



**Tender systems for outpatient pharmaceuticals in the
European Union: Evidence from the Netherlands,
Germany and Belgium**

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LIST OF ABBREVIATIONS

AIO	: All in One
AOK	: Allgemeine Ortskrankenkassen
BEK	: Barmer Ersatzkasse
CvZ	: College voor zorgverzekeringen
DAK	: Deutsche Angestellten Krankenkasse
ECJ	: European Court of Justice
EEA	: European Economic Area
EGA	: European Generics Association
EU	: European Union
GMP	: Good Manufacturing Practice
IMS	: Intercontinental Medical Statistics
KNMP	: Royal Dutch Pharmacists Association
MEAT	: Most Economically Advantageous Tender
PGEU	: Pharmaceutical Group of the European Union
PPP	: Pharmacy Purchase Price
PPR	: Pharma Pricing Review
SFK	: Stichting Farmaceutische Kengetallen
TA	: Transition Agreement
TK	: Techniker Krankenkasse
VAT	: Value Added Tax
WGP	: Pharmaceuticals Price Act
ZN	: Association of Dutch Healthcare Insurers (Zorgverzekeraars Nederland)

1. Background and objective

In an effort to achieve lower pharmaceutical prices, health insurers in the Netherlands have devised a new purchasing method called preference policy. This system of drug reimbursement is comparable to the “Kiwi Model”¹, where national drug procurement is tendered for drugs within certain classes, which may include patented, originator drugs. Based on that model, the manufacturer that offers the lowest price wins the national contract for a given period, after which point procurement begins again in order to stimulate further price concessions and give other manufacturers the chance to supply the market.²

In 2005, a group of seven health plans in the Netherlands, representing approximately 60% of the insured population, collectively decided to “tender” the purchasing of three active ingredients—simvastatin, pravastatin and omeprazole—all off-patent products. A key underlying rationale for the *initiation* of this policy was the fact that pharmacies could negotiate discounts from individual manufacturers, which health insurers would not be in a position to re-coup in their entirety. In the follow-up stages of the policy, an agreement was in place with agreed upon savings. It was recognized that pharmacies should obtain part of their income out of discounts as the dispensing fee³ was not at the appropriate level.

Under this scheme, which came to be known as “Preference Policy”, only manufacturers with the lowest price, or prices within 5% of the lowest price, were able to contract with these health plans. In this sense, they became “preferred” manufacturers. Manufacturers whose products did not fall into the 5% range were altogether excluded from the purchasing process, unless prescribing doctors state that there is a need for the medicine(s) in question. Their products were only available to patients as “non-preferred” products that had to be purchased exclusively out-of-pocket. The result was that because originator brand medicines were priced higher for these ingredients during the mid-2005 to December 2007 period, only generic manufacturers achieved preferred status. Moreover, in some cases, generic manufacturers that previously only had a small share of the market managed to secure the vast majority of the market once receiving preferred status. In the case of simvastatin, Focus Farma (Ranbaxy), a generic producer, undercut the rest of the market offering a (significantly) lower price and, consequently, captured 100% of the simvastatin market (for participating insurers).

A key implication of this new practice is that it shifts the balance of power in favour of the insurance company as the latter now becomes a key player in the procurement process.

¹ Named after the experience of New Zealand in implementing this model, although important differences exist between the New Zealand system and the Netherlands in this respect, e.g. in terms of health care financing. In addition, Dutch Health Care Insurers are ordinary private companies with profit and loss accounts and to which the usual competition laws actually apply.

² <http://health.apmnews.com/story.php?mots=GENERICs&searchScope=1&searchType=0&depsPage=12&numero=L2847>, accessed on March 2, 2009; <http://www.globalinsight.com/SDA/SDADetail6160.htm> accessed on March 2, 2009.

³ A key component of pharmacy remuneration in the Netherlands.

Before the Netherlands' preference policy system can be hailed as a successful or innovative approach to pharmaceutical cost containment, there are a number of unresolved issues that need to be addressed, particularly the implications for the other stakeholders.

In light of the above, this paper conducts a qualitative analysis of the preference policy in the Netherlands in order to determine its effects domestically and the implications for other Member States. In building the evidence base, the paper also compares and contrasts the relative merits of the Dutch Preference Policy experience with those of similar or comparable experiences in Germany and Belgium.

Section 2 places the subject of tenders for outpatient prescription medicines in context by discussing the situation for tenders in Europe; section 3 outlines the data collection process for this paper, while section 4 presents the evidence from the Netherlands, Germany and Belgium. Section 5 debates the implications for the different stakeholders. Finally, section 6 draws the main lessons for EU Member States.

2. Tender systems for pharmaceuticals in EU Member States

Tendering is an important tool for purchasing pharmaceuticals, used in most EU Member States. According to a recent survey analyzing tendering processes in 18 EU and EEA countries, it emerges that tendering is particularly used in hospital settings, but also serves in many countries to purchase pharmaceuticals for a specific public function (e.g. vaccines or for army purposes) (OEBIG, 2008). These tenders are conducted with specific objectives and clear conditions for all bidders and include, among others, desired quantities to be purchased and the duration of the tender. Of the countries quoted in that survey, only few apply it for pharmaceuticals in ambulatory care distributed through retail pharmacies. In particular, Belgium⁴, Cyprus, the Czech Republic, Estonia, Germany, Hungary, Ireland, Lithuania, The Netherlands, Romania, Slovenia and Iceland use tendering for pharmaceuticals in ambulatory care (see Table 1). While tendering can easily be used for up to 25% of the medicines in a hospital setting, only Cyprus and Iceland use it for a significant volume of medicines in ambulatory care.⁵

In principle, an effective tendering process takes into account several criteria, rather than focusing on a single criterion, in order to ensure the *availability* of the needed pharmaceuticals in the required quantities, at *reasonable prices* and at a recognized *quality standard*. Most of the countries quoted in Table 1 have the best or the lowest price as their key criterion for awarding the tender, but, on several occasions, quality and the ability to supply are also explicitly mentioned. Typically these elements are the main criteria used in tendering processes. The survey yielded that “due to tendering a certain added value may be reached in terms of transparency when using public funds to purchase pharmaceuticals” (OEBIG, 2008).

Given the impact of tendering activities on the effectiveness of health services, especially in hospital settings, and given their impact on the competitive industry landscape, it is essential that these activities are performed in a pre-defined and structured framework, meaning that there should be an underlying legal basis specifying e.g. award criteria, the frequency of tenders and the obligation of publishing the outcomes. Hence of further importance is the implementation and the surveillance of tendering processes by competent institutions. All 18 participating countries with public tendering of pharmaceuticals (though in differing volumes, extend and coverage) claim to follow the EU Procurement Directive 2004/18/EC. Many national systems add to this Directive.

In general, the countries seem to have positive experiences with tendering in hospital settings, but little evidence is available about the effects of tendering in ambulatory care settings. Through tendering procedures lower prices for purchasers and increased transparency are achieved with the use of public funds. But it is also important to realize that occasionally difficulties are experienced in estimating the necessary quantity of the products needed. Additionally, tendering procedures require a lot of expertise and

⁴ Which at the time had ambulatory care tenders. Presently, Belgium has stopped performing tenders.

⁵ Both Iceland and Cyprus have very small markets. Due to their limited (and by competition fragmented) market size, it is not implausible to assume that few manufacturers would be interested in being present, in which case, the authorities may want to improve access by bundling volume and offering to a single manufacturer that can guarantee supply.

resources. In particular, tendering in ambulatory care seems to be relatively new and not much is known to date except that legal complaints significantly complicate the set-up (Belgium) and that dedicated tendering teams may be needed (e.g. Ireland).

Overall, tendering is a well established tool to purchase pharmaceuticals mostly in hospital settings, but increasingly also in ambulatory care settings. A key argument in favour of tendering is that it should in principle enhance transparency in the use of public funds. However, little evidence is available to date on the value of tendering in the ambulatory sector, which is what this paper is trying to address .

