Chapter [●]

Netherlands

Cees Jan de Boer and Maria Geilmann

Cees Jan de Boer
Van Doorne Advocaten, Amsterdam
E-Mail: BoerC@vandoorne.com

Maria Geilmann
Van Doorne Advocaten, Amsterdam
E-Mail: Geilmann@vandoorne.com

1 Introduction

The pharmaceutical sector has been the subject of many discussions in Dutch politics over the past few years. These discussions are largely due to the increasing amount of expensive, new pharmaceuticals entering the market and the strain this puts on the Dutch healthcare budget. A report published by the Dutch Cancer Society estimates that costs for pharmaceuticals have tripled between 2003 and 2013, to a large extent due to a five-fold increase in spending on expensive new forms of cancer treatment.[1] A more recent report shows that hospital expenditure on expensive anti-cancer pharmaceuticals is still increasing by approximately 10% each year in the Netherlands.[2] Also, recent research suggests that procurement prices for certain expensive pharmaceuticals are approximately 20% higher in the Netherlands than in (certain) other EU countries.[3] This increases the pressure on the affordability of healthcare in general, with the risk of disadvantaging patients with other needs.

The Dutch Minister of Health, Welfare and Sport has concluded that her current policies on pharmaceuticals, which have been used successfully in the past to control expenditure, may no longer suffice in the (very) near future.[4] She is now actively pursuing new policies and adopting these in close communication with health insurers, hospitals, pharmaceutical companies and relevant Dutch authorities, to ensure accessibility and affordability of pharmaceuticals. It will come as no surprise that a vast amount of these new policies focus on expensive (cancer) medicines. As a highlight, on 8 September 2016 the Minister gave EUR 2,8 million to an innovative foundation, *Stichting Fair Medicine,* whose purpose it is to make medicine prices more transparent and produce cheaper medicines for a number of important treatments.[5]

Against this background there have also been interesting developments in the application of Dutch competition rules in the pharmaceutical sector and in the policy approach of the Netherlands Authority for Consumers & Markets, the *Autoriteit Consument en Markt* (hereinafter "the ACM").

This report will highlight these developments by, firstly, providing an overview of the relevant Dutch legislation on pharmaceuticals and market organisation (Section 2). Following this overview, the market definitions developed by the ACM specifically in the pharmaceutical sector will be analysed (Section 3). Consequently, the application of the Dutch Competition Act (hereinafter "DCA") on these markets will be discussed as regards abuse of a dominant position (Section 4), cartels (Section 5) and mergers (Section 6) respectively. In these parts

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[1] Dutch Cancer Society, Toegankelijkheid van dure kankergeneesmiddelen nu en in de toekomst *("*Accessibility of expensive cancer treatment now and in the future"), June 2014, to be found at https://www.kwf.nl/SiteCollectionDocuments/SCK%20rapport%20Toegankelijkheid%20van%20dure%20kankergeneesmiddelen.pdf, p. 22-23.

[2] Dutch Cancer Society, Effective new anti-cancer drugs, but the funding system is creaking at the seams. *Obstacles to, and solutions for, the use of expensive anti-cancer drugs.* July 2015, to be found at https://www.kwf.nl/SiteCollectionDocuments/english-summary-signalingreport-expensive-cancermedication.pdf.

[3] Harten, van W., Wind, A., Paoli, de P., Saghatchian, M., Oberst, S., Actual costs of cancer drugs in 15 European countries, Lancet Oncology, 3 December 2015, to be found at www.thelancet.com/oncology.

[4] Communication from the Minister of Healthcare to the Dutch parliament of 29 January 20016, reference 8994567-145972-GMT.

[5] See the press release on the Dutch government website from 8 September 2016: https://www.rijksoverheid.nl/actueel/nieuws/2016/09/08/schippers-steunt-ontwikkeling-goedkopere-medicijnen.

it will be discussed how the application of the DCA has been affected by the specific characteristics of pharmaceutical products and markets, before concluding on this discussion with some recommendations (Section 7).

2 Regulation Pharmaceuticals and Healthcare in the Netherlands

2 . 1 Dutch Medicines Act

The Dutch Medicines Act (*Geneesmiddelenwet*) is the implementation of Directive 2001/83/EC[6] and provides the framework for the 'life-cycle' of pharmaceuticals. Manufacturers and wholesale companies each require a permit to produce and trade pharmaceuticals.[7] Also, no product may be brought into the market within the internal market unless a marketing authorisation has been granted for this product, either by the European Union authorities based on Regulation 726/2004[8] and/or Regulation 1394/2007[9], or by the Dutch Medicines Evaluation Board (hereinafter "MEB").[10] The Healthcare Inspectorate, a department of the Dutch Ministry of Health, Welfare and Sport, is in charge of enforcement.[11] The inspectorate can recall, confiscate and (temporarily) prohibit the sale of pharmaceuticals, for instance by closing down pharmacies. Fines may be imposed if necessary.

Pharmaceuticals are placed in one of four categories, (i) prescription only, (ii) pharmacy only, (iii) pharmacy & general drug store and (iv) freely obtainable.[12] Prescribing (prescription only) pharmaceuticals is reserved for medical doctors and dentists.[13] Under certain conditions, nurses and midwives may also fill in prescriptions.

2 . 2 Dutch Healthcare Market Regulation Act

The Dutch Healthcare Market Regulation Act (*Wet Marktordening Gezondheidszorg*) has established the Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*, hereinafter "NZa"). The NZa is responsible for organising, developing and supervising healthcare markets in the Netherlands.[14] To enable the NZa to perform these tasks, the NZa has the competence to define specific products and set prices[15] for the products.[16]

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[6] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ 2001, L 311, p. 67.

[7] Dutch Medicines Act, chapter 3.

[8] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ 2004, L 136, p. 1.

[9] Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004OJ 2007, 324, p. 121.

[10] Dutch Medicines Act, chapter 4.

[11] Ibid., chapter 11.

[12] Ibid., chapters 5 and 6, implementing articles 70 et seq. of Directive 2001/83/EC.

[13] Section 36 subsection 14 of the Dutch Individual Healthcare Professions Act (*Wet op de beroepen in de individuele gezondheidszorg*).

[14] Dutch Healthcare Market Regulation Act, section 16.

[15] The NZa can set different types of prices, for instance a fixed price, maximum price or minimum price.

[16] Dutch Healthcare Market Regulation Act, chapter 4.4.

Non-hospital pharmaceutical care, i.e. care obtained by the patient directly from pharmacies, is in principle exempted from product and price regulation by the NZa.[17] However, product and price regulation does apply to pharmaceutical care that is a part of another type of healthcare, most notably administration of pharmaceuticals as a part of hospital care and care in nursing homes.

The product and price regulation for hospital care is of particular importance. Hospitals in the Netherlands can only send invoices for products which followed the procedure of diagnosis and treatment (called *DBC-zorgproducten* or *DOT's*).[18] This system is loosely based on the American diagnosis-related-groups (DRG's). The Dutch system uses approximately 3,000 unique products to describe (almost) every possible procedure a hospital might offer.

The definition of each procedure includes regular pharmaceutical treatment that is (or should be) part of good (hospital) healthcare. Expensive pharmaceuticals, however, are not included because of the (possible) distortive effects on the price for each procedure. Instead they can be recorded and invoiced separately as an "add-on" to a procedure.[19]

Since 2012, for approximately 80% of Dutch hospital care products the NZa has not set mandatory or maximum prices. Therefore, healthcare providers and health insurers are free to negotiate any price for the procedures falling within this 80%. A maximum price has been set for the remaining 20% of hospital care, giving healthcare providers and health insurers freedom to negotiate any price not exceeding that maximum.

