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## 1. Introduction

Innovative medicines are not available to all European citizens at the same time, and in some markets patients may have to wait more than two years before being able to access a new medicine.

From the industry's and patient's perspective it is imperative to ensure that products come to European markets in:

1. a timely fashion, in accordance with the timelines established by the relevant European Directive
2. at an adequate price and
3. with the appropriate reimbursement conditions (eg no undue restrictions on use/coverage).

This study addresses the first issue by providing an assessment of delays in patients' access to newly introduced medicines in Europe over the period January 1997 – June 2001.

Each Member State has competence over price and reimbursement decisions. However, European Union Directive 89/105<sup>1</sup> sets out time limits within which they are required to assess and decide on applications for pricing and reimbursement, and requires that their decisions are based on objective and verifiable criteria.

In the majority of Member States, a marketing authorisation alone is not sufficient to enable a medicinal product to actually be sold. The medicine will only be able to appear on the market once the competent authorities have fixed a price and/or the medicine has been registered on the positive list defining the conditions under which it is covered by healthcare insurance for residents of the Member State in question. Previous surveys by Europe Economics<sup>2</sup> demonstrated that there are, in practice, significant delays in gaining reimbursed market access above the permitted timetable.

Other studies examining delays in reimbursed market access are available, including studies by some of the national pharmaceutical industry associations. While these studies cover different time periods and different products they show results broadly consistent with those presented in this report.

The objective of this work is to provide comprehensive, reliable and up-to-date information on the extent of delays, as a basis for discussions with the relevant member states and the European Commission aimed at improving member state performance/compliance.

This project has been undertaken with support from a consortium of pharmaceutical companies (AstraZeneca, Aventis, Bayer, Bristol-Myers Squibb, Boehringer Ingelheim, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Organon, Pfizer, Roche, Schering-Plough and Wyeth) and national associations (AGIM-Belgium, Farmindustria-Italy, Farmaindustria-Spain, LMI-Norway, NEFARMA-Netherlands, PIF-

<sup>1</sup> Official Journal of the European Union, [www.europa.eu.int/eur-lex/index.htm](http://www.europa.eu.int/eur-lex/index.htm) OJ L40, 11/2 -1989, p8-11.

<sup>2</sup> Europe Economics December 1998. Access to important new medicines: where and why do patients wait? [[www.eer.co.uk](http://www.eer.co.uk)]

Finland, and SNIP-France), under the auspices of EFPIA (the European Federation of Pharmaceutical Industries and Associations).

Note that this analysis does not attempt to establish the underlying causes for the patterns observed.

## 2. Definitions Of Terms Used

In this report:

- **Pricing delay** is defined as the date from when the company submitted the price application to the date price approval was granted<sup>3</sup>.
- **Reimbursement delay** is defined as the date from when the company submitted an application for reimbursement to the date the company was first informed about the reimbursement decision<sup>3</sup>.
- **Publication delays** are defined as the time between the company being notified of the reimbursement decision by the authorities to the actual publication of that decision in the official national reimbursement lists/journals. The time taken for publication has only been illustrated where formal listing in an official publication is a prerequisite for reimbursement. An additional delay may apply when reimbursement is not available on the day of publication in the official journal, but on a later date indicated in the official journal.
- **Restrictions to reimbursement** refer to special conditions imposed by reimbursement authorities which limit use beyond any restriction in the approved label. Such restrictions include limitation to hospitalised patients, use after failure of first/second line treatment, prescription by specialised doctors only, pre-approval by sickness funds *etc.*

At the time the study was completed, some products were still not available in some markets. **Pending products** will be shown in different charts, as appropriate. Pending products are those medicines that did not reach the end-point of all post-marketing approval procedures.

### Note:

These analyses are based on the existing regulations in each market at the time when the pricing and/or reimbursement application was submitted. Consequently the impact of recent reforms in Belgium and Italy are not reflected in the results. In Spain, anecdotal evidence suggests that the approval process has slowed this year, but again our study does not address this situation.

<sup>3</sup> For France and Belgium, medicines may be examined by a Transparency Commission, which will make a recommendation based on the positioning of the new medicine in comparison to already available treatments. In Belgium the Transparency Commission's appraisal takes place in parallel with the pricing procedure.



