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THE PHARMACEUTICAL MARKET UNDER THE MICROSCOPE

Opportunities for entry of generic drugs and options for patients

A contribution by ACM, February 2015

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Executive summary

Controlling the cost of prescription drugs has been a topic of public debate in the Netherlands for several years now. The Dutch Ministry of Health, Welfare and Sport (VWS), health insurers, and others have already launched several initiatives aimed at cost control. However, it has proven difficult to design a system which provides enough incentives for drug manufacturers to introduce new drugs, while ensuring affordability. In addition, the market is very dynamic. The focus on the high costs of chemical-based drugs such as heart burn drugs, cholesterol-lowering drugs or anti-coagulants has given way to a new focus on the costs of biological drugs such as for certain cancer drugs.

Over the past few years, the Netherlands Authority for Consumers and Markets (ACM) has paid a lot of attention to the pharmaceutical industry. ACM primarily focused on the behavior of drug manufacturers with regard to the development and selling of chemical-based drugs. ACM has established that manufacturers of chemical-based brand-name drugs have impeded the market entry and use of cheaper, so-called generic drugs. This has been done by maintaining and extending market exclusivity of brand-name drugs, and by increasing sales through marketing efforts and influencing prescribers of drugs. Such practices are undesirable because they lead to unnecessarily high health care costs. This is harmful to consumers.

There can of course be practices, and ACM describes these in this paper, which can constitute violations of competition law, and regulators can penalize and combat them. Examples include abuses of dominant positions by drug manufacturers, and mutual arrangements between brand-name drug manufacturers and generic-drug manufacturers. However, other practices described in this contribution fall outside the scope of competition law.

When it comes to preventing such practices, ACM also looks at solutions that are closely associated with the way in which drug costs are funded and reimbursed in the Netherlands. First, ACM sees opportunities to reduce the incentives for brand-name drug manufacturers to use the strategies identified above. In addition, there are possibilities for changing the prescription behavior of physicians. ACM believes that the problem could be greatly reduced if physicians were to take (more so than now) the cost aspects of the drugs they prescribe into consideration.

1 Introduction

In April 2013, the Netherlands Authority for Consumers and Markets (ACM) named 'High purchase costs of drugs' as one of its key priorities. In the Netherlands, high health care costs pose a social problem. Health care affordability is under constant pressure. Today, the costs of prescription drugs continue to be a major driver behind the high social costs of health care.[1]

ACM has established that health care costs are affected negatively by certain pricing and marketing strategies employed by manufacturers of brand-name (or branded) drugs. In that context, this contribution primarily concerns behavior of manufacturers of chemical-based branded drugs, which may result in generic drugs that are of similar quality, but which are cheaper, entering the market later or even failing to enter the market at all. From a social-cost perspective, this is an undesirable situation. ACM wishes to prevent or deal with practices that harm consumer welfare. There are some practices exhibited by pharmaceutical companies that can be penalized and combated under competition law. However, other practices exhibited by pharmaceutical companies fall outside the scope of competition law. One such practice, exhibited by AstraZeneca, and about which ACM recently published a decision, is an example thereof.

This contribution by ACM is based on practices of the pharmaceutical industry, which predominantly concern chemical-based drugs. At the same time, ACM sees that the pharmaceutical industry is developing rapidly. Whereas several years ago, much attention was mostly given to chemical-based drugs, today's emphasis is more on, for example, more complex, biological drugs.[2] The process of how prices of biological drugs are determined has different dynamics, which means that any conclusions drawn in this contribution cannot automatically be extrapolated. However, it is beyond any doubt that pharmaceutical companies will adapt their practices to changing market conditions. In that changed environment, too, unnecessarily high social costs cannot be ruled out.

With this contribution, ACM provides insight into practices of pharmaceutical companies, and into the scope of the application of competition law on these practices. First, the relationship between the funding and reimbursement system in the Dutch health care industry on the one hand, and the practices of brand-name drug manufacturers on the other is explained. Next, it is discussed what practices of pharmaceutical companies could lead to a violation of competition law, and what practices appear to fall outside the scope thereof. Finally, other solutions for dealing with practices that are harmful to consumers are discussed.

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[1] In 2013, the costs of drugs totaled EUR 4.3 billion (source: GIP / Zorginstituut Nederland). In 2013, approximately EUR 94 billion was spent on health care (source: CBS/Statistics Netherlands).

[2] See: http://www.economist.com/news/business/21637387-wave-new-medicines-known-biologics-will-be-good-drugmakers-may-not-be-so-good?frsc=dg%7Cd

2 How drugs are funded and reimbursed

ACM has established that two elements of the funding and reimbursement systems with regard to drugs in the Netherlands play a key role in the behavior of pharmaceutical companies. First, the prescription behavior is important. Drugs are prescribed by medical specialists in hospitals, and by GPs outside hospitals. A second critical aspect is patent law. The aim of this branch of law is to recoup the investments that a pharmaceutical company makes when developing new drugs.

2.1 Major role of physicians inside and outside of hospitals

Patients get certain drugs[3] only when they have been prescribed by physicians. Inside hospitals, prescriptions are given by medical specialists, and, outside hospitals, by GPs. Physicians select a certain drug, and prescribe patients that drug.

In principle, physicians prescribe drugs on the basis of the active ingredient, not the brand name.[4] After all, the active ingredient is intended to treat a specific condition in a patient. Sometimes, there is only one drug that contains the active ingredient in question, and sometimes there are several drugs with that active ingredient. In this context, it is important to make the distinction between the so-called "brand-name drugs" (also called "specialty drugs") and "generic drugs" (also called "unbranded drugs").

A brand-name drug is a drug for which a patent has been applied by its manufacturer.[5] If the patent is granted, there is only a single drug with a certain active ingredient. Generic drugs are, so to speak, copies of a brand-name drug, and are produced by so-called generic-drug manufacturers. If generic drugs enter the market, there are multiple drugs with a specific active ingredient, next to the brand-name drug.

The drugs prescribed by physicians are not paid for by them. Drugs prescribed by the medical specialists inside hospitals (for inpatient usage) are paid for through the hospital budgets. These drug costs thus directly affect hospital budgets. Drugs that are prescribed for use by patients outside of hospitals are reimbursed by health insurers. These drug costs ultimately affect the level of the premiums that insured consumers pay. Physicians themselves however do not carry the financial

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[3] In this contribution, whenever 'drugs' are used in a sentence, these are understood to be chemical-based drugs, unless stated otherwise. A chemical substance or chemical compound has a certain effect to the human body. Next to chemical-based drugs, there are also biological drugs. These are drugs that are based on substances that are or should be naturally produced in the human body.