The same system of maximum prices applies to the aforementioned add-ons relating to expensive pharmaceuticals. The maximum price for each add-on is set annually by the NZa based on the lowest pharmacy purchase price (*apotheekinkoopprijs* or AIP).[20] The NZa bases the AIP on an online database holding pricing data provided by pharmaceutical companies.

2 . 3 Dutch Act on the Prices of Medicines

The Dutch Medicines Prices Act (*Wet Geneesmiddelenprijzen)* authorises the Dutch Minster of Health, Welfare and Sport to set maximum prices for certain pharmaceuticals if deemed necessary for the public accessibility of this pharmaceutical.[21] For the purpose of this Medicines Prices Act, pharmaceuticals are grouped by similar pharmaceuticals with the same active components and the same or similar efficacy. The Dutch Council of State

[17] Decree on expansion and restriction of the scope of the Dutch Healthcare Market Regulation Act (*Besluit uitbreiding en beperking werkingssfeer WMG*) section 3, subsection 1 under a.

[18] NZa policy rule on products and tariffs for medical specialist care (*Beleidsregels Prestaties en Tarieven Medisch Specialistische Zorg*). The most recent version of which, valid in 2016, has reference BR/CU-2147.

[19] Ibid.

[20] Ibid.

[21] Dutch Medicines Prices Act, section 2 subsection 1.

(*Raad van State*), which is the Supreme Court on administrative law in this case, has established that such groups within the meaning of the Act can also consist of biosimilars.[22]

A maximum price for a (group of) pharmaceutical(s) is determined by comparing the average accepted prices as set per unit in Belgium, Germany, France and the United Kingdom.[23] If, in accordance with this comparison, a maximum price is set, then it is subsequently prohibited to offer, sell or distribute this (group of) pharmaceutical(s) to healthcare providers, including pharmacies and hospitals[24], or to patients for a price higher than the set maximum price.[25]

2.4 Dutch Healthcare Insurance Act

The Dutch Healthcare Insurance Act (*Zorgverzekeringswet)* stipulates that all residents of the Netherlands are obliged to have health insurance.[26] This insurance covers a basic healthcare package (*basispakket*), including pharmaceutical care. Annually, the exact content of this package will be determined by the Dutch Minister of Health, Welfare and Sport based on what is considered to be regular healthcare according to scientific knowledge and/or in practice.[27] The entitlement to pharmaceutical care and reimbursement of costs incurred for it is described per pharmaceutical product in a ministerial decree; otherwise referred to as the medicine reimbursement system (*geneesmiddelenvergoedingsysteem*).[28]

The ministerial decree regulating the entitlement to pharmaceutical care distinguishes between two types of pharmaceuticals: those that are interchangeable with other pharmaceuticals (unique products and generics) and those that are not (per definition unique products). Pharmaceuticals are deemed interchangeable if they have a similar application, can be administered the same way and are in general intended for the same age group.[29] Pharmaceuticals that are deemed interchangeable are placed on annex 1A of the ministerial decree. Per (sub)group of pharmaceuticals an average price will be calculated, which in turn provides for the limit of reimbursement under the healthcare insurance.[30] In general this limit is equal to or near to the lowest priced pharmaceutical(s) in each (sub)group.[31]

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[22] Dutch Council of State, judgment of 15 August 2012, ECLI:NL:RVS:2012:BX4645 (*Pfizer/Dutch State).*

[23] Dutch Medicines Prices Act, section 2 subsection 2.

[24] Dutch Parliamentary Papers (*Kamerstukken*), 1994-1995, 24266, 3, p. 28.

[25] Dutch Medicines Prices Act, sections 4 and 5.

[26] Dutch Health Insurance Act, section 2.

[27] Decree on the Dutch Health Insurance Act, chapter 2.

[28] Ministerial decree on the Dutch Health Insurance Act, section 2.5.

[29] Ibid., section 2.40.

[30] Prices of parallel imports are excluded from this calculation pursuant to section 2.42 sub 3 of the Ministerial decree on the Dutch Health Insurance Act.

[31] Ministerial decree on the Dutch Health Insurance Act, section 2.43 – 2.48.

If a pharmaceutical is deemed not to be interchangeable, then it will be placed on annex 1B if it is (also) part of the basic healthcare package. For the pharmaceuticals on this annex B, no limit for reimbursement has been set.[32] It will therefore come as no surprise that case law concerning the issue of whether or not a pharmaceutical product is interchangeable is readily available.

In order to guarantee availability of certain basic pharmaceuticals, health insurers are required to designate at least one pharmaceutical per active substance, i.e. per (sub)group on annex 1A, for which a patient can receive reimbursement under the basic health insurance package.[33] When designating a pharmaceutical, the health insurer only has to look at the active substance and can disregard dosage, forms of administering and brand/label. Health insurers require pharmacies to adhere to these designated pharmaceuticals in the standard contracts offered. This is called the preference policy (*preferentiebeleid*). This has been the subject of an interesting dominance case in the Netherlands (Section 4.4).

2.5 Summary

Pharmaceutical markets in the Netherlands are subject to a variety of legislation.

Important regulatory barriers to entry are found (i) in the Dutch Medicines Act which provides the framework for market entry in accordance with the EU directive and (ii) in whether or not a specific pharmaceutical product is reimbursed under the Dutch Healthcare Insurance Act.

Also, if a product is successfully introduced into the market, prices may be regulated or influenced on three levels.

- Firstly, if a product is deemed interchangeable then health insurance will only cover (approximately) the costs of the lowest priced pharmaceutical. Costs in excess of this price will therefore have to be covered by the patient itself.

- Secondly, the Dutch Minister of Health, Welfare and Sport can intervene if necessary to guarantee accessibility to a certain pharmaceutical product and set a maximum price based on the average price in certain (neighbouring) EU countries. Manufacturers and wholesale companies cannot charge prices in excess of this maximum.

- Thirdly, in the case of expensive pharmaceuticals – as defined by the NZa – a maximum is set for the price to be negotiated by healthcare insurers and healthcare providers.

2.6 Policy Developments

[32] Note that this only covers reimbursement. The price of such a pharmaceutical may still be regulated pursuant to the aforementioned Dutch Medicines Prices Act.

[33] Decree on the Dutch Health Insurance Act, section 2.8.

It has been estimated that costs of pharmaceuticals in the Netherlands have decreased by as much as 60% in the past 20 years largely due to the aforementioned legislation.[34]

However, as noted in the introduction, the Dutch Minister of Health, Welfare and Sport estimates that the legislation set out in Sections 2.1 to 2.5 above will no longer suffice in the near future, which is largely due to using expensive cancer treatment exclusively on a small group of patients.

In a recent briefing of the Dutch parliament several measures were proposed to ensure quick access to innovative treatment and lower prices,[35] including amongst others:

a. Considering more flexible market approval procedures;

b. Reforms in the system for reimbursement of pharmaceuticals and for including pharmaceuticals in the basic healthcare package;

c. Providing guidance to market players on possibilities for cooperating in the purchase of pharmaceuticals in conformity with competition law;

d. Various measures designed to improve knowledge and exchange of information on drug therapy, ranging from the patient level to exchange of information between EU Member States. Regarding the exchange of information on pharmaceutical prices between Member States, a pilot project with Belgium and Luxembourg has already been started to that effect, including a pilot on joint negotiations for one pharmaceutical;[36]

e. Imposing conditions on the granting of subsidies for the development of new pharmaceuticals and stimulating measures on the use of biosimilars.

