

Website DCTF

Welkom bij de DCTF!

Masterplan Professionalisering voorbereiding mensgebonden genees- en hulpmiddelenonderzoek en bijlagen zijn hier beschikbaar!

Welkom op de site van de DCTF!

Onderzoek met mensen is essentieel voor de ontwikkeling van nieuwe en betere medicijnen, vaccins en medische hulpmiddelen.

Het doel van de Dutch Clinical Trial Foundation, kortweg DCTF, is het verbeteren van het klimaat voor klinisch onderzoek in Nederland. Zij heeft als taak het bijebrengen van verschillende partijen om weerbaardige onderwerpen op het gebied van klinisch onderzoek met elkaar te bespreken en oplossingen aan te dragen. DCTF speelt daarbij een coördinerende rol.

De DCTF heeft de ambitie de aantrekkelijkheid van Nederland als klinisch onderzoeksland te optimaliseren, zodat ons land niet alleen wereldwijd volop aanwezig blijft bij de ontwikkeling van geneesmiddelen, vaccins en medische hulpmiddelen, maar ook een leidende rol speelt bij klinisch-wetenschappelijk onderzoek in een meer brede zin.

De DCTF is tot stand gekomen door

Nieuws

- TI Pharma Spring Meeting 2013 op 25 april, Assen/Leuven Utrecht
- Masterplan Professionalisering mensgebonden genees- en hulpmiddelenonderzoek hier beschikbaar
- CCMO Richtlijn Externe Toetsing 2012 onze toelichting hier beschikbaar
- Platform Professionalisering Klinisch Onderzoek

Dutch Clinical Trial Foundation

- Platform of stakeholders in clinical research *including patients*
- Masterplan:
 - interview stakeholders: *points for improvement*
 - Owner?
 - Partners?
 - three working groups:
 - Start-up procedures
 - Certification and training researchers
 - Patient protection, information and recruitment
 - 2012:
 - Implementation (all stakeholders)
 - Full-time project manager Ministry of Health

Masterplan DCTF

Masterplan professionalisering voorbereiding
mensgebonden genees- en hulpmiddelen
onderzoek;



Nefarma members

- Patient Information Form (PIF)
every institute / Review Board / company - individual PIF
 - Many amendments
 - Prolonged start-up procedures
- One PIF accepted by all stakeholders:
 - Initiative agreement Nefarma members for one PIF
focuss on 'why not' in stead of 'I prefer'
 - Consulting other parties: CCMO initiative
now incorporated in Masterplan DCTF

Information to public

- General information on clinical trials
 - In cooperation with stakeholders:
 - DCTF topic
 - Brochure Ministry of Health
- Details information on specific trials:
 - Publication by companies on:
 - Clinicaltrials.gov
 - Toetsing on Line (NL)
 - Social media ?????
 - Which information can be shared?
 - Protection patients?
 - What do patients like to know?

