat of periodic penalty payments. If such an order is not complied with, the NMa must take a separate decision imposing fines.

If immediate action is required in the interest of the undertakings affected by an infringement or with the aim of preserving actual competition, the NMa can impose a provisional order with the threat of periodic penalty payment, pending its main enquiry.

The NMa's decisional practice in the pharmaceutical sector is relatively limited.

In 2002, the NMa imposed fines of €9.7 million and €250,000 on two wholesalers of veterinary medicinal products for maintaining a policy of refusing to supply to veterinarians acting as wholesalers. The NMa also imposed cease-and-desist orders on both companies.

In 2003, the NMa imposed a cease-and-desist order on pharmacists in the town of Assen who had set up a network for the sharing of patient data for the purposes of an outside-of-business-hours replacement scheme, but who had excluded access to that

network during normal opening hours.

In 2004, the NMa imposed a cease-and-desist order on pharmacists in the town of Tilburg who had agreed to set up and operate on a joint basis a hospital pharmacy with outpatient capacity, thereby restricting competition between themselves and a hospital pharmacy that would have been set up by a third party.

In these cases involving pharmacists, the NMa decided not to impose fines because competition in the pharmacy market was new and there was little experience with the application of competition law in that sector.

Under the HMRA, the NZa has powers to impose ex-ante remedies where it finds that: competition in the context of health-care provision contracts must be stimulated; or that an undertaking has significant market power on a health-care market. The remedies in case of significant market power include information obligations, non-discrimination obligations, the untying of tied health-care services, third-party access to facilities, the keeping of separate accounts for specific services and the use of specific rate-setting systems.

If these remedies are not complied with, the NZa can:

- apply administrative coercion;
- impose an order with the threat of periodic penalty payments; or
- impose fines up to a maximum of €0.5 million or 10 per cent of the Dutch turnover of the undertaking concerned in the preceding calendar year, whichever is higher.

To date, these powers have not been exercised in the pharmaceutical sector.

9 Do private parties have competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and through which means can they be obtained?

Remedies are available under Dutch civil law, which is laid down in the Dutch Civil Code (DCC).

The cartel and abuse prohibitions contained in the DCA and in the EC Treaty have direct effect. Private parties can therefore initiate legal proceedings to obtain injunctive relief (pursuant to article 3:296 of the DCC) or to recover damages. Actions for damages are based on article 6:162 of the DCC (unlawful act) or article 6:212 of the DCC (undue enrichment). Punitive damages are not provided for.

Parties to an anti-competitive agreement can also initiate civil procedures to obtain a declaratory judgment to the effect that such agreement is null and void. Pursuant to article 3:41 of the DCC, an agreement can be partially null and void.

The use of civil proceedings is being encouraged by the minister of economic affairs and the NMa, in line with similar promotion at EC level.

In cases concerning civil enforcement, the burden of proof rests with the claimant unless any special rule or the requirement for reasonableness and fairness prescribes otherwise.

Article 3:305a of the DCC provides for class actions but its practical relevance in respect of claims based on infringements of the DCA is limited as these class actions cannot be used to obtain damages.

A new instrument for civil enforcement is provided for by the Class Action Financial Settlement Act, which entered into force on 27 July 2005. Pursuant to this Act, article 7:907 of the DCC provides for a system whereby collective settlement agreements between infringers and foundations or associations acting on behalf of claimants can be declared collectively binding by the Amsterdam Court of Appeal, with a possibility for individual claimants to opt out within a period with a minimum of three months from the date of publication of the judgment concerned. There is, to date, only limited experience with the application of this system in cases involving infringements of competition law.

In the last few years, damages have been awarded in respect of the infringement of the cartel prohibition in the construction sector and in the pin payments sector, in damage proceedings initiated by individual parties.

An alternative open to parties harmed by anti-competitive conduct is to file a complaint with the NZa or the NMa, asking for injunctive relief or for measures in main proceedings.

10 Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation distinct from the general competition rules?

As set out in question 7, the NMa is the regulator for general competition law while the NZa is the sector-specific market regulator for the health-care sector.