[4] See for example "Leidraad doelmatig voorschrijven van geneesmiddelen door medisch specialisten", *Orde van Medisch Specialisten*, 2011. See: http://www.kwaliteitskoepel.nl/assets/structured-files/2011/OMS_leidraad_doelmatig_vdeflr.pdf. Medical necessity is one of the reasons for prescribing a specific drug.

[5] A patent is an exclusive property right granted for an invention. See: http://www.rijksoverheid.nl/onderwerpen/intellectueel-eigendom/vraag-en-antwoord/wat-is-octrooi-of-patent.html

burden of the drugs that they prescribe inpatients and patients outside of hospitals. Drug costs thus play a secondary role when deciding to prescribe a certain drug.[6]

Moreover, hospital pharmacies or independent pharmacies (outside of hospitals) are required to provide patients with the drugs that physicians prescribe[7]. In other words: physicians determine what drugs patients use. Drugs manufacturers will therefore direct their attention to physicians when selling their drugs. This is also called 'getting a drug into the pen' in Dutch, since physicians will then prescribe certain drugs to patients. That is one of the reasons why manufacturers invest in creating a positive image (for example, through marketing efforts) among physicians about the effects of their drugs. Building a relationship with the medical specialists inside hospitals can be an effective way to create that positive image.

A final important aspect is that GPs outside hospitals are inclined to prescribe the same drug as the medical specialists inside hospitals have[8]. This is called the 'spillover effect': the prescription behavior of medical specialists inside hospitals spills over to the prescription behavior of GPs outside hospitals. In section 3.2, it is discussed how pharmaceutical companies take advantage of this spillover effect.

2.2 Patent law for drugs

A brand-name drug manufacturer can apply for a patent on a drug's innovative active ingredient. Patents are granted to manufacturers in order to protect an invention, and to promote innovation. Patents are awarded for a certain period of time. During that period, the patented drug cannot be copied by another drug company. That means that the brand-name drug manufacturer enjoys so-called 'market exclusivity' for that period. This manufacturer is the sole supplier of a certain active ingredient.

The period that a brand-name drug manufacturer is able to take advantage of market exclusivity is effectively ten years or so. Even though a patent can offer manufacturers up to 20 years of legal protection against copies of a drug, part of that time however is spent on testing, which is necessary

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[6] That is why the government, health insurers, and professionals try to direct attention to cost considerations. ACM will discuss this in section 4.3.

[7] If a certain active ingredient is prescribed (on the prescription), the pharmacy in question is required to offer this active ingredient. See: annex to proceedings of the Dutch House of Representatives about possible substitution of drugs by pharmacies, page 2. See also: Article 26a of the Decision on the practice of drug manufacturing, valid until July 1, 2007; articles 23 and 36, paragraph 14 of the Act on Health Care Professions.

[8] See a document published by the Dutch National Association of General Practitioners (LHV), called "maatregelen_patientenfolder.pdf", see: https://www.lhv.nl/sites/default/files/content/lhv_nl/uploads/artikel/maatregelen_patientenfolder.pdf.

for gaining entry to the market with that drug.[9] An important factor is so-called "data exclusivity," which results in the brand-name drug manufacturer being afforded protection. Without these data about the brand-name drug, generic-drug manufacturers are unable to reproduce the drug, and are thus unable to enter the market with a copy.[10]

Once the patent expires, the brand-name drug manufacturer's market exclusivity expires with it. From that moment, generic drugs are allowed to enter and *can* enter a market. That is the moment when a brand-name drug manufacturer starts to face competition: physicians are able to choose between different suppliers of the same active ingredient.

The period in which a brand-name drug manufacturer enjoys market exclusivity is a very lucrative one. Such is clear from the difference between the drug's price during the period of market exclusivity, and the drug's price when generic-drug manufacturers have entered the market. Competition between brand-name drug manufacturers and generic-drug manufacturers lead to falling drug prices. The European Commission estimates that prices drop between 25 and 40 percent two years after the introduction of generic drugs.[11]

In the Netherlands, the abovementioned price effect turns out to be even stronger. This is because the effectiveness of the Dutch drug preference policy has had significant consequences on the reimbursement of drugs.[12] The drug preference policy aims to keep drug prices as low as possible, within statutory restrictions. Physicians always decide what active ingredient is prescribed, while insurers can only choose what drug with that particular active ingredient is covered. A patented drug is, as mentioned previously, by definition the only variety with that particular active ingredient that is available. As a result, health insurers have little to choose from (yet). Once generic drugs enter the market, and multiple products meet the prescriptions of physicians, health insurers are able to decide

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[9] A study by SEO Economic Research mentions a period of 12 years. L. Kok and J. van der Voort, "De farmaceutische industrie in het maatschappelijk debat: een feitelijke beschrijving van de markt voor innovatieve geneesmiddelen in Nederland", *SEO report no. 2014-22*, commissioned by Nefarma and Amcham, Amsterdam, May 2014, page 12. (hereafter referred to as: "the SEO study")

[10] See: http://www.cbg-meb.nl/CBG/nl/humane-geneesmiddelen/registratiezaken/generieke-geneesmiddelen/registreren_generieke_geneesmiddelen/default.htm

[11] This has been concluded in a 2009 sector scan of the European Commission. See http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_nl.pdf, page 10.

[12] The origins of the drug preference policy can be traced back to 2004 in the 2004 Covenant on Pharmacy ('Convenant Farmacie 2004') in order to realize savings in prescription drug expenditures. The following organizations were involved: the Ministry of Health, Welfare, and Sport (VWS), Netherlands Health Insurers (ZN), the umbrella organization for both professional pharmacists and the pharmacy in general (Royal Dutch Pharmacists Association, KNMP) and Bogin (the Association of the Dutch Generic Medicines Industry). In 2005, the joint drug-preference policy was introduced by Dutch health insurers CZ, Menzis, Agis Univé and VGZ. In 2008, the individual drug-preference policy was introduced, where only a single drug was designated 'preferred.'

to cover the cheapest generic drug only. Until then, a brand-name drug manufacturer is thus immune to generic competition. According to the Dutch Foundation for Pharmaceutical Statistics (SFK), the introduction of the individual drug preference policy in 2008 led to a 90 percent price decrease of the most important generic drugs.

For example: the recently published ACM decision about AstraZeneca reveals that, in the period of October 1, 2008 until November 1. 2010, the purchasing price of Nexium 20mg tablets for pharmacists was approximately EUR 0.70, and that of generic omeprazol (an active ingredient that is similar to that of Nexium) in the same period was between EUR 0.03 and EUR 0.07.[13]

The elements of the Dutch funding and reimbursement system for drugs, as described above, play an important role in the behavior of pharmaceutical companies, which is discussed in chapter 3.

