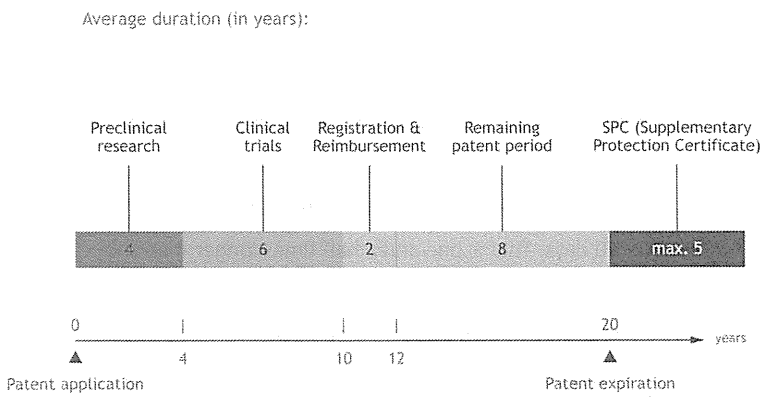
Development of a new medicine takes on average twelve years

On average there is a 12-year period between the discovery of a new active compound and the availability of a new medicine to patients. Preclinical research takes 4 years, clinical trials take 6 years, and the registration and reimbursement procedures take another 2 years. The remaining patent period is then about 8 years, after which a supplementary protection certificate (SPC) may be granted for a maximum of 5 years.

Development and patent period of a medicine

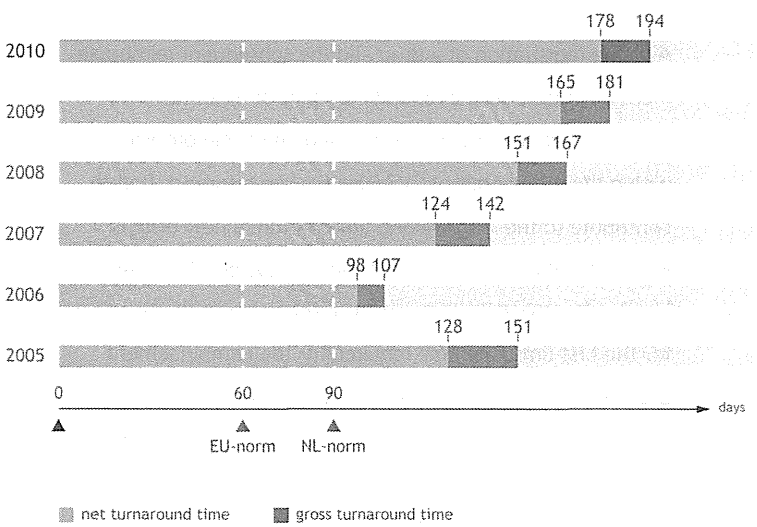


Source: Nefarma

A long wait for permission to conduct clinical trials

Clinical trials are a crucial part of the development of a new medicine. The safety of a substance is first studied in a small group of healthy volunteers, then in a small group of patients and finally in large groups of patients. These trials require authorisation from the medical ethics committees of the participating hospitals. The Dutch law for medical research involving humans states that clinical trial applications are to be processed within 90 days. That is one and a half times longer than the requirement stipulated by the EU directive. Yet, for years now the 90-day term is substantially exceeded in The Netherlands, which makes for unnecessarily long delays before a company can begin a clinical trail.

The average assessment period for authorisation of a clinical trial in the Netherlands (in days)



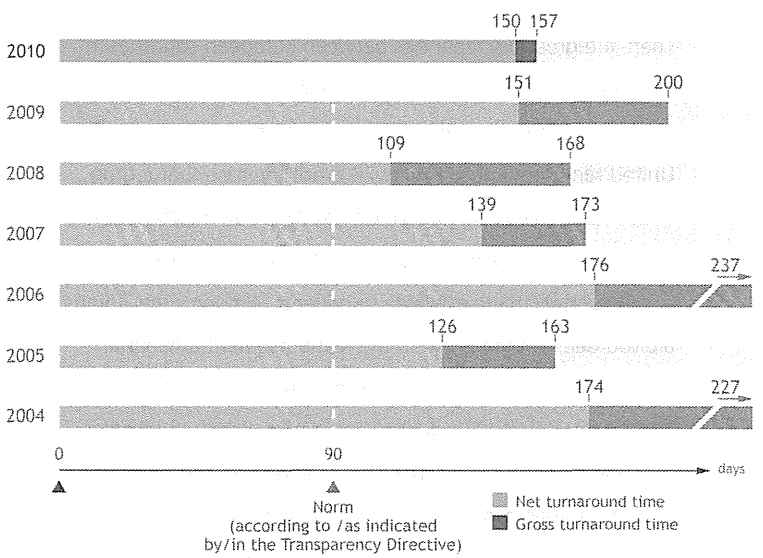
In the gross turnaround time, the time required to provide additional information requested by the assessment committee is included. These 'clock stop' periods are not included in the net turnaround time.

