

# Penny Wise, Pound Foolish?

Accessible, affordable and high-quality pharmaceutical healthcare for the Dutch patient – Today and tomorrow



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## Executive Summary

Accessible, affordable and high-quality pharmaceutical healthcare for Dutch patients – Today and tomorrow – is one of our society’s top priorities. As we live longer, the number of multi-morbid chronic patients is growing. Fortunately, so is our (technological) ability to treat, cure and even prevent diseases. However, adjustments to our healthcare system are needed to keep it affordable and to ensure the continuous supply of increasingly advanced, high-quality (bio)pharmaceutical treatments.

Current healthcare reforms have set objectives on both quality and cost containment. As these reforms have begun to be implemented, however, the emphasis has been almost exclusively on cost. Although successful at first glance (prices have fallen), these reforms risk overshooting their objective. The pharmaceutical sector plays a pivotal role in developing and delivering high-quality, (cost) effective treatments to patients. But increasingly one-sided cost pressure is now threatening the ability of originators, generics producers, wholesalers and pharmacists to fulfill their roles, forcing them to cut back jobs, research, investments and services. The result may be that both generic and patented drugs become less, not more, available and that the distribution and pharmacy infrastructure needed to save lives is severely diminished – but cost effective.

Three challenges must be overcome for Dutch patients to continue to benefit from accessible, affordable and high-quality (bio)pharmaceutical healthcare:

- > Establish a **well-functioning market** for (bio)pharmaceuticals where patients can exercise choice and where quality of care is assured;
- > Develop **sustainable business models** for players in the pharmaceutical sector that allow:
  - Originators to keep innovating despite increasing cost pressure and complexity
  - Generics producers to guarantee availability and continuity while remaining competitive
  - Wholesale distributors to deliver added value despite lower distribution margins
  - Pharmacies to fulfill all service requirements while fees are under pressure; and
- > Secure the Netherlands’ **innovation capacity** in (bio)pharmaceuticals.

Overcoming these challenges, and opening up opportunities and benefits for Dutch society and patients, requires a sector-wide rethink by all stakeholders of their roles and contributions. Three solutions that should be part of this debate are:

- > **Incentivizing health insurers** to measure and safeguard the quality, instead of just the costs, of pharmaceutical healthcare for the patient;
- > **Enabling new business models** for players in the pharmaceutical sector by:
  - Accelerating patient access to new treatments which enable continuous innovation
  - Developing alternatives to the preference policy that optimize cost and quality of service
  - Reaching sector-wide agreement on adjustment of the business model
  - Developing transparent and sustainable compensation schemes for additional quality and service levels; and
- > **Becoming a front-runner** in the research and development, testing and evaluation of new treatments.

Seizing these opportunities is something the pharmaceutical sector, insurers and policymakers can only do together. If all stakeholders engage in constructive dialogue and commit themselves to doing their part, Dutch patients can look forward to accessible, affordable and high-quality healthcare – Today and tomorrow.

The development, production and distribution of (bio)pharmaceutical treatments and the way this is organized and paid for will be a key topic in the coming years. A number of representative companies throughout the pharmaceutical sector have asked Roland Berger Strategy Consultants for an independent, outsider's perspective of the priorities for the Netherlands and the contributions that the sector and other stakeholders should aspire to make. This paper presents a summary of our findings.

## Part 1 - Context and developments

### **A one-sided cost focus in healthcare reform may put the long-term accessibility, affordability and quality of pharmaceutical healthcare at risk**

*The Ministry of Health, Welfare and Sport's top priority is meeting Dutch patients' increasing demand for accessible, affordable and high-quality (bio) pharmaceutical healthcare. That requires complex, innovative and a wide range of generic (bio)pharmaceutical treatments – supplied by a pharmaceutical sector that, in doing so, delivers not only health but also wealth to Dutch society. Healthcare reform in recent years has aimed at both quality and cost. In implementation, however, the emphasis has been almost exclusively on cost containment, giving a central role to health insurers which are neither equipped nor incentivized to uphold quality. Although prices have undeniably fallen, and negative side effects appear limited to policymakers, in the longer term this policy – however well-intentioned – risks doing more harm than good.*

If current trends continue, Dutch patients in 2020 will have delayed access to innovative and affordable (bio)pharmaceutical treatments, and research and development of new treatments will be limited. Well-established producers may cease to offer generics, and changing between generics suppliers will result in continuously changing packaging, labeling and administration method. Patients will have to wait longer and travel further for treatments because wholesaler stocks are kept low and pharmacies close down branches. All in all, the quality level of the entire pharmaceutical infrastructure will slowly deteriorate, putting the continued accessibility, affordability and quality of pharmaceutical healthcare in the Netherlands at risk.

### **Dutch patients' increasing demand for more and better pharmaceutical healthcare has prompted healthcare reform to guarantee quality and contain costs**

Healthcare is the number one priority in a society facing the benefits and challenges of prosperity. We can expect to live longer, but with ageing comes a higher prevalence of complex and chronic diseases. Our growing prosperity leads us to demand a high quality of life and access to the best possible healthcare. Although we obviously want and need healthcare to be affordable, we are increasingly prepared to pay a premium for our (quality) demand. At the same time, we are evolving from docile patients into health consumers who demand greater transparency in quality and costs from insurers and health care providers, and the right to choose what treatment and medication we receive.



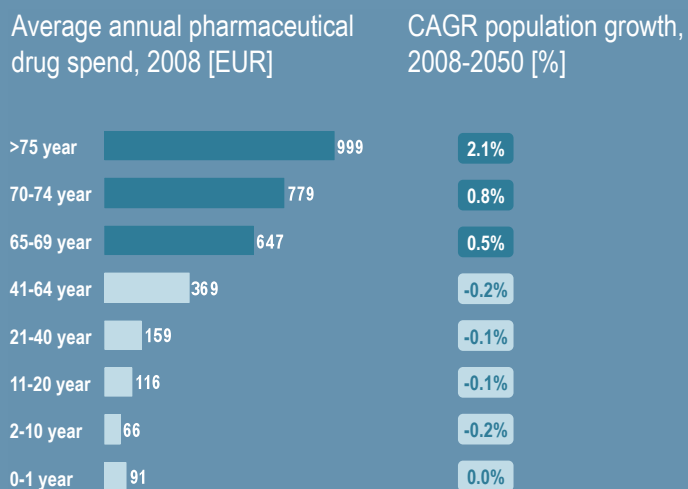
These trends lead to a growing demand for a broad supply of high-quality (bio) pharmaceutical treatments that enable prevention of, early intervention in and personalized medication for both chronic and infectious diseases (see box).