[13] See ACM's decision of 24 September 2014 in case number 7069/1832/OV (AstraZeneca), section 4.4.4 and particularly table 5, via: https://www.acm.nl/nl/publicaties/publicatie/13594/AstraZeneca-geen-misbruik-machtspositie/, (in Dutch), hereafter referred to as: "the AstraZeneca case."

3 Insight into the behavior of brand-name drug manufacturers

It has been established that there is a large price difference between brand-name drugs and generic drugs. As a result, brand-name drug manufacturers wish to take advantage of the period in which there are higher prices as long as possible. Maintaining or extending the period of market exclusivity is therefore a profitable strategy for brand-name drug manufacturers. In addition, physicians as the ones prescribing the drugs play a key role. Pharmaceutical companies will therefore try to maximize the sales volumes of their drugs by binding patients to these drugs through their GPs.

3.1 Maintaining and extending market exclusivity

Manufacturers that develop innovative drugs are rightfully entitled to a period of market exclusivity. As discussed earlier, innovations can be protected that way, and significant investments can be recouped. In practice, ACM observe that brand-name drug manufacturers attempt to maintain or extend the period of market exclusivity. This is a profitable strategy due to the large price difference between the period of market exclusivity, and the period in which competitors enter the market with generic versions.

Maintaining and extending the period of market exclusivity can be realized by any of the following:

1. Making minor changes to the original patent on an active ingredient;
2. Concluding mutual arrangements between brand-name drug manufacturers and generic-drug manufacturers about the timing of entry into the market; and
3. Withdrawing brand-name drugs even before generic-drug manufacturers are able to enter.

Each of these three strategies are discussed below.

3.1.1 Minor changes to original patents

Brand-name drug manufacturers can extend the period of market exclusivity by making minor changes to the original active ingredient on which a patent was granted. In practice, this behavior is called ‘evergreening’.[14] The brand-name drug manufacturer will present such changes as improvements to the original drug on which a patent had originally been granted. A variation on this strategy is when other manufacturers try to do this. They will try to manufacture drugs that differ only fractionally from the brand-name drug that is already on the market. These are called ‘me-too’-drugs. This way, they will attempt to benefit from the protective effect of a patent (new or existing). Yet another form of evergreening is when the brand-name drug manufacturer applies for additional patents next to the patent on the active ingredient. For example, these additional patents could be on the drug’s route of administration.

[14] Another name for evergreening is product hopping. See: Michael A. Carrier, “A real-world analysis of pharmaceutical settlements: The missing dimension of product hopping”, *Florida Law Review*, volume 62, 2010. In this article, emphasis is explicitly placed on the consequences of choosing a different route of administration, for example capsules instead of powder for oral solution or tablets.

For example: Evergreening results in a new active ingredient that marginally differs from the active ingredient of the original patent. A well-known example of this strategy is the heartburn drug Losec manufactured by AstraZeneca, which is a so-called "blockbuster"[15]. When Losec's period of market exclusivity expired, AstraZeneca released its successor with the name Nexium. Nexium is a drug that, at the very least, bears a close resemblance to Losec.[16]

3.1.2 Mutual arrangements with generic-drug manufacturers about entry

Next to minor changes to the original patent, there is yet another way to extend market exclusivity. Brand-name drug manufacturers sometimes conclude mutual arrangements with generic-drug manufacturers about the timing of their entry.

Manufacturers of generic drugs wish to enter the market as soon as possible, meaning as soon as the patent (the period of market exclusivity) expires (see section 2.2). These manufacturers, too, must have permission to enter the market with a new drug.[17] The sooner they are able to initiate this process, the sooner they are able to offer their drugs to patients. And, the sooner a generic drug enters the market, the faster the prices of drugs will drop as well. That is why brand-name drug manufacturers will try to delay the moment of entry of generic-drug manufacturers for as long as possible.

In practice, the wish of generic-drug manufacturers to enter the market as soon as possible, and the wish of brand-name drug manufacturers to maintain the period of market exclusivity results in legal conflicts. In order to be able to enter the market sooner, generic-drug manufacturers try, for example, to challenge the validity of a patent on a brand-name drug.[18] Challenging the validity of a patent could, for example, be about the question of whether a drug is truly innovative. And since such legal conflicts cost money, a brand-name drug manufacturer will definitely calculate his odds.

ACM has observed in practice that these types of legal conflicts are often settled out of court.[19] What

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[15] A drug is considered a "blockbuster" if its annual turnover exceeds USD 1 billion. See http://gebu.artsennet.nl/Archief/Tijdschriftartikel/De-evolutie-van-de-rol-van-de-farmaceutische-industrie-in-degezondheidszorg.htm.

[16] See the SEO study, previously cited, page 19. In the AstraZeneca case, AstraZeneca argued that Nexium stood out positively from other heart burn drugs in terms of therapeutic effect on certain medical conditions.

[17] Among other steps, drugs need to be registered with the Medicines Evaluation Board (CBG) first before they are allowed to enter the market.

[18] See for example: European Commission, "Pharmaceutical Sector Inquiry", *Final Report*, 8 July 2009, via http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry. In it, the European Commission describes various kinds of disputes.

[19] Another observed practice is brand-name drug manufacturers filing lawsuits against generic-drug manufacturers with the intention to delay market entry (this is also called "sham litigation"). In the SEO study, which was previously cited, on page 20, this practice is called "frivolous litigation."

basically happens, is that the brand-name manufacturer buys off the generic-drug manufacturer's threat to enter the marker earlier before the period of market exclusivity expires. These types of mutual arrangements between brand-name drug manufacturers and generic-drug manufacturers are called "pay-for-delay-settlements".[20] The brand-name drug manufacturer is able to buy off the generic-drug manufacturer's entry in several ways: (1) transferring a sum of money, (2) refraining from introducing a new drug that is virtually identical to the previous one (he basically refrains from evergreening). By settling, both parties thus win.

3.1.3 Withdrawal of brand-name drugs

A third option to fight off competition from generic-drug manufacturers is to withdraw the brand-name drug or the marketing authorization right before the patent expires, which is a strategy that is attractive if the brand-name drug manufacturer has a successor to the original brand-name drug. As described in section 2.2, generic-drug manufacturers need the data files of brand-name drug manufacturers in order to be allowed to enter the market with generic varieties of the original brand-name drug. By withdrawing the brand-name drug, it becomes impossible for generic-drug manufacturers to conduct the necessary tests in order to gain entry to the market.