Table 1
Key features of tendering systems in European countries , 2008 - 2009

Country	Tendering system in place	Year of introduction	Hospital care	Ambulatory care	Types of procured pharmaceuticals	Frequency	Criteria
Austria	Y	NA	b	No	Vaccines, pharmaceuticals as defined in pandemic plans; also pharmaceuticals for military and prisoner population	Depending on need	Best price/offer
Belgium	Y	NA	b	b	Hospital care: Vaccines, pharmaceuticals as defined in pandemic plans and specific therapeutic groups of pharmaceuticals; also pharmaceuticals for military and prisoner population	Annually (hospital care)	NA
Cyprus	Y ¹	Before 1970	b ²	b ²	NA	Bi-annually (hospital care)	NA
Czech R	Y	NA	b	b	Hospital care: Vaccines, pharmaceuticals as defined in pandemic plans; pharmaceuticals relevant for public hygiene in competence of MoH	Annually (hospital care)	NA
Germany	Y ³	2003	No	b	Pharmaceuticals in ambulatory care; mostly generics (also biosimilars), some branded ; AOK tenders for >90 molecules; tenders can be regionalized for AOK	Annually or every 2 years	Lowest price, product portfolio, supply
Denmark	Y	1990	b	No	Vaccines, pharmaceuticals against communicable diseases, pandemics	Annually	NA
Estonia	Y	NA	b	b	Hospital care: Vaccines, pharmaceuticals against communicable diseases and drug addiction disorders	Annually (hospital care)	NA
Finland	Y	NA	b	No	NA	At 1-3 year interval	Price, quality, supply, availability
France	Y	NA	b	No	NA	Annually or every 2 years	NA
Hungary	Y	1994	b	b	Hospital care: Vaccines, pharmaceuticals	Annually	Lowest

					against communicable diseases, pandemics	(hospital care)	price; most reliable supplier
Ireland	Y	NA	b	b	Hospital care: Vaccines, pharmaceuticals against communicable diseases, pandemics	Annually or multi-annually (hospital care)	MEAT ⁴
Latvia	Y	1998	b	b	Hospital care: Vaccines, pharmaceuticals against communicable diseases, pandemics and oncology drugs	3-4 months before the agreement with the seller expires; irregular (hospital care)	Lowest price
Malta	Y	NA	b ²	b ²	NA	3 years (hospital care)	NA
The Netherlands ⁵	Y	Q3 2005	No	b	Currently 33 molecules; vary by insurer; possibility to extend to more molecules	<ul style="list-style-type: none"> 6-monthly (originally for the 3 molecules of the combined preference system introduced in 2005) Currently the duration is 12 months 	Lowest price
Romania	Y	March 2002	b ²	b ²	Hospital care: Vaccines and pharmaceuticals as defined in pandemic plans	Annually (hospital care)	Lowest price
Sweden	Y	NA	b	No	NA	Locally decided, most commonly bi-annual	NA
Slovenia	Y	Jan. 1998	b ²	b ²	NA	Annually (hospital care)	NA
UK	Y	NA	b	No	Vaccines, pharmaceuticals against communicable diseases, pandemics	Determined by tendering strategy	Generally MEAT ⁴
Switzerland	Y	NA	b	No	Vaccines, pharmaceuticals as defined in pandemic plans	Only in specific cases	NA

Iceland	Y	Jan. 2004	b	b	NA	Every 2 years (hospital care)	NA
Norway	Y	NA	b	No	Pharmaceuticals as defined in pandemic plans	Annually	Lowest price; best economic offer

- Notes:**
- ¹ E.g. for military service or pandemic plans.
 - ² Only valid for public sector (hospital and ambulatory care sector).
 - ³ Sickness funds in Germany can negotiate discounts for pharmaceuticals. Following a recent European Court of Justice (ECJ) decision [case C-300/07, 11 June 2009] these contractual discounts can be considered as tendering (ECJ, 2009).
 - ⁴ Most Economically Advantageous Tender.
 - ⁵ Information applies to the case of ambulatory care drugs under the Preference Policy

Source: Adaptation based on OEBIG, 2008 and updated by the authors for Germany and the Netherlands.

3. Data and Methods

The evidence presented in the paper relies on both secondary and primary data sources. Secondary data sources were identified from the published and unpublished literature by scanning the peer review literature on Medline, Embase, BIDS/ISI, and ECONLIT. The data sources identified from this search were very limited.

Primary data collection entailed the conduct of a number of semi-structured interviews with stakeholders in the Netherlands, Germany and Belgium that took place either by telephone or face-to-face. The questions that formed the basis for the semi-structured interviews are shown in Box 1.

Box 1

Tool for semi-structured interviews with stakeholders in the Netherlands, Belgium and Germany

1. Where did the health insurers derive the idea from about the preference or rebate policy? Was the New Zealand model used as a reference guide?
2. Which stakeholders (associations) were involved with the initial preferential policy contract?
3. What were each of the stakeholders' views and positions on the policy?
4. How (if at all) have stakeholders' views and positions changed?
5. What criteria were used in deciding which drugs to include in the new scheme? By whom?
6. Have the preferred manufacturers shown any signs of difficulty in supplying the market? What provisions are in place to ensure that manufacturers are in a position to supply?
7. Have there been any instances of manufacturers (brand or generic) exiting the market as a result of losing the tender? What is the overall impact on the pharmaceutical industry?
8. Is there any way in which patients' access to these participating drugs (or other drugs) been affected, either positively or negatively?
9. How are pharmacies incentivised/compensated in the preference/rebate policy system?
10. Are further drugs being considered in future rounds of the scheme?
11. Are certain parties still contemplating extending this scheme to therapeutic classes? If so, which ones and what is the likelihood that this will happen?

The stakeholders that were contacted in each of the three countries included policy-makers, retail associations and the pharmaceutical industry (both originator and generic). Within the timeframe for this paper, the stakeholders that provided input either in writing or via meetings (face-to-face or via telephone) were: from the Netherlands, decision makers (CZ), the Association of Generic Manufacturers (Bogin), a retail chain (ASKA), and a retail & distribution group (OPG). From Germany and Belgium, information was collected from various sources including the local pharmacy association, originator pharmaceutical manufacturers and generic manufacturers. Additional input and

perspectives at EU level were obtained from the European Generics Association (EGA) and the Pharmaceutical Group of the European Union (PGEU).

4. Results

4.1. The Preference Policy in the Netherlands

Background

Although the Dutch healthcare system now relies on private insurers, the Government still plays a pivotal role in assuring Healthcare services to its citizens. In 2006 a new law was introduced that regulates the role Healthcare Insurers should play. At the same time there was an agreement between the Ministry of Health, Bogin (the Association of the Dutch Generic medicines Industry), KNMP (the Association of the pharmacists in the Netherlands), Nefarma (Association of the Innovative Medicines Industry in the Netherlands), ZN (Association of the Dutch Healthcare Insurers) . This agreement was formulated in a covenant in 2006/2007⁶ and aimed at

- (a) agreed cost savings;
- (b) planning the necessary changes in the regulated system; and
- (c) determining what the dispensing fee should be for pharmacies.

In late 2007 a new agreement was signed, “The Transition Agreement 2008/2009”, aiming to introduce greater market dynamics through intensifying competition in 2010. This would be a model of a less regulated market based on competition on quality and price. The overall high level responsibility for quality, accessibility and affordability of healthcare would remain with the Government.

The “Transition Agreement” for pharmaceutical healthcare 2008-2009

In September 2007, the Ministry of Health, Welfare and Sport, the sector organization representing the healthcare insurers in the Netherlands [Zorgverzekeraars Nederland (ZN)], the pharmaceutical industry's umbrella organisations and the pharmacists' umbrella organisation [KNMP] concluded on a multi-party pharmaceuticals agreement – known as the Transition Agreement (TA) – for 2008 and 2009. This agreement provided that:

- The prices of branded pharmaceuticals whose patents have expired and their generic variants would decline by 10% on average in 2008 compared to year-end 2007 price levels;
- The prices of pharmaceuticals whose patents expire in 2008 and their new generic variants would be cut by 50% compared to the price of the branded pharmaceutical immediately before its patent expiry. The previous agreement was based on a 40% cut;
- The Ministry of Health, Welfare and Sport would extend the application of the Pharmaceuticals Price Act (WGP) by including the prices of generic

⁶ Although a covenant was already in place since 2004.

pharmaceuticals in the UK in the "WGP basket", in addition to the prices in France, Belgium and Germany .