Source: Nefarma Clinical Trial Database (NCTD), 2011

A long wait before a drug is included in the medicines reimbursement system

Also the registration of a drug and the subsequent reimbursement procedure take a requisite amount of time. Time-consuming regulatory procedures and personnel problems within the rating agency CVZ (Health Care Insurance Board) contribute to the long waiting times before a new drug is included in the medicines reimbursement system (GVS). And it is only after this that it is made available to patients. This year for the first time, the time required for the reimbursement procedure for expensive medicines has been measured using the Nefarma database. Applications registered this year had an average turnaround time of no less than 376 days, while the legal maximum is set at 60 days.

Average time required for the reimbursement procedure (in days)



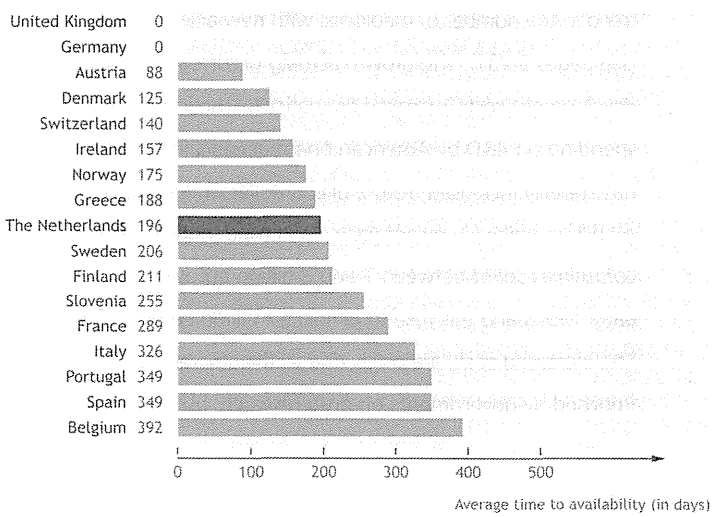
In the gross turnaround time, time is stopped when there is a request for additional information from the applicant. Net turnaround time does not have these delays.

Source: Nefarma Reimbursement Database (NVD), 2011 (reference date: October 2011)

It takes too long before a medicine is available to patients

There are great discrepancies between European countries in the delays patients experience before a new drug becomes available to them. In most countries (with the exception of The United Kingdom and Germany) it is not the case that a drug which has successfully completed the registration process, and for which consequently a commercial license has been issued, is immediately made available to patients. Among other things, a good deal of time is lost in the reimbursement procedure before a doctor can actually prescribe the latest medicines. The Patients' W.A.I.T. indicator ('waiting to access innovative therapies') compares this period for various EU countries. The periods are based on the data of 84 new medicines. With an average delay of 196 days the Netherlands falls somewhere in the middle range of performances of European countries.

The average time that elapses between the commercial licensing of a medicine and its availability to patients

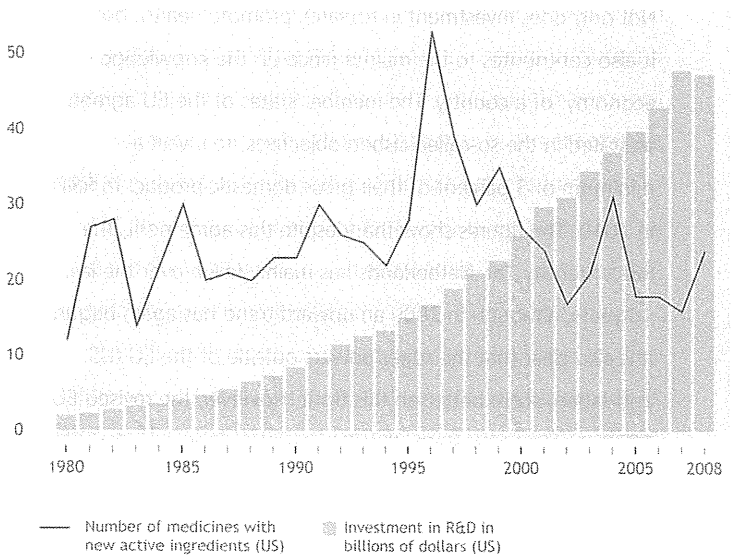


Source: Efpia, Patients' W.A.I.T. Indicator, 2010

Innovation requires ever increasing investments

Earlier we saw, when viewed over a longer period, the increasing trend in the number of medicines with new active compounds (see pages 30/31). This growth actually occurred in an era when development costs increased dramatically. The international spending on R&D by American pharmaceutical companies has steadily increased from 2 billion dollars in 1980 to nearly 48 billion dollars in recent years. In Europe, pharmaceutical companies spent between 7 and 8 billion euros on R&D in the early 1990s and this rose to almost 27 billion euros in 2009. The increased costs are partly due to the stricter regulations imposed by governments on drug research, but also because of registration and reimbursement procedures that have greatly increased the administrative burden on companies.