The powers of the NMa and the NZa overlap in the field of unilateral conduct in the health-care sector, where the NZa is entitled to take ex ante measures in case of significant market power, even in the absence of abusive behaviour, and the NMa is entitled to take ex post measures in case of the abuse of dominance.

The NMa and the NZa have therefore entered into a protocol providing that where such overlap occurs, they aim at letting the NZa exercise its powers before the NMa exercises its own powers. That protocol also provides that the NZa will follow the NMa's interpretation of concepts that are common to the DCA and the HMRA, such as significant market power and the definition of the relevant market.

11 Can antitrust concerns be addressed with industrial-policy type arguments, such as strengthening the local or regional research and development activities?

As far as mergers are concerned, only competition issues are relevant in the NMa's review process.

The same applies for the NMa's assessment of behavioural cases.

The minister of economic affairs can override an NMa decision to block a concentration for general interest reasons, but these powers have not been exercised to date.

12 Do non-government groups address antitrust concerns relating to the pharmaceutical sector?

No.

Review of mergers

13 To what extent are the sector-specific features of the pharmaceutical industry taken into account when reviewing mergers between two pharmaceutical companies?

There are no special guidelines for assessing concentrations involving undertakings in the pharmaceutical industry. As in other concentration cases, the assessment revolves around the definition of the affected markets and the identification of the effects of the intended concentration on these markets. Just like in any other industry, this assessment will of course focus on the specific aspects of the pharmaceutical industry.

There are no precedents in which concentrations involving pharmaceutical companies have been reviewed by the NMa. The only Dutch concentration control cases to date involving companies in the pharmaceutical sector are concentrations between wholesalers on the one hand and wholesalers or pharmacist chains on the other hand. In all cases concerned, the NMa cleared the concentrations on the basis of low market shares alone.

In these cases, the NMa took a specific aspect of the sector into account when determining the amount of the wholesalers' turnover to be taken into account when assessing whether the jurisdictional thresholds for mandatory notification to the NMa are met. It took the view that, for the purposes of said thresholds, the discounts that wholesalers generally offer on the official wholesale price may be deducted from the wholesalers' overall turnover. The wholesalers' relevant turnover therefore was 15 to 20 per cent lower than their overall turnover (see question 7 for the turnover thresholds).

14 How are product markets and geographic markets typically defined in the pharmaceutical sector?

The NMa follows the European Commission's Notice on the definition of the relevant market and the European Commission's decisional practice in defining relevant markets in both behavioural and merger cases.

It therefore identifies relevant product markets for each level 3 class of the World Health Organizations's Anatomical Therapeutic Chemical (ATC) classification system. In addition, it refers to the classes of the system used in the Netherlands to set down reimbursement rates for medicinal products, the Medicinal Product Reimbursement System.

The geographic dimension of these product markets is always delineated at national level.

15 In what circumstances will a product and geographical overlap between two merging parties be considered problematic?

The statutory test for the assessment of mergers is identical to that provided for in the EC Merger Regulation: the NMa must assess whether a concentration significantly impedes effective competition in the Dutch market, or part of it, in particular as a result of the creation or strengthening of a dominant position.

As under the EC Merger Regulation, this test therefore covers all competition issues raised by mergers, including unilateral, coordinated, vertical and conglomerate effects, taking into account the European Commission's Guidelines on horizontal and on non-horizontal concentrations.

Circumstances that the NMa takes into account when assessing the unilateral effects of a horizontal concentration therefore include:

- market shares and market concentration, expressed in terms of the Herfindahl-Hirschman Index;
- whether the parties are each other's closest competitors;
- switching costs;
- capacity constraints;
- whether the parties can impede the growth of competitors; and
- whether either one of the parties was a maverick premerger.

The assessment of coordinated effects includes the following elements:

- an increased incentive or ability to coordinate;
- the ability to monitor deviant behaviour;
- the ability to punish such behaviour; and
- the inability of outsiders to render coordination ineffective.

The European Commission's approach is also followed in respect of potential competition. The NMa will examine anti-competitive effects involving a potential competitor where that competitor possesses assets that could easily be used to enter the market without incurring significant sunk costs or is very likely to incur the necessary sunk costs to enter the market in a relatively short period of time. The NMa will only block a merger on the basis of potential competition where:

- the potential competitor already exerts a significant constraining influence or is likely to grow into an effective competitive force; and
- there is no sufficient number of other potential competitors which could maintain sufficient competitive pressure after the merger.