### 3. Methodology

This study covers the pharmaceutical markets in Western Europe, *ie* 14 Member States of the EU (excluding Luxembourg), together with Norway and Switzerland.

It includes 78 medicinal products for which marketing authorisation was granted over the period 1 January 1997 to 30 June 2001, through a centralised or mutual recognition procedure.

The following products have been excluded:

- combination products not containing a New Active Substance (NAS)
- diagnostic agents
- generic products
- line extensions or new formulations of products that had already been approved
- nutritional supplements
- products (including several vaccines) that had been granted market authorisation on the basis of an abridged application.

The final list of medicinal products included in the study is provided in Annex 1.

The questionnaire was designed to collect information on the time taken from application to receipt of pricing and reimbursement in the respective European countries. It was sent to the marketing authorisation holders for each product.

Not all companies completed the questionnaire for all 16 countries, and some of the products were not launched in all markets. This resulted in an average of 56 products being included in the study for each country. With the exception of Norway and Switzerland, each country comprised an average of 33 centralised products, 22 MRP products and 1 national product (refer to Table 1).

**Table 1**      **Number Of Products By Market Authorisation Procedure In Each Market**

<b>Country</b>	<b>Total number of products*</b>	<b>Number of products approved through a centralised procedure</b>	<b>Number of products approved through a MRP procedure</b>	<b>Number of products approved through a national procedure</b>
Austria	63	35	27	1
Belgium	54	32	21	1
Denmark	51	30	20	1
Finland	64	38	25	1
France	52	30	20	2
Germany	63	38	24	1
Greece	50	31	18	1
Ireland	56	33	22	1
Italy	50	30	19	1
Netherlands	55	33	22	0
Norway	54	0	20	34
Portugal	57	34	23	0
Spain	56	33	22	1
Sweden	52	30	21	1
Switzerland	53	0	0	53
UK	64	38	20	6

\* The number of products included in subsequent analyses may vary due to pending products (products still awaiting a final pricing and reimbursement decision) and incomplete questionnaires

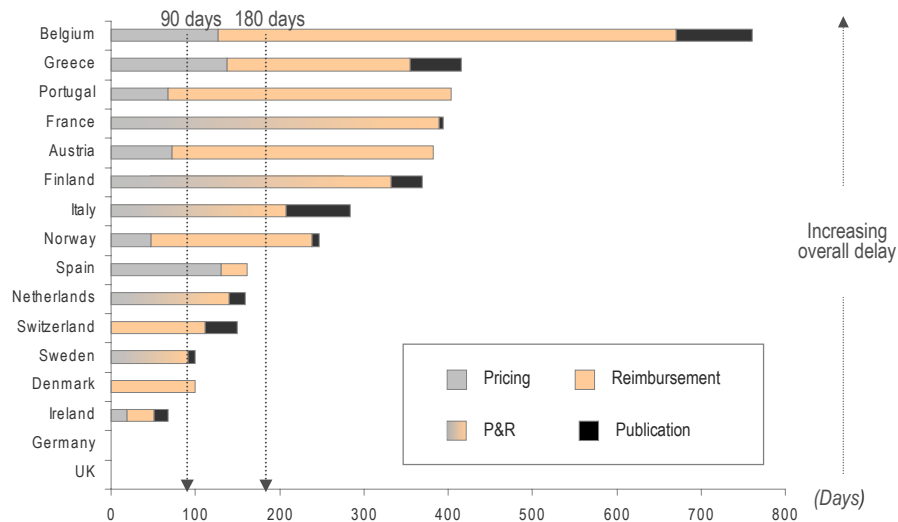
## 4. Analysis Of Time Taken For Pricing And/Or Reimbursement Approval

### 4.1 Overall Pricing And Reimbursement Delays In Each Market

In the UK and Germany, new medicines can be put on the market immediately after marketing authorisation has been granted. Typically, all medicines will be covered by the national healthcare system (save a few exceptions).

In the other countries, our study has highlighted a wide variation in the time taken for pricing and reimbursement authorities in each market to agree on the price and reimbursement level of new medicinal products, as shown in Table 2 and Figure 1. Of these countries only Ireland, Sweden, the Netherlands and Spain are on average meeting the Transparency Directive timescales, although not for all products. Denmark, where there is no formal pricing decision, is marginally exceeding the 90-day limit for reimbursement. Switzerland is not a signatory to the Transparency Directive, and thus not bound by this timescale.