3.2 Increasing the use of brand-name drugs

A second practice that is typical of pharmaceutical companies is the desire to increase the use of their drugs through marketing efforts and by influencing physicians. After all, physicians inside and outside hospitals prescribe drugs to patients. Brand-name drug manufacturers have an interest in creating a positive image of their brand-name drugs among these physicians. That is why brand-name drug manufacturers spend a large share of their budgets on marketing. According to a recent study approximately 63 percent of total expenditures of brand-name drug manufacturers is spent on marketing.

For example: In the definition used by SEO, marketing encompasses the following: pharmaceutical representative visits (in which representatives of the brand-name drug manufacturer inform physicians about the drug in question), publications in trade journals, organization and sponsoring of conferences, collaboration with and sponsoring of patient organizations and knowledge platforms, and offering continuing education and information to physicians.[21]

[20] See: SEO study, which was previously cited, page 8. It should be noted that, since the US Supreme Court's ruling in FTC v. Actavis, Inc., the term "reverse-payment-settlement" is used in the American system. See section 4.1.2.

[21] See: SEO study, which was previously cited, tables 4.7 and 4.8. In it, SEO discusses a survey, which it carried out, commissioned by, among others, Nefarma, the trade organization for brand-name drug manufacturers. Eleven pharmaceutical companies were surveyed. The survey revealed that, in 2012, 31 percent of the costs were spent on "sales" (including pharmaceutical representative visits), 18 percent on "advertising and promotion" and 13 percent on "consumer and market research".

The opposite happens as well, which is creating a *negative* image of a competing drug. This strategy can currently be observed, for example, with regard to biological drugs.

For example: Biological brand-name drugs (also called "biologicals") are allegedly not identical to generic biological drugs ("biosimilars").[22] On its website, the Dutch trade organization for brand-name drug manufacturers draws attention to this, and argues that switching patients from biological drugs to biosimilars can be risky.[23]

Brand-name drug manufacturers may combine marketing with other strategies that are able to influence physicians more indirectly. In practice, brand-name drug manufacturers sell their drugs, for example, at a steep discount to hospitals. This increases the likelihood that the drug will be prescribed a lot to patients inside hospitals. As GPs outside hospitals are inclined to follow the drug that has been prescribed by medical specialists inside hospitals (the so-called "spillover effect"), brand-name drug manufacturers are also able to benefit from higher sales volumes among patients outside hospitals.

[22] For chemical-based drugs, the chemical composition of a brand-name drug is identical to that of the generic variety. For biological drugs, it is about 'similarity' or 'equivalence'.

[23] See Nefarma, Biologische geneesmiddelen en biosimilars, www.nefarma.nl, April 2013.

4 Scope of competition law in approach to problem

The practices of pharmaceutical companies that have been described in chapter 0 may lead to generic-drug manufacturers entering the market at a later point in time or not entering at all. ACM will discuss below the options that competition law offers to combat this undesirable situation. At the same time, competition law has its limitations. Not all of these practices fall under its scope.

4.1 Violations of competition law

Businesses violate competition law by abusing their dominant positions[24] or by concluding price-fixing or market-sharing agreements. First, it is discussed what practices of pharmaceutical companies constitute an abuse of a dominant position. This is followed by a description of practices of pharmaceutical companies that are considered cartels[25].

4.1.1 Abuse of dominant position

Competition authorities in Europe and the US have, on several occasions, imposed fines on brand-name drug manufacturers for independent behavior in connection with abuse of a dominant position. Imposition of a sanction is conditional on the establishment of a dominant position enjoyed by the brand-name drug manufacturer. If such is the case, several practices may actually produce 'abuses' of dominant positions, including:[26]

- Misleading the patent agency by the brand-name drug manufacturer, by providing incorrect information about the moment of certification;[27]
- Refusal to grant a license to a manufacturer, who possibly wishes to enter the market with a generic version of the drug;[28]

[24] Examples include behavior that leads to exclusion of competitors or charging excessive prices.

[25] For a general overview, see: C.S. Hemphill, "Unjustified Delay in Generic Drug Competition", expert paper for Item VI of the 121st meeting of OECD Competition Committee on 18-19 June 2014, which can be downloaded here: http://www.oecd.org/daf/competition/generic-pharmaceuticals-competition.htm.

[26] There are no known cases (including recent) in which action was taken against the pharmaceutical companies' exclusionary use of excessive prices. Competition authorities place emphasis on abuse that leads to exclusion of competitors, and much less on the reaping of benefits in connection with the dominant position. For an explanation, see: European Commission, Excessive Prices, *Discussion Paper for the OECD Working Party 2*, 17 October 2011, which can be found here: http://ec.europa.eu/competition/international/multilateral/2011_oct_excessive_prices.pdf. The *Napp* case, which is also discussed in this contribution, has a combination of predatory pricing in the hospital segment, and excessive pricing outside hospitals.

[27] See the European Commission's case against *AstraZeneca*: http://curia.europa.eu/jcms/upload/docs/application/pdf/2012-12/cp120158en.pdf. In the *Boehringer-Ingelheim* case, the European Commnission decided not to institute proceedings after the company said it was willing to lift blockades because of possible patent misuse. See: http://europa.eu/rapid/press-release_IP-11-842_en.htm?locale=en.

[28] The Italian competition authority (Autorità Garante della Concorrenza e del Mercato, AGCM) suspected brand-name drug manufacturer *Merck* of abusing its dominant position by refusing to issue a license for entering the Italian market

- Influencing the prescribers by making “denigrating remarks” about generic-drug competitors in order to extend the period of market exclusivity.[29]

As far as we know, a strategy that aims to bring about minor changes to the original patent (‘evergreening’) as such has never been fined yet. However, this strategy is sometimes combined with withdrawing (‘deregistration’) the original drug. The objective of this dual strategy is to prevent generic-drug manufacturers from entering the market with a copy of the drug with a specific active ingredient. The period of market exclusivity is artificially extended this way. This practice of deregistration however has been fined by competition authorities.[30] As it only leads to protection of the patent holder (the brand-name drug manufacturer), and not to drug innovation.

Finally, there are also examples of brand-name drug manufacturers that employ pricing strategies in order to extend the period of market exclusivity at the expense of entry by generic-drug competitors. These pricing strategies entail, for example, selling drugs at very low prices. Competitors are not able to sell their drugs profitably at such very low prices.

For example: In the Napp case[31], brand-name drug manufacturer Napp took advantage of the earlier described spillover effect. The drug in question was a powerful painkiller. After it had entered the market, Napp began giving hospitals very high discounts. Its market share in the hospital segment rose from 80 percent to 93 percent. Prices outside hospitals (the community market) were many times higher. Because of the combination of predatory pricing within the hospital segment, and charging users outside hospitals excessive prices, the then Office of Fair Trading imposed a

with a generic version of a drug the patent on which had already expired outside of Italy, but not in Italy itself. AGCM suspended the investigation when it turned out that Merck was open to making commitments. See: http://www.agcm.it/en/newsroom/press%ADreleases/1096%ADa364%ADmerck%ADactive%ADingredients%ADconclusion%ADof%ADinvestigation.html.