FDA-approved medicines containing a new active compound, versus R&D investment (1980-2008)

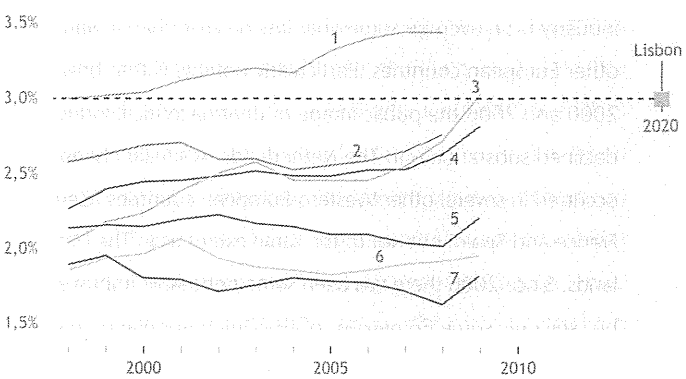


Source: DiMasi, Tufts center for study of drug development, FDA PhRMA

Deteriorating climate for innovation threatens knowledge economy

Not only does investment in research promote health, but it also contributes to the maintenance of 'the knowledge economy' of a country. The member states of the EU agreed, as stated in the so-called Lisbon objectives, to invest a minimum of 3 percent of their gross domestic product in R&D in 2010. The figures show that despite this agreement, the R&D intensity The Netherlands has mainly fallen over the last 10 years, although in 2009 an upward trend has again begun. It is also clear that the super powers outside of the EU (US and Japan) score better on this front. However, the revised EU 2020 strategy now states that the target of 3 percent must be realised in 2020.

R&D intensity* in various countries (relative to the Lisbon objective) 1998-2009 (in percentages)



1. Japan
2. United States
3. Denmark
4. Germany
5. France
6. Belgium
7. The Netherlands

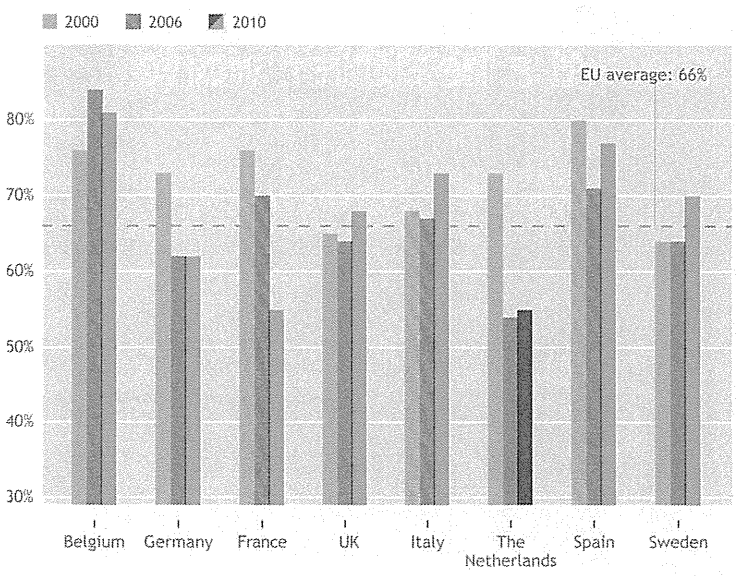
** The R&D intensity shows the percentage of GDP spent on research & development.*

Source: CBS/Eurostat (Central Bureau for Statistics/European Statistical Data), 2010