#### PHARMACEUTICAL HEALTHCARE ACCESSIBILITY AND QUALITY REQUIREMENTS

1. **Security of supply:** ensuring all approved pharmaceutical drugs are immediately available
2. **Up-to-date pharmaceutical drugs:** ensuring the latest innovations are quickly adopted and reimbursed
3. **High efficacy:** ensuring the right pharmaceutical drugs are used in the right way to maximize results
4. **Efficient distribution:** ensuring drugs are made available in the right quantity, price and on time
5. **Easy access:** ensuring every Dutch citizen has easy access to supply via pharmacist or the hospital

That demand obviously comes at a cost. As a society we are increasingly able to treat diseases earlier, for longer and better – and both benefits and costs are highest for the higher age groups that also grow at the highest rate (see figure 1). Healthcare reform has therefore rightly focused on both quality and cost containment, however not on productivity of the health-care sector in general.

**Figure 1: Increasing future pharmaceutical drug expenditure in the Netherlands <sup>1</sup>**



<sup>1</sup> SFK, Data en Feiten 2009

**The pharmaceutical sector contributes to high-quality, cost-effective healthcare by supplying complex (bio)pharmaceutical treatments that deliver health and wealth to Dutch society**

The pharmaceutical sector plays a pivotal role in realizing accessible, affordable and high-quality healthcare in the Netherlands. Developing, producing and distributing complex (bio)pharmaceutical treatments is essential to delivering health by creating more effective treatments that can be better administered and have fewer side effects. But this also contributes to our economic prosperity – and thus to our ability to pay for more and better healthcare – by creating jobs, attracting investment and enabling the knowledge economy.

**PHARMACEUTICAL SECTOR AT A GLANCE**

- > Employs over 50,000 people<sup>2</sup>
- > Revenues of EUR 4.7 bn from pharmacists<sup>3</sup>
- > Revenues of EUR 4.9 bn in R&D and production<sup>4</sup>
- > 27% of employees working in R&D<sup>5</sup>
- > 15-20% of sales is (re)invested in R&D, more than any other sector<sup>3</sup>
- > 9% of private Dutch R&D investment<sup>5</sup>
- > 6% of the private Dutch R&D workforce<sup>5</sup>
- > EUR 1.5 billion joint investment in public-private life sciences research programs until 2011<sup>4</sup>

(Bio)pharmaceutical treatments are one of the most effective ways to realize high-quality healthcare for the patient and prevent, cure, contain or alleviate diseases – from skin diseases to cancer, from coronary heart disease to depression. Millions of people in the Netherlands, many of them chronic patients and often under the age of 50, depend on (bio)pharmaceutical treatments for their quality of life.<sup>6</sup> For example, 19% of the Dutch population relies on cholesterol medication. Thanks to pharmaceutical treatments, breast cancer need no longer be fatal, and women diagnosed and treated early go on to live long and productive lives (see box on the next page for more examples of pharmaceutical innovation).

<sup>2</sup> CBS, 2008, *Pharmaceutical production: 16,200 (SBI 244), Pharmaceutical wholesaler: 10,100 (SBI 51461), Pharmacies; 26,700 (SBI 5231)*

<sup>3</sup> Nefarma

<sup>4</sup> EIM, *Economische betekenis van 'Life sciences en Gezondheid' voor Nederland*

<sup>5</sup> CBS

<sup>6</sup> SFK, *Data en Feiten 2009*

## EXAMPLES OF PHARMACEUTICAL INNOVATION

A patient with **rheumatoid arthritis** would end up in a wheelchair just 20 years ago. New therapy and biologicals such as TNF alpha blockers have managed to reduce infections and ease the pain, while reducing the number of hospital admissions by 60%. Rheumatoid arthritis patients are now able to stay mobile and live normal lives.<sup>7</sup>

**Asthma** is still a chronic condition, but patients suffering from asthma have been able to live normal lives since the introduction of airway wideners and anti-inflammatory products. The increasing effectiveness of bronchodilators and the better effectiveness/side effect ratio of the inflammatory agents have improved treatment and reduced hospital admissions by 40%. The combination of these innovative drugs in a single inhaler has enhanced persistence and compliance and decreased the asthma burden for patients.<sup>8</sup>

**Diabetes** is no longer an uncontrollable disease. The discovery of synthetic insulin and mixing of slow and fast operating insulins have helped to keep insulin levels balanced throughout the day. New blood sugar decreasing drugs can stimulate insulin delivery, and the discovery of high blood pressure treatments that reduce kidney damage have greatly increased the treatability of diabetes. Diabetes medication has reduced the number of hospital admissions by 35% in just 25 years.<sup>9</sup>

Pharmaceutical treatments are a cost-effective way to realize high-quality healthcare. In 2008, the Netherlands spent only EUR 313 per person on drugs – 10% less than the European average.<sup>10</sup> In 2010, pharmaceutical care is estimated to account for 9% of the EUR 60 bn total Dutch healthcare expenditure.<sup>11</sup> Yet every euro spent on cardiovascular treatments, for example, reduces expenditure in other healthcare areas by four times.<sup>12</sup> The pharmaceutical distribution sector has relatively low transportation costs and a higher productivity than could have been expected considering the Dutch market circumstances.<sup>13</sup> Dutch pharmacies perform better than those in the UK, Germany, Denmark, Belgium and France with regard to electronic information systems, control of drug interactions (side effects), pharmacotherapeutic programs and promotion of lower priced treatments.<sup>14</sup> Moreover, without drugs to prevent the rejection of organ transplants and support chemotherapy, revascularization surgery or home diabetics care, no radiotherapist, specialist or nurse could be effective and many (costly) treatments would be to little or no avail.