- The Ministry of Health, Welfare and Sport would develop and discuss with the partners a Long Term Vision on the future of pharmaceutical care. Time was needed to develop the plan, change the legislation and solve the income problem with the pharmacists.

This package of measures, in conjunction with the existing instruments at the government's disposal and with volume effects, was intended to achieve savings for the entire market of €340 million in 2008, €35 million of which on the basis of healthcare insurers' preference policies, and €116 million in 2009 (including VAT).

The parties to the agreement have made two supplementary arrangements to support the package. First, the pharmacy sector would generate additional non-recurrent savings of €50 million (including VAT) by means of a temporary increase of the clawback⁷ percentage to 11.3% - subject to an unchanged maximum of €6.80 per prescription. This arrangement became effective on 1 December 2007 and remained in operation for a term of seven months. Second, during the term of the agreement, a transition was made to a system of decentralized negotiations between pharmacies and healthcare insurers.

Pharmaceutical preference policy

In the Netherlands, healthcare insurers have a statutory entitlement to designate specific pharmaceutical labels, within a group of pharmaceuticals with the same active ingredient and mode of administration that are eligible for reimbursement. This policy seeks to stimulate price competition between manufacturers. A number of healthcare insurers have been making use of this entitlement since 1 July 2005.

Joint or Collective Preference Policy

With effect from 2005, healthcare insurers are operating a joint preference policy for three groups of pharmaceuticals: simvastatin, pravastatin and omeprazole. These healthcare insurers represent over 70% of the insurers' market. Under the Transition Agreement, they are not permitted to extend this preference policy to new groups of pharmaceuticals.

The joint preference policy of these healthcare insurers operates as follows:

- For each active substance with the same mode of administration, presentation and strength, the healthcare insurers designate one or more preferred medication labels if there is a price difference of 5% or more between the branded or unbranded products.

⁷ Since the 1990s, the government has clawed back part of pharmacies' profit margin. In principle, the clawback is 6.82% of the list price of pharmaceuticals up to a maximum of €6.80 per item. This percentage rate has been raised temporarily to 11.3% from 1 December 2007 to 1 July 2008, with the maximum of €6.80 remaining unchanged.

- The cheapest available product (branded or unbranded) is then designated as the preferred product, together with all other medication labels within a range capped at 5% above the price of the cheapest label. Products outside that range are not eligible for reimbursement.
- The designation/status as preferred product remains valid for a period of six months in each instance.

Individual preference policy and its effect

In addition to the joint preference policy, healthcare insurers can apply an individual preference policy, under which they can also individually designate other groups of pharmaceuticals other than the pharmaceuticals covered by the joint preference policy. This individual preference policy operates in the same way as the joint (collective) preference policy. There can be differences between healthcare insurers in terms of the range and designation period applied, however.

Indeed, in mid-2008, the price reductions from the first wave of the preference policy encouraged four of the health plans to extend the collective scheme to additional active ingredients under an individual preference policy scheme. Under this provision, 33 ingredients were listed as potential additions to the scheme. Ultimately, one of the insurers added 6 of the ingredients, another added 10, another 11 and one all 33. Table 2 lists these ingredients. Moreover, the four insurers tightened the pricing requirements and the number of manufacturers with which they would contract. One of the insurers announced that it would only contract with the lowest priced manufacturer, assuming that they could supply the entire market. Another insurer reduced the price range to 3% and the other two insurers retained the 5%, but would only contract with a maximum of two preferred manufacturers. This resulted in fierce price competition in addition to the already existing price competition. Generic market leaders Teva and Sandoz lost their market presence to smaller companies such as Ratiopharm, Centrafarm and Actavis which were willing to offer significant price concessions, averaging 85% in June 2008, as seen in Table 3. Winning manufacturers would need to procure evidence of their ability to supply the market for which they have won the contract.

The total initial savings from this preference policy scheme have exceeded expectations. The 2008 price cuts alone projected annual savings of €55 million, €10 million of which came from generics, representing approximately a third of their total market value (for the given ingredients). The other €45 million in savings were projected to come from the shift from originator brand products to generics. By contracting directly with insurance companies, (a significant part of) the discount that was usually passed on to the distribution chain, was now delivered as saving to the insurance companies as part of the preference policy. Pharmacists have claimed that without the ability to supplement the € per prescription dispensing fee with discounts⁸, up to 40% of pharmacies could end up out of business. To ensure income stability, pharmacies requested an increase in the fixed fee from € to €25. As a consequence of the July introduction of individual

⁸ Which form part of pharmacies' remuneration.

preference policy the prescription dispensing fee increased in January 2009 resulting in an overall cost increase of more than €200 million⁹.

Undoubtedly, this development erodes the net value of originally projected savings, but the balance is still positive. There is still ongoing debate as to whether the remaining sum would be needed to cover the cost of running a pharmacy¹⁰ on the grounds that the deteriorating business environment and the preference policy are threatening the financial viability of several pharmacies. In early September 2009, seven pharmacies from the pharmacy chain All-In-One (AIO) filed for receivership and are threatened with closure, blaming the deteriorating business environment following the implementation of the preference policy (KNMP, 2009).

The Dutch preference policy, particularly the individual preference policy, has also attracted criticism by generic manufacturers on the grounds that, first, an individual preference policy amounts to a joint preference policy in which the insurers have a dominant position giving rise to competition policy concerns; second, the rules of the preference policy are unfair in that currently, there is one month between the decision and introduction of the system. This jeopardizes the logistical arrangements, as the time needed for production and transportation of products usually exceeds one month. The exclusion for 12 months, which is the current average duration of contracts, for all Healthcare insurers leads to excess of stock. This in itself leads to increased pressure to sell in the next round as the shelf life of medicines is also a limiting factor. And third, generic producers argue that they do not have a direct business relationship with health insurers as their customers are wholesalers and pharmacies. Health insurers reimburse medicines at the pharmacy level, and, consequently, if they wanted to take action they should have taken measures at the pharmacy level.

The preference policy in the Netherlands may result in fewer generic manufacturers selling in the country and a financially struggling retail distribution system. The outcome for purchasers is likely to be more positive, at least in the short-term, with evidence of continued cost reductions as long as new drugs are being added to the scheme. Meanwhile, it is expected that at this stage, patients will not have been significantly affected. Assuming the policy continues, as decision-makers argue it will, the long-term effects could be significant in terms of the intensity of competition and the resulting cost of medicines, although officials would contend that there is sufficient capacity for generic medicines production globally to ensure comparable deals over the longer-term.

Health insurers will also need to guarantee the supply of a given product so that no shortages occur. This has not been the case to date on a grand scale, but on one occasion the winner of the tender was not able to guarantee the continuous supply of the market for four weeks with simvastatin and pravastatin; on another occasion one local producer of generic medicines withdrew several generic medicines from the Dutch market due to tender pricing pressures (Carradinha, 2009). It is unknown what impact on the risk of shortages might the dependence on global supply have, but, reportedly, this occurred in

⁹ This appears to be a transitory measure as health insurance companies will introduce a free negotiable tariff for the dispensing fee for pharmacies based on a number of good dispensing and pharmaceutical care criteria from 2011 onwards.

¹⁰ Personal communication with stakeholders.

early 2009. Continuation of such incidents resulting in shortages may result in corrective measures from the competent authorities in order to safeguard supply.

Moving forward, some health insurers have expressed the desire to expand the preference policy to therapeutic clusters of drugs with significant price differences, but small clinical differences, i.e. move towards “therapeutic” tendering. Already, controlled-release and fast-acting formulations have been excluded from reimbursement under the individual preference policy scheme. While the cost implications of this practice have been clear, the effects of this policy (as well as the potential expansion) on patients are not known. Thus, the future of preferential policy is yet to be determined.

