

Danish Ministry of Health and Prevention

**Analysis of hospital
pharmaceuticals**

Country report - The Netherlands

March 2009

COWI



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1 Introduction

Almost all Dutch hospitals are private non-profit organisations; however, the hospitals - as is general for the entire health care system - are subject to heavy government regulation. Financing of hospital pharmaceuticals is based on a mix of insurance funds (public and private) and of the hospital's own budget. The Dutch hospital system is characterised by a high degree of decentralisation; hospitals are individually responsible for purchasing pharmaceuticals for own use. Each hospital is required to have an overall annual budget, including a budget for hospital pharmaceuticals. The budget is calculated prospectively and there is no compensation afterwards if the hospital exceeds its budget.

In the Netherlands - as in Denmark - there is no standard definition of "Hospital Pharmaceuticals". However, the Dutch Ministry of Health, Welfare and Sports has confirmed that the definition applied for Danish Hospital Pharmaceuticals may also apply for Hospital Pharmaceuticals in the Netherlands for the purpose of this study, i.e.:

Pharmaceuticals which are purchased by hospitals and used for treatment of hospital patients, which may be either inpatients or outpatients¹.

COWI has conducted interviews with:

- Huib Kooijman, Beleidscoördinator, (Policy advisor), Ministry of Health, Welfare and Sports, and
- Pieter Knoester, hospital pharmacist, Leiden Hospital. Member of the Dutch Organisation for Hospital Pharmacists.

The Ministry of Health, Welfare and Sports has kindly contributed information on list prices (Pharmacist Purchase Prices) as well as information on average negotiated discounts and rebates on some products relevant for this assignment.

¹ In Denmark patients with chronic or long lasting disease may receive some drugs from the hospital, when the drug is part of a treatment managed by hospital specialists from an out-patient clinic in a hospital setting.

2 Regulation and legislation

Legal framework	In accordance with the Medicines Law on pharmaceutical dispensing in the Netherlands (Geneesmiddelenwet) in force since July 2007, pharmaceuticals may be marketed only once the Medicines Evaluation Board has issued a positive assessment of their quality, safety and effectiveness. As a part of this authorisation procedure, the legal status of a pharmaceutical is decided by the Medicines Evaluation Board.
Hospital organisation	<p>Almost all Dutch hospitals (90%, i.e. approximately 120 hospitals²) are private non-profit organizations. The rest are publicly owned. The government heavily regulates the Dutch health care system, e.g. with regard to production and capacity of hospitals, and the government has ultimate control over the health care expenditures.</p> <p>Hospitals predominantly dispense pharmaceuticals for inpatients, however, since 2000 hospitals have been allowed to run pharmacies in out-patient clinics, which may dispense pharmaceuticals to out-patients.</p>
Price-setting of 'expensive' pharmaceuticals	<p>In general hospital pharmaceuticals are subject to free pricing. However, since 2008 some hospital pharmaceuticals have been made subject to international reference pricing.</p> <p>Since 2008, a limited number of 'expensive' hospital pharmaceuticals (that are included in the legislation on 'expensive hospital pharmaceuticals) have been subject to the Pharmaceutical Products Pricing Act. The Pharmaceutical Products Pricing Act specifies that the price may not exceed a maximum level. The maximum wholesale prices (the Pharmacy Purchase Price, PPP) of pharmaceuticals are set by the Ministry of Health.</p> <p>The maximum level is determined twice a year by calculating the average price of comparable pharmaceutical products (same active substance, strength and pharmaceutical dosage form) in four reference countries: Germany, France, Belgium and the United Kingdom and fluctuations in the exchange rate of the euro and the British pound. A maximum price can be determined if a comparable product is on the market in a least two of the four reference countries.</p>

² 1999-figures, Health Care Systems in Transition, p. 71.

The prices are divided by the pack size to get the price per unit and an average is calculated for each country. The mean of these average prices is the maximum price per unit of the comparable pharmaceutical in the Netherlands. When a product is not marketed in at least two of these countries, no maximum price is calculated. In countries where the product is marketed, that product must appear on the national official price-list. Hospital products, unlike outpatient drugs, are not always included in those lists.

The list of 'expensive pharmaceuticals' is dynamic and includes typically 'expensive' new biological drugs mostly for cancer and auto-immune diseases. Only new hospital drugs that are projected to be a burden for the hospital budgets are included on the list. In practice hospital drugs that are forecasted to exceed a total national cost of 2.5 million Euro within three years after market introduction can be included in the list.

Price-setting of orphan pharmaceuticals

Price-setting of orphan pharmaceuticals (included in the legislation for orphan pharmaceuticals) is based on reference-pricing following the same method as the 'expensive' pharmaceuticals³.