<sup>7</sup> Nefarma: 2009, *Rheumatoïde Artritis*

<sup>8</sup> Nefarma: 2009, *Astma*

<sup>9</sup> Nefarma: 2009, *Diabetes*

<sup>10</sup> SFK, *Data en feiten 2009, Comptes Nationaux de la Santé 2007*

<sup>11</sup> *Beleidsagenda 2010, Ministry of Health, Welfare and Sport*

<sup>12</sup> Lichtenberg, 2008, *Have newer cardiovascular drugs reduced hospitalization? Evidence from longitudinal country-level data on 20 OECD countries, 1995-2003*

<sup>13</sup> Roland Berger

<sup>14</sup> IMS Health, 2008, *Apotheken, kostenpost of toegevoegde waarde?*

**Health insurers, in implementing reforms, focus heavily on cost containment – putting the long-term accessibility, affordability and quality of pharmaceutical healthcare at risk**

In recent decades, there have been successive attempts by the government to contain (pharmaceutical) healthcare costs. In 1996, the “Wet geneesmiddelenprijzen” introduced reference pricing by setting the Dutch drug price at the maximum of the levels in Belgium, France, Germany and the United Kingdom. Ten years later the “Zorgverzekeringswet” obliged each Dutch citizen to have health insurance, shifting control from the supply to the demand side and changing the role of the health insurer from administrator to director.<sup>15</sup>

Recent reforms let the insurer, rather than the doctor and pharmacist, decide which versions of generics are prescribed, reimbursing only the cheapest product selected. This so-called preference policy currently only applies to multisource generic pharmaceutical treatments but may be extended to other treatments through “therapeutic substitution” – i.e. replacing (expensive) drugs with (cheaper) alternatives from the same therapeutic class.<sup>17</sup> Prices of generic medicine have decreased significantly: by over 50% on average and up to 90% in some cases over the last years (see figure 2).<sup>18</sup> Although the majority of prescriptions, generic drugs now account for only 15% of total drug spend – which is less than 2% of total healthcare spend (see figure 3).<sup>19</sup>

#### HEALTH INSURER QUALITY CONTROL

“Health insurers should organize care so that it has or reasonably should lead to reliable care. They must systematically monitor, control and improve the quality of care, thus developing systems for quality measurement – insurers increased the number of quality certifications but the relationship between quality certifications and quality of healthcare yet needs to be determined” – Court of Audit<sup>16</sup>

<sup>15</sup> “Wet Geneesmiddelenprijzen”(Wgp), Staatsblad 90, 1996 and “Zorgverzekeringswet” (Zw), Staatsblad 358, 2005

<sup>16</sup> Algemene Rekenkamer, 2009, Implementatie kwaliteitswet zorginstellingen

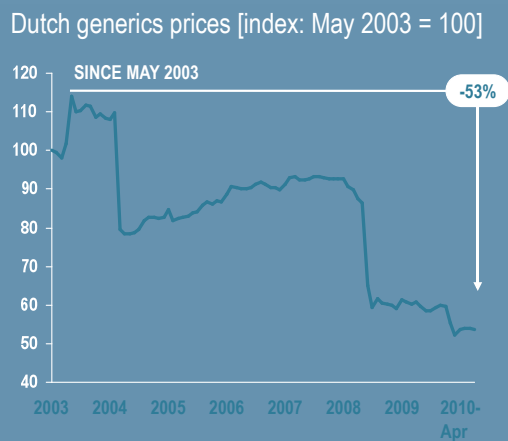
<sup>17</sup> Depending on the health insurer

<sup>18</sup> Farminform 2009 and MS Health MIDAS Sept 2009; Netherlands Xponent

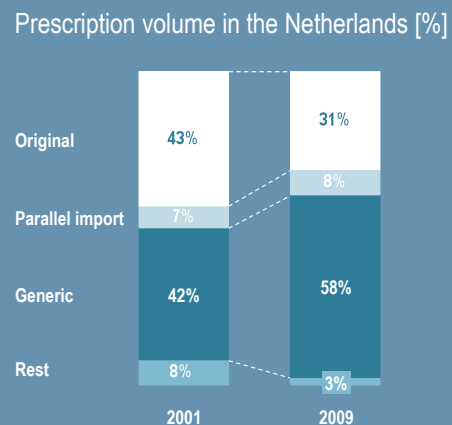
<sup>19</sup> SFK, Data en Feiten 2009

However, these figures tell only half the story. Health insurers have not explicitly defined quality of service standards and quality verification processes to the patient. Not surprisingly, for the task of evaluating and upholding quality is new to them and they have no previous experience to build upon. One could say that developers, producers and distributors have developed a set of principles that is described in “good development”, “good manufacturing” and “good distribution practices”, but currently there is no “good insurance practice”. As a result, where the focus of healthcare reform was on both quality and cost, the emphasis in implementation has come to be, rather one-sidedly, on cost containment alone. Instead of focusing on the use and compliance of the prescribed pharmacotherapies, the emphasis is primarily on the cost of drugs and related services. This may lead to short-term savings (and it has) – but in the long term, as the next chapter shows, it may put at risk the very objective that the reforms were meant to attain: the (sustainable) accessibility, affordability and quality of pharmaceutical healthcare.

**Figure 2: Decreasing prices of generics <sup>20</sup>**



**Figure 3: Increasing share of generics in total prescriptions <sup>21</sup>**



<sup>20</sup> Farminform, May 2010

<sup>21</sup> PhRma profile, 2009, Roland Berger estimation

## Part 2 - Key challenges

### The Netherlands needs to establish a well-functioning market, develop sustainable business models and secure its innovation capacity

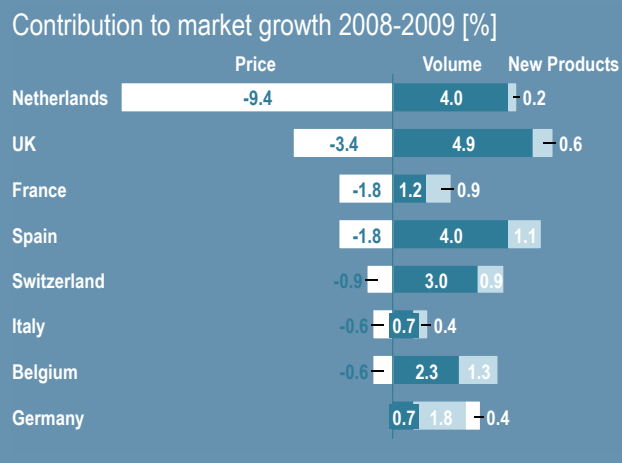
*In the Dutch pharmaceutical market today, cost saving success seems to come at a risk to quality of care. The entire pharmaceutical sector is struggling to deliver the products and services expected of them. To strike a better balance and ensure the long-term accessibility, affordability and quality of pharmaceutical healthcare, the Netherlands must address three challenges: establishing a well-functioning market in which patients can exercise choice and where effects are measured and quality is assured, developing sustainable business models for all players in the pharmaceutical sector and securing our innovation capacity.*