[29] For example, see a decision of the French competition authority, which imposed a fine on pharmaceutical company Sanofi-Aventis for denigrating market behavior. In its communications to prescribers, brand-name drug manufacturer Sanofi-Aventis suggested widely and wrongfully that, among other claims, the type of sodium chloride (an additive) in a generic drug of a competitor posed health risks. See the decision of the Autorité de la Concurrence, no 13-D-11 of 14 May 2013. See for a further explanation about this decision: Dosogne, L. “Denigrating competitors: To what extent is it permissible under Article 102 TFEU (France)”, *Journal of European Competition Law & Practice*, 2014, Vol. 5, No. 1.

[30] See the European Commission’s case against *AstraZeneca*: http://curia.europa.eu/jcms/upload/docs/application/pdf/2012-12/cp120158en.pdf.). Another example of this behavior is the British *Reckitt Benckiser* case: http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www.oft.gov.uk/OFTwork/competition-act-and-cartels/ca98/decisions/reckitt-benckiser.

[31] See: http://webarchive.nationalarchives.gov.uk/20140402142426/http:/www.oft.gov.uk/OFTwork/competition-act-and-cartels/ca98/decisions/napp. For a detailed description of this case, see: Schrijvershof, D., “De geneesmiddelensector: de ‘tool-box’ en (‘evergreening’ van) het mededingingsrecht. Een tussenstand”, *Actualiteiten Mededingingsrecht*, number 4/5, September 2011, pages 93 through 103.

fine of more than GBP 3 million.

In order to give an idea of the harm that Dutch society may suffer as a result of the abovementioned strategies exhibited by pharmaceutical companies, a hypothetical estimate of the implications of such a strategy is given below as an example. In this hypothetical case, a brand-name drug manufacturer employs a pricing strategy where the price of its drug outside hospitals is much higher than the price inside hospitals. It gladly takes advantage of the spillover effect (see section 2.1). After all, because of this effect, it is able to secure a foothold in the much larger market outside of hospitals (the community market) at the expense of manufacturers of cheaper, similar generic drugs. The example shows how profitable this pricing strategy can be for a pharmaceutical company, and how harmful it can be to health care costs for Dutch consumers.

Example:
Suppose a frequently used type of drug has one brand-name drug manufacturer, and one or more generic-drug manufacturers. We assume there are no appreciable, clinical benefits of using the brand-name drug over the generic version.[32] *Annual sales volumes are 10 million units inside hospitals, and 200 million units outside hospitals (the community market). Furthermore, suppose the brand-name drug manufacturer offers its drug inside hospitals for EUR 0.01 and on the community market for EUR 1, and that the generic version costs EUR 0.10 both inside and outside hospitals.*[33] *If the brand-name drug manufacturer, using this pricing strategy, is able to realize 40 percent of sales inside hospitals, and 15 percent of sales on the community market, it will have the following implications for health care costs for consumers.*

*Fifteen percent of 200 million pills are sold at EUR 1 apiece on the extramural market, whereas these could have easily been replaced with generic pills of EUR 0.10 apiece. The costs therefore amount to: 0.15 * 200 million * (EUR 1 -/- EUR 0.10) = EUR 27 million per year. On the other hand, hospitals were able to purchase these drugs at a lower cost, which was 40 percent of 10 million units for EUR 0.01 instead of EUR 0.10. That is a benefit of 0.4 * 10 million * (EUR 0.10 -/- EUR 0.01) = EUR 360,000. The net costs for society are EUR 27 million -/- EUR 360,000 = EUR 26,640,000 per year. If the brand-name drug manufacturer is able to continue employing this strategy for four years, the total amount of unnecessary health costs will be more than EUR 100 million.*

4.1.2 Cartel agreements between multiple drug manufacturers

Mutual arrangements between brand-name manufacturers and generic-drug manufacturers appear to be successful in delaying the entry of generic drugs. Such settlements, as described in section 3.1,

[32] If the brand-name drug does offer a therapeutic advantage for a limited share of users, it results in a minor correction of this figure.

[33] These hypothetical price differences are in line with the price differences that ACM have found between Nexium offered inside and outside hospitals. See text box in section 2.2.

may constitute violations of competition law.

The European Commission actively investigates such settlements. This has led to two cases: one involving the antidepressant *citalopram* by brand-name drug manufacturer Lundbeck, and one case involving antihypertensive *perindopril* by brand-name drug manufacturer Servier.[34] Several cases are currently still ongoing. Unfortunately, the details of these cases are not known at this point, as the settlements have yet to be published.

There has also been a case in the US that involved a settlement, which was the settlement between Solvay Pharmaceuticals and Actavis. The ruling of the US Supreme Court in FTC v. Actavis[35] is of great importance in the discussion about whether or not settlements can be considered agreements between undertakings that contravene the applicability of competition law. Furthermore, this ruling also comments about the drawbacks of these types of "pay-for-delay" strategies for consumers. This case is discussed in more detail in the text box below. In the US, several other settlements are currently given a closer look by the courts.

For example: the Actavis case

In 2003, Solvay Pharmaceuticals obtained a patent on its brand-name drug 'Androgel,' which was used to treat low testosterone levels in men. In late-2003, multiple generic-drug manufacturers, including Actavis, applied for market entry for a generic drug that was based on Androgel. Solvay sued Actavis for patent infringement. Instead of entering the market with the generic drug, Actavis and Solvay in 2006 came to an agreement.[36] According to the agreement, Actavis would wait until September 2015 with the introduction of its generic drug (65 months after the patent on Androgel expired), and with recommending Androgel among prescribers. In exchange, Actavis was compensated financially, which was between USD 19 to 30 million a year.[37]

In June 2013, the US Supreme Court ruled in the case. Up to that point, justices had ruled that these types of settlements were in line with the patent system, and thus that competition law did not offer any basis for intervention. The ruling effectively meant that such settlements had to be analyzed on a case-by-case basis using a structured "rule-of-reason" standard. This standard means that, in each case, a plausible case must be made for the potential benefits and drawbacks

[34] See the *Lundbeck* case (Case COMP/AT. 39226), http://ec.europa.eu/competition/antitrust/cases/dec_docs/39226/39226_8310_11. and the *Servier* case (Case COMP/AT. 39612) http://europa.eu/rapid/press-release_IP-14-799_en.htm.

[35] See: *FTC v. Actavis, Inc.*, 570 U.S. ____ 2013.