Please also refer to the chapter on EC competition law.

16 When is an overlap with respect to pipeline products likely to be problematic?

Pipeline products are treated as sources of potential competition. See question 15 for how the NMa is likely to deal with potential competition.

17 Which remedies will typically be required to resolve any issues that have been identified?

Remedies can be offered in first and second phase. They can only be offered in first phase, however, if the competition concerns are clear and if it is certain that the remedies will remove this problem.

On 21 September 2007, the NMa published new guidelines setting out its policy for remedies, both in terms of substance and procedure. By and large, these guidelines correspond to the European Commission's Remedies Notice. The NMa guidelines distinguish between:

- structural remedies, involving the divestment of a company or assets of either the purchaser or the target to an upfront third party buyer;
- behavioural remedies, such as guarantees in relation to:
  - third-party access to specific facilities;
  - fair, non discriminatory and objective pricing; and
  - arm's-length operation of certain integrated facilities; and
- quasi-structural remedies, such as the grant of a sole licence to another undertaking with regard to a certain essential technology or facility.

18 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Similarly to the situation obtaining under the EC Merger Regulation, assets can qualify as an 'undertaking' within the meaning of the DCA's merger control rules if specific turnover is attributable to these assets. In this vein, transfers of account portfolios in the banking and insurance sector have been treated as concentrations within the meaning of the DCA's merger control rules, regardless of whether they also involved the transfer of personnel or tangible assets. Although there are no precedents under the Dutch merger control rules, the same analysis could apply with regard to patents or licences.

Anti-competitive agreements

19 What is the general framework for assessing whether an agreement or practice can be considered anti-competitive?

Pursuant to article 6 of the DCA (which, as noted above, is equivalent to article 81 of the EC Treaty, with the difference that there is no requirement relating to an effect on interstate trade and that reference is made to the national market instead of the EC market), agreements, trade association decisions and concerted practices are prohibited if they have as their object or effect the appreciable restriction of competition on the whole or a part of the Dutch market.

This prohibition covers all types of restrictive behaviour, whether horizontal or vertical. Although article 6 of the DCA does not provide specific examples of restrictive clauses, it covers the same type of behaviour as article 81 of the EC Treaty, such as price fixing, output limitation, market sharing, tying, etc.

Aside from the EC Block Exemption Regulations, which apply mutatis mutandis under article 6 of the DCA, article 6(3) of the DCA provides for a legal exception with direct effect similar to that contained in article 81(3) of the EC Treaty. Since 1 August 2004, there is no provision for requesting administrative exemptions.

There are also two de minimis exemptions, provided for in article 7 of the DCA, for:

- agreements between a maximum of eight undertakings with a maximum combined turnover of €5.5 million (in case of goods) or €1.1 million (in case of services); and
- agreements between undertakings with a maximum combined market share of 5 per cent and a maximum combined turnover of €40 million.

20 Have there been cartel investigations into the pharmaceutical sector?

In 1998, the NMa investigated a stock management system applied by Merck Sharp & Dohme, following a complaint filed by wholesaler Euromedica. In its 2002 decision (upheld on administrative appeal), the NMa applied the reasoning developed in the ECJ joined cases C-2/01 P and C-3/01 P *Adalat* [2004] ECR I-23 in holding that the stock management system did not infringe article 6 of the DCA because it was enforced unilaterally without having to rely on the co-operation of clients.

In 2003, the NMa initiated an inquiry into the pricing behaviour of generic producers and wholesalers on the Dutch market. Company inspections were carried out in January 2004. In August 2006, the NMa closed the case and stated that it had not found sufficient evidence of an infringement.

Please refer to question 8 for further examples relating to veterinary medicinal products wholesalers and pharmacies.

21 To what extent are technology licensing agreements considered to be anti-competitive?

As indicated above, the EC Block Exemption Regulation on technology transfer agreements (TTBER) and the corresponding European Commission Guidelines (TT Guidelines) apply under article 6 of the DCA.