Last year, prices for pharmaceutical treatments fell in the Netherlands more than in any other European country (see figure 4). But cost containment alone does not guarantee (long-term) accessibility, affordability and quality of pharmaceutical healthcare. For that, the patient needs three things:

- > Ability to choose, and get the quality required;
- > Ability to rely on stable actors in the pharmaceutical sector to develop, produce, deliver and monitor the treatments required; and, last but not least,
- > Access to the newest treatments as early as possible.

Current experience suggests that on all three conditions the Netherlands risks falling short. We cannot yet speak of a true, well-functioning market for pharmaceutical healthcare in which choice and quality are assured: all players in the pharmaceutical sector struggle with adapting or reinventing their business models to be able to fulfill their respective roles, and especially the innovation capacity of the sector in the Netherlands is not secured in the long term. Each of these challenges is briefly discussed below.

**Figure 4: Price decrease in the Netherlands stronger than any other European market <sup>22</sup>**



<sup>22</sup> IMS Health MIDAS MAT September 2009

**Challenge 1. Establishing a well-functioning market for (bio)pharmaceuticals where patients can exercise choice and where quality of care is assured**

The healthcare market does not work according to a traditional buyer-seller relationship. The purchaser of pharmaceutical treatments and care (the insurer) is not the one who receives pharmaceutical treatments and care (the patient), and they must both rely on expert opinions on what should be used (the pharmacist, the physician). The patient cannot evaluate the quality of the care received, as he/she lacks knowledge of the alternatives and the results that can be reasonably expected from pharmacotherapy. For this indirect market mechanism to work, two conditions must be met. First, the patient must have a choice – meaning that insurers must differ from each other in quality and service. Right now, this differentiation is limited: there are only four main players, which cover 90% of the market, and their product offers differ very little, if at all.<sup>23,24</sup> Second, patients must know and understand these differences to be able to choose between rival offerings. Though patients are more active, they often mistake web-based information for transparency, and patient education is currently not available. In fact, information on contracted healthcare is often not known at the time the patient decides on an insurance.<sup>25</sup> Therefore, patients cannot make an informed choice between different health insurers.

Conversely, because patients cannot (and do not) choose on the basis of quality, and patients are unaware of the instruments available to influence their health insurer<sup>25</sup>, health insurers lack the patient feedback that would help them further refine and optimize their offerings. Under such circumstances, and considering the relative inexperience of the health insurers themselves with evaluating quality and productivity, the focus on reducing the cost base is hardly surprising: cost is easier to measure. However, this also means that “normal” demand and supply mechanisms to balance price and quality do not function as they would in a “true” market. The “buyer” (the insurer) is disproportionately powerful but it is also neither equipped nor incentivized to exercise that power for anything other than obtaining the lowest possible price. Thus quality may fall by the wayside – even if nobody intends it to.

**Challenge 2. Developing sustainable business models for players in the pharmaceutical sector**

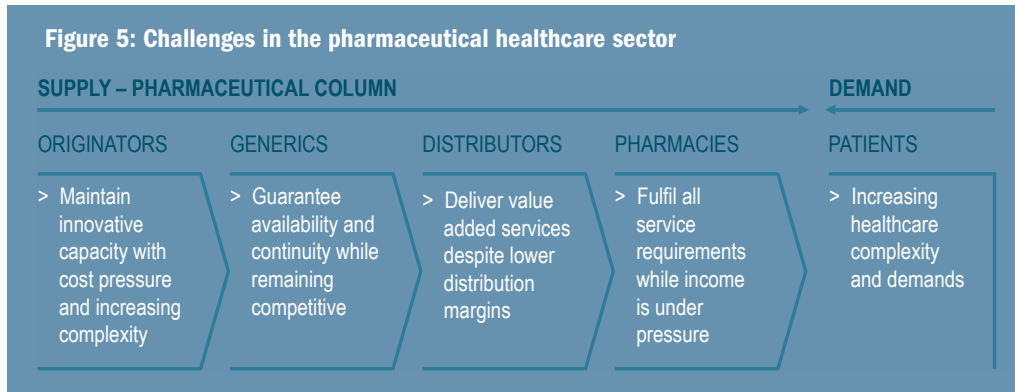
In the context of this developing market, successive cost containment policies have accumulated to impact the entire pharmaceutical sector: originators, generics producers, wholesalers, pharmacies and eventually patients (see figure 5).

<sup>23</sup> Menzis, April 29, 2009, Roger van Boxtel presentation

<sup>24</sup> Roland Berger, Zorgstudie 2009, De Zeven Zorgen

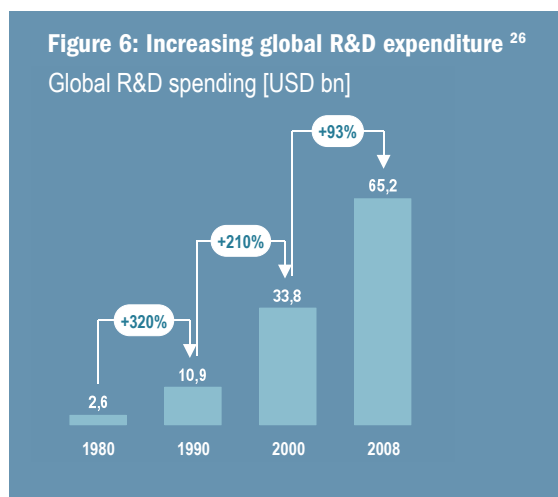
<sup>25</sup> ZonMw, September 2009, Evaluatie Zorgverzekeringswet en wet op de zorgtoeslag

All now struggle to adapt or reinvent their business models so they can continue to develop and deliver their products and services. The following paragraphs analyze the specific challenges facing each player along the pharmaceutical value chain.