Price-setting of other hospital pharmaceuticals

Hospital pharmaceuticals other than 'expensive' and orphans pharmaceuticals are not subject to any government regulation or reference pricing⁴. Manufacturers publish the price in the so-called "Taxe"-list (Cf. the text box below) and negotiation between hospitals and manufactures or wholesalers will have this as a starting point.

Hospitals can negotiate a reduction in prices compared to the "Taxe"-list price. According to the Ministry of Health, Welfare and Sports, the net purchase price may be 1-5 % lower than the list price for monopoly patented expensive drugs; for off-patent expensive hospital drugs (with multiple suppliers), the net purchase price may be 60 - 80% lower than the "Taxe"-list price.⁵

Textbox 1: The "Taxe"-list

The 'Taxe'-list is a list containing recommended pharmacy purchase prices (PPPs) for all pharmaceuticals that are available on the Dutch market (including hospital pharmaceuticals - although actual prices of hospital pharmaceuticals may be lacking). The list is published monthly by the Z-Index (www.zindex.nl). The prices in the "Taxe" are regularly updated by wholesalers and manufacturers, and must be equal to or below the maximum price defined under the Law on pharmaceuticals' prices (Wet Geneesmiddelenprijzen). The prices are exclusive VAT.

³ The reference price system for 'expensive' and orphan pharmaceuticals is based on the same legal framework and the same method as applied for outpatient pharmaceuticals.

⁴ Reference pricing for these pharmaceuticals may be introduced next year (2010).

⁵ The "Taxe"-list price does not deviate much from the list prices in neighbouring countries (due to international pricing policies by companies), no matter whether a maximum price has been set or not. The official "Taxe"-price is however, important for the manufacturer since other countries with international reference pricing that use the Netherlands as a reference country will refer to this price-list. In other words, the "Taxe"-list will be the price list of reference for other countries.

These prices in the "Taxe"-list are the official prices. In case a maximum price has been identified for a (expensive hospital) pharmaceutical based on the international reference price system, the list price in the 'Taxe' can never exceed this maximum price. In case no maximum price has been identified for a particular pharmaceutical, there is no limit to the 'Taxe' price.

Financing of hospital pharmaceuticals

Financing of hospital pharmaceuticals is based on a mix of insurance money/government funds⁶ and of the hospital's own budget.

Hospital financing of pharmaceuticals

As part of the cost-containment policy, all hospitals are required to have an overall annual budget, which is calculated prospectively. In principle, no possibility of recalculation or compensation exists if the hospital exceeds its budget.

Hospital pharmaceuticals may be divided into three groups:

1. General pharmaceuticals: The prices of general pharmaceuticals are generally subject to negotiation between the hospital and the manufacturers. Hospitals should pay for these drugs out of their lump-sum budget.
2. 'Expensive' pharmaceuticals - The expensive pharmaceuticals cover a list of around 25 pharmaceuticals, which in 2008 accounted for up to 50% of the annual expenses on hospital pharmaceuticals in the Netherlands. The costs for these drugs are growing at an average annual rate of around 20%. Hospitals get additional reimbursement for 80% of their expenses on these pharmaceuticals by insurance companies/government - in accordance with the regulation for 'Expensive Pharmaceutical Products within Hospitals, 2002'⁷. The remaining costs (20%) are financed by the hospital's lump sum budget.

This financing module is conditional: after three years outcomes research (on real life (cost-) effectiveness) must be completed in order to qualify for an indefinite inclusion on this list. Using pharmaco-economic data, costs, benefits and effects of pharmaceuticals are increasingly being considered from a societal perspective, thus going beyond the impact on the pharma-

⁶ Medical care in the Netherlands is largely funded by a system of public and private insurance schemes. The system is divided into three compartments: The first compartment is governed by the Exceptional Medical Expenses Act (AWBZ). It covers the exceptional medical expenses associated with long-term care of high-cost treatment. Everybody subject to Dutch income tax is covered. The second compartment covers normal necessary medical care. Costs are covered by sickness fund insurance, private medical insurance of health insurance scheme for public servants. The most important being the Sickness Fund Act (ZFW). 63% of the population is covered by sickness funds; the remaining population is covered by private health insurance. The third compartment covers supplementary form of care regarded as being less necessary.

⁷ Beleidsregel dure geneesmiddelen in ziekenhuizen, 2002. If the macro expenses for a single pharmaceutical product is estimated to be higher than 0,5% of the macro (national) budget on pharmaceutical expenses in hospitals, this products was reimbursed for 80% by the government.

ceutical budget.

The outcome studies are to be authorized by the Healthcare Insurance Board, and parties of interest – such as manufacturers – are expected to bear the costs. In special cases where manufacturers cannot or do not conduct the required studies, the authorities can fund research conducted by independent researchers. The temporary and conditional listing of drugs on the list is valid since 2006.