Table 2

Active ingredients impacted by the Preference Policy in the Netherlands, 2008

Collective Preference Policy	Individual Preference Policy
Simvastatin, Pravastatin, Omeprazole	As of July 2008: Alendronic acid, Alfuzosin, amlodipine, captopril, ciprofloxacin, Citalopram, Clarithromycin, Codeine, Enalapril, Levonorgestrel, Finasteride, Fluoxetine, Fluvoxamine, Fosinopril, Gliclazide, Glimepiride, Ibuprofen, Lansoprazole, Lisinopril, Metformin, Metoprolol, Mirtazapine, Ondansetron, Paroxetine, Perindopril, Quinapril, Ramipril, Ranitidine, Risperidone, Sertraline, Sumatriptan, Tamsulozin, Tolbutamide
Na	Additions as of July 2009: Amoxicillin, Amoxicillin + Clavulanic Acid, Bethi stine, Biclutamide, Cyproterone + Ethinylestradiol, Diclofenac, Fentanyl (patch), Fluticasone (nasal spray), Granisetron, Naproxen, Octreotide, Oxycodone, Pergolide, Ropinirole, Sotalol, Venlafaxine, Pantoprazole

Source: IMS Health, quoted in PPR, July 20 08 and presentation of Huib Kooijman, July 2009.

Table 3

The Netherlands: Top – 10 preferred packs by market impact, May -June 2008

Product	Preferred supplier	PPP¹ (May 2008)	PPP¹ (June 2008)	Change
1. Omeprazole tablets/capsules, 20mg	Ratiopharm	€0.36	€0.05	-88%
2. Alendroninezuur tables, 70mg	Centrafarm	€4.99	€0.36	-93%
3. Omeprazole tablets/capsules, 40mg	Centrafarm	€0.65	€0.09	-86%

4. Paroxetine tablets, 20mg	Ratiopharm	€0.37	€0.07	-82%
5. Simvastatin tablets, 40mg	Actavis	€0.27	€0.04	-84%
6. Pravastatin tablets, 40mg	Focus Farma	€0.54	€0.13	-76%
7. Simvastatin tablets, 20mg	Ratiopharm/Actavis	€0.17	€0.03	-85%
8. Tamsulozine tablets/capsules, 0.4mg	Centrafarm	€0.34	€0.07	-80%
9. Amlodipine tablets, 5mg	Ratiopharm	€0.19	€0.03	-85%
10. Citalopram tablets, 20mg	Ratiopharm	€0.34	€0.04	-88%

Note: ¹ Pharmacy Purchase Price (PPP).

Source: Stichting Farmaceutische Kengetallen (SFK).

4.2. The German Rebate System

Background

Tendering is a relatively novel concept in the procurement of pharmaceutical products in Germany and dates as far back as 2003 when sickness funds commenced requesting discounts on specific products. Nevertheless, the whole process has been subject to judicial review(s) due to legal issues centered around the question of whether sickness funds qualify as public contracting bodies.

The question whether German public health insurance companies qualify as public contracting authorities pursuant to European and national procurement law was submitted to the European Court of Justice (ECJ) in 2007. On June 11th, 2009 the European Court of Justice finally ruled that German public health insurance companies qualify as contracting authorities pursuant to European public procurement law [case C-300/07] (ECJ, 2009). The decision puts an end to a discussion, which has lasted several years and entailed many judicial disputes in Germany. Though recently German public health insurance companies have already started to apply public procurement law to some extent when concluding certain contracts, this normally happened without acceptance of a respective statutory duty. However, now the ECJ has made application of public procurement law obligatory for German public health insurance companies. From now on German healthcare insurance companies have to apply public procurement law whenever they conclude public contracts. Any decision or action related to the procurement process may be reviewed by German public procurement review bodies, which have already started to consider public health insurance companies as public contracting authorities and apply procurement law on contracts awarded by them.

The Rebate Policy

Tendering is viewed upon as a cost containment measure for sickness funds to control rising levels of pharmaceutical expenditure. They work on the basis of manufacturers responding to an “invitation” to reduce their list price by providing a discount on that price (rebate).

When rebate contracts were first granted by the sickness funds in 2003, they were largely negotiations resulting in discount deals between the sickness funds and individual (generic) manufacturers. In most cases, they were conducted without a European-wide tender process, involving directly selected companies. It was only when they were legally challenged that a proper Europe-wide tendering process should be applied, that the system evolved into a tender inviting offers of best (lowest) price from the list price.

In Germany, unlike other European countries, the government does not set the prices of pharmaceutical products and this includes generic medicines. Manufacturers are free to determine their own prices based on market conditions and, as in the case of the Netherlands, a reference pricing system applies at molecular level, which has also been extended to molecules that are considered to be therapeutically equivalent (known as “jumbo reference groups”, e.g. statins).

The majority of organised tenders in Germany concern generic products. Indeed, 98% of all tenders up to June 2008 were for generic products and 2% for patent protected products. By sales volume, 63.4% of rebates concerned generics, 10.6% old branded drugs and 2.9% in-patent drugs, in the first quarter of 2009 (personal communication).

A large number of generic companies have contracts generally based on a price and volume agreement. Although the lowest possible price is a key factor to win a contract, other factors also influence this. Thus, the award of a contract is not only dependent on the lowest price for a particular product, but is also dependent on the extent to which the successful bidder is able to procure a more or less complete range of that product's portfolio (i.e. the number of product presentations based on dosage) (see Table 1). The organizations that issue the tenders have a system in place that is able to evaluate and combine the price and “full range of portfolio” criteria. Occasionally, and given that not all companies are in a position to supply the entire range out of a molecule's portfolio, companies pool together with a view to offering a viable alternative to a sickness fund that combines price with completeness.

Most of the tenders are organised in two main ways (personal communication):

- *At molecule (active ingredient) level*; this is the most commonly used method by Allgemeine Ortskrankenkassen (AOK), one of the largest sickness funds that accounts for a significant (40%) part of the pharmaceutical (tender) market; companies bid for each of the molecules separately.
- *Portfolio contracts*; whereby products are grouped and companies are assessed by the level of rebate they can offer for that group of products; two other sickness funds (the Deutsche Angestellten Krankenkasse [DAK] and the Techniker Krankenkasse [TK]) have pursued this avenue.

If tenders are Europe-wide, they are published on the European Union tendering website, the trade association website, and the sickness fund's website. As discussed, the evaluation criteria are often seen as relatively opaque but normally they include price and completeness. Quality may be included in terms of whether bidders have established

relations with doctors, notifying the pharmacies, training for relevant parties, which might be important in some cases. The duration of the contracts vary in time but normally they are between 1-2 years.

The lack of a single transparent procedure for rebate contracts has caused variation in the tender process organised by different health insurers. The procedures of procuring the rebate contracts vary from negotiated contracts directly with specific manufacturers to competitive procedures that allow manufacturers to compete with each other. As a result, sickness funds have been facing a flood of legal challenges by pharmaceutical companies. The alleged irregularities can be categorized as follows:

- **Not organizing an open tender where all the interested companies have the option to compete.** For example, the Barmer Ersatzkasse (BEK) signed contracts with Hexal and Stada in 2007 without any public notification or any public tender process.
- **Failure to provide all the relevant information to interested participants.** In February 2008, the Higher Social Court ruled that in one of the country's 16 regions, AOK's tender conditions for 61 active ingredients were illegal. AOK did not make available to the participating drug manufacturers comprehensive prescription data and this prevented medium-sized manufacturers from having a fair chance to participate.
- **Obstructing competition:** In June 2008, The Deutsche Angestellten Krankenkasse (DAK) called for a tender for beta blockers, fentanyl-based analgesics and neuroleptics in the European Union's Official Journal. Dexcel Pharma challenged this at the German Federal Cartel Office on the basis that the tender treated different active ingredients as groups rather than as individual products. Grouping several active ingredients together in a group put small firms at a disadvantage because, given the small product portfolio, they are eclipsed by the large generic companies that can offer a wide range of products. Following a hearing at the Federal Cartel Office, the DAK withdrew the tender announcement.

While most of the sickness funds sign contracts for generic products, some of them have ventured into rebate contracts on patent-protected brands, which currently account for 2.9% of total rebate sales volume. Nearly all rebate contracts for in-patent products are signed as exclusive deals between the manufacturer in question and the sickness fund. There has not been yet any experience with patented products being included in tenders or for the jumbo reference groups to be included in a tender. Recently, one sickness fund extended the tender to the TNF-alfa blockers group and also managed to bring the tender through on legal grounds, but the tender was not executed due to other legal challenges.