**Figure 1 Delays From Pricing And/Or Reimbursement Application To Reimbursement**



\* In Belgium - until January 2002, the transparency commission process had to be conducted before a company could apply for reimbursement of a given product. In France, only ambulatory care products have been included in this analysis. In Italy and Sweden the pricing and/or reimbursement procedure can start as soon as CPMP opinion is available (for centrally approved medicines). This analysis does not reflect the impact of recent reforms in Italy. In Spain anecdotal evidence suggests that delays have increased recently. In Switzerland a more comprehensive study concerning 191 files shows an average delay over 180 days. Finland has a two-tier reimbursement system, with a slower process for treatments of chronic diseases (reimbursed at 75%) and serious or life-threatening diseases, and a faster one for acute diseases. Delays shown in this study do not reflect this distinction, and actual pricing and reimbursement delays are typically longer for medicines in the 75%/100% reimbursement categories.

**Table 2 Average Time From Pricing And/Or Reimbursement Application To Reimbursement (Days)**

Country	Time for pricing decision	Time for reimbursement decision	Time taken for publication	Total time	Number of products with P&R decision 'pending'
Belgium	127	544	90	761	11
Greece	138	217	60	415	11
Portugal	68	336	0	404	9
France		389	5	394	6
Austria	72	310	0	382	2
Finland		332	37	369	5
Italy		208	76	284	1
Norway	47	192	8	247	5
Spain	131	30	0	161	3
Netherlands		140	19	159	2
Switzerland	0	112	37	149	0
Sweden		91	9	100	0
Denmark	0	100	0	100	2
Ireland	19	32	17	68	0
Germany		0	0	0	0
UK		0	0	0	0

\* In Belgium - until January 2002, the transparency commission process had to be conducted before a company could apply for reimbursement of a given product. In France, only ambulatory care products have been included in this analysis. In Italy and Sweden the pricing and/or reimbursement procedure can start as soon as CPMP opinion is available (for centrally approved medicines). This analysis does not reflect the impact of recent reforms in Italy. In Spain anecdotal evidence suggests that delays have increased recently. In Switzerland a more comprehensive study concerning 191 files shows an average delay over 180 days. Finland has a two-tier reimbursement system, with a slower process for treatments of chronic diseases (reimbursed at 75%) and serious or life-threatening diseases, and a faster one for acute diseases. Delays shown in this study do not reflect this distinction, and actual pricing and reimbursement delays are typically longer for medicines in the 75%/100% reimbursement categories"

In the majority of countries there are further delays for medicinal products before they can achieve market access. These are imposed by a requirement that the decision is published in the official national reimbursement lists/journals before the product can be reimbursed. The longest publication delays are observed in Belgium, Italy and Greece.

In several countries there are medicines that have not reached the end-point of all post-marketing authorisation procedures, the pending products. Table 3 below provides a breakdown of the number of products from the total sample for which a pricing and/or reimbursement decision was still pending at the time of our survey (effectively still awaiting a decision on the 30 June 2002). As one might expect those countries with longer delays tend to have more pending products. Belgium and Greece have the most products awaiting P&R approval, with 11 of our sample being products of 'pending' status.

**Table 3**      **Number Of Products With A Pricing And/Or Reimbursement Decision Still Pending By Year Of Market Authorisation**

Country*	1997	1998	1999	2000	2001	Total
Austria	0	0	0	0	2	2
Belgium	1	1	0	6	3	11
Denmark	0	0	0	1	1	2
Finland	0	1	0	1	3	5-21
France	0	0	0	3	3	6
Greece	0	2	1	6	2	11
Ireland	0	0	0	0	0	0
Italy	0	0	0	0	1	1
Netherlands	0	1	0	0	1	2
Norway	0	0	1	4	0	5
Portugal	0	2	2	4	1	9
Spain	0	0	1	0	2	3
Sweden	0	0	0	0	0	0
Switzerland	0	0	0	0	0	0

\* No pricing and/or reimbursement decision is required in Germany and UK. Recent reforms introduced in Italy will have a detrimental impact on pending products. (Recent reforms are not covered by this study). In Finland, many products will initially be granted 50% reimbursement, and only after further negotiations with the national authorities can products be awarded the 75% or 100% reimbursement category. Since "pending" is interpreted to include products with 50% reimbursement, which are pending a decision to achieve 75% or 100% reimbursement, the number of pending products in Finland is high. Considering delays to achieve reimbursement in the appropriate category would increase the number of "pending" products to 21.