3. Orphan pharmaceuticals - Academic hospitals are entitled to 100% reimbursement of orphan products by insurance companies/government⁸. For these products, similar rules apply as for expensive drugs.

When the above cost requirements are not met (cf. footnotes 5 and 6), the medicines have to be funded from the hospital budget.

Hospital pharmaceuticals are subject to 6% VAT. VAT and pharmacy-dispensing fees are not included in the 'taxe' - list price.

⁸ According to the policy on expensive orphan medicinal products (2006), academic hospitals that offered expensive orphan medicinal products were able to get 95% of those costs reimbursed. Expensive meant that over 5% of the hospital's budget on pharmaceuticals was estimated to be used on a single orphan medicinal product. The reimbursement was paid by the government; the remaining 5% was paid from the hospital's own budget.

3 Market place and purchase

The purchase organisation

Hospitals are individually responsible for the purchase of pharmaceuticals for their own use. Pharmaceutical products are negotiated product by product directly between the hospital and the manufacturer.

Hospitals may cluster in the purchase of individual products by region, but academic hospitals have their own cluster, which then negotiate directly with the manufactures. Typically, a cluster consists of 10 - 11 hospitals.

Negotiations between hospitals or clusters of hospitals with manufacturers can take place directly or through a wholesaler. This does not apply for the list of 25 most expensive pharmaceuticals.

Price negotiations

Within an overall national hospital budget the individual hospital set a budget for pharmaceuticals. In general the hospitals pay less for pharmaceutical products than the public pharmacies.⁹ Hospitals are responsible for their own medicines costs except for some very expensive products (e.g. HIV) that have an earmarked budget.¹⁰

In the case of outpatient reimbursable pharmaceutical products the buying prices are subject to the Pharmaceutical Product Price Act.

Price negotiations of hospital pharmaceuticals are based on a tri-partite system. The hospital typically negotiates the price with manufacturers, however, buys via a wholesaler. At the manufacturer level price-setting on pharmaceutical products is free. Wholesalers are not allowed to set their prices above the statutory maximum prices. Any manufacturer or wholesaler is free to enter the Dutch market as long as the product has been approved by the Medicines Evaluation Board.

The wholesaler may be able to negotiate an even better price with the manufacturer and will also offer logistical services to the hospital such as transport. Wholesalers have a mark-up of 2%

⁹ Jansen, Petra: The Netherlands. Pharmaceutical Pricing and Reimbursement Policies.

¹⁰ Jansen, Petra: The Netherlands: Pharmaceutical Pricing and Reimbursement Policies

Tender procedures The acquisition of hospital pharmaceuticals are sometimes put out into open EU tenders. However, tender procedures are subject to Dutch rules and legislation and hence not to EU tendering procedures.

Besides safety price constitutes an important parameter in the selection of the winning tender of generic products; however, quality measures are also taken into account.

Competition structure The competition structure - i.e. the possibility for the hospitals to obtain rebates/discounts on products - is listed below:

- On patented monopoly products the possibility to get a discount is limited. On unique products discounts are small - up to 2 %
- On analogue products hospitals may get 40 - 50% discount (seen on immunoglobulines). It is anticipated that there will be a lot of analogue products in the future.
- On generic products hospitals are able to receive up to 90% discounts.

Other issues influencing prices and discounts:

- Insurance companies may be reluctant to negotiate discounts since hospitals on some products are reimbursed with up to 80% of product expenses through the insurance system.
- According to a recent study, Vervolgadvies bekostiging dure en weesgeneesmiddelen October 2008, volume does not influence the price that hospitals or cluster of hospitals are able to negotiate vis-à-vis the manufacturers. Hence, the purpose of clustering hospitals is to reduce the administrative costs of negotiating.
- An issue, also seen in other countries, which may give the manufacturers an incentive to dump prices on some patented products vis-à-vis hospital purchasers is to opportunity to influence the use of these pharmaceuticals. If the pharmaceutical product has been used to treat a patient in the in-patient system it is likely that the same product will be prescribed to the patient in the out-patient system.

Add-on value In some cases purchasers are offered add-on-value in the negotiation process. This is rarely seen, but has been seen in the purchase of NeoRecormon, where research money and training was offered.

4 Professional management

Prescription monitoring and other Doctors-related Measures

Although doctors are not subject to budgets, other mechanisms are in place to encourage doctors to prescribe rationally. These include treatment guidelines and the monitoring of prescribing patterns by practice.

There is also a growing trend for insurance funds to encourage doctors to abide by a formulary and prescribe by active substance.

Decentralisation and management participation

During the last decade the organisational development of the hospital sector can be characterised by i) decentralisation and ii) management participation of the medical specialists, i.e. hospitals have become decentralised organisations within which authority and responsibility are transferred to the operational units. As such, decentralisation has shifted responsibility and accountability to specialists in the clinical departments. The concept of decentralisation is most effective when the medical specialists participate in the management of the decentralised operational units, which have their own budgets. Hence, almost all large hospitals and academic hospitals have installed (or are going to install) a form of decentralisation and management participation.