Although these measures have been proposed quite recently, the ACM has already made some progress providing guidance (sub c above). This will be covered hereafter in Section 5. The Dutch Minister of Health, Welfare and Sport has already been experimenting with a new policy on access to the basic healthcare package since 2012. In this policy the Dutch Minister of Health, Welfare and Sport would conclude a financial agreement with the pharmaceutical company, such an agreement being a condition for that (expensive) pharmaceutical product to be covered under the basic healthcare package. This policy has recently been reviewed, mostly favourable.[37]

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[34] See publication of 14 April 2016 in the "Pharmaceutical Weekly", vol. 151, no 15, of the Dutch Association for Healthcare Statistics, to be found online at: https://www.sfk.nl/nieuws-publicaties/PW/2016/vanaf-april-weer-lagere-geneesmiddelprijzen.

[35] See footnote 4.

[36] Dutch Parliamentary Papers, *Kamerstukken II 2015-2016, 29477, p. 358.*

[37] Dutch Parliamentary Papers, annex to *Kamerstukken II, 2015–2016, 34 300 XVI, p. 153.*

Also of particular note is the fact that the Minister has introduced a so-called *lock-chamber* system last year. In this system, expensive pharmaceuticals are at first explicitly *excluded* from the basic healthcare package (i.e. placed in the *lock chamber*) if their potential costs are predicted to be very high. Within this *lock chamber,* the expensive pharmaceuticals await further expert advice on whether or not they should be added to the basic healthcare package.[38] The Minister has indicated that this policy will be expanded and even suggests the *lock chamber* may be used to enable health insurers and healthcare providers jointly or independently to negotiate (better) prices before allowing coverage under the basic health care package.[39] This kind of policy would mean a significant intervention from the State in negotiations otherwise governed by private law. It will be interesting to see whether the Minister will actually implement this policy and if so, how.

3 Definitions of Relevant Markets in the Pharmaceutical Sector

3 . 1 Introduction

In general, the ACM keeps a close eye on the approach taken by the European Commission concerning market definitions. Two important cases in which the ACM investigated the pharmaceuticals market were the *AstraZeneca* case,[40] concerning an alleged investigation into abuse of a dominant position, and the *Brocacef - Mediq* case,[41] an investigation within the first phase of the proposed merger of these two parties. The market definitions and considerations of the ACM will be presented on the basis of these two cases.

3 . 2 Geographical Market

In the *AstraZeneca* case, concerning an alleged abuse of a dominant position under article 24 DCA, being the Dutch equivalent of article 102 TFEU, the ACM considered the relevant geographical market as the national pharmaceuticals market.[42] Furthermore, the ACM aligned its position with the position of the Commission in previous decisions, including the *Hoffmann La Roche*[43] and *Solvay* cases[44]. This conclusion is based on the fact that the sale of pharmaceutical products is strongly dependent on national administrative procedures and regulations. Furthermore, the Member States exhibit great differences in packaging, branding and distribution of pharmaceuticals. According to the ACM, the geographical market for production and distribution of pharmaceuticals is therefore limited to the Netherlands.[45]

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[38] Nivolumab was the first pharmaceutical to be placed in the *lock chamber*. See Parliamentary Papers, *Kamerstukken II 2015-2016, 29477, p. 343 and 357.*

[39] Dutch Parliamentary Papers, *Kamerstukken II 2015-2016, 29477, 358, p. 14*.

[40] Decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca)*.

[41] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*).

[42] Decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca)*, para. 269.

[43] Commission decision in case IV/M.950 of 4 February 1998 (*Hoffmann La Roche/Boehringer Mannheim),* para. 15-17.

[44] Commission decision in case COMP/M5661 of 11 February 2010 (*Abbott/Solvay Pharmaceuticals)*, para. 13.

[45] Decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca)*, para. 2 and 269.

In the *Brocacef - Mediq* case, the ACM distinguishes three different product markets for each of which it concludes on the geographical market.[46] The ACM has not delimited the retail market of pharmacies ,as it is irrelevant for establishing whether this is a national or a local market. For the wholesale market, which the ACM considers a national market, it is based on its own research and the submissions of the parties. With regard to the pre-wholesale market, the parties in this case argued that competition between logistic services for pharmaceuticals takes place at national level and the ACM seemed to have concurred with those arguments. Finally, however, the ACM considers that, in line with Commission decisions,[47] the pre-wholesale market is at least a national market, but possibly a wider market.

3 . 3 Relevant Product Markets

3 . 3 . 1 *AstraZeneca*

AstraZeneca is an example of how the ACM determines the relevant product market for the sale of pharmaceuticals. This case concerned the market for gastric acid blockers. At the time of the decision, the market for this type of pharmaceutical consisted of the AstraZeneca product, called Nexium, and generic pharmaceuticals.[48]

Most pharmaceuticals, like Nexium in this particular case, show special characteristics, which in theory would make it possible to identify separate markets for them. In determining the relevant market, the ACM specifically paid attention to the delineation of the product market in light of the special characteristics of gastric acid blockers in general, and Nexium in particular. The first question that needed to be answered was whether Nexium actually belonged to the same product market as other, generic gastric acid blockers. In other words, the substitutability of Nexium for other generic gastric acid blockers in relation to their different purchasers had to be examined.[49]

In its assessment the ACM took the market for gastric acid blockers in general as the relevant product market. However, in line with the Commission Notice on the definition of the relevant market, the ACM distinguished two separate product markets for the different purchasers.[50] A distinction was made between the extramural and the intramural market for gastric acid blockers. In examining the clearly distinguishable groups of Nexium purchasers and the various prices for the same product on both markets, the ACM came to this conclusion due to the fact that the legal context, competitive situation and the factors that restrain the behaviour of undertakings on both markets were too different to influence each other in case of price differences on both markets.[51]

The Intramural Market

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[46] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*), para. 45-48.

[47] Commission decision in case COMP/M6044 of 16 December 2010 *(Alliance Boots/Andreae-Noris Zahn),* para. 12.

[48] Decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca),* para. 270.

[49] Ibid., para. 271.

[50] Ibid., para. 274-277.

[51] Ibid., para. 278.

Apart from Nexium, four other gastric acid blockers have been sold on the intramural market. According to the ACM, there have been no institutional or structural obstacles hindering these products from freely competing with each other. In their procurement decision, hospitals take the quality, as well as the price of a gastric acid blocker into account. This means that the manufacturers of gastric acid blockers are competing on all relevant aspects on the intramural market. However, Nexium, not being a generic product, was still taking advantage of its time as a patented product, which resulted in certain *endorsement effects*.[52] These endorsement effects also had effects on another, separate product market for Nexium, the extramural market.