Agreements that qualify as technology transfer agreements within the meaning of article 1(b) of the TTBER and that involve parties that have a combined market share below 20 per cent where the parties compete on the product or technology markets concerned or individual market shares below 30 per cent where the parties do not compete, are block exempted, except if they contain a hard-core restriction listed in article 4 of the TTBER.

The TT Guidelines provide guidance for those technology transfer agreements that are not exempted, dealing with the following issues that may be problematic from a competition law point of view:

- royalty obligations;
- exclusive licensing and sales restrictions;
- output restrictions;
- field-of-use restrictions;
- captive-use restrictions;
- tying and bundling; and
- non-compete obligations.

Please also refer to the chapter on EC competition law.

22 To what extent are co-promotion and co-marketing agreements considered to be anti-competitive?

As indicated above, the EC Block Exemption Regulations on specialisation agreements and on R&D agreements and the corresponding European Commission Guidelines on horizontal cooperation apply under article 6 of the DCA.

Where co-promotion and co-marketing follow from an R&D agreement or from a specialisation or joint-production agreement within the meaning of these block exemptions, it can benefit from these exemptions. Where such cooperation is agreed upon separately or in agreements that are not block exempted, it must be analysed separately.

- Cooperation between non-competitors will usually not be restrictive of competition.
- Cooperation between competitors will be problematic from a competition point of view if it leads, inter alia, to price fixing, the exchange of sensitive commercial information, the commonality of a major cost component or market sharing.

Please also refer to the chapter on EC competition law.

23 When is an agreement with a competitor (actual or potential) likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

Agreements between competitors can be exempted pursuant to an EC Block Exemption Regulation, pursuant to the EC De Minimis Notice or pursuant to the de minimis rules contained in article 7 of the DCA (see question 19).

If they are not exempted under these rules, agreements between competitors must be analysed individually. Such agreements will always lead to competition concerns if they lead, inter alia, to price fixing, output restriction, market sharing, tying or the exchange of commercially sensitive information.

Please also refer to the chapter on EC competition law.

24 Which aspects of vertical agreements are most likely to raise antitrust concerns?

As indicated above, the EC Block Exemption Regulations on vertical agreements and the European Commission Guidelines on vertical agreements apply under article 6 of the DCA.

Problematic aspects would be retail price maintenance, territorial restrictions, end user sales restrictions and cross-supplies restrictions in a selective distribution system and exclusive supply or exclusive purchase clauses that last for longer than five years.

Dual-pricing systems relating to pharmaceutical products would be qualified as territorial restrictions and would have to

be analysed individually under articles 6(3) of the DCA and article 81(3) of the EC Treaty along the lines of CFI case T-168/01 *GlaxoSmithKline* [2006] ECR II-2969.

In 2002, the NMa rejected an exemption request filed by AstraZeneca in respect of distribution agreements providing for a special rebate for medicinal products sold to intramural patients, with a prohibition to distribute the products concerned to extramural patients or to parties likely to distribute to such patients. (Until 1 August 2004, article 17 of the DCA provided for an individual administrative exemption system, which was replaced on that date by the current legal exception system of article 6(3), akin to that existing under article 81(3) of the EC Treaty.) In rejecting the application, the NMa took the view that that restriction did not have pro-competitive effects offsetting its restrictive effects.

Please also refer to the chapter on EC competition law.

Anti-competitive unilateral conduct

25 In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

Article 24 of the DCA contains an abuse prohibition identical to that contained in article 82 of the EC Treaty, with the difference that there is no requirement relating to an effect on interstate trade and that reference is made to the national market instead of the EC market.

The concept of abuse under article 24 of the DCA is therefore identical to that under article 82 of the EC Treaty and includes excessive pricing, output restrictions, discrimination, tying and bundling, predatory pricing, rebate systems, refusal to supply essential facilities, price squeeze, etc.

Pending the outcome of the European Commission's article 82 review procedure, the European Commission's December 2005 discussion paper on exclusionary abuses under article 82 is currently used as a guideline under article 24 of the DCA.

Please also refer to the chapter on EC competition law.