It is illustrative to explore the extent of these delays and assess what proportion of products have been awaiting pricing and/or reimbursement approval for more than 3 years.

Table 3 overleaf shows the number of products by year of market authorisation (1997-2001) for which the pricing and reimbursement process is still incomplete. Most of the pending products received market authorisation in 2000-2001, but there are also several instances where products authorised as far back as 1997-1998 are still pending. Belgium, Greece and Portugal in particular have some of the longest pending products in the sample.

Country-specific commentaries that should be considered when interpreting the market access delays and related results are included in Section 4.6.

## 4.2 Specific Delays For Hospital Only And Ambulatory Care Products

In the above analyses we have included both ambulatory care and hospital only products, except for France. In many countries hospital only products are not required to go through a pricing and/or reimbursement procedure. If we exclude hospital only products (as defined at the time of the market authorisation) from the analysis, the delays are even longer in several markets. In Norway, for example, the average delays would increase from 247 days to 323 days.

## 4.3 Countries With Separate Pricing And Reimbursement Procedures

In the following countries there is a separate pricing and reimbursement decision:

Austria	Belgium	(Denmark)
Greece	Ireland	Norway
Portugal	Spain	Switzerland

It is in these markets, where there is a separate pricing and reimbursement process the longest delays tend to occur -refer to Table 2. The longest delays are encountered in Belgium (a total of 761 days), followed by Greece (415 days) and Portugal (404 days). The shortest delays occur in Ireland (68 days), which also has separate pricing and reimbursement procedures. In fact it is only in Ireland and Spain that both procedures are on average completed within 180 days. (Note: In Spain, anecdotal evidence suggests that the delays have increased recently).

It is typically the reimbursement component that gives rise to the greatest delay – on average 73% of the total. Only in Spain did the time to pricing decision represent more than half of the total time to market access.

The range of delays within each market also varies considerably as illustrated in Table 4. For example in Austria the delays ranged from 144 days to 959 days, and in Norway even more from 86 days to 1230 days.

## 4.4 Countries With A Combined Pricing And Reimbursement Procedure

In the countries listed below the pricing and reimbursement procedure is combined, and it is not possible to identify separately the timescales for pricing and reimbursement decisions.

Finland                      France                      Italy  
 Netherlands              Sweden

In this sub-group, it is in France, Finland, and Italy that the longest delays occur (389, 332 and 208 days respectively). On average, Netherlands and Sweden complete the pricing and reimbursement assessment within 180 days (140 and 91 days respectively).

The range of delays within each market also shows significant variation as illustrated in Table 4. For example in Finland, the delays range from 41 days to 1264 days, and in France from 78 days to 953 days.

**Table 4              Range Of Pricing And/Or Reimbursement Delays (Days) In Each Country (Excluding Publication Delays)**

Country	Minimum	Maximum	Mean
Austria	144	959	382
Belgium	190	1123	671
Denmark	40	277	100
Finland	41	1264*	332
France	78	953	389
Germany	0	0	0
Greece	99	868	355
Ireland	28	94	51
Italy	51	815	208
Netherlands	35	629	140
Norway	86	1230	239
Portugal	134	635	404
Spain	111	266	161
Sweden	14	269	91
Switzerland	52	443	112
UK	0	0	0

\* Finland has a two-tier reimbursement system, with a slower process for treatments of chronic diseases (reimbursed at 75%) and serious or life-threatening diseases, and a faster one for acute diseases. Delays shown in this study do not reflect this distinction, and actual pricing and reimbursement delays are typically longer for medicines in the 75%/100% reimbursement categories.