The Extramural Market

The ACM investigated whether a separate market for the users of Nexium could be established within the extramural market for acid gastric blockers. The circumstances under consideration for this delimitation were Nexium's former protection by its patent, the endorsement effects and the Dutch reimbursement system which results in a low price sensitivity of prescribers and consumers.[53] During its investigation the ACM had based its theory of harm on the conclusion of the preliminary report, especially concerning the possible results of the endorsement effect. According to the report, patients who were prescribed Nexium on the intramural level, would tend to continue using Nexium after they left the hospital, whereby Nexium was given an advantage on the extramural market. However, in its decision, ACM could not prove that there was a separate product market for Nexium users who had been influenced by the endorsement effect on the intramural market. ACM had, based on the submissions of AstraZeneca, too many doubts to conclude that Nexium users were bound by the endorsement effect in such a way that this would justify establishing separate markets for Nexium and generic products (read more on this in Section 4).[54]

3.3.2 *Brocacef - Mediq*

On 13 July 2016 the ACM published its decision on the proposed acquisition by Brocacef of the pharmacies and wholesale activities of the Dutch pharmacy chain Mediq. The ACM declared that this merger could only be approved subject to strict conditions.[55]

Both Brocacef and Mediq run wholesale operations, supplying pharmacies, hospitals and care institutions with pharmaceutical products such as prescription drugs. Both of them also own a large number of wholesale pharmacies and related pharmacies (franchise and partners) in the Netherlands. Furthermore, both Brocacef and Mediq are wholesalers in the field of pharmaceutical products and distribute these to pharmacies, hospitals and healthcare providers. In this decision, the ACM made detailed observations concerning the relevant markets.

Product Market

[52] Ibid., para. 279-83.

[53] Ibid., para. 299-303.

[54] Decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca)*, para. 299-303.

[55] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*).

The ACM identified three different relevant product markets, namely the retail market, the wholesale market and the pre-wholesale market. Within some of these markets, the ACM also defined sub-markets.

Retail Market

The retail market in this case was the market for products and services for public pharmacies. For the first time, the ACM made a subdivision in the type of pharmacy in addition to the division of products to be sold.[56]

ACM concluded that the market had to be subdivided into, as regards the type of pharmacy, (i) regular pharmacies, (ii) polyclinic pharmacies and (iii) self-dispensing general practitioners. With regard to the type of product, the ACM distinguishes between (i) the provision of prescribed medication, (ii) the provision of medical devices and (iii) the provision of over-the-counter (**"OTC"**) pharmaceuticals. The market for OTC-pharmaceuticals is a very restricted market with high legislative entry-barriers, as has also been confirmed in the *Holland Pharma - FACO* case.[57]

What is interesting in this case, is that according to the ACM, internet pharmacies are still not part of the retail market on products and services by public pharmacies as they do not emanate from competitive pressure in practice.[58] This is due to the fact that purchasing pharmaceuticals via an internet pharmacy is not yet common in the Netherlands, as some of the pharmaceuticals are not suited for dispatching (e.g. medicines which require storage in a cool place) and the market share of internet pharmacies is still quite low. Also, the Dutch Medicines Act stipulates that pharmaceuticals can only be prescribed if the prescriber has met the patient face-to-face at least once.[59] It is likely that patients will visit (or are referred to) a local, brick-and-mortar pharmacy after visiting the prescriber. Finally, the network of pharmacies is very dense in the Netherlands and many patients feel a need for a brick-and-mortar pharmacy as these are increasingly acquiring a bigger, general role in offering healthcare in addition to simply offering pharmaceutical products.[60]

Overall, the ACM focuses on the market for retail of prescribed pharmaceuticals by pharmacies since such prescribed pharmaceuticals make up more than 90% of the profit of pharmacies.

Wholesale Market

With regard to the wholesale market, the ACM had strong indications in this case to decide that there was a different market for wholesalers supplying to hospitals and wholesalers supplying to extramural customers. This is in essence the same division as can be found in the *AstraZeneca* case. The ACM finds that within the

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[56] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*), following the decisions in case no. 15.0484.22 of 23 July 2015 (*Brocacef/Mediq*), para. 43-46, NMa of 23 November 2010, 6989 (*Brocacef - Lloyds Nederland)*, para. 12; decision of the NMa of 31 July 2010, 5691 (*Brocacef Holding - Viafarma)*, para 12 and decision of the NMA of 13 May 2001, 2451 (*Mediveen - TPP en Coriopharma)*, para 19.

[57] Decision in case no. 16.0062.224 of July 2016 (*Holland Pharma/Faco*), para. 82.

[58] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*), para. 34 - 42.

[59] Dutch Medicines Act, article 67.

[60] Ibid., para. 38 - 40.

wholesale market, further sub-markets can be distinguished: (i) a market for wholesale supply in medical products and services to hospitals and (ii) a market for wholesale supply in medical products and services to extramural customers.[61]

However, the ACM did not differentiate the market into the two categories of wholesalers. Instead the ACM divided the market by (i) products and services and (ii) categories of customers.[62]

With regard to (i) products and services, the ACM concluded that there is one market for pharmaceutical wholesale, which does not require further subdivision.[63] Brocacef and Mediq had argued in this decision that there is one market for wholesale as customers want the supply of both products and services and that even additional services have been integrated in the wholesale market.

With regard to (ii) the types of customers, the ACM developed the market differentiation made in the case *AstraZeneca*,[64] by distinguishing between intramural customers, extramural customers and, building on that, other healthcare institutions.[65]

The investigation in *Brocacef/Mediq* has shown that for wholesale activities the supply of pharmaceuticals to hospitals differs significantly from the supply to extramural customers. The first reason regards the difference in the supply requirements, for example hospitals demand certain packaging and service. Furthermore, a wholesaler has to be able to deliver certain services which support the hospital in whatever way, for example, a wholesaler for hospitals should have a program which monitors cost analysis/logistics and can respond to the direct needs of hospitals.[66]

Another reason regards the difference in the supply distribution models, as there are two different distribution models. Hospitals conclude contracts with pharmaceutical manufacturers themselves for a large number of products. The hospital then enters into a so-called distribution agreement with a wholesaler of their choice. The wholesaler will then deliver the agreed products (i) for the price as agreed in the contract with the pharmaceutical manufacturer, (ii) for a compensation for the distribution of the manufacturer to the wholesaler and (iii) for a compensation of the hospital to the wholesaler. In the second distribution model the wholesaler negotiates the purchase price with the manufacturer. The hospital then buys the products from the stock of the wholesaler, either for a price which has been determined by the wholesaler or which the hospital has negotiated with the wholesaler. While hospitals use both of them, extramural customers – such as pharmacies - only use this latter model.[67]

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[61] Decision in case no. 15.0484.22 of 23 July 2015 (*Brocacef/Mediq*), para. 28.

[62] Ibid., para. 29-35.

[63] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*), para. 206.

[64] See section 3.3.1. above and decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca),* para. 273 ff.

[65] Decision in case no. 15.0484.22 of 23 July 2015 (*Brocacef/Mediq*), para. 29.

[66] Ibid., para 31-34.

[67] Ibid., para 32.

Furthermore, only three out of five full lined wholesalers supply hospitals in the Netherlands. Competitors on this market mentioned that the investments a wholesaler needs to make in order to be able to supply hospitals are big and the margins too low.[68]

Considering all of the above, the ACM decided that there are important differences regarding the supply to hospitals and the supply to extramural customers.