26 When is a party likely to be considered dominant or jointly dominant?

Dominance within the meaning of article 24 of the DCA is defined in article 1(i) of the DCA in terms identical to those developed by the ECJ in its *United Brands* case law: a dominant position exists where the undertaking concerned is in a position of economic strength that enables it to prevent effective competition being maintained on the relevant market by giving it the power to behave to an appreciable extent independently of its competitors, its customers and, ultimately, consumers.

The dominance test described in paragraph 4 of the European Commission's December 2005 discussion paper (see previous question) applies. It focuses on market shares, barriers to expansion and entry and the market position of buyers.

Where market shares are above 50 per cent, there is a rebuttable presumption that the undertaking concerned is dominant. With market shares below 50 per cent, additional elements must be furnished to make a finding of dominance.

The ECJ case law on joint dominance applies. Under that case law, two or more undertakings have joint dominance where:

- they have the ability to monitor deviant behaviour;
- they have the ability to punish such behaviour; and
- outsiders are not able to render coordination ineffective.

Please also refer to the chapter on EC competition law.

27 Can a patent holder be dominant simply on account of the patent that it holds?

The ECJ case law derived from ECJ case 78/70 *Deutsche Grammophon* [1971] ECR 487 applies under article 24 of the DCA.

According to this case law, a patent holder may be considered dominant if it holds a patent that is essential for the manufacturing of a medicinal product that has a high market share (usually more than 50 per cent) within a certain level 3 ATC class.

Please also refer to the chapter on EC competition law.

28 To what extent can the application for the acquisition of a patent expose the patent owner to liability for an antitrust violation?

The case law developed in CFI case T-51/89 *Tetra Pak I* [1990] ECR II-309 applies under article 24 of the DCA.

According to this case law, the acquisition by a dominant undertaking of an exclusive patent licence for a new industrial process constitutes an abuse of a dominant position where it has the effect of strengthening the undertaking's already very considerable dominance of a market where very little competition is found and of preventing, or at least considerably delaying, the entry of a new competitor into that market, since it has the practical effect of precluding all competition in the relevant market.

There are no precedents for the application of this case law in the Netherlands.

Please also refer to the chapter on EC competition law.

29 To what extent can the enforcement of a patent expose the patent owner to liability for an antitrust violation?

The case law developed in the ECJ's and the CFI's *Volvo*, *Magill*, *Bronner*, *IMS Health* and *Microsoft* cases applies under article 24 of the DCA.

According to this case law, the refusal to licence or the enforcement of an IP right cannot in itself constitute an abuse because it forms the very subject-matter of the exclusive right. The exercise of such a right may however, in exceptional circumstances, involve abusive conduct. A refusal to licence will give rise to such an abuse, in the absence of an objective justification, if the following conditions are met:

- the refusal relates to a product or service indispensable to the exercise of a particular activity on a neighbouring market;
- the refusal is of such a kind as to exclude any effective competition on that neighbouring market; and
- the refusal prevents the appearance of a new product for which there is potential consumer demand.

This case law was applied by the NMa in a case involving the licensing of TV programme listings to a newspaper for a weekly TV supplement. The NMa's finding that these listings had to be licensed was quashed on appeal before the Trade and Industry Appeals Tribunal because such a supplement was not found to constitute a new product within the meaning of said case law.

Please also refer to the chapter on EC competition law.

30 To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

The TTBER and the TT Guidelines apply under article 6 of the DCA.

Settlement agreements involving a licence can be block exempted under the TTBER if they comply with the requirements of that exemption. Non-challenge clauses are block exempted if they are limited to the ability, on the part of the licensor, to end

Update and trends

In light of the fact that concentrations in the health-care sector may lead to competition concerns despite relatively low turnovers, the Ministry of Economic Affairs is preparing an implementing decree whereby the turnover thresholds for mandatory notification of an intended concentration are lowered in respect of concentrations where at least two of the undertakings concerned generated turnover in excess of €5.5 million in the health-care sector in the preceding calendar year. According to the proposal which has been tabled by the Ministry, such concentrations will have to be notified to the NMa if, in the preceding calendar year:

- the aggregate worldwide turnover of all undertakings concerned exceeds €55 million; and
- the individual turnover in the Netherlands of each of at least two of the undertakings concerned exceeds €10 million.