## 4.5 Publication Delays

As mentioned, in many countries there are further delays for medicinal products before they can achieve market access. These are imposed by a requirement that the decision is published in the official national reimbursement lists/journals before the product can be reimbursed. The time to publication varies from 5 days in France to 76 days in Italy and 90 days in Belgium (refer to Table 2).

However in some countries publication of a decision does not mean immediate implementation. Delaying enforcement of publicised decisions create yet another hurdle for access to new medicines.

## 4.6 Country-Specific Issues To Be Considered In Analysing Market Access Delays

### Austria

A new pricing and reimbursement system came into effect in 1999 that involves a price notification procedure instead of the former price setting system.

### Belgium

On 1 January 2002, new procedures have been adopted, and the Transparency Commission (TC) no longer exists. Authorities are now legally obliged to make the pricing and reimbursement decision within 180 days. The new provisions were not applicable to medicinal products included in the present study.

### Finland

There is a two-tier reimbursement system, with a slower process for treatments of chronic diseases (75% special reimbursement category) and more serious or life-threatening diseases (100% special reimbursement category), and a faster one for acute diseases (50% basic reimbursement category).

Products for chronic disease will initially be granted 50% reimbursement, and only after further extended negotiations with the national authorities can they be awarded the 75% or 100% reimbursement category. There is an application procedure according to the EU Transparency Directive for the fast process, but not for the slow one. Thus, in reality, the actual pricing and reimbursement delay for some products in Finland may be longer than our results indicate.

Since "pending" is interpreted to include products with 50% reimbursement, which are pending a decision to achieve 75% or 100% reimbursement, the number of pending products in Finland is high. In our analysis 21 products can be classified as pending, when considering delays to achieve reimbursement in the appropriate category.

### Greece

Since the end of 2000, no new reimbursement list has been approved. The data therefore do not reflect the current situation.

### Italy

In Italy it is possible to apply for pricing and reimbursement for products authorised through the centralised procedure following the CPMP opinion and before the final market authorisation. For products authorised under the Mutual Recognition procedure,

application for price is possible from “day 90” of the procedure. Recent reforms to the Italian healthcare system are expected to adversely affect market access delays.

## Netherlands

The price of pharmaceuticals is capped by the non-weighted average of prices in Germany, UK, Belgium and France. Reimbursement requires inclusion in the positive list and by setting a cluster-maximum reimbursement at the average price of “interchangeable” products, including generics. Patients have to pay out of pocket any difference between price and reimbursement level, where appropriate.

## Norway

In Norway the authorities usually refer to Parliament for a final decision regarding reimbursement of new active substances. The reimbursement decision is not finalised until Parliament’s review of the fiscal budget in Autumn. Thus reimbursement decisions for products containing new active substances are routinely severely delayed.

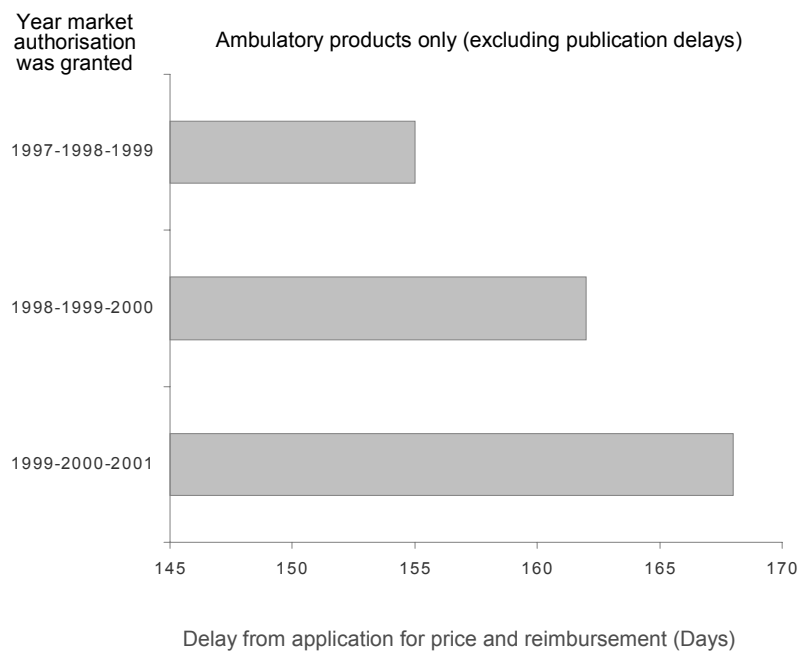
## Sweden

In Sweden it is possible to apply for pricing and reimbursement for products authorised through the centralised procedure following the CPMP opinion and before the final market authorisation, thus increasing the efficiency of the overall process of gaining market access. Sweden is on average one of the faster access markets for new medicines.