Finally, the investigation of the market parties (competitors) and the answers from the parties indicated that there are also differences regarding the supply to other healthcare institutions than hospitals. The ACM intends to investigate at a later stadium whether there is a different market for the supply of wholesalers to other healthcare institutions.[69]

Pre-Wholesale Market

Pre-wholesale services are essentially the provision of logistic services to manufacturers of pharmaceutical products. These are services such as storage and distribution to wholesalers, pharmacies and hospitals. Pre-wholesale services can be distinguished from regular wholesalers by the fact that they do not become the owner of the pharmaceutical products they deliver (which would be the case with a regular wholesaler). Also, pre-wholesalers provide their services only to pharmaceutical companies and have to have special knowledge in the area of transport of pharmaceuticals.[70]

In this regard, the European Commission already indicated this separate market.[71] The parties followed the European Commission, and so does the ACM. Therefore, in this case, the ACM considers pre-wholesale services a different product market.[72]

3 . 4 Conclusion on Market Definitions

With regard to the geographical market, there are no indications that the market for pharmaceutical products and their sale and distribution is broader than the national market. With regard to the product markets, both *AstraZeneca* and *Brocacef - Mediq* show that the intramural and extramural markets are clearly separate due to their different characteristics. The *AstraZeneca* case highlights the difficulties of further subdividing a market where the market for one pharmaceutical product is concerned; this raises the technical question of whether certain pharmaceutical products can be substituted in view of their therapeutic qualities and the users readiness to switch. This kind of problem does not arise in *Brocacef - Mediq*, where the market division relates to the sale and distribution of pharmaceutical products as a whole.

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[68] Ibid., para 35.

[69] Ibid., para 38.

[70] Decision in case no. 15.0484.22 of 23 July 2015 (*Brocacef/Mediq*), para. 39-41.

[71] European Commission, decision of 16 December 2010, COMP/M.6044 (*Alliance Boots / Andreae - Noris Zahn)*, para. 9.

[72] Decision in case no. 15.0484.22 of 23 July 2015 (*Brocacef/Mediq*), para. 41.

4 Abuse of a Dominant Position under Article 102 TFEU and/or Article 24 DCA

4.1 Introduction

It should be noted at the outset that the number of investigations, decisions and case law where abuse of a dominant position was successfully established under Dutch law is very low, as well as for the separate regime for dominant positions in Dutch healthcare. However, several observations can be made. It is also noteworthy that the Dutch healthcare legislation provides for an additional regime on dominant positions in addition to the equivalent of article 102 TFEU in article 24 DCA, namely the concept of significant market power, which will be discussed here first.

4.2 The Concept of "Significant Market Power" in the Dutch Healthcare Market

Article 47 et seq. of the Dutch Healthcare Market Regulation Act provides the NZa with the authority to intervene if one or more health care providers or health insurers has significant market power (*aanmerkelijke marktmacht*).[73] Significant market power is defined as the ability to – alone or conjointly – restrict the development of the actual competition on the Dutch market or a part thereof as a result of the possibility to act independently from (i) its competitors, (ii) health insurers, if it's a health care provider, (iii) health care providers and (iv) consumers. It is important to note that the legal definition of significant market power does not require abuse of this position.

Significant market power is a rebuttal assumption for parties with a market share of 55% or more. The NZa defines the relevant market in accordance with the guidelines of the Commission. If the market share is between 40% and 55% significant market power is deemed plausible and between 25% and 40% it is considered a possibility. Below 25% significant market power is considered implausible.[74]

The mere existence of significant market power is sufficient for the NZa to exercise its powers.[75] The NZa has a wide range of legal powers and can, amongst other things, oblige parties with significant market power to enter into fair and reasonable contracts, require parties to provide information to interested third parties and impose methods for calculating prices. The first case in which the NZa has exercised its powers concerned a pharmacy in a remote region of the Netherlands and will be covered further on in Section 4.4. First we shall cover relevant developments under 102 TFEU and 24 DCA in the Netherlands.

4.3 The *AstraZeneca* Decision of the ACM

[73] A system comparable to the instruments introduced in the Directive 2002/21/EC of the European Parliament and of the Council of 7 March 2002 on a common regulatory framework for electronic communications networks and services (Framework Directive), *OJ* L 108, 24 April 2002, p. 33.

[74] Parliamentary proceedings on the Dutch Healthcare Market Regulation Act (*Kamerstukken II, 2004/2005, 30186, nr. 3*).

[75] A legislative proposal has been sent to the Dutch parliament to transfer these powers to the ACM per 1 January 2017 (*Kamerstukken II, 2015/2016, 34445,* p. 2).

In 2011, the ACM published a preliminary report in which it established the presumption that AstraZeneca was abusing its dominant position. [76] As stated previously, this case concerned the market for gastric acid blockers. At the time of the decision, the market for this type of pharmaceutical consisted of the product of on the one hand AstraZeneca, called Nexium, which contains esomeprazole, and on the other hand generic pharmaceuticals, based on omeprazole. AstraZeneca has been distributing Nexium to hospitals as well as pharmacies. The prices it offered to hospitals were much lower and even beneath the cost price, than those offered to pharmacies (the price offered to hospitals was about 90% lower than the one offered to pharmacies). In spite of the low prices it applied to hospitals, AstraZeneca was able to compensate its losses with its high prices for Nexium distributed to pharmacies.[77] However, in the final decision, after nearly four years of investigation, it could not be established, as the ACM emphasised, that AstraZeneca had infringed article 24 DCA.

Concerning the factual research of the case, the preliminary report presumed that the reason why AstraZeneca kept the prices low for hospitals was that there was an *endorsement effect* of Nexium. If medical specialists prescribed a pharmaceutical in a hospital, later on it would be prescribed outside the hospital again since patients have a tendency not to switch pharmaceuticals and doctors continue to prescribe brands that patients have already used before. Therefore, it would be advantageous to AstraZeneca to have higher sales through hospitals so that patients will be committed to Nexium afterwards.[78]

AstraZeneca offered extensive argumentation against the conclusions of the preliminary report. AstraZeneca contested especially the conclusion that the sales of Nexium beneath cost price were the reason why the growth of sales of generic blockers has been less successful than would normally be expected. AstraZeneca submitted several reasons that could have been responsible for this.[79] This argument was successful; AstraZeneca was able to convince the ACM that for example the therapeutic differences between Nexium and the generic medicines could have been a factor in the development of generic medicine manufacturers on the market. Furthermore, AstraZeneca argued successfully that other generic products based on pantozole could also have an influence on the pharmaceutical market prices.[80]

Therefore, when the ACM assessed the market position of AstraZeneca, it concluded that AstraZeneca did not have a dominant position on the intramural market, where it had a market share below 30%. In the separate, extramural market, looking at the arguments of AstraZeneca, the ACM in the end did not give an assessment on the question in which way certain factors had led to the higher price level of gastric acid blocker than might have been expected with the introduction and availability of generic blockers. The ACM did not have enough evidence to conclude that Nexium users were committed to Nexium by its endorsement effect to such an extent that AstraZeneca could behave independently on the market in the sense of article 24 DCA and 102 TFEU. As a

[76] Decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca*).

[77] Ibid., para. 40.

[78] Ibid., para. 34-43.

[79] Decision in case no. 7069 of 2 December 2014 (1832) (*AstraZeneca*), para. 288-298.

[80] Ibid., para. 308-309.

consequence, the ACM could not establish that there was a separate market for users of Nexium and that AstraZeneca would have had a dominant position on such a market.[81]

In the view of the ACM, it reached the limits of the application of competition law rules in this case; in their view, the rules of competition law could not stop the pricing strategy of AstraZeneca.[82] In its report on pharmaceutical markets the ACM also takes the view that the question of what the added value and therapeutic qualities of pharmaceutical medicines is, would have to be investigated rather by a patent office and that the instruments of competition law are "not the most suitable" to assess this.[83] This explains that the ACM did in the end abstain from a definite assessment of whether AstraZeneca had a dominant position or not, it only stated that it could not prove such a position.