[36] The US Supreme Court used the term "reverse payment". In most settlements between patent holders and infringing parties, the infringing party pays the patent holder. In this case, it is the other way round. The term "pay-for-delay" refers to the same type of settlements, and is an alternative name for the same kind of practices.

[37] Source: http://www.supremecourt.gov/opinions/12pdf/12-416_m5n0.pdf.

resulting from a restriction of competition, but that presumptive evidence is used in the case in question. In this case, the level of the settlement amount plays a role in this presumptive evidence. The higher the settlement amount is, the weaker the patent is, and the more plausible it is that, as a result of the settlement, entry of the generic drug was delayed. This means that it is more likely that consumers have been harmed.[38]

Several competition authorities have made an estimate of the financial harm for consumers resulting from "pay-for-delay" strategies. The European Commission investigated the harm from settlements based on a sample of drugs that had been studied for the period of 2000-2007 as part of a sector inquiry. The European Commission estimated that, if market entry of generic drugs had taken place immediately after market exclusivity of the brand-name drugs had expired, EUR 3 billion in health care costs could have been saved more. [39]

In 2010, the FTC in the US estimated that settlements between brand-name drug manufacturers and generic-drug manufacturers have led to cheaper generic drugs entering the market with an average delay of 17 months in the period 2004 through 2009. Based on that figure, the FTC estimated the financial harm to consumers, and concluded that settlements cost American consumers USD 3.5 billion per year, and USD 35 billion over a 10-year period.[40] [41]

4.2 Limitations of competition law

ACM has established that not all practices can be dealt with using competition law. However, some of these practices may yet lead to the development of generic drugs being hindered. For consumers, this is an undesirable situation from a social-cost perspective.[42]

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[38] Based on the available data, it can be deduced that, in any case, the settlement, which was relatively high, probably led to financial harm for consumers. A court still needs to hand down a final ruling.

[39] See for example: European Commission, "Pharmaceutical Sector Inquiry", *Final Report*, 8 July 2009, which can be found here: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry.

[40] Federal Trade Commission, "Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions", *An FTC Staff Document*, ftc.gov, January 2010.

[41] There are also opposing views. See: Addanki, S. and H.N. Butler, "Activating Actavis, Economic issues in applying the rule of reason in reverse payment settlements", *Minnesota Journal of Law, Science & Technology,* Vol. 15, No. 1, page 77 through 94, 2014.

[42] The fact that evergreening can also have disadvantages for consumers is revealed by a study into the situation in Australia. See: Moir, H.V.J. and Palombi, L. "Patents and Trademarks: empirical evidence on 'evergreening' from Australia", paper gepubliceerd op het *Social Sciences Research Network*, 7 December 2013, which can be found here http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2365786. In the paper, the authors discuss in detail multiple specific examples, and quantify the harm for consumers caused by this strategy. The protected effectiveness of Losec (active ingredient is stof omeprazol) was extended based on a change to the route of administration. For this drug alone, the authors estimated that the harm to Australian taxpayers was AUD 607 million.

By stimulating innovation, some practices actually have a net positive effect for consumers. In those instances, interventions by competition authorities are not appropriate, and would also be counterproductive. It would be different if such practices helped innovation only marginally, and a brand-name drug manufacturer deployed a strategy to extend the benefit of its market exclusivity artificially. But in that case too, competition law cannot always be used to stop the behavior.

For example, competition authorities do not deal with the practice of making changes to the original patent (evergreening) as such. As a result of this kind of strategies, new drugs enter the market with limited added value for consumers[43] while the development of generic drugs is hindered. One explanation could be that the question of whether a drug either has much or little added value compared with all of the existing drugs cannot be answered properly using the tools that competition law offers. If anywhere, such a discussion should be held at the level of the patent agency.

Another example is the AstraZeneca case of ACM from 2014.

AstraZeneca decision[44]

ACM investigated a certain pricing strategy employed by AstraZeneca. AstraZeneca offered hospitals a brand-name drug, which was heart burn drug Nexium, at below cost price most of the time. During the time when AstraZeneca offered Nexium at below cost price (2004-2010), multiple heart burn drugs (PPIs) were available. Next to Nexium (with the active ingredient esomeprazol), consumers could also choose between numerous other active ingredients of the same type, including omeprazol (both Losec by AstraZeneca and the generic drugs based thereon), pantoprazol (Pantozol by–currently– Takeda), lansoprazol (Prezal by Sanofi-Aventis) and rabeprazol (Pariet by Johnson&Johnson).

AstraZeneca benefited from the spillover effect. By offering hospitals very high discounts (sometimes discounts of more than 90 percent on the purchasing prices for pharmacies), AstraZeneca promoted the use of Nexium inside hospitals, and the group of Nexium users outside hospitals (the community market) was increased. Prices of Nexium on the community market were much higher[45]*than prices inside hospitals.*

Nexium entered the market in 2001. Not long after, in 2002, the first generic versions of omeprazol

[43] According to the SEO study, which was previously cited, only 28 percent of the drugs that entered the market between 2000 and 2012 had a new active ingredient. Twelve percent concerned drugs that did not have a new ingredient, but had therapeutic added value.

[44] See: https://www.acm.nl/nl/publicaties/publicatie/13594/AstraZeneca-geen-misbruik-machtspositie/

[45] The decision sets a ratio that has a maximum factor of 90. If the intramural price is one eurocent for one unit, the same units are sold on the extramural market at almost one euro.

entered the market. As previously explained, consumer harm arises when brand-name drug manufacturers artificially exclude generic drugs. That is why ACM wished to investigate whether or not that was the case.[46]

In the decision, the historic development of generic omeprazol is explained. When AstraZeneca was offering very high discounts to hospitals, the sales of generic omeprazol lagged behind its trend-based projected growth.[47] *ACM argues that the sluggish growth of generic PPIs on the community market had a negative effect on the moderating effect that the introduction of generic PPIs normally could have had on prices. As a result, drug costs could have been lower than they are now, according to ACM.*

It is taken into consideration in the decision that various factors could have explained the sluggish growth of generic omeprazol. For example, next to the prices of Nexium, the therapeutic qualities of the drug may have played a role, just like the development of, for example, Pantozol. Finally, ACM therefore refrained, in this case, from giving an opinion about the extent to which different factors may have contributed to 'more expensive' drug use, and thus to unnecessarily high drug costs.[48]

Having carried out an extensive investigation, ACM was unable to establish a violation of the Dutch Competition Act by AstraZeneca. Abuse of a dominant position can only be established if a company actually enjoys a dominant position.[49] ACM had insufficient evidence to prove one.