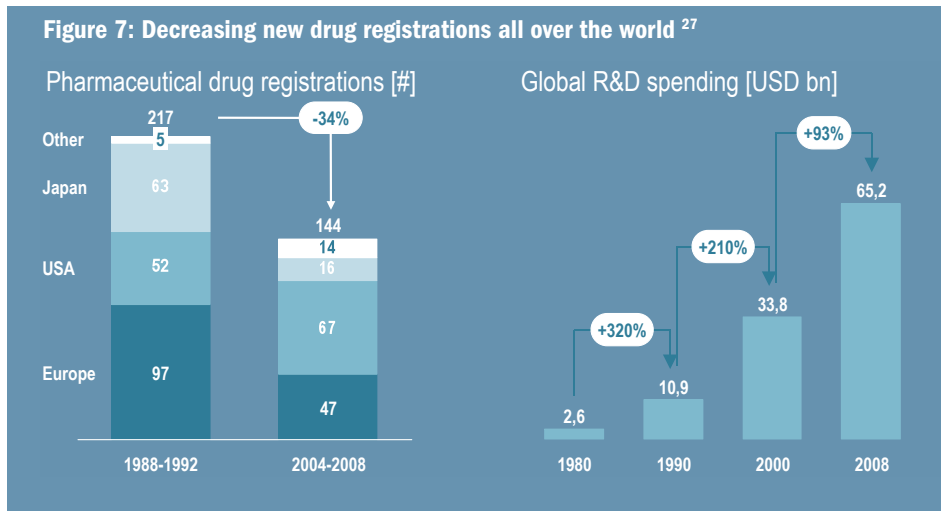
*Originators: “How to maintain innovative capacity despite increasing cost pressure and complexity”*

Patients can only benefit from affordable treatments if these treatments are first developed and produced. If innovators cannot recoup their investments, no new or improved treatments will reach the market – i.e. Dutch patients. Developing more sophisticated and personalized (bio)pharmaceutical treatments is becoming ever more complex. It requires increasingly larger and riskier R&D efforts (see figure 6). Over the last decade, R&D productivity declined as fewer radically new molecules were discovered despite increased spending (see figure 7).



<sup>26</sup> EU Industrial R&D Investment scoreboard, 2008





In addition, advances in molecular biology, genomics and imaging technology are beginning to enable the industry to tailor pharmaceutical treatments to ever smaller and better defined target groups – increasing their effectiveness, but dismantling a business model that depends on volumes. At the same time, the incoherent outcomes of the pharmaceutical pricing act, the drug reimbursement system (GVS) and preference policies inhibit long-term investment planning. Further cost pressure and increased uncertainty directly decrease the innovative capacity necessary to discover new and improve existing pharmaceutical treatments.

*Generic producers: “How to remain competitive without compromising availability and continuity”*

In the long term, applying preference policies could harm the availability and continuity of generics supply. Under the preference policy, providers are selected on lowest price, often resulting in an all-or-nothing situation. An indiscriminate selection on price risks cutting into the range of supply – restricting choice and endangering the continuity of supply and overall access to treatments. This is especially dangerous since prices in the Netherlands are already much lower than in other European countries (see figure 8).

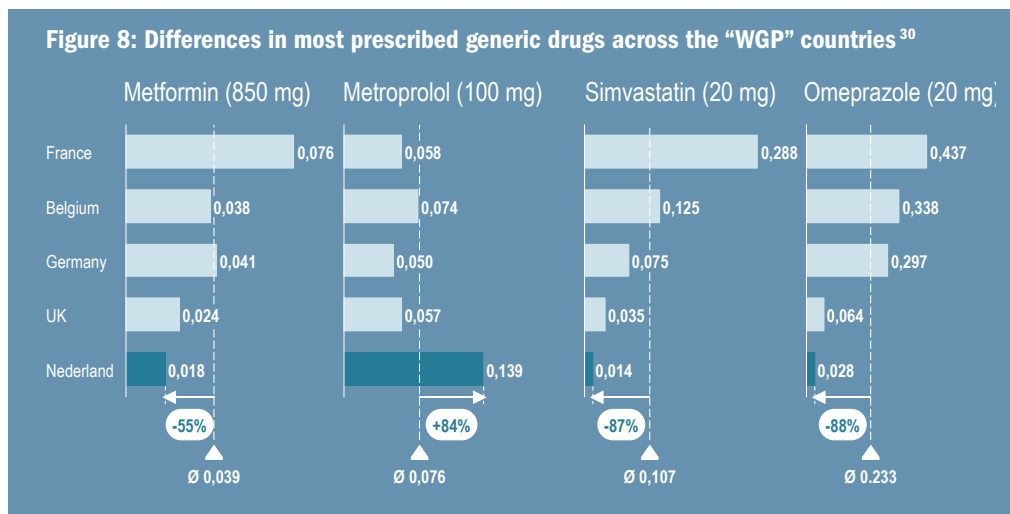
#### NEGATIVE EFFECTS OF PREFERENCE POLICY IN OTHER COUNTRIES

- > Slows down the development of generic versions of pharmaceuticals, forcing patients to continue to pay higher prices for pharmaceuticals<sup>28</sup>
- > Leads to a decrease in pharmaceutical research and development<sup>28</sup>
- > Decreases the number of active players in a market<sup>29</sup>

<sup>27</sup> PhRma profile, 2009

<sup>28</sup> PWC, Ontario Public Drug Programs Competitive Agreement Initiative, February 2009

<sup>29</sup> P. Kanavos, L. Seeley and S. Vardoros, London School of Economics, 2009, Tender systems for outpatient pharmaceuticals in the European Union



Current generics providers are committed to the Dutch generics pharmaceutical healthcare market and have actively pursued continuity of supply, information provision and therapy compliance programs for the Dutch patient. But the preference policy has left the market open for opportunistic suppliers without these long-term commitments. This will lead to a potentially undesirable situation in which generics, on which we increasingly depend as a main source of affordable pharmaceutical treatments, will be provided by ultra low-cost companies that are not invested in the market as a whole. Eventually, the willingness of other suppliers to further invest in early generics introduction will decrease, leading to delayed patient access to affordable generic treatments.<sup>30</sup>

*Wholesale distributors: "How to deliver value added services with decreasing distribution margins"*

Wholesale distributors, specifically full-line wholesalers, have seen their profits greatly reduced by falling generics prices, generics substitution and exclusive distribution through direct distributors. The wholesalers rely on percentage discounts that are no longer sufficient to cover (fixed) costs. Many provide value added services at no extra charge, such as rush orders, stockpiling vaccines against pandemics and cold-chain logistics to extend and ensure the shelf life of temperature-sensitive pharmaceutical drugs. Individual attempts to introduce new systems of remuneration (e.g. service level differentiation, premium offerings and fees for extras) are bound to fail as their customers are poached by competitors which see an opportunity to prolong their business models by increasing volumes. This deadlock eventually leads to the erosion of value added services, limitation of access to the full product range, and ultimately wholesalers will exit the market due to bankruptcy or mergers.