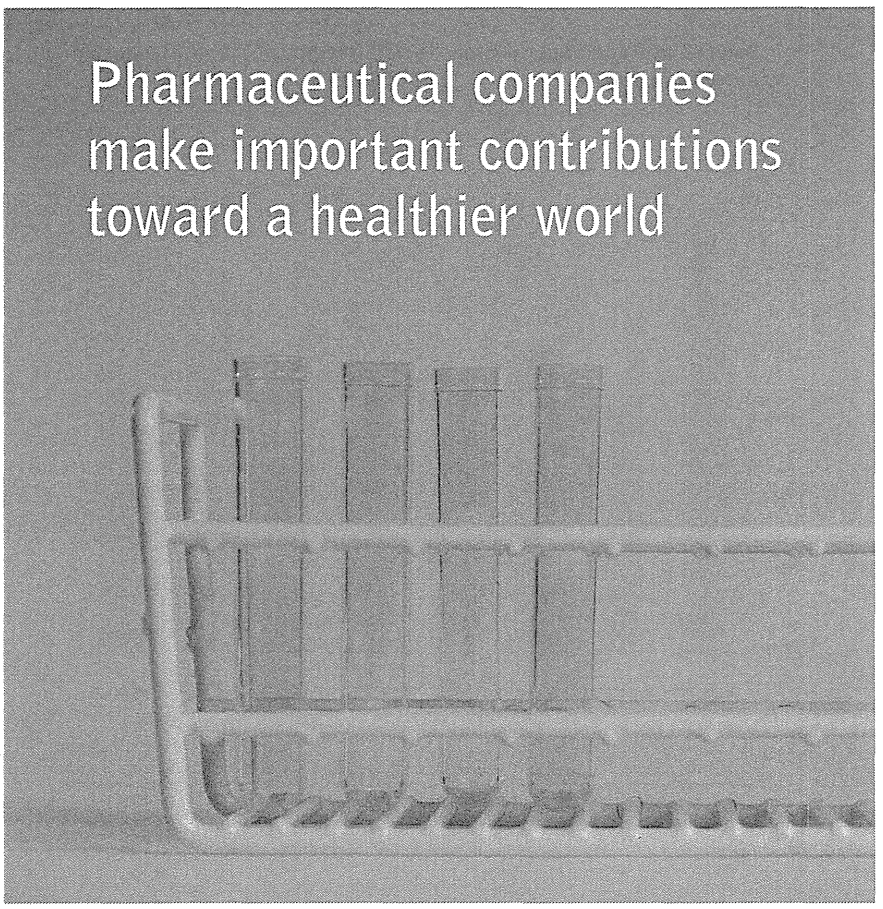
Pharma has a better public image in other EU countries

The attitude of the Dutch population toward the pharmaceutical industry is on average somewhat less positive than in various other European countries. Particularly notable is that between 2000 and 2006 the public image of pharmaceutical industry declined substantially in The Netherlands. A similar change occurred in several other Western-European countries (Germany, France and Spain) but not to the same extent as in The Netherlands. Since 2006 there has been some noticeable improvement, but still only some 56 percent of the Dutch population have a positive attitude toward the pharmaceutical industry. This is 10 percent below the EU average.

Positive attitude of populations toward the pharmaceutical industry (in percentages)



Source: European Chemical Industry Council (Cefic), Public Image Survey


Pharmaceutical companies
make important contributions
toward a healthier world

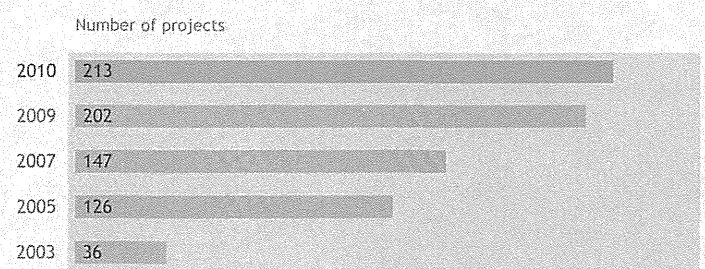
6

Pharmaceutical companies are commercial enterprises that have to make a profit to ensure their continuity and development of products and applications. But that is not the whole story. Their products make an important contribution to people's health. Unfortunately, these products are not within reach of everyone. Therefore many companies are trying to give populations in poorer areas access to medicines. These efforts are expanding, as is evident from the Access to Medicine Index, introduced in 2008, which charts these activities per company. It is also evident from the growing number of projects specifically intended for developing countries, which are being set up by pharmaceutical companies.

Pharmaceutical companies are working toward better health in developing countries

In collaboration with The World Health Organisation (WHO) and The United Nations (UN), pharmaceutical companies use their knowledge and resources related to health and illness to make significant contributions to the improvement of health in developing countries. Over the past 7 years, innovative pharmaceutical companies have contributed more than 9 billion dollars to over 200 projects worldwide directed at preventing and combating diseases. As a result, 1.7 billion people have been helped. Most projects are carried out in collaboration with local parties and non-governmental organisations, and are aimed at preventing and combating HIV/AIDS, tuberculosis and malaria.

Health projects of pharmaceutical companies in developing countries



Source: IFPMA Developing World Health Partnership Database, 2011

Nefarma
vereniging innovatieve geneesmiddelen Nederland

PO Box 11633
2502 AP The Hague

+31 (0)70 313 22 22

info@nefarma.nl
www.nefarma.nl