ACM only investigated AstraZeneca's behavior with regard to Nexium. At the same time, there are indications that this strategy (selling drugs to hospitals at high discounts, and possibly at below cost price) is more prevalent or at least was employed in the past more often.[50]

In conclusion, one can say that competition law has its limitations when dealing with certain behavior of pharmaceutical companies, which, from a social-cost perspective, is undesirable.

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[46] The rationale was: with regard to those consumers who could have easily used omeprazol instead of Nexium, the higher extramural price of Nexium (sometimes 10 to 30 times more expensive) multiplied by the number of sold units can be considered consumer harm. The benefit from the lower intramural prices still needs to be subtracted from that figure. See the AstraZeneca decision, previously cited, table 5.

[47] See ACM's decision about AstraZeneca, previously cited, section 5.1.6.

[48] See ACM's decision about AstraZeneca, previously cited, section 260.

[49] ACM's AstraZeneca case shares similarities with the Napp case in the United Kingdom, where a dominant position *has* been established (for a description, see section 4.1.1). Contrary to Napp's position, AstraZeneca was in a situation where there were alternatives for its active ingredient. As a result, AstraZeneca's position with Nexium was less strong than Napp's in its case.

[50] AstraZeneca argued for example that other manufacturers of heart burn drugs offered hospitals similarly high discounts.

4.3 Other possible solutions to the problem

ACM sees other measures that could help reduce the negative effects of the practices identified by ACM.

ACM has established there are two reasons for the high level of drug costs in the Netherlands. The first cause is the way drug costs are reimbursed in the Netherlands. The current patent system, in combination with the funding system, results in incentives for brand-name drug manufacturers to focus primarily on drugs with relatively limited added value, and to focus less on new drugs. A second cause lies in the prescription behavior of physicians, which is another reason why these strategies can be so successful. Medical specialists within the hospital, and GPs outside hospitals prescribe relatively expensive, patented brand-name drugs, whereas cheaper (generic) drugs often turn out to be just as good.

The two causes behind the social costs can be dealt with as follows. First, the incentives for brand-name drug manufacturers to employ the abovementioned strategies must be reduced. Second, the problem would also be considerably reduced if physicians were to take into account cost aspects with regard to the drugs they prescribe in their prescription behavior. ACM will discuss below other possible solutions to this problem.

4.3.1 Reducing incentives that lead to identified strategies of drug manufacturers

ACM sees two possible adjustments in order to change the incentives that currently lead to employing the strategies as previously described. First, adjustments to the inclusion of drugs in the standard health care package are conceivable. In addition, the way the funding system for drugs in the Netherlands functions can be overhauled, too.

Adjustments to the inclusion of drugs in the standard health care package

First, the way drugs are included in the standard health care package can be adjusted. Reimbursement by health insurers is based on inclusion in this package.

In a joint position paper, the Wemos foundation, European Public Health Alliance, International Society of Drug Bulletins and The Centre for Research on Multinational Corporations (SOMO) argue, for example, to link the reimbursement of a drug to its therapeutic added value compared with current treatments. That makes the development of “me-too” drugs (see section 3.1) less attractive, and lead to more investments in drugs that actually serve a medical need.[51]

Current legislation seems to offer little room for such adjustments. When deciding what drugs are to be included in the standard health care package, the Dutch Ministry of Health, Welfare, and Sport

[51] See: http://www.wemos.nl/files/Documenten%20Informatief/Bestanden%20voor%20'Medicijnen'/Position%20paper%20ATV%20Wemos%20SOMO%20EPHA%20ISDS.pdf, September 2014.

(VWS) could take into account the annual costs of the drug per patient. Possible 'indication expansions' should also be taken into account. This means that drugs with high added value for some patients will be used by much larger groups of patients than originally intended. If a drug's sales volumes increase as a result thereof, the marketing strategies of brand-name drug manufacturers could thus also affect more consumers. Therefore, it should be explored to what extent limits can be imposed on the degree to which certain expensive drugs should be funded through the basic health care package[52]. The National Health Care Institute[53] (*Zorginstituut Nederland*) could formulate recommendations on this. The Institute advises VWS on the actual products and services included in the mandatory health care package, as well as the scope thereof.

Adjustments to the funding system for drugs

The opportunity to obtain a patent on a new active ingredient is crucial in stimulating businesses to innovate, meaning to develop new drugs. If a manufacturer develops a new drug, it is rewarded with the exclusive rights for a certain period of time, in which it can ask a relatively high price. That is the period of market exclusivity. This market exclusivity leads to incentives to keep it as long as possible, and to make the group of users who pay that high price as large as possible. Pharmaceutical companies take advantage of the spillover effect by offering the drug inside hospitals at a very cheap price, and at a much higher price outside hospitals. There are several ways to break this pattern.

From the above, the question may arise as to whether it would not be a good idea to adjust the patent system if it apparently offers room to pharmaceutical companies to maintain and extend the period of market exclusivity. However, ACM believes that overhauling the patent system as such is not a realistic option in the short run. First, when a patent on a new active ingredient is granted, it is not clear what its therapeutic added value is. Second, changing the patent system is very difficult or even impossible at a national level. Furthermore, such an overhaul calls for great care, because you want to avoid eliminating the positive effects of patents and of extending market exclusivity. The same goes for any changes to the system of admission. After its admission to the market by the European Medicines Agency (EMA), it is checked whether the drug works, and whether it is safe. This is normally also done at a European level. A more expanded role for EMA does not seem obvious either. After all, it is up to the buyers of the drug to assess its costs and quality.

First, under certain circumstances, it could be effective to intervene in the resale prices of brand-name drug manufacturers. Intervention could prevent brand-name drug manufacturers, using their pricing strategies, from gaining a larger market position with an expensive brand-name drug with a limited therapeutic added value compared with existing, cheaper generic drugs. Although price

[52] As such, this suggestion would also take into account more aspects than the existing assessment of cost effectiveness. This is one of the four so-called package criteria according to the National Health Care Institute . See http://www.zorginstituutnederland.nl/pakket/lopende+dossiers/procedures+en+methodieken/programmakosteneffectiviteit.html.

[53] See https://www.zorginstituutnederland.nl/.

interventions do not solve the underlying problem, they could prevent the entry of generic-drug manufacturers from being impeded.

More specifically, one system that comes to mind is where several[54] restrictions are imposed on the price mechanism of brand-name drugs, for example a system where the price of a drug inside hospitals must be the same as the price of the same drug outside hospitals. This will result in pharmaceutical companies no longer taking advantage of the spillover effect at the expense of consumers. This is in line with a funding-system proposal offered by NIVEL[55], which would ensure similar prices inside and outside hospitals.[56]

For example: AstraZeneca offered heart burn drug Nexium to hospitals at a steep discount. As a result of the spillover effect, it was able to benefit from increased usage of the drug by patients outside the hospital. Generic heart burn drugs were unable to compete profitably with the same pricing strategy.[57] In this example, if AstraZeneca had been required to offer Nexium to hospitals at a similar price inside and outside hospitals, normal competition on price could have existed in this market, and companies would have been able to benefit from the spillover effect less easily.