<sup>30</sup> IMS Health 9/2009, Top four reimbursed pharmaceutical drugs by volume, Acenocoumarol and Hydrochlorothiazide are excluded as data was not available

*Pharmacies: “How to fulfill all service requirements while income is under pressure”*

The role of a pharmacy is to deliver pharmaceutical care and to distribute drugs. Traditionally, the pharmacist gets paid by negotiating discounts from the wholesale distributors on top of a fixed prescription fee. In recent years, claw backs, covenants and the introduction of the preference policy have significantly reduced pharmacies’ margin-based income, while the fixed fee a pharmacy receives for each prescription is not enough to cover its costs for both distribution and the desired value added services, many of which prevent drug-related hospitalizations.<sup>31</sup> Right now, pharmacies are absorbing the administrative, logistical and inventory costs of the health insurers’ preference policy without compensation.<sup>32,33</sup>

Full-service pharmacies and wholesalers have a crucial function in a future healthcare system. More diverse and tailored products, more demanding customers who seek advice, the increasing threat of counterfeits and increasing attention to pharmacoeconomic studies – all require a professional distribution sector that can provide value added services and supply the necessary information.

#### **CASE – PREFERENCE POLICY IN PRACTICE**

A Dutch patient took more than five different pharmaceutical drugs every day. When the preference policy came into effect, the make of each changed almost monthly. Pills would change in color and shape. She could not keep track and sometimes took too many of one or forgot the other. Some pills contained additives that gave her a rare skin disease that took two months and several visits to her doctor and specialists to discover and correct. The health insurer saved EUR 0.29 on each of her 270 tablets, at the expense of three extra doctor visits, two blood tests and an X-ray session.<sup>34</sup>

<sup>31</sup> *Monitor werking farmaciemarkt, HARM-studie (Hospital Admissions Related to Medication) 2006 – 2.4% of hospital admissions and 5.6% of all emergency admissions are caused by medication errors, half of which are preventable, in total 19,000 cases. Alertness in prescribing drugs is of vital importance, in terms of healthcare costs by preventing (expensive) hospitalizations, but also in terms of quality of patient care*

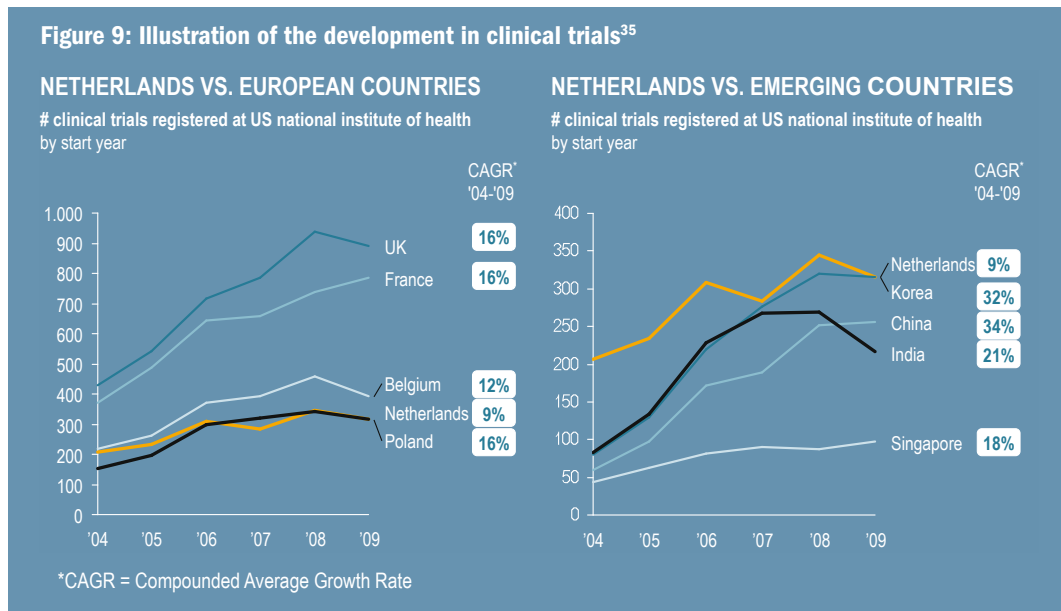
<sup>32</sup> *The Dutch healthcare regulator (NZa) has acknowledged this and raised the fee per prescription by almost 9% to EUR 7.91 in 2010. Pharmacists and insurers may set fees to a maximum of EUR 10 per prescription in contracts with additional quality guarantees*

<sup>33</sup> *KNMP Rapport 1/6 januari 2010, Invloed preferentiebeleid op handelingsprocessen in de apotheek*

<sup>34</sup> *Medisch Contact, December 2009, Preferentiebeleid kent bijwerkingen*

### Challenge 3. Securing the Netherlands' innovation capacity in (bio)pharmaceuticals

High-quality pharmaceutical healthcare in the Netherlands implies that the best and newest treatments are available to Dutch patients as early as possible. Patient access to new therapies is quickest if Dutch physicians and pharmacists have been actively involved in their development and (clinical) testing. That in turn depends on a knowledge base and infrastructure (university medical centers, public-private partnerships, company research departments, pharmacies, patient groups), both of which have world-class standing in the Netherlands today. The Netherlands has a very good position and academic record in clinical trials but other countries seem to be catching up or accelerating (see figure 9). Without continued investment in both basic and clinical (translational) research and in the quality control system, that knowledge base and infrastructure will erode, and research, development and clinical trials may leave the Netherlands – resulting in a reduction of quality of pharmaceutical healthcare as well as the loss of experience, education and the investment and jobs to support the knowledge economy.