The rebate system in Germany has been in operation for longer than the preference policy in the Netherlands. The debate surrounding rebates also includes health care professionals (doctors) and their acceptance of the system, pharmacies and patients. Although explicit incentives for doctors and pharmacists are either not yet in operation or are being experimented upon, clearly, sickness funds are beginning to recognize that the role they

play for the rebate scheme to be successful is very important. To that end, a sickness fund in North-Rhine Westphalia is giving all pharmacies in that Land a €1,000 cash injection (bonus) to implement the scheme and inform patients of any changes to their drug regimen (Apotheke adhoc, 2008). This only applies to a single Land (region) at this stage, but it is plausible that as tenders/rebates intensify, other regions might follow suit.

Financial incentives are also planned for physicians - €0.50 per prescription – for informing patients about likely changes in the product they will be prescribed. Patients, on the other hand have a financial incentive favouring the rebated product, according to which the co-payment is zero if the price for the rebated product is 30% below the reference price.

Whereas some incentives are beginning to emerge for doctors, pharmacists and patients, the same is not the case for the generics industry. The generics trade association is opposed to tendering and would prefer that rebate contracts be abolished from the procurement system. The argument put forward is that tenders are not delivering any significant cost savings but, instead, are causing unnecessary confusion to doctors, pharmacists and patients.

Overall, the sustainability of the current policy remains a key issue in Germany, partly because of the continued challenges to the legal framework in which the system operates. One such challenge is the extent to which cartel law applies to the operation of sickness funds, particularly since AOK, one of the larger insurers accounts for about 40% of the market. It may be the case that these challenges will fine tune the way the system operates and that a system of regional (or Land-based) tenders might emerge.

A further threat to sustainability relates to the actual level of discounts currently achieved. Many believe that they are unsustainable in the long-run, not least because they create a discontinuous and uncertain environment for (generic) manufacturers.

4.3. The tender system in Belgium

Background

The Belgian experience with tenders for outpatient drugs has been significantly less dramatic than its counterparts in the Netherlands and in Germany. It also has far fewer results to display since its implementation on January 1st 2008 and the scheme focused on simvastatin (which was actually tendered) to start with and was subsequently extended to the case of amlodipine (which was eventually not tendered). Currently, there are no plans to procure further substances.

By the end of 2005, the legal basis for a new tendering procedure (designed for the modification of reimbursement conditions of pharmaceuticals for budgetary reasons) was introduced as a “*sui generis*” tendering procedure. In general terms, a non-direct competitive benefit is offered to the pharmaceutical company - by means of a lower co-payment for the patients for its pharmaceutical - offering the lowest cost (perspective of health insurance and patient) of therapy.

The tender policy in practice

In mid-2007, the Minister of Social Affairs launched two of these procedures (for Simvastatin and Amlodipine). In the case of simvastatin, the winner of the tender is compensated for having the lowest price by becoming eligible for a preferential 75% reimbursement rate, while all other existing versions of the same drug will be reimbursed at just 50%. The tendering procedure launched for Simvastatin in 2007 (implementation date: January 1st 2008) has resulted in €15 million direct savings. The procedure itself has been confronted (legally) quite strongly by different companies, as the boundaries and the status of winner and losers were not clear. Reportedly, the price discount achieved on simvastatin was -40% of originator. However, it can be questioned whether the tendering for simvastatin was an appropriate cost containment measure for the overall statins market, since the Belgian Reimbursement Agency stated that in the same year (2008) expenses for atorvastatin and rosuvastatin grew by €13.4 million and €12.7 million respectively. It could be argued that the increase (or switch) in atorvastatin or rosuvastatin consumption neutralized the savings made on simvastatin, although it is not possible to determine what would have happened had the simvastatin tendering not been in place.

Since the Belgian market of reimbursed medicines is clearly a prescription driven market, the lack of incentives for prescribing physicians to prescribe the most cost-effective product in the therapeutic class (i.e. simvastatin) admittedly resulted in a failure to contain the overall costs in this class. This raises an additional question: however low the prices of multi-source products may be, prescribing of single-source products is not always affected and measures such as tendering do not always reach the problem at its base, namely to prevent the prescribing of expensive medicines when there is no medical need for it.

For Amlodipine, the procedure was launched but the winner of the tender was a company with no capacity to procure and, as a result, the tender was abandoned.

The move to introduce a tender system has been unpopular in Belgium's generics and originator industry, and producers fear heavy losses in turnover. A proposal that was put forward by the generic manufacturers as an alternative model suggested that market conditions should be reviewed every six months, and that reimbursement levels should be calculated based on the weighted average price of drugs in a therapeutic class.

5. Tender systems for ambulatory care drugs: Impact on and implications for stakeholders

In this section we outline the implications of the Dutch preference policy, the German rebate policy and the evidence from Belgium for all stakeholders, notably sickness funds, patients, physicians, pharmacists, the generics industry and the originator brand industry. A summary of the results is also presented in Table 4.

5.1. Sickness funds

Sickness funds clearly emerge as the leading players in this set of tendering schemes.¹¹ They have initiated the policies and have experimented with a number of variations in the three countries discussed in this paper. The tender systems for ambulatory care medicines highlight a shift in focus from *pharmacy* purchasing to *insurance* purchasing.

The primary objective of sickness funds is to achieve the lowest possible price from this activity, whilst at the same time ensuring that supply will not be adversely affected. The evidence from the Netherlands and Germany, where the winner is one bidder, suggests that beyond having to participate in the market in order to sell their stock, bidders are obliged to undercut each other for the prize which guarantees almost 100% market share. Based on that, sickness funds have made considerable short term savings on off-patent drugs. Clearly, the focus has been on products with significant market sizes and high degree of substitutability among available alternatives; it is not necessarily the case that the same or similar results will be achieved for all (genericised) products, and that may include bio-similars. A small number of bidders may be attracted by products with small market sizes and that could have an effect on the outcome of the tender process, in terms of the actual price discount. For bio-similars the higher production costs need to be added to the small number of bidders; both factors put together could influence a likely tender price upwards, rather than downwards.

The challenges that sickness funds face relate, first of all, to the long-term sustainability of the prices achieved over the past few years. A further challenge relates to the size of the savings and what incentives need to be given to doctors and pharmacists to sign up/promote the system. Clearly, in the case of the Netherlands, health insurers needed to introduce changes to pharmacy reimbursement. As the German experience suggests, incentives might also be considered. A third challenge relates to the legal basis for operating tenders in ambulatory care. As the German evidence shows, the actions of sickness funds can be challenged by stakeholders who feel their business interests are threatened. A final challenge relates to the operational robustness of the tender system. Often the winners of the tender are small manufacturers and although they need to guarantee the supply of products, on few occasions this has reportedly not been the case. Additional concerns in this respect may arise due to the limited shelf life of products as well as the implications of the sunset clause, which stipulates that if a product is off the

¹¹ Depending on the organizational structure of the health care system, tenders could be managed by ministries of health rather than sickness funds.

market for 3 years, its marketing authorization can be revoked. It is critical that the supply of product to the market is guaranteed in order for access not to be threatened.

5.2. Patients

The issue for patients is whether they benefit directly or indirectly from the savings that sickness funds realize from the rebate system. Direct benefits relate to the cost they incur by consuming a pharmaceutical product which is subject to a rebate contract, whereas indirect benefits relate to whether the savings achieved through the tenders are being passed on to the insurance premium.

Direct benefits

With regard to the direct benefits to patients, our interviews suggest that in **Germany**, there seems to be an impact that works through the cost sharing system. In particular, if the rebated product is priced 30% or more below the reference price, then the co-payment for the patient is reduced to zero. Therefore, there is a direct incentive for patients in Germany to “prefer” the rebated product.

A similar incentive does not seem to operate in the **Netherlands**, because of the nature of cost sharing arrangements, although it is a stated policy that the cost of medicines is being deducted from patients’ deductible.¹² As a result, the cheaper the medicine, the less will be deducted from this deductible and patients will spend less out-of-pocket as a result.