Finally

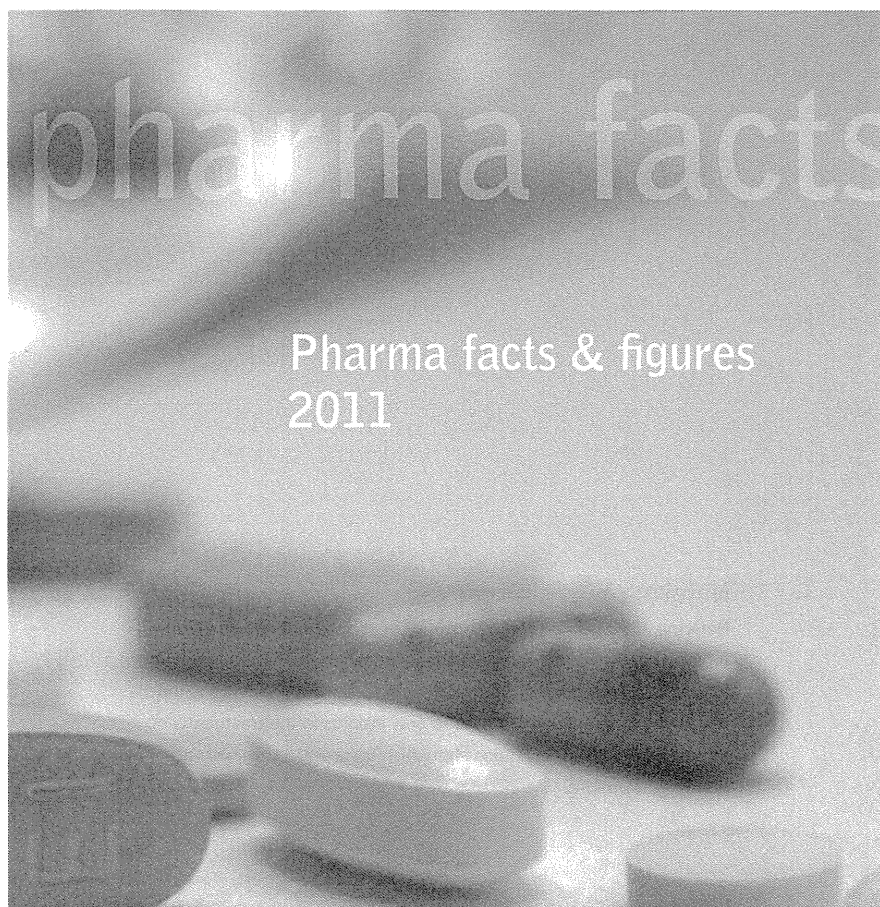
ご清聴ありがとうございます

オランダでの快適な滞在



nefarma

vereniging innovatieve geneesmiddelen Nederland



Nefarma >

Nefarma, the association for innovative medicines in the Netherlands, represents pharmaceutical companies engaged in the development and marketing of new and innovative medicines. These are medicines that have been developed in response to new insights in the treatments of diseases and medical conditions for which there were previously no therapeutic options.

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- 2 Not only are the Dutch frugal when it comes to medicines, in the Netherlands medicines are also steadily becoming cheaper
- 3 No other sector invests as much in research & development as the pharmaceutical industry
- 4 As a result of all the research there is an ever increasing number of new medicines
- 5 Innovative pharmaceutical companies have to contend with unnecessary obstacles
- 6 Pharmaceutical companies make important contributions toward a healthier world

The Dutch are frugal when it comes to medicines



1

Health care costs money, a lot of money. The rising costs are a perpetually recurring theme in the health care debate. The total expenditure on health care is around 63.5 billion euros, which amounts to approximately 10 percent of the Dutch gross domestic product.

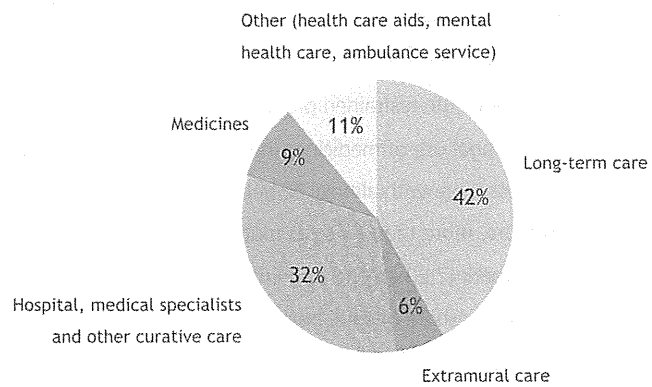
However, this is not the whole story. In order to form a valid opinion concerning the costs of health care, the returns have to be taken into account as well. Health care expenditure has a remarkably high return: on average, for every euro spent on health care there is a 1.30 euro return. This is based on the study '*Een beter Nederland. De Gouden eieren van de gezondheidszorg*' (A healthier Netherlands. The golden eggs of health care) conducted for the Ministry of Health in 2010.

Medicines in the Netherlands: one-tenth of total health care costs

According to the National budget, medicines will represent approximately 9 percent of the 63.5 billion euros that will be spent on health care in the Netherlands in 2012. This is excluding drugs prescribed through hospitals, as these costs are part of hospital budgets. If these costs are included, then the share of medicines is slightly higher.

The largest share of health care costs is long-term care (42 percent). Hospitals account for approximately a third (32 percent) of total expenditure.

Share of pharmaceutical care in gross health care expenditure
(in percentages)

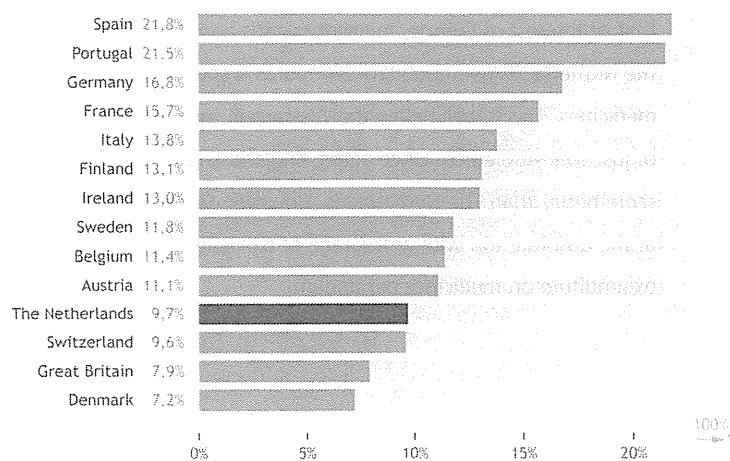


Source: National budget, Ministry of Health, Welfare and Sport (VWS), 2011

Costs of the use of medicines in the Netherlands is well below the European average

The total costs of medicines in the Netherlands in 2009 was 9.7 percent of the total health care expenditure, which is significantly lower than most other European countries. This is indicative of the restrained prescription policy and thus relatively frugal use of medicines in the Netherlands. Spain has the highest share with almost 22 percent of total health care expenditure, more than twice as much as the Netherlands. Only Denmark (7.2 percent) and England (7.9 percent) have an even lower share of total health care expenditure than the Netherlands. While Switzerland with 9.6 percent, is comparable to the Netherlands.