<sup>35</sup> U.S. National Institutes of Health, Registrations from 1/1/1999 to 05/17/2010 – Shows number of registered at the U.S. National Institutes of Health it does not represent the number of participants or academic outputs

Besides the innovation capacity to deliver new treatments, a flexible evaluation system is required to process feedback on expected and delivered quality of new and existing treatments in the research, clinical and real-life phases. The current value assessment, which forms the basis for reimbursement, is a rigid approach that does not often assess the real value of an innovative product for the patient and his/her social environment. More flexibility in the assessment will lead to better patient access to innovative therapies. Also, the current evaluation and monitoring systems are not implemented or optimally used across the sector, not by health insurers, care providers or the patient, leaving a large amount of potentially valuable information untapped. Building this system is key to a well-functioning healthcare market and to the further advancement of the innovation capacity in the Netherlands.

## Part 3 - Identified opportunities

### **Stakeholders should act to incentivize health insurers to measure and safeguard quality, enable new business models and make the Netherlands a front-runner in pharmaceutical innovation**

*The accessibility, affordability and quality of pharmaceutical healthcare is paramount to sustaining health and wealth in the Netherlands. All stakeholders should rethink their role and contribution. Resolving the challenges described in the previous chapter will also bring opportunities. To establish a well-functioning market, health insurers must be incentivized to factor quality into their purchasing decisions. This in turn will help safeguard and increase quality across the board. Enabling new business models in the pharmaceutical sector will entail earlier patient access to new therapies, a better balance of price and quality considerations and remuneration schemes that allow for (and encourage) greater innovation capacity. The Netherlands could thus become a front-runner in pharmaceutical innovation.*

#### **Opportunity 1: Incentivize health insurers to measure and safeguard the quality, instead of just the cost, of pharmaceutical healthcare for the patient**

The preference policy effectively allows health insurers to reduce healthcare expenditures for their policyholders. What it lacks is a system of quality control, measurement and comparison and the incentives to measure and safeguard quality in the purchasing and reimbursement decisions surrounding pharmaceutical healthcare. All suppliers that meet threshold requirements (marketing authorization and some guarantees on the ability to supply) may participate. All suppliers being equal, every insurer will naturally opt for the cheapest. The best incentive for health insurers to safeguard and increase quality is to enable them to differentiate themselves and compete on that differentiation. Policies to encourage patients to make an active choice between suppliers are demonstrably required in order for this market to become competitive.<sup>36</sup>

Health insurers, players in the pharmaceutical sector and government should adjust the structure to allow evaluation, differentiation and competition on quality criteria – both for the health insurers and for their suppliers. An option would be to stimulate cooperation between health insurers and other sectors to share benefits of effective pharmacotherapies, such as shorter hospital stays and quicker reintegration of employees.

<sup>36</sup> ZonMw, September 2009, *Evaluatie Wet Marktordening Gezondheidszorg*

## **Opportunity 2: Enable new business models for the players in the pharmaceutical sector**

The pharmaceutical sector is under pressure and all parts of the sector need to rethink their roles and reshape their business models. For each player, possible solutions are discussed below.

### *Originators: accelerate patient access to new treatments*

Originators must be able to recoup their investment before their patent expires. Price pressure at the end of the patent period will only increase as therapeutic substitution brings more generics under the preference policy. This pressure could be partly offset by creating room for the use of new (bio) pharmaceutical treatments.

The earlier (bio)pharmaceutical treatments are adopted, the more value is created and captured by patients, the pharmaceutical sector and society alike. Timely, early interventions reduce hospitalization, residential care and other healthcare expenditures while also increasing productivity. Early adoption of (bio)pharmaceutical treatments could save as much as EUR 140 m for every month that introduction is accelerated.<sup>37</sup> This reduction will be largely realized through a reduction in required hospital staff, thereby contributing to solutions to the increasing shortage of hospital personnel.

Early adoption requires faster clinical trials and reimbursement decisions. This will both reduce development costs and allow originators to sell a new drug earlier in the patent period. The Netherlands enjoys a strong reputation in quality clinical research, but clinical trials in the Netherlands can take relatively long. Priority should be given to finding new ways to safely reduce the time needed, for example through the pharmacokinetic-pharmacodynamic modeling that is currently being researched at TI Pharma (and could also help, for example, reduce the need for animal trials), and by reviewing excessive regulation.

The maximum period for an application for pharmaceutical drug reimbursement is currently set at 90 days.<sup>38</sup> However, in practice the average number of days needed before reimbursement starts often exceeds 160 and varies greatly among drugs.<sup>39</sup> This reimbursement decision often needs to be made before all evaluation results are known. One way to reduce the time to reimbursement is thus by granting provisional reimbursement, allowing treatment for a targeted number or group of patients in immediate need and evaluating the outcome in practice with the pharmaceutical sector.

<sup>37</sup> Maastricht University and APE, Tsiachristas, Groot, Goudriaan, *The welfare effects of innovative pharmaceutical drugs*

<sup>38</sup> CVZ, *Een zorgvuldige afweging. Procedure bij de aanvraag voor vergoeding van geneesmiddelen*

<sup>39</sup> CVZ website 2009

*Generics producers: develop alternatives to the preference policy that optimize cost and quality of service*

The preference policy in the Netherlands has driven down generics prices by as much as 90% in some cases, to mere cents per dose. There is a point at which further cost savings no longer make up for the cost of delayed introduction of generics (i.e. continued reimbursement of the patented product) as it becomes unattractive to launch products in the Netherlands. Alternatives should be explored to strike a better balance between lower cost and early introduction, and between cost and quality of service – allowing producers to compete on other criteria besides cost (e.g. ease-of-use, compliance).

These alternatives could include:

- > A reimbursement model for low-cost generics based on patient contribution – reducing administrative costs at the insurer and pharmacist and guaranteeing patient awareness of both cost and quality of service;
- > A delay in enforcing preference policies after a patented drug expires – to stimulate the quick introduction of generics;
- > Other contract forms that do not only focus on price and which allow the sector and insurers to jointly work on quality improvements. An example is the IDEA contract, offered by the largest insurer and signed by the majority of pharmacies<sup>40</sup>.