Indirect benefits

With regard to indirect benefits and the extent to which any savings are being passed on to the insurance premium the situation in both countries is unclear.

In the **Netherlands**, there is a demonstrated willingness by the CZ to see that any savings will be passed on to the insurance premium. Similar is the situation in **Germany**. However, there is recognition that the exact size of any savings is still unclear, partly due to the fluidity of the overall environment and the fact that certain parties commenced legal proceedings against the preference policy in the first half of 2008. It is, nevertheless, unclear what the actual pecuniary benefit will be to patients/insurees and whether it will have demonstrable effect on the insurance premium. Indeed, it may be the case that the

¹² In an [insurance](#) policy, the deductible (North American term) or excess (UK term) is the portion of any claim that is not covered by the insurance provider. It is the amount of expenses that must be paid out of pocket before an insurer will cover any expenses. In the Netherlands, a new statutory health insurance system was introduced in January 2006. Under this system, the public health insurers have been privatized or have merged with private health insurers, and all citizens are required to purchase a basic package of essential health care services, along with “own-risk coverage” (essentially an annual deductible) of €150 each year. The premium for this package is set by insurers in competition with one another, but they must accept all applicants without selecting risks. People with low incomes receive a subsidy for the basic insurance, and there is an option to purchase an additional package to cover nonvital extras (Knottnernus and ten Velden, 2007).

only effect on the premium will be a reduction in its rate of increase, as insurance companies or sickness funds reduce their costs through the preference policy or the rebate system, although this remains to be determined yet.

5.3. Physicians

Physicians are frequently complaining about increased workload at having to inform patients about changes in their drug regimen, particularly if these changes are induced by action from health insurers. It is rarely the case that physicians are remunerated for the time invested in informing and explaining these changes.

In both the German and the Dutch cases the rebate and the preference policies are likely to lead to a higher workload for physicians. This is because patients will require more information particularly when their medicines are switched. Frequently, switching to a different medicine may be challenged on the grounds that patients are well informed about their therapeutic options.

While in the **Netherlands**, there is no additional remuneration envisaged for this type of work, in the **German** case this type of incentive to prescribing physicians is envisaged. In particular, a fee of €0.50 per prescription is envisaged for informing patients about likely changes to their product. In the Belgian case, the simvastatin tendering seems to have resulted in spending increases in other statins due to prescribing switch. It is, however, unclear what the prescribing incentives were in this case.

5.4. Pharmacies

In both Germany and the Netherlands, pharmacies have an obligation to dispense the cheaper alternative as part of national regulations concerning generic substitution. In both Germany and the Netherlands, sickness funds and health insurers provide advice to pharmacies on the treatment of choice when a new product or manufacturer wins a particular tender.

Although in principle the implications for pharmacies of introducing a tender system should at best be neutral, in practice there are two channels through which pharmacies can be affected. The first channel relates to the remuneration system for pharmacies while the second has to do with the overall incentive structure at retailing level to undertake patient-related work and to dispense the cheaper alternative (which, under the tender system is the alternative of choice). In both cases, the experiences from the Netherlands and Germany reveal different results.

Pharmacy remuneration

Pharmacies in the **Netherlands** are remunerated on the basis of a fixed fee per prescription¹³; in addition, they receive income from discounts given to them by

¹³ As of 2011, this fee will have to be negotiated between the Health Care Insurers and the pharmacies. How this will work is currently unknown.

manufacturers, net of the applicable clawback, which currently stands at 6.82%¹⁴ of the list price of pharmaceuticals or a maximum of €6.80 per item. Pharmacies as a result rely quite significantly on this source of income. As insurance companies have stepped in to tender directly with manufacturers of off-patent molecules, the available discount has been significantly eroded. Loss of income over the long term would imply considerable pressure on pharmacy viability and could lead to (further) consolidation. The fact that the Dutch authorities have increased the fixed dispensing fee by over €1 in 2008 (from an average of €6.08 to an average of €7.28) to counteract the negative effect of losses from reduced discounts is indicative of the situation. The long-term effects, however, are yet to be felt and assessed as the policy has only been in operation for the past two years. However, the fixed fee can go up to €7.95 if the pharmacist and the insurer have a written agreement. The maximum purchase fee is the list-price minus the clawback, the latter being 6.82% per prescription.

In **Germany**, pharmacy remuneration is not dependent on discounts as this practice is in principle disallowed. Rather, pharmacies are remunerated on the basis of a fixed fee plus a regressive margin. Consequently, the rebate policy has in principle a neutral effect on the income pharmacies receive in the German environment.

In either case, the successful implementation of a system similar to that in the Netherlands or Germany would need to be at least neutral with regard to pharmacy income and would possibly also need to provide some incentive because of the amount of work may imply for operating pharmacies to enforce the policy and inform patients about likely changes to their treatment regimes each time there is a different winner for a particular molecule and for each of the sickness funds.

If the policy were adopted in other European countries, the extent of impact on remuneration would depend on how the scheme is operated, the extent of generic penetration in the country, whether there are extensive rights to (generic) substitution at pharmacy level, and on the remuneration system applying in a particular country. As a general rule, it is likely that substantial drops in generic prices will have negative effects on pharmacy remuneration, notwithstanding the regressive nature of margins, unless remuneration is on a fixed fee basis.

It is, however, possible to substantially reduce generic prices and keep the supply chain intact, as is illustrated by the German system. In Germany, the price cut arising from tendering is given as a form of discount to the insurer, while the supply chain margin is still calculated on the original pre-tendered list price. This has the advantage of giving the benefits to the ultimate payers, while minimising disruption to the supply chain. In both the German and the Dutch cases, however, manufacturers are affected by the tender policies in place.

Incentive structure

In the **Netherlands**, there were no additional incentives for pharmacies to enforce the preference policy as of June 2009.

¹⁴ Temporarily risen to 11.3% from December 1st 2007 to July 1st, 2008.

In **Germany**, by contrast, sickness funds are beginning to recognize the additional work pharmacies undertake and are in certain cases prepared to remunerate them for this work. As a result, pharmacies in the North-Rhine Westphalia region, are receiving a €1,000 “bonus” per pharmacy to implement the rebate scheme and inform patients of any changes to their treatment regime. As changes occur when each wave of tenders is taking place, the bonus is re-administered. Little additional evidence on incentives to pharmacy was available from other regions in Germany at the time of writing, with the exception of initiatives in Saxony and Bavaria. Both regions have experimented with and recently implemented different incentives for pharmacies, which are linked to a fulfillment quota for rebate products. Come what may, such schemes and incentives would be subject to negotiation between insurers and pharmacy representatives.

Overall, the pharmacist plays a crucial role in managing the switching of patients from 'losing' to 'winning' drugs, and explaining the cost implications of choosing to persist with a drug that has not been given 'preference'. That might partly explain why the German system keeps the pharmacist 'whole'.

Finally, as with any generic substitution system with price fluctuations, the issue of existing stock can not be ignored. If the pharmacist has substantial stocks of non-preference drugs, they have a cost that probably can never be recovered.

5.5. The generics industry

The implications of the Dutch preference system and the German rebate system on the generics industry relate, first, to the current and future structure of the generics industry, second, its ability to deliver quality medicines at reduced cost in a sustainable manner and, third, the impact that competition may have on its structure and performance. These elements are explored in turn.

Although in the short-term tendering drives prices down since it is usually an “all or nothing” situation, in the long-term the number of available players on the market may decline. Although this may be contestable in a global environment characterized by multiple players (as well as consolidation), it is not a completely unlikely scenario and could lead to fewer companies as well as less competition and higher prices. It is probably too early to predict the long-term implications of the Dutch and German policies and, as one Dutch official put it, “there have not been cases of exit from the market as so far it has been possible to balance companies’ stocks with the tendering process”..

That does not take into account the likely implications for the long-term sustainability of small and medium-sized generic companies. Indeed, from an industrial organization perspective, it is conceivable that in an environment that rewards the lowest possible price without possibility to differentiate on the basis of quality or additional value added to patients¹⁵, exit will unavoidably follow.

¹⁵ Generic pharmaceutical companies often market themselves not only through pricing, but also by adding value to the product via rigorous quality programmes, improved packaging concepts in support of patient compliance and anti-counterfeiting programmes. Such investments, intended to better serve patient needs, are not rewarded by tender systems.