Share of pharmaceuticals in total health care expenditure in 2009
(in percentages)

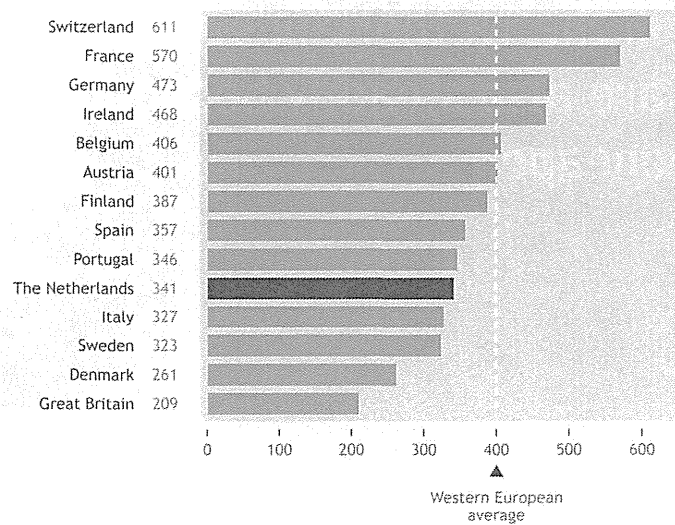


Source: Stichting Farmaceutische Kengetallen (Foundation for Pharmaceutical Statistics), 2011

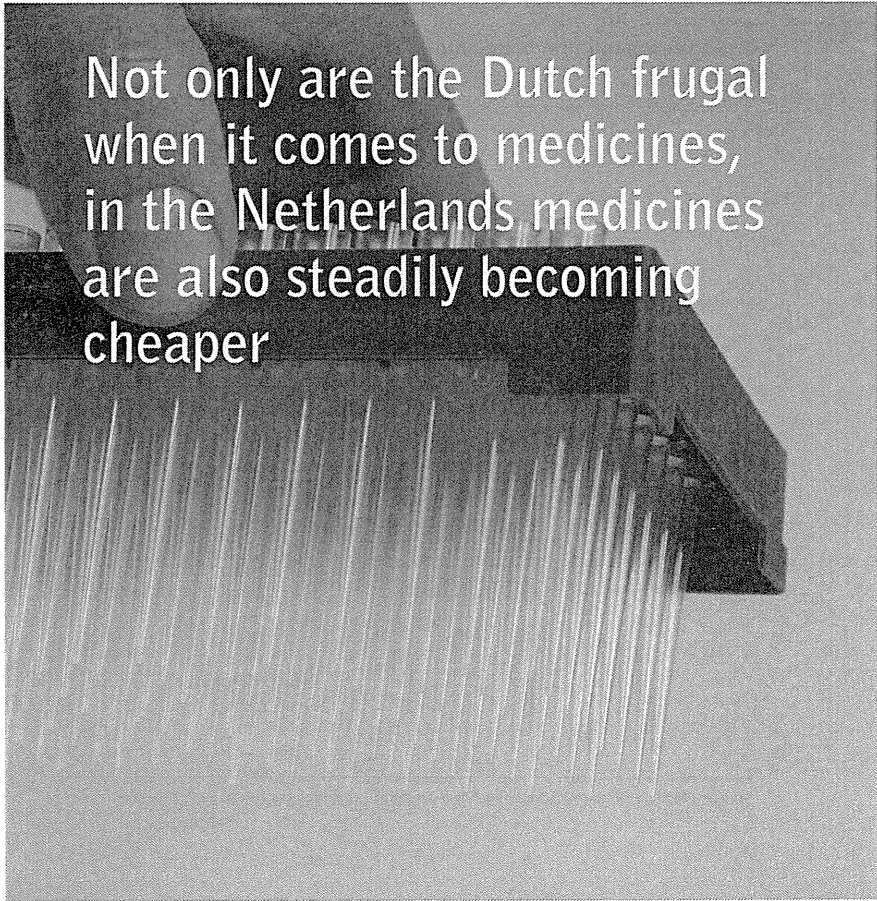
Per capita expenditure for medicines is also lower than elsewhere in Europe

If we compare the per capita expenditure for medicines with that of the rest of Europe, the Netherlands also scores well. In the Netherlands per inhabitant 341 euros is spent annually on medicines. This is well below the Western-European average of just over 400 euros. Once again, England and Denmark score better than The Netherlands. However, Switzerland is at the absolute top with an average of 611 euros per capita expenditure on medicines per annum.