In conclusion, this case demonstrates that the technical complexities of pharmaceutical products can get in the way of investigations by competition authorities. It appears the ACM was not ready to assess the technical challenges brought forward by the pharmaceutical company on the substitutability, therapeutic effects and the patients behaviour of switching products. In this regard the decision is disappointing as the ACM neither assesses nor provides guidance on the substitutability of this brand product and the generic alternatives, nor does it (as no dominant position has been found) give a legal assessment of the commercial behaviour and pricing strategy of AstraZeneca.

4 . 4 The *Breskens* Case[84] on Significant Market Power

Even though the NZa receives at least a hundred complaints relating to significant market power each year, the NZa has taken only two decisions on average per year since 2011, mostly decisions not to intervene.[85] Partially this might be due to the fact that the NZa considers significant market power of health insurers desirable. The NZa assumes that, if the Dutch health insurance market functions adequately, health insurers will pass on profits gained to consumers.[86] The NZa will therefore not start a formal investigation for (most) complaints by healthcare providers against health insurers.

The first major investigation instigated by the NZa on significant market power followed a complaint of a Dutch health insurer, Menzis, against a healthcare provider. A local pharmacy refused to enter into a contract with

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[81] Ibid., para. 308-314.

[82] See the ACM, *Farmacie onder de loep*, February 2015, to be found online at: https://www.acm.nl/nl/download/publicatie/?id=13893, p. 17 and comment by the ACM's president for consumer issues, Anita Vegter, during a presentation at the UNCTAD roundtable, " Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers - The Netherlands", to be found at http://unctad.org/meetings/en/Presentation/CCPB_7RC2015_RTPharma_NethSTAT_en.pdf, p. 3.

[83] See the ACM, *Farmacie onder de loep*, February 2015, to be found online at: https://www.acm.nl/nl/download/publicatie/?id=13893, p. 18.

[84] Decision no. 11D000515 of the NZa of 22 February 2011 *(Menzis/Apotheek Van Dalen)*.

[85] The NZa publishes reports on its activities, the last of which is *Jaarrapportage Signaaltoezicht 2013*.

[86] Commentary by the NZa on its policy rule on significant market power (*Toelichting op de beleidsregel Aanmerkelijke marktmacht in de Zorg*, p 23-24). The ACM shares this view that market power is desirable if profits are passed on to consumers (*Richtsnoeren voor de Zorgsector (2010), 104*).

Menzis. The contract in question concerned the basis for the health insurer's preferential policy (see 2.4). Menzis complained that in and around the village of Breskens it could not fulfil its legal obligation to procure sufficient health care for its customers[87] or at least not on terms and conditions similar to the rest of the Netherlands. The pharmacy was the only one in Breskens, a village in a remote area in the southeast of the Netherlands near the Belgian border. Residents of Breskens in general would not (or could not) receive their pharmaceuticals anywhere else than at this pharmacy. Because of this, the NZa concluded that the pharmacy had a significant market power.

In its decision the NZa imposed an obligation on the pharmacy to enter into the contract offered by Menzis containing the preferential policy. This decision was the subject of various legal proceedings, and eventually (mostly) upheld by the Trade and Industry Appeals Tribunal (*College van beroep voor het bedrijfsleven*, hereinafter "CBb").[88] Amongst the various objections raised by the pharmacy, one is of particular interest. The pharmacy argued that trade between Member States was affected by the behaviour of the pharmacy on the relevant market as defined by the NZa and that therefore article 102 TFEU would have to be applied. In that situation the NZa could then not exercise its powers. However, the Dutch Minister of Health, Welfare and Sport had stated during the parliamentary discussions concerning the Dutch Healthcare Market Organisation Act that article 3(2) of Regulation 1/2003[89] does not prohibit stricter national laws in the Netherlands and that therefore the powers of the NZa are in accordance with EU law.[90]

The CBb dismissed the objections of the pharmacy on the basis that trade between Member States was not affected. The CBb based its decision that trade between Member States was not affected on the fact that the complaint concerned a contractual relationship between a Dutch health insurer and a Dutch pharmacy.[91] Also, research provided by the NZa showed that patients in general did not seem to travel across the Dutch-Belgian border to purchase pharmaceuticals.[92] The question whether the NZa can investigate and exercise its powers concerning significant market power in situations where trade between Member States is affected remains unanswered.

In a hypothetical scenario where the CBb would have ruled that trade between Member States has been affected[93], it could have dismissed the argument of the pharmacy on the basis that the problems with significant market power arose from unilateral conduct of the pharmacy and thus in accordance with article 3(2) of Regulation 1/2003. However, even with this outcome it should be noted that article 47 of the Dutch Healthcare

[87] Dutch Healthcare Insurance Act, article 11.

[88] *College van Beroep voor het bedrijfsleven*, 7 June 2012, ECLI:NL:CBB:2012:BW7731.

[89] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, Official Journal L 1, 4 January 2003, p. 1.

[90] Dutch parliamentary proceedings (*Kamerstukken II 2004/05, 30 186, nr. 8, p. 40*).

[91] Which is in accordance with Commission Notice - Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, para 91 (2004/C 101/07).

[92] See footnote 88 and sections 3.3 and 6.3.2 of this report.

[93] For instance because evidence was provided on foreseeable market developments in the region or increasing market shares of internet pharmacies, which could constitute a potential effect on trade between Member States. See commission notice in footnote 91 para 43.

Market Regulation Act concerning significant market power also provides that healthcare providers and/or health insurers can have conjoint significant market power. Such joint significant market power would then probably not profit from the exemption in the last sentence of article 3(2) of Regulation 1/2003 and fall within the scope of the prohibition to implement stricter rules than in article 101 TFEU, as stipulated in the first part of article 3(2) of Regulation 1/2003.

This leads us to the conclusion that the Dutch regime on significant market power in healthcare might be vulnerable in situations of conjoint significant market power where trade between member states is (potentially) affected. Because of the (very) low number of investigations up until now, this has not (yet) been the subject of NZa decisions and/or case law.

5 Agreements, Restrictions and Collusion under 101 TFEU and/or 6 DCA

5 . 1 Introduction

There have not been any (published) decisions of the ACM or the Dutch courts concerning 101 TFEU and/or its Dutch equivalent in article 6 DCA, in pharmaceutical markets. That does not mean that the ACM is not interested in these markets. On the contrary, in February 2015 it published a report on the current state of pharmaceutical markets and the possibilities to intervene.[94]

5 . 2 The ACM Report on Pharmaceutical Markets (*Farmacie onder de loep*)

In the introduction of the report the ACM explicitly states that pharmaceutical companies have, amongst other things, hindered generics from entering markets by prolonging market exclusivity and influencing prescribers. The ACM bases this conclusion on investigations and decisions by the European Commission and the Federal Trade Commission in the United States of America.[95] However, no concrete competition law investigations or decisions are available in this regard in the Netherlands. This does not prevent the ACM from concluding that such market behaviour is undesirable because it leads to higher prices for consumers.

These restrictions should, according to the ACM, be properly addressed by competition law or other means. The ACM also states, however, that competition law is unable to contest all practices and that some restraint needs to be exercised. For instance, competition law should not limit behaviour that - ultimately - leads to innovation. But it is not always clear where market exclusivity to protect innovation ends and *evergreening* to artificially boost earnings – resulting in higher costs for consumers - begins.