It is also likely that small local or regional generic manufacturers will suffer considerably. Companies that have not been awarded tendering for products cannot keep stock for longer periods of time due to financing concerns and shelf-life risk, and will need to discontinue these products. In addition, health authorities will revoke the marketing authorization of the products that will be out of the market for more than three years by virtue of the sunset clause. For smaller local and regional companies this can be devastating, ultimately reducing competition, creating serious competitive imbalances amongst companies, and potentially decreasing the availability of medicines to patients. There have been some reports of some companies withdrawing products from the market (e.g. Apotex removed 15 products in the Netherlands) or for others planning to scale down operations (e.g. Ratiopharm closing down its production plant in the Netherlands at the end of 2009).¹⁶

The above may further impact the development of new generic medicines and could result in delays in delivering these to the market. The risk of developed generic medicines being excluded from the market due to their not being selected through tendering is likely to impact negatively the development of new generic medicines.

Tendering dynamics compromise the structure of generic medicines companies as only part of their portfolio will be on the market due to the limitative nature of tendering. This narrows a company's capability to sustain a position on the market, in some cases forcing companies to switch commercial strategies to markets that offer better conditions. Furthermore, the lack of incentives for companies to remain on tendering driven markets will reduce the availability of certain medicines as well as patient choice, and pharmaceutical companies might not find it viable to distribute their products on markets where the return on the investment is low or insecure.

Overall, generic manufacturers are negatively predisposed towards tender systems on the grounds that they lead to a risk of interruptions to the supply of medicines, they fail to motivate dynamic competition among pharmaceutical companies, they reduce the potential for incremental innovation by focusing solely on price, they increase unnecessary administrative costs for both manufacturers and health authorities, and may have an adverse impact on patient access, among others (Carradinha, 2009). There is no evidence that preference or rebate policies will have an impact on quality or good manufacturing practice (GMP), although continuous enforcement of these standards in the EU will continue to ensure quality.

5.6. The originator-brand industry

The implication of policies and practices such as the preference policy or rebate policy for branded originator products are momentous and can be subdivided into the pre-patent expiry period and the post-patent expiry period.

¹⁶ Personal communication.

The pre-patent expiry period

In the **Netherlands**, products under patent are not included in the preference policy, although some health insurers have expressed the desire to expand the preference policy to therapeutic clusters of drugs with significant price differences, but small clinical differences, i.e. move towards “therapeutic” tendering. This could also impact patented products. Already, controlled-release and fast-acting formulations have been excluded from reimbursement under the individual preference policy scheme.

In **Germany**, at present, rebate contracts for patented products tend to play a minor role. All insulin analogues (A10C) are included in this and they account for 87% of the patented drug sales under the rebate contract. Other products include Mircera (B03C), a number of ACE II inhibitors (C09, notably Aprovel, Coaprovel, Lorzaar, Lorzaar plus, Olmetec and Olmetec plus), Femara (L02B), Enbrel (M01C), Aclasta and Zometa (M05B) and Reminyl (N07D). The environment for rebates of patented products has not changed significantly since 2007 and these contracts still account for 3% of sales in the first quarter of 2009 just as they did in the first half of 2007. Some originator companies view rebate contracts as strategic opportunity for a different market approach which includes care management elements.

The environment for the so-called “jumbo groups” being subjected to a rebate contract is still evolving. Indeed, one sickness fund extended the rebate policy to the TNF -alpha blockers and managed to bring the tender through with its legal basis not being challenged, but the tender was eventually not executed due to other legal reasons.

It is conceivable that manufacturers of originator brands can conclude rebate deals with sickness funds prior to the relevant molecule’s patent expiry, thus allowing them access to the reimbursement market before generic competition commences. It is unclear what the overall implications for competition policy may be, although one might be inclined to argue that at the time when these deals are concluded no further party is excluded from them.

Conceptually, however, and bearing in mind the recent success in both the Netherlands and Germany in terms of achieving rebates/discounts in excess of 80% off list price, it is also conceivable that insurance companies or sickness funds will be inclined to demand similar discounts from originator brands in order to allow them to stay on the market as the preferred provider for a (short) period after patent expiry.

The post-patent expiry period

The implications for originator brand manufacturers in the post-patent expiry period are comparable to generic manufacturers. Whereas both originator brands and generic brands could stay on the market (and also command a positive market share) under the reference pricing system, the implications of the Dutch preference system and the German rebate system are that one manufacturer wins the contract for a particular molecule for a period and all other manufacturers are excluded from reimbursement.¹⁷ Thus, unless originator

¹⁷ Although, in practice, they can still be reimbursed if the prescribing doctor ascertains that a product other than the preferred product is suitable for a patient on medical/clinical grounds,

brands can win a tender in the post-patent expiry period, they will be out of the market completely with a zero market share. Losing all market share in this market could impact pricing decisions in newly launched products as manufacturers might want to recoup lost revenues in that segment via higher prices in the new products segment.

Table 4

Likely effects of tendering practices for retail market drugs in the Netherlands and Germany, 2009

Stakeholder	The Netherlands	Germany
Sickness funds	<p><u>Short-term</u>: significant savings through discounts, by influencing price directly through tender process; these need to be benchmarked against pharmacy remuneration</p> <p><u>Long-term</u>: sustain the same or comparable level of savings provided there is sufficient competition on the supply -side</p>	<p><u>Short-term</u>: significant savings through rebates, by influencing price directly through rebate process</p> <p><u>Long-term</u>: sustain the same or comparable level of savings provided there is sufficient competition on the supply-side</p>
Indirect impact on Patients	Likelihood of reduced premium or smaller increases in premium depending on size of savings	Likelihood of reduced premium or smaller increases in premium depending on size of savings
Direct impact on Patients	Smaller deductions from their (annual) excess	Zero co-pays if rebated price is 30% below reference price
Physicians	No incentives; complaints about increased workload at having to explain changes in treatment	Fiscal incentives planned: doctors to receive €0.50 per prescription for informing patients about likely changes to the product prescribed
Pharmacies	<ul style="list-style-type: none"> • Discount eliminated (or vastly reduced) from the pharmacy remuneration • Significant opposition to the preference policy due to its impact on overall remuneration level • Increase in dispensing fee by over €1 to counteract the effect on remuneration 	<ul style="list-style-type: none"> • A bonus of €1,000 per pharmacy to enable them enforce the policy and tackle increased workload (only in North Rhine Westphalia) • Pharmacy remuneration based on the list price, not the tender price • Pharmacy remuneration does not encompass discounts

<p>Generics industry</p>	<ul style="list-style-type: none"> • One company wins entire molecule market • Lowest price is the winning factor • Price competition can lead to exit over the longer term 	<ul style="list-style-type: none"> • One company wins molecule market • Lowest price is key in determining contract, but other factors such as product portfolio (for a specific molecule) are important • Possibility for more than one company to join forces and offer an inclusive deal for a molecule based on price and portfolio (number of putups based on dosage) • Price competition can lead to exit over the longer term
<p>Originator-brand industry</p>	<ul style="list-style-type: none"> • Complete exclusion from market if tender is not won • In-patent products (currently) excluded from preference policy • Based on the clustering the prices for patented products can be influenced downwards by generic products in the same cluster. 	<ul style="list-style-type: none"> • Legal uncertainty about whether jumbo groups can be included in rebate policy • Individual in-patent products are included in rebate policy (with sales exceeding €800,000 pa) • Complete exclusion from market if tender is not won • Possibility to conclude rebate contracts prior to patent expiry which may also be valid for a certain time period beyond patent expiry • Increasing generic erosion via tendering may put more pressure on margins of originator companies. This may subsequently lead to higher prices of new products.

Source: The authors.

6. Conclusions and lessons for the Member States

Several lessons emerge for Member States from the evidence presented. They relate to (a) the shift in the balance of power; (b) the sustainability of the tender system, both in the short- and the long-term; (c) competition in the insurance and the pharmaceutical markets; (d) the stakeholder costs and benefits; (e) the issue of access to care and medicines for citizens; and (f) the extent to which other policy objectives, e.g. industrial policy and the competitiveness of the European generics industry should also be included in the overall debate. These are explored in turn.