As such, decentralisation and management participation of medical specialists may contribute to solving problems between professional autonomy and budgetary constraints.

Pharmaceutical committees

Pharmaceutical committees are established at each hospital. The pharmaceutical committees establish lists of pharmaceutical products for the use at the hospital on the basis of national guidelines. The guidelines are not product specific, but more on a generic/analogue level, and focus mostly on efficacy rather than on product costs.

5 Expenditure and medicine prices

Below the total pharmaceutical expenditure in Dutch hospitals related to the 'expensive' hospitals drugs is listed. No other public data on total pharmaceutical expenditure per hospital product are available in the Netherlands.

Netto-inkoopkosten dure geneesmiddelen per geneesmiddel, 2004-2007 (1 = € 1 mln.)

Geneesmiddel	Merknaam	2004	2005	2006	2007
Infliximab	Remicade	33,5	40,1	54,2	66,6
Trastuzumab	Herceptin	8,9	18	51,1	59,3
Rituximab	Mabthera	10,6	28,9	36,7	43,4
Bevacizumab	Avastin	-	3,1	11,9	27,5
Docetaxel	Taxotere	14,4	18,4	23,2	26,6
Oxaliplatin	diverse preparaten	11,2	24,8	29,3	19,5
immunoglobuline i.v.	diverse preparaten	12,2	14	13,9	15,4
Gemcitabine	Gemzar	11,3	12,5	13,1	14,6
Irinotecan	Campto	7,4	7,2	6,7	7,5
Pemetrexed	Alimta	-	1,9	5,1	6,4
Paclitaxel	(Taxol), paclitaxel	13,9	7,8	6,5	6,3
Bortezomib	Velcade	-	-	3,3	5,9
Doxorubicine	Caelyx, Myocet	2,1	3,2	3,7	4,5
Botulinetoxine	Botox, Dysport	2,9	3,2	3,1	3,5
Omalizumab	Xolair	-	-	0,5	2,9
Natalizumab	Tysabri	-	-	0,1	2,1
Cetuximab	Erbitux	-	-	-	1,3
Vinorelbine	Navelbine, Navirel	-	0,7	0,9	0,6
Drotrecogin alfa	Xigris	-	-	0,7	0,6
Alemtuzumab	Mabcampath	-	-	0,5	0,6
Verteporfin	Visudyne	1,7	1,8	1,5	0,5
Ranibizumab	Lucentis	-	-	-	0,5
Palifermin	Kepivance	-	-	0	0,4
Abatacept	Orencia	-	-	-	0,2
Ibritumomab	Zevalin	-	-	0	0,2
Pegaptanib	Macugen	-	-	0	0
Totaal dure geneesmiddelen		130,1	185,7	266,0	316,4
			+42,7%	+43,2%	+19,1%

Bron: Stichting Farmaceutische Kengetallen

Netto-inkoopkosten weesgeneesmiddelen per geneesmiddel, 2004-2007 (1 = € 1 mln.)

Geneesmiddel	Merknaam	2004	2005	2006	2007
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Alglucosidase alfa	-	-	3,9	20,2
Agalsidase bèta	-	-		6,0
Laronidase	-	-	4,6	5,5
Agalsidase alfa	-	-	-	3,5
Indursulfase	-	-	-	1,9
Galsulfase	-	-	-	0,2
totaal weesgeneesmiddelen	-	-	8,6	37,2

Bron: Stichting Farmaceutische Kengetallen

Appendix I: List of literature

Advies. Vervolgadvies bekostiging dure en weesgeneesmiddelen. Onderzoeksresultaten X-factor. October 2008

den Exter, André, Herbert Hermans, Milena Dosljak, and Reinhard Busse: Health Care Systems in Transition, edited by Reinhard Busse, Ewout van Ginneken, Jonas Schreyögg, and Wendy Wisbaum, the Netherlands, 2004

Ewout Adriaan Vermeer, Diederik: Introducing orphan medicinal products in the Netherlands: how to shorten the process?, Hardenberg, the Netherlands, December 2007

Jansen, Petra: The Netherlands. Pharmaceutical Pricing and Reimbursement Policies.

Österreichisches Bundesinstitut für Gesundheitswesen: Surveying, Assessing and Analysing the Pharmaceutical Sector, in the 25 EU Member States, for the European Commission - DG Competition, 2006

Appendix II: List of persons interviewed

COWI has conducted interviews with:

- Huib Kooijman, Beleidscoördinator, (Policy advisor), Ministry of Health, Welfare and Sports, and
- Pieter Knoester, hospital pharmacist, Leiden Hospital. Member of the Dutch Organisation for Hospital Pharmacists.