**Average expenditure on medicines per capita in 2009
(in euros)**



Source: Stichting Farmaceutische Kengetallen (Foundation for Pharmaceutical Statistics), 2011



Not only are the Dutch frugal when it comes to medicines, in the Netherlands medicines are also steadily becoming cheaper

2

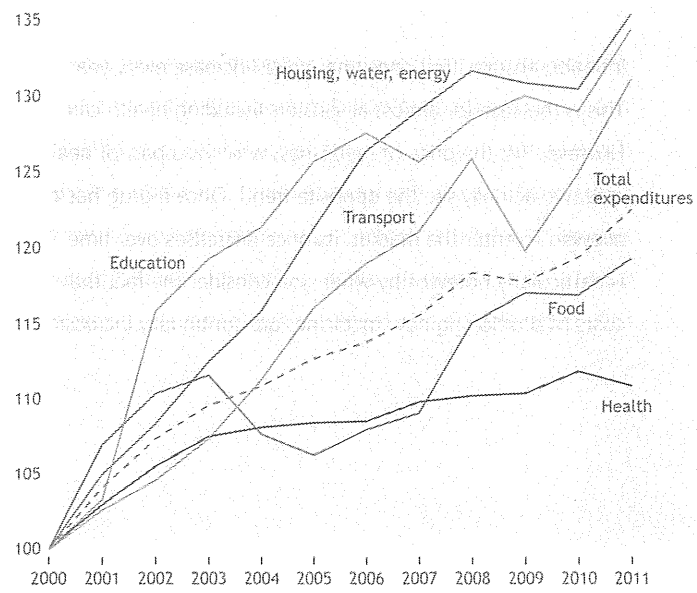
There are various reasons for why the costs of medicines constitute a relatively minor share of the total health care expenditure in the Netherlands. One important explanation is restraint, by both doctors (in prescribing medicines) and patients (in using medicines).

Another reason is that the prices for drugs are regulated under the Dutch law for pricing medicines (WGP), which ensures that prices in the Netherlands are in line with those in neighbouring countries. Furthermore, prices for medicines with expired patents are lower in the Netherlands than in many other European Countries. This is due to past voluntary price agreement between suppliers, pharmacists and the government, as well as to the policies of health insurers.

Everything is becoming more expensive, including health care

Life is becoming more expensive on almost every front. Inflation ensures that prices of most products and services increase by a few percent each year. Since 2000, the amount of money spent by the average household on housing, water and energy has increased by more than 35 percent. A similar increase can be seen in the costs of education. Considerably more is also spent on transportation and food, and the costs per family that had to make use of health care has increased by about 11 percent over the last 11 years.

Development of consumer prices (per average household) in various categories (2000 = 100)

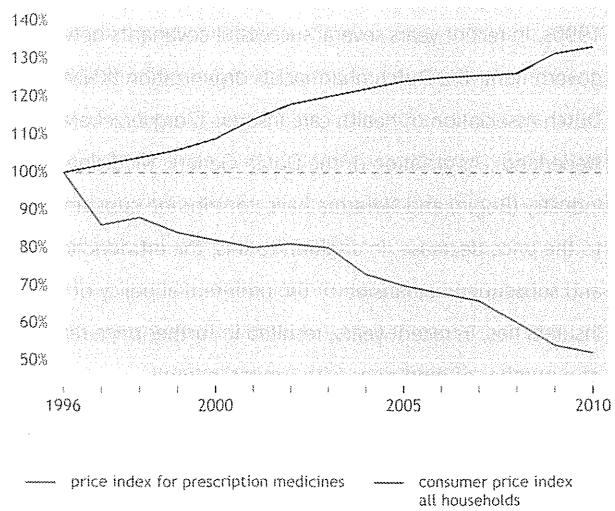


Source: Centraal Bureau voor de Statistiek (CBS/Statistics Netherlands), 2011
(reference date for 2011 is September 30)

The prices of medicines are falling while for many other consumables prices are rising

Inflation ensures that consumer prices increase every year. This is the case for almost all clusters including health care. However, for the price of medicines, which is a part of health care, we actually see the opposite trend. Once a drug has been allowed to enter the market, its price decreases over time. This is particularly noteworthy when you consider the fact that the costs of developing new medicines are continually increasing.

Consumer price index compared to the price index for prescription medicines (January 1996 = 100)



Source: Stichting Farmaceutische Kengetallen (Foundation for Pharmaceutical Statistics), CBS, 2011