Another hot topic is the bargaining power of individual pharmacists vis-à-vis health-care insurance companies.

In response to a complaint filed by the Dutch Society of Physiotherapists against a series of health-care insurance companies, the NMa has held in various decisions taken in autumn 2005 (upheld upon administrative appeal) that, in light of the fact that the public health-care insurance system has recently been replaced by a system of private health insurance with a compulsory statutory standard package, the health-care markets are still in a state of flux and it would therefore only interfere in the contractual relations between health-care providers and health-care insurance companies in case of gross infringements. The NMa went on to hold that the bargaining behaviour of the insurance companies concerned, such as the refusal to bargain individually with physiotherapists, the tying of servicing for the compulsory standard package with servicing for additional packages, low compensation rates and a narrow spread between the lowest and the highest compensation, did not constitute abusive behaviour in the current state of the market. A similar analysis applies where individual pharmacists are concerned.

In response to that decision, various groups of individual health-care practitioners have asked the minister of economic affairs to raise the thresholds set down in article 7 of the DCA for application of the DCA's two de minimis exemptions (see question 19 for these thresholds). The Minister has recently indicated that it would not raise these thresholds, because such a raise would be incompatible with EC competition law.

the licence in the event that a licensee challenges the validity of a licensed right.

Paragraphs 204ff of the European Commission's TT Guidelines apply where such agreements are not block exempted.

Settlement agreements between parties that are not competitors due to blocking positions derived from their patents do not normally restrict competition, provided the patent rights concerned are valid.

Agreements whereby the parties cross-license each other and impose restrictions on the use of their technologies, including restrictions on the licensing to third parties, may be caught by article 6(1) of the DCA and article 81(1) of the EC Treaty. Where the parties have a significant degree of market power and the agreement imposes restrictions that clearly go beyond what is required in order to unblock, the agreement is likely to be caught by these articles even if it is likely that a mutual blocking position exists. The cartel prohibition is particularly likely to apply where the parties share markets or fix reciprocal running royalties that have a significant impact on market price.

Please also refer to the chapter on EC competition law.

31 To what extent can certain life-cycle management strategies expose the patent owner to liability for an antitrust violation?

The practice developed in the European Commission's 15 July 2005 *AstraZeneca* decision applies under article 24 of the DCA.

In that case, the European Commission found that AstraZeneca had abused its dominant position on the Omeprazole market by implementing a strategy of selectively withdrawing its Losec capsule products, replacing them with Losec tablets and requesting the deregistration of the marketing authorisation for capsules in various countries, thereby blocking or delaying market access for generic versions of Losec and preventing parallel

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imports of Losec.

An appeal has been lodged against that decision by AstraZeneca, but judgment in that case, which has been registered as case T-321/05, is still pending.

There are no precedents in the Netherlands for the application of competition law to life-cycle management strategies.

Please also refer to the chapter on EC competition law.

32 Does the practice of authorised generics raise issues under the competition law?

EC competition rules on the abuse of dominance apply mutatis mutandis under article 24 of the DCA.

Where an originator manufacturer is dominant within a certain level 3 ATC class, the non-discrimination rules of the abuse prohibition apply and the manufacturer granting access to facilities necessary for generic authorisation must do so under reasonable, objective and non discriminatory terms.

Please also refer to the chapter on EC competition law.

33 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise be infringing antitrust rules?

As indicated above, the case law of the ECJ and EC CFI and the European Commission's decisional practice apply mutatis mutandis under Dutch competition rules.

It follows that the approach followed in the CFI judgment in case T-168/01 *GlaxoSmithKline* [2006] ECR II-2969 (on dual pricing systems under article 81 of the EC Treaty), by AG Jacobs in his 28 October 2004 opinion in case C-53/03 *Syfait* and by AG Ruiz-Jarabo Colomer in his 1 April 2008 opinion in joined cases C-486/06 to C-478/09 *Sot Lélos kai Sia* (on stock management systems implemented by dominant undertakings under article 82 of the EC Treaty), where the specific features of the pharmaceutical sector were taken into account, apply.

Please also refer to the chapter on EC competition law.