*Wholesale distributors: enable a sector-wide adjustment of the business model and uphold full-line character of distributors*

Government policy and market developments have changed market dynamics. The introduction of an adjusted, sustainable market structure requires policy-based coordination and cannot be realized by a single company. To introduce a remuneration system that is not only based on discounts, and to resolve the deadlock that inhibits change, a coordinated transformation in business models is needed. This requires government facilitation. To enable a sustainable full-line wholesale sector, several objectives must be met. One objective would be to secure continued access to all listed products from pharmaceutical manufacturers to enable the wholesaler to meet its public service function, while not excluding alternative distribution models like homecare or direct delivery. Another can be a minimum logistic fee per pack, independent of the ex-factory price of the product, for the full-line tasks performed on the pharmaceuticals distributed by the full-line wholesalers. By jointly realizing a controlled change to a business model where full-line wholesalers are paid for their services, the full-line wholesalers and the government enable a sustainable, patient centered, pharmaceutical distribution which is less dependent on the mix of discounts obtained from generic and branded pharmaceutical suppliers.

<sup>40</sup> [www.ideacontract.nl](http://www.ideacontract.nl)



*Pharmacies: developing transparent and sustainable compensation schemes for additional quality and service levels*

Pharmacies are the last link in the sector chain that delivers drugs to patients. They take care of patient education, compliance, stock-keeping and quality control – value added services that are critical to the safe and effective use of (bio)pharmaceutical treatments and that they must continue to provide. Therefore, government, insurers and players in the pharmaceutical sector should agree on minimum quality standards and service levels and transparent and sustainable compensation schemes for additional quality and service. The government should further deregulate the sector to create an environment for entrepreneurship, innovation and client focus in which pharmacies, wholesalers and insurers are free to negotiate prices and services. Steps have been taken in the Dutch Health Authority's development of 14 functionally-described performance measures to be used for rate negotiation and to compensate pharmacies for the extra quality and innovation delivered<sup>41</sup>. The pharmacies in turn should commit themselves to further performance improvement and implementation of standards.

**Opportunity 3: Become a front-runner in research and development, testing and evaluation of new (innovative) pharmaceutical treatments**

Most pharmaceutical activities in the Netherlands are related to R&D and clinical trials. In an open innovation paradigm, the quality and continuity of the knowledge infrastructure attracts researchers, entrepreneurs and investors. For example, MSD has undertaken to conduct 70% of all its clinical trials for cancer medication in a network of 19 centers around the world that includes the Anthony van Leeuwenhoek hospital in Amsterdam; GSK in the Netherlands holds the 10th position of all generate patients, which is far beyond the size of our population. Furthermore, focusing on patient centric R&D and clinical trials helps reinforce trust in the sector and overcome the internal focus of all stakeholders by working together on what benefits the patient in the long term.

Research and development, especially clinical trials, not only support innovation but also familiarize doctors with new treatments, thus increasing the absorptive capacity of Dutch healthcare. The knowledge infrastructure is the foundation for both health and wealth. Dutch databases such as Parelsnoer, Lifelines and the Mondriaan project use medical and bioinformatics to process huge quantities of lifestyle, medical and biogenetic information on both patients and healthy people and could help design better and quicker clinical trials and evaluate the efficacy and efficiency of pharmaceutical treatments. But though the knowledge infrastructure and means to conduct trials in the Netherlands is particularly strong, investments in public-private partnerships is set to drop sharply after 2011<sup>42</sup>.

<sup>41</sup> NZA, 2010, *Prestaties en activiteiten farmaceutische zorg*

<sup>42</sup> *Partners in de Polder*, 2009

Becoming a leading pharmaceutical research nation can have a flywheel effect and bring additional economic opportunities. First, the health benefits would pay off in increased productivity of Dutch society. Second, the Netherlands would become an attractive location for the pharmaceutical sector to develop, test, launch and evaluate its products for the European market. As a leading pharmaceutical research nation with a high-quality pharmacy network, the leading infrastructure and knowledge base could attract other companies and investments in research, clinical trials, manufacturing and distribution. Continued investment in the knowledge infrastructure should be a first priority for all stakeholders, both public and private.

## Part 4 - Conclusion and actions

### The pharmaceutical sector, government and insurers should work together to ensure accessible, affordable and high-quality pharmaceutical healthcare

Pharmaceutical healthcare is crucial for the health and wealth of Dutch society and its citizens. Healthcare reforms have mainly focused on cost containment, and implementation has successfully begun. But risks have been identified that threaten the quality and sustainability of pharmaceutical healthcare in the long term (see figure 10).



Now, stakeholders must follow through and ensure the conditions for the (continued) accessibility, affordability and quality of pharmaceutical healthcare in the Netherlands. They can only do so by taking the following actions together:

- Action 1: Develop a quality control system and make quality transparent to the patient
- Action 2: Accelerate patient access to new pharmaceutical therapies with value for the patient
- Action 3: Develop new solutions to create a sustainable, accessible generics market
- Action 4: Enable a sector-wide change in remuneration for the wholesale distributor
- Action 5: Link the remuneration scheme of pharmacies to the value added services of the pharmacy
- Action 6: Stimulate joint investments in infrastructure and (public-private) innovation programs

<sup>43</sup> EIM, Economische betekenis van 'Life sciences en Gezondheid' voor Nederland

<sup>44</sup> Maastricht University and APE, Tsiachristas, Groot, Goudriaan, *The welfare effects of innovative pharmaceutical drugs*

<sup>45</sup> PWC, *Ontario Public Drug Programs Competitive Agreement Initiative, February 2009*

<sup>46</sup> P. Kanavos, L. Seeley and S. Vondros, *London School of Economics, 2009, Tender systems for outpatient pharmaceuticals in the European Union*

<sup>47</sup> *Monitor werking farmaciemarkt, HARM-studie (Hospital Admissions Related to Medication) 2006*

<sup>48</sup> NZA, *December 2008, Werking farmaciemarkt*

The pharmaceutical sector will continue investing in the pharmaceutical infrastructure to develop new (bio)pharmaceutical treatments and more efficient ways of production and distribution. Key companies from the pharmaceutical sector have expressed their interest in a joint approach – with government and insurers – to deal with the challenges and opportunities the sector is facing. Together, they can ensure accessible, affordable and high-quality pharmaceutical healthcare in the Netherlands – Today and tomorrow.

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