In the report, the ACM suggests two other - non competition law - solutions for high costs related to pharmaceuticals and removing the stimuli for brand manufacturers to employ harmful strategies. The most interesting suggestion of these two is to change the way in which pharmaceuticals are added to the primary

[94] ACM, *Farmacie onder de loep*, February 2015, to be found online at: https://www.acm.nl/nl/download/publicatie/?id=13893.

[95] The ACM for instance refers to the decisions of the European Commission, decision of 19 June 2013 in case COMP/AT. 39226 (*Lundbeck*) and decision of 9 July 2014, case COMP/AT. 39612 (*Servier*). ACM also refers to the case *FTC v. Actavis*, Inc. 570 U.S. 2013 by the US Federal Trade Commission, for its conclusion that generics have been prohibited to enter markets.

healthcare package. If the added therapeutic value of pharmaceutical products were to be taken into account in this, then the incentive of *evergreening*, by developing more "me-too" pharmaceuticals[96], could be lowered according to the ACM. This could in turn result in higher investments by pharmaceutical companies in wholly new pharmaceuticals with added therapeutic value.

It can be pointed out here of course that these are two big "ifs". Firstly, the proposal does not distinguish between potentially undesirable effects of *evergreening* and the benefits gained by further developing existing medicines, such as for instance the ease of use for consumers or less dependence on cooled storage. Secondly, even if the incentive to develop "me-too" pharmaceuticals were lowered, that does not necessarily mean that investment in new pharmaceuticals will increase. Presumably, the ACM is of the same opinion as it suggests further research into this question should such a strategy as suggested by it be implemented.

In summary the report makes two things clear. Firstly**,** even though (successful) intervention by the ACM is not yet a reality, the ACM is keeping a close eye on pharmaceutical markets in the Netherlands. Secondly, the ACM suggests that competition law alone is not the solution to all perceived problems on these markets.

5 . 3 Prices and Joint Purchasing

Following its report, the ACM recently published its Guidelines on the joint purchase of pharmaceuticals for hospital care.[97] The purpose of the guideline is to offer a safe haven for certain forms of joint purchase and describe the way the ACM assesses these types of agreements. Although in the past the ACM had provided some guidance on this matter, [98] this safe haven for certain joint purchasing agreements is a new policy. The guideline applies to the joint purchase of pharmaceuticals by hospitals and one or more health insurers. The guideline focuses on these parties but leaves the option open for other parties to participate in the joint purchase, such as scientific associations.

In general the ACM does not expect joint purchase agreements concerning medicines for hospital care to have harmful effects on competition. According to the ACM, pharmaceutical companies are (in general) geographically active on a much larger scale than the Dutch market and as such have a strong position as sellers.

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[96] The process in which a manufacturer develops a new pharmaceutical that is only slightly different from an existing pharmaceutical, for instance a slightly different method of administering, in order to obtain a new patent. The goal of this process is to prolong market exclusivity (*evergreening*).

[97] Guidelines for joint purchasing pharmaceuticals ("*Leidraad gezamenlijke inkoop geneesmiddelen voor de medisch specialistische zorg"),* 23 June 2016, to be found at https://www.acm.nl/nl/publicaties/publicatie/15963/Leidraad-gezamenlijke-inkoop-geneesmiddelen--meer-slagkracht-voor-ziekenhuizen-en-zorgverzekeraars/.

[98] See: Informal view of the ACM on joint purchasing by health insurer Achmea of certain expensive pharmaceuticals, 14.0840.15, 24 July 2014 and the ACM guidelines for the health care markets (*Richtsnoeren voor de Zorgsector (2010),* to be found at https://www.acm.nl/nl/publicaties/publicatie/7083/Richtsnoeren-voor-de-zorgsector/).

Also, the total costs of pharmaceuticals for hospitals, although increasing is not so high as to make (anti-competitive) price harmonisation likely. [99]

Based on that assessment, the ACM provides a safe haven if the agreement for joint purchase falls within the following three criteria:

1. The total costs of the jointly purchased pharmaceuticals are limited to 15% of the turnover of each hospital and 5% of the turnover for each health insurer involved.

2. The joint purchasing organisation must be sufficiently accessible for other participants based on transparent, objective and non-discriminatory terms in order to prevent foreclosure. These terms can provide for a certain (quality) standard, for instance a minimum volume, as long as this is fair and reasonable.

3. There may be no unnecessary restrictions (legal or factual) for participants, for instance concerning the duration of the participation, purchasing obligations, restrictions on the purchase of pharmaceuticals outside of the organisation and leaving of the organisation.

The ACM stresses that any information exchange will only be acceptable if it is indispensable for the adequate functioning of the purchase organisation and that measures should be in place to prevent the exchange of commercially sensitive information. Also, the purchase organisation should – of course – not have the object of limiting competition, for instance if the hospitals should (also) agree on how to best negotiate with health insurers on the reimbursement of pharmaceuticals.

It is noteworthy that the ACM thus chooses a different approach form the European Commission's view on joint purchasing agreements where a safe harbour is only provided if the combined market share does not exceed 15%.[100] This implies that parties wanting to use this safe harbour provided by the ACM also need to carefully assess any (potential) effect on trade between Member States beforehand as the conditions posed by the European Commission are different ones.

Outside of the safe harbour the ACM states that it will only interfere if the joint purchasing has harmful effects on competition and the efficiencies of the agreement do not sufficiently outweigh these harmful effects on competition. It is not entirely clear if this is just the ACM explaining the application of section 6 DCA, or whether this is an indication of an additional policy, for example in the form of a commitment to not enforce under certain circumstances.

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[99] Of note is the fact that two members of the Dutch parliament have requested the Dutch parliament to investigate whether the so called "Kiwi-model" could be applied in the Netherlands. The Kiwi-model refers to centralised purchasing of generic pharmaceuticals by New Zealand's government (*Kamerstukken II, vergaderjaar 2015–2016, 29 477, nr. 383*). The outcome of this request is unknown at the time of writing this article.

[100] Communication from the Commission — Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ 2011, C 11 p. 1- 72, recital 208.

The scope of the 'safe harbour' is, however, not as straightforward as it may seem. For instance, the conditions require the costs of the collective procured pharmaceuticals to be monitored continuously in order to establish if the joint collaboration meets the requirements as specified by ACM.

6 Mergers in the Pharmaceutical Sector

6 . 1 The ACM Decisions

As stated before a recent high profile merger case was the first phase investigation of the ACM in Brocacef - Mediq. Before we cover this case a short remark should be made on merger thresholds in the Netherlands, as these can also have an impact on certain downstream pharmaceutical markets.

6 . 2 Thresholds in Dutch Healthcare

In the Netherlands lower merger thresholds apply if healthcare is concerned. Instead of the normal thresholds for Dutch mergers of EUR 150.000.000turnover of the undertakings jointly and at least two with 30 million euro turnover each, lowered thresholds of EUR 55.000.000 euro jointly and EUR 10.000.000 euro each apply. Of this EUR 10.000.000 at least EUR 5.500.000 is required to be health care related.[101]

The ACM has stated in an informal view that these thresholds apply in respect of medical devices only if the undertaking is payed directly by patients or health insurers.[102] In the informal view a supplier of medical devices did not fall under the lower health care thresholds because it delivered its medical devices only to health care providers and not directly to patients.

For the pharmaceutical markets as described before this implies that suppliers who are only active on the upstream markets (wholesale and pre-wholesale) fall within the scope of the normal (Dutch) thresholds. Suppliers active on downstream retail markets will have to deal with the lower thresholds.