## Spain

Spain has actually shown an increase in overall delays over the period 1997-2001, as illustrated in Figure 2 below. These increased delays are typically encountered during

**Figure 2 Spanish Market Access Delays Over The Period 1997-2001**



the reimbursement process. There is increasing concern about more lengthy delays since end 2001 – beginning 2002, but we have not been able to capture that in this study. Indeed, anecdotal evidence suggests that the delays have increased recently.

#### **4.7 Restrictions On Usage**

In addition to delays in reimbursed access to markets, there are also restrictions on the reimbursement of new medicines, over and above those restrictions reflected in the terms of the marketing authorisation. Restriction to hospital only use and patient-specific limitations are the most common restrictions. Other restrictions include: use after failure of 1<sup>st</sup>/2<sup>nd</sup> line treatment only, medicine can only be prescribed by a (hospital) specialist, and prescription/administration is subject to pre-approval by the local sickness fund.

In Finland, most products will initially only be granted 50% reimbursement, and only after further negotiations with the national authorities can products be awarded the 75% or 100% reimbursement category. Clearly this is a form of reimbursement restriction.

In some markets, even though restrictions are not formally imposed by the pricing and reimbursement authorities these may occur in clinical practice. For example, in the UK NICE may recommend restrictions on use, and even the prospect of a NICE review may cause doctors to delay prescribing products until NICE has given its opinion.

## 5. Conclusions

The European Directive 89/105/EEC requires that applications to the competent authorities to secure a price or reimbursement for new medicines must be decided within 90 days, or 180 days where it is necessary to agree price before applying for reimbursement.

Overall this survey provides evidence that all countries with formal pricing and/or reimbursement approval systems, with the exception of Ireland, Sweden, Denmark and Spain, have significantly exceeded the 90 or 180-day targets, as defined above, for granting pricing and reimbursement status for medicinal products.

Patients in Belgium on average wait 2 years longer to receive new medicines than in the UK and Germany. Although the average delays are lower in other countries, patients could still wait more than 2 years in Austria, Greece, Finland, France, Italy and Norway. These delays are usually attributable to extended reimbursement negotiations.

In fact in many countries the time taken exceeds the respective target (90 or 180 days) by more than 100%. This applies to Austria, Belgium, Finland, France, Greece and Portugal.

The delay was longest in Belgium, which took on average 671 days to grant new medicines pricing and reimbursement status (other publication delays are not included in this figure). Austria, Finland, France, Greece and Portugal took an average of between 332 and 404 days. This implies that patients in Austria, France, Greece and Portugal have on average had to wait over 12 months longer to gain access to new medicines than citizens in UK and Germany.

When considering countries with separate pricing and reimbursement procedures, it is apparent that most countries are broadly able to comply with the 90-day target for pricing approval, and the largest delays are introduced as a result of the reimbursement approval procedure. A notable exception to this trend is Spain, where the pricing procedure incurs a considerably longer delay than reimbursement. However it is noticeable that Spain has actually shown an increase in overall delays over this time period. These increased delays are typically encountered during the reimbursement process. Anecdotal evidence suggests that delays in Spain have increased again during the period 2001/2002, but we have not been able to capture that in this study.

It is instructive to compare the number of products still awaiting a reimbursement decision as of 30th June 2002 (bearing in mind that the study covers products registered between 1st January 1997 – 30th June 2001). The results confirm that in those markets where the delays are longest, the highest numbers of products are pending pricing and reimbursement approval. Consequently Belgium and Greece show 11, and Portugal 9, products pending pricing and reimbursement approval. In Finland, 21 products are either pending or not reimbursed in the appropriate category.

Incidentally, the study noted additional restrictions on patient access as defined by the conditions of reimbursement. The restrictions most commonly applied by the reimbursement authorities were those limiting use to particular treatment setting (hospital only) or patient-specific restriction. In all markets there appears to be an increasing tendency by the reimbursement authorities to impose restriction on access.