An alternative approach that could lead to breaking the pattern as described above is transferring to hospital budgets the costs that patients outside hospitals incur for certain drugs. In that scenario, medical specialists in hospitals *will* take account into the costs outside hospitals when they decide what drug to prescribe patients. This approach is currently already applied to certain drugs.

Insofar this or a similar approach results in the elimination of the incentives for brand-name drug manufacturers, it is a more preferable approach than intervening (even a minor intervention) in the price mechanism. Based on current legislation concerning drug prices, it is not possible to assess price levels. It is therefore technically not feasible to determine whether or not a price is at below cost price, or whether or not prices are different for patients inside or outside hospitals. Existing legislation would therefore have to be amended.

[54] A more drastic proposal would be the introduction of a ban on selling drugs at below cost price. And an even more drastic idea would be price regulation by the government. In October 2014, Marcel Levi, chairman of the Executive Board of the Academic Medical Center (AMC) in Amsterdam, argued in favor of this in Dutch daily newspaper NRC Handelsblad. Marcel Levi, “Medicijnen horen niet op een vrije markt”, *NRC Handelsblad*, 6 October 2014.

[55] ‘NIVEL’ stand for “Nederlands instituut voor onderzoek van de gezondheidszorg,” which is the Netherlands institute for health services research.

[56] Kerpershoek E, Hermsen J, Kroezen M, Van Dijk L, “Voorschrijven door internisten en cardiologen. Een verkenning naar oorzaken van verschillen in voorschrijven van cholesterolverlagers en bloeddrukverlagers voor extramuraal gebruik”, NIVEL, Utrecht, October 2012.

[57] After all, generic drugs are prescribed based on active ingredient, not brand name.

4.3.2 Changes in prescription behavior of physicians

As previously discussed in section 2.1, physicians inside and outside hospitals play a major role as prescribers of drugs to patients. It is therefore obvious to find a solution in the way prescribers come to their decisions. This goes for both the medical specialists inside hospitals, and GPs outside hospitals. They may be not fully aware of the options available to them, and of the price differences between the different drugs when used by patients outside hospitals. In addition, they are also insufficiently stimulated to make choices in the interest of consumers.

As ACM already established, prices of drugs often differ for patients inside hospitals and for patients outside hospitals. Physicians should be aware of the consequences of their choices. In a study into the prescription behavior of physicians concerning statins and antihypertensives, NIVEL[58] argued in favor of, among other things, focusing attention on drawing up policies for hospitals with the intention to change the prescribed drugs when patients are released from hospitals. The opposite is also possible (and is actually observed): that patients continue to use in hospitals the drugs that they use at home. Health insurers, too, can play a role in this process by encouraging effective drug-prescription behavior.

For example: In ACM's AstraZeneca case, it turned out that the Dutch National Association of General Practitioners (LHV) appeared to be susceptible to an initiative of the health insurers. Health insurers called on GPs to prescribe more effectively. LHV subsequently called on GPs to give more attention to generic heart burn drugs, and, when patients ask for repeat prescriptions outside hospitals, to no longer automatically continue the prescriptions that patients had been given in hospitals. Judging from the information found in the AstraZeneca case, this initiative seems to have been successful.[59]

Numerous initiatives are already in place, aiming to make prescribers more aware of their key role in the system, and to stimulate them to take the idea of effective prescription behavior into account even more. Policymakers, health insurers[60] and prescribers[61] play a role in this process. Several of these initiatives are paying off,[62] but in practice, the benefits sometimes turn out to fall short of the

[58] See the study of NIVEL, previously cited in section 566.

[59] See the AstraZeneca decision, previously cited, particularly figure 4. This figure reveals that the sales trend of generic omeprazol is line again with the trend-based projection.

[60] Prescribing effectively was one of the three topics in the funding system for GPs. See: https://zn.nl/nieuws/zn-nieuws/nieuwsbericht/?newsitemid=34930688.

[61] See "Leidraad doelmatig voorschrijven van geneesmiddelen door Medisch specialisten" (previously cited).

[62] See a document published by the Dutch National Association of General Practitioners (LHV), titled "maatregelen_patientenfolder.pdf", which can be downloaded at www.lhv.nl. In it, LHV explains that GPs will no longer continue the prescription issued by the hospital "as a service" if it prescribes a brand-name drug while a generic alternative is available.

targets.[63] As this contribution has made clear, major manufacturers have an interest in discouraging effective prescription behavior. ACM therefore believes that constant attention for this topic, by GPs, health insurers, and also policymakers is of the essence.

[63] See: http://www.sfk.nl/nieuws-publicaties/PW/2014/Triptanenstrijd.

5 Conclusion

In this contribution, ACM provided insight into the practices of pharmaceutical companies with regard to brand-name chemical-based drugs. From a social-cost perspective, it would be undesirable if such practices led to cheaper, generic drugs entering the market later or even not entering at all.

With competition law, ACM has the opportunity to deal with some types of these practices. As of yet, ACM has not conducted any investigations into such practices, although foreign authorities have. At the same time, ACM acknowledges that competition law has its limitations when trying to combat all types of practices. That is why ACM makes several recommendations for other solutions to this problem.

At the end of the day, ACM wishes to have a level playing field in the pharmaceutical market, where generic-drug manufacturers are able to compete with brand-name drug manufacturers for the patient's favor. That way, ACM believes there will be opportunities for cheaper, generic drugs to enter the market, and for more options between drugs to emerge for patients.

This contribution primarily looks at practices that have been observed over the last few years. However, ACM also reckons with future developments. For example, brand-name drug manufacturers nowadays no longer appear to focus on chemical-based drugs as described in this contribution, but seem to concentrate on biological drugs. The market dynamics of these types of drugs share some similarities with those of chemical-based drugs, but they also have differences. For example, biological drugs also have generic varieties, which are called biosimilars. One difference is that the costs that biosimilar manufacturers incur in order to gain access to the market are generally higher than with chemical-based drugs. In addition, sales volumes are sometimes lower.

At this point, ACM is unable to determine to what extent the strategies as employed by brand-name drug manufacturers are also employed in the context of biological drugs. If such strategies are similar to practices that have been penalized by competition authorities, then it can be assumed that ACM *will* take action. ACM will continue to keep a close watch on future developments, and remains alert to indications that certain strategies that are undesirable for consumers are employed with biological drugs.