6 . 3 Case *Brocacef - Mediq*: Merger Approved Subject to Strict Conditions

On 13 June 2016, after extensive investigation into the proposed merger since July 2015, the ACM decided that Brocacef may, subject to a number of conditions and the sale of 89 pharmacies, take over the pharmacies of the Dutch pharmacy chain Mediq.[103] However, with regard to the wholesale activities of Mediq, the ACM ordered Mediq to sell its wholesale business so that the market would also remain a three-player market in the future.

As described above in section 3.3.2, both Brocacef and Mediq run wholesale and retail operations, supplying pharmacies, hospitals and healthcare institutions with pharmaceutical products such as prescription drugs.

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[101] Based on an administrative decree valid until 1 January 2018 (*Besluit tijdelijke verruiming toepassingsbereik concentratietoezicht op ondernemingen die zorg verlenen*). It is expected that this decree will be renewed.

[102] Informal view of the ACM in case 14.0406.15, 17 July 2013.

[103] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*), to be found at https://www.acm.nl/nl/publicaties/publicatie/15912/Brocacef-mag-onder-strikte-voorwaarden-Mediq-overnemen-eindmededeling/.

Retail to pharmacies

With regard to the market of supply to pharmacies, the ACM concluded on the basis of its investigation that there are 27 municipalities in the Netherlands where Brocacef/Mediq would have obtained such a strong position (more than 50% market share) after the concentration that competition would have been significantly hindered. [104] In these territories the concentration would have led to less choice for the healthcare insurers and consumers. Pharmacies of Brocacef/Mediq would, as a consequence of less local competitive pressure, have had less incentive to meet their quality standards.[105]

The ACM moreover saw a great risk that through the concentration healthcare insurers would have had less room to negotiate prices for products with Brocacef as in some case there would have been be no alternative to Brocacef pharmacies. This could have led to higher prices for healthcare insurers and, through the insurers, for consumers.[106]

With regard to hospitals as buyers on the wholesale market, these have a preference for buying all products, if possible, from one wholesaler. This wholesaler will in many cases also fulfil the role of supporting the hospital in keeping stock records. The ACM concluded that there are currently three companies active on the wholesale market. After the proposed acquisition there would be a reduction from three to two players, resulting in significantly less choice for hospitals. In this regard, Brocacef/Mediq would then have obtained a much too strong position regarding the wholesale market for hospitals and could significantly have raised prices and/or lowered the quality of its services. In order to guarantee competition between wholesalers, a condition for the merger was therefore that Mediq would have to sell its wholesale business (Distrimed) to a third party who was already delivering wholesale services, but not yet to hospitals. Through this condition, after the merger there will still be three participants in the Dutch market for hospital wholesale services.[107]

6 . 4 Market Regulation and the ACM's "Consumer Welfare" Policy

As is apparent from the previous Sections, the Dutch healthcare market is a tightly regulated one. Even on highly regulated markets, the ACM seems to focus on consumer protection rather than on protection of competition as such. This is also apparent under Dutch merger control, as can be seen especially from one recent example.
An interesting example for this is also the recent *KPN/Reggefiber* decision from the ACM[108] and the judgment in appeal of the District court of Rotterdam.[109] In this case, the court confirmed the ACM's decision under Dutch merger control allowing the Dutch telecom giant KPN to obtain sole control over glass fibre provider Reggefiber. The court accepted the conclusion of the ACM that where a market player has to comply with a high level of regulation, including regulation of prices and obligations to allow other parties to offer their services via

[104] Decision in case no. 15.0849.24 of 13 June 2016 (*Brocacef/Mediq*), p. 5.

[105] Ibid., para. 137.

[106] Ibid., para. 167.

[107] Ibid., para. 198-199 en 417-418.

[108] Decision in case no. 14.0672.24 of 6 November 2014 (*KPN/Reggefiber*).

[109] District court of Rotterdam, judgment of 12 May 2016, ECLI:NL:RBROT:2016:3476, *Vodaphonen/KPN and ACM.*

this network, consumer welfare will be safeguarded. In such a market environment the merger will, according to the ACM, not significantly impede effective competition.

In relation to the healthcare and pharmaceutical markets, which are also highly regulated, this leads to the question whether the ACM is of the opinion that legislation such as the Dutch Act on the Prices of Medicines[110] provides additional room for mergers in this sector? The same reasoning could also be applied to cartel cases and abuse of dominance cases brought before the ACM. Which leads to the question of whether there are a lot of (up until now) untapped possibilities in pharmaceutical markets under the DCA. Following the argumentation of the ACM, a reduction of competition will apparently not easily be regarded as significant in these markets.[111]

7 Conclusion and Recommendations

Possibly the most important development in the Netherlands regarding pharmaceuticals is the way in which the new policies of the Dutch Minister of Health, Welfare and Sport are limiting entry into the Dutch market by using the *lock chamber*. In these policies the Minister has taken an active role in trying to reduce prices for pharmaceuticals. All this is characterised by an effort to protect the public budget in an already tightly regulated Dutch pharmaceutical market.

Meanwhile, with regard to agreements and cooperation between pharmaceutical undertakings, the ACM – directed by the same minister – is developing new guidelines to strengthen the position of health insurers and healthcare providers in their negotiations to procure pharmaceutical products. The joint purchasing agreements should, or at the very least could possibly, result in lower prices for pharmaceutical products. In the view of the ACM this will then result in profits for consumers, as they will pay less for their healthcare and/or health insurance. The ACM – and in cases concerning significant market power, the NZa – thus have a strong focus on consumer protection as the primary goal of the competition law enforcement in the healthcare sector.

However, there is always a risk that a market will be foreclosed and loses its competitive elements when it becomes overregulated. While regulation of the market could protect certain rights and prices effectively, the effects of such regulation do not necessarily provide for the integral health of a sector. Regulation is therefore not always the long-term solution. The effect of taking regulation into account as an important pillar to analysing the competition effects of certain measures can also be that this regulation will become indispensable in the future, even where it was actually meant to be limited in time.

Also, the effects on competition in upstream markets should not be disregarded. In this regard, the ACM should consider whether its "consumer welfare" policy does not allow for too much distortion of competition in upstream markets. The pharmaceutical markets should, despite the safeguards of regulation, be monitored carefully to prevent long term harmful effects for pharmaceutical companies who might – for instance - be less

[110] See Section 2.

[111] Remaining objections, for instance relating to refusal to supply, might be addressed with (behavioural) remedies.

inclined to invest in innovative treatment or – in the case of generics – to enter the market after market exclusivity has ended. In other words, the ACM should monitor whether short term financial gains for consumers justify possible long term lessening of innovation and/or competition.

In the case *Brocacef - Mediq,* the ACM has in the end reacted to the concerns for competition when reducing the market from three to two players and has addressed this by safeguarding that after the merger there will still be three players. The case *AstraZeneca* showed that the potential problems of establishing a separate market for a given pharmaceutical product and a dominant position of its manufacturer where the manufacturer offers detailed argumentation on the technical question of substitutability and therapeutic effects of products. Seeing these difficulties, generally and especially in the pharmaceutical sector of proving a dominant position or an abuse, article 102 TFEU and article 24 DCA do not seem to be highly effective enforcement instruments in this market at the moment.

In conclusion, the pharmaceutical markets in the Netherlands are very much in development and the government, including the ACM, is keeping a close eye and has in some cases even taken an active role. It will be interesting to see whether a balance will be found between the need to promote innovation and, at the same time, to protect public budgets. For now, the focus is on the latter.