## Annex 1: Medicinal Products Included In This Study

Trade name	<i>International Non-Proprietary Name (INN)</i>	Market authorisation procedure
Accolate	<i>zafirlukast</i>	MRP
Actos	<i>pioglitazone</i>	Centralised
Agenerase	<i>amprenavir</i>	Centralised
Aggrastat	<i>tirofiban hydrochloride</i>	MRP
Airtal	<i>aceclofenac</i>	MRP
Almogran	<i>almotriptan</i>	MRP
Arava	<i>leflunomide</i>	Centralised
Aricept	<i>donepezil hydrochloride</i>	MRP
Aromasin	<i>exemestane</i>	MRP
Atacand	<i>candesartan</i>	MRP
Avandia	<i>rosiglitazone</i>	Centralised
Avelox	<i>moxifloxacin hydrochloride</i>	MRP
BeneFix	<i>nonacog alfa</i>	Centralised
Beromun	<i>tasonermin</i>	Centralised
Ceprothin	<i>human protein C</i>	Centralised
Colazide	<i>balsalazide</i>	MRP
Cytoglobin	<i>human CMV immunoglobulin G</i>	MRP
Detrusitol	<i>tolterodine tartate</i>	MRP
Diastabol	<i>miglitol</i>	MRP

<b>Trade name</b>	<b>International Non-Proprietary Name (INN)</b>	<b>Market authorisation procedure</b>
Enbrel	<i>etanercept</i>	Centralised
Eloxatin	<i>oxaliplatin</i>	Centralised
Evista	<i>raloxifene</i>	Centralised
Exelon	<i>rivastigmine</i>	Centralised
Fasturtec	<i>recombinant urate oxidase</i>	Centralised
Fortovase	<i>saquinavir</i>	Centralised
Hexaphlogin	<i>hexaphlogin a</i>	MRP
Infanrix Hexa	<i>diphtheria, tetanus, hepatitis B, influenzae type b</i>	Centralised
Kaletra	<i>lopinavir/ritonavir</i>	Centralised
Karvea	<i>irbesartan</i>	Centralised
Ketek	<i>telithromycin</i>	Centralised
Lipitor	<i>atorvastatin</i>	MRP
Lipobay	<i>cerivastatin</i>	MRP
Luveris	<i>lutropin alpha</i>	Centralised
Mabthera	<i>rituximab</i>	Centralised
Maxalt	<i>rizatriptan</i>	MRP
Meningitec	<i>meningococcal Group C</i>	MRP
Metalyse	<i>tenecteplase</i>	Centralised
Micardis	<i>telmisartan</i>	Centralised
Midotens	<i>lacidipine</i>	MRP
Minesse	<i>gestodene</i>	MRP

<b>Trade name</b>	<b><i>International Non-Proprietary Name (INN)</i></b>	<b>Market authorisation procedure</b>
Naramig	<i>naratriptan</i>	MRP
Neis Vac-C	<i>meningococcal Group C</i>	MRP
Nexium	<i>esomeprazole</i>	MRP
Novomix 30	<i>insulin aspart</i>	Centralised
NovoNorm	<i>repaglinide</i>	Centralised
Novorapid	<i>insulin aspart</i>	Centralised
Omnicef	<i>cefdinir</i>	MRP
Prevenar	<i>pneumococcal saccharide</i>	Centralised
Pritor	<i>telmisartan</i>	Centralised
Pro-Epanutin	<i>fosphenpoin</i>	MRP
Quomem	<i>bupropion hydrochloride</i>	MRP
Rapamune	<i>sirolimus</i>	Centralised
Raxar	<i>grepafloxacin</i>	MRP
Refacto	<i>moroctocog alfa</i>	Centralised
Refludan	<i>cepirudin</i>	Centralised
Relenza	<i>zanamivir</i>	MRP
Remicade	<i>infliximab</i>	Centralised
Reminyl	<i>galantamine hydrobromide</i>	MRP
Riamet	<i>artemether+lumefantrine</i>	MRP
Mirapexin	<i>pramipexole</i>	Centralised
Simulect	<