6.1. Shift in the balance of power

The organization of tenders by insurance companies in the Netherlands and sickness funds in Germany implies a shift in the balance of power in favour of the insurers. Insurers have the purchasing power and are leveraging this through the tender systems to maximize their pecuniary benefits and generate additional savings on drug purchasing. This is a clear departure from existing paradigms in both Germany and the Netherlands, where insurers were setting reimbursement rules for prescription medicines based on reference prices, the latter being directly observable, without directly intervening on the market. The shift in the balance of power also implies that any (allowable) discounts that were available in the system prior to the introduction of the tender system(s) are now going to accrue to the insurers through reduced prices for the tendered medicines. Importantly, insurance companies have revealed their preferences, which rest firmly on a very competitive price rather than product differentiation. This does not imply, however, that the adequacy of the supply chain has not been taken into account.

6.2. Sustainability

Questions unavoidably arise about the sustainability of the tender systems and the savings they produce for off-patent molecules particularly over the longer term. The German experience suggests that short-term benefits of very low prices can be replicated for a few years and the same might be the case in the Netherlands. This may mean one of more things: either that prices of generic molecules are closer to cost at this low level and that payers had been overpaying for a long time, or that there are sufficient numbers of generic manufacturers globally, who, in the name of achieving a positive market share, can reduce their price enough – and probably below cost – to drive others out of the market, before raising prices again, or a combination of the two. Clearly, the jury is still out on this front, but it is possible that some players will not be in a position to sustain these prices over the long term, in which case, exit from the market is a natural consequence. Two questions still remain, however: first, what proportion of the global number of generic manufacturers are not able to continue with discounts/rebates close to +90% - in other words, what is the likely impact on the market structure of generic manufacturers - and, second, how is the overall pattern of generic production, including logistics and stock management going to be affected, especially if more countries introduce similar systems.

6.3. Competition

Two issues related to competition arise from the discussion; the first relates to whether health insurance companies or sickness funds violate competition rules, e.g. by abusing

their dominant position. Overall, relative clarity has been obtained on this issue both in the Netherlands and in Germany. Whereas health insurers in the Netherlands could jointly issue tenders for specific products, this is no longer possible, following discussion with competition authorities and earlier legal challenges. Insurance companies are now issuing tenders singularly, to avoid being classified as monopsonies

Similarly, in the German setting, AOK, the largest sickness fund that accounts for approximately 40% of the market pursues tenders on a regional basis for the same reasons.

The second area relates to competition among generic manufacturers with a view to winning the tender for a particular product (molecule). The evidence from the Netherlands suggests that it only takes one player to deviate from the existing status quo and trigger intense price competition among incumbent firms, particularly if the prize is for a single bidder to win 100% of a product market. The effects of competition on firms are widely unknown. One could conjecture that exclusion from the market will unavoidably drive some firms out of the market and others to scale down operations. If this occurs, it is also unavoidable that over the long-term this is likely to result in price increases, *ceteris paribus*. From an insurance company's perspective and if achieving the lowest price is the single most important criterion, then the "single winner takes all" is likely to lead to very low prices as winning the tender is preferable to staying out of the market, provided this does not have any impact on quality or the continuity of supply resulting in risk to patients.

6.4. Access to treatment

Access to medicines for patients in the countries concerned does not seem to have been affected so far. Continuity of treatment with the *same* product does not seem to be on the mind of sickness funds and this by no means implies gaps in access, problems with safety or threatening quality of care. Continuity of treatment with the same product is of ten an issue for patients and could result in psychological effects as well as have an impact on adherence to treatment. If there is a case for a particular treatment to be dispensed rather than the one that has won the tender, then based on clinical opinion the current system in the Netherlands allows for this. Should tenders extend beyond the molecular level to include different alternatives within the same therapeutic category, such provisions need to be visible to ensure both access to and continuity of treatment. What is important, however, is that no interruptions to the supply of medicines occur due to tender pricing pressures, or the inability of manufacturers to supply the market with product (which may lead to shortages) or regulatory implications such as the sunset clause. Policy-makers should focus on these aspects and enforce the terms and conditions of the tender contracts as well as ensure that the winning bidders are really in a position to supply for the duration of the contract.

6.5. Balancing health and industrial policy

Clearly, the prime interest in initiating the tendering schemes lies in the generation of savings on products that are perceived to be homogeneous. While the primary objective of the tender schemes is to achieve the lowest possible prices for insurers consideration could also be given to the contribution of (generic) industry and the likely implications of tender schemes for employment, manufacturing capacity and the ability to bring new

generic versions on the market. Clearly, the globalization of industry can provide numerous opportunities for the supply of European markets with generic medicines even if producers located on European territory fail to win tenders. National policy-makers may wish to reflect on this issue and whether maintaining a competitive industrial base remains a valid policy objective. Bringing new generic products on the market is also very important in terms of generating competition post-patent expiry. In other policy environments, this is rewarded by exclusivity for a limited time period. This creates market stability prior to aggressive price competition.

6.6. Stakeholder costs and benefits

The success of tendering schemes rests on their acceptance by key stakeholders. Satisfying the interests of all stakeholders requires a very careful balancing act.

Patients need to be aware of generic alternatives and their interchangeability at molecular level and feel that if they require a medicine which is not in principle available through the tender process, appropriate safeguards are available for this to be obtained; importantly, any form of financial incentive, particularly relating to cost-sharing arrangements would also be advantageous. Finally, it is doubtful that any savings from tender policies will have a visible impact on insurance premia.

Physicians are concerned about the time they need to invest to inform patients about changes to their drug regimen; to avoid constant complaints by physicians about time waste, a modest financial incentive could remunerate for time lost, although such an incentive needs to be balanced against the magnitude of savings made from the tender policy. At the same time, physicians need to be able to prescribe outside the tender options, should this be medically necessary; this could be arranged on the basis of prior authorization in order to safeguard the interests of patients as well as the robustness of the policies initiated by health insurers.

Pharmacies are critical in the implementation, monitoring and subsequent success of tender schemes. Clearly, a culture of generic substitution with wide substitution rights is required in the first instance. Again, incentives providing a stimulus to pharmacies to explain clinical options to patients may be important. Critically, however, tender policies need to be neutral to pharmacies' income as in all other cases significant opposition will emerge. Again, any financial incentives provided from health insurers will reduce the net benefit from the implementation of the tender policy.

For *manufacturers*, tender policies are likely to have a detrimental effect on market structure over the medium- to long-term, particularly in situations where a single company wins the entire market. Smaller companies are likely to be affected mostly in the first instance and it is likely that larger companies may also be affected subsequently. The overall implications for market structure could be significant and might lead to some of the contract manufacturers rising further in prominence. As the returns to any investment that generic companies may have incurred in terms of launching a new (generic) product evaporate upon patent expiry of the originator the incentive to invest in bringing further (generic) products to market declines, unless there is a perception of temporary stability in market conditions before tenders are issued and aggressive price competition takes place.

Sickness funds have clearly been experimenting with tenders over the past few years. Importantly, in order to maximize savings from genericised molecules tenders should encompass a large number of patent -expired molecules. In this way, any additional costs incurred through incentives to other stakeholders are spread across a large number of tendered drugs. Tendering across molecules at therapeutic class level is likely to be contestable and could be avoided on these grounds, unless health insurers pledge to have in place safeguards to ensure prescriber (and, consequently, patient) choice in cases where this is medically necessary. Finally, it is possible that the very low prices/high discounts achieved may not be sustainable over the longer-term; similarly, it may not be feasible to achieve high discounts across the entire range of products tendered.

6.7. Overall

The preference and rebates policies in the Netherlands and Germany, respectively, have created a lot of interest within the policy -making community, having shown that significant cost savings can be achieved through them. While the short -term perspective seems to yield such pecuniary benefits to health insurance, there is lack of evidence about the long-term implications of such policies, and their impact on the stakeholder community, notably physicians, the retail distribution chain and the generic and research -based pharmaceutical industry. It is important that the overall effects of preference and rebate policies are monitored over the longer-term and from a multi-stakeholder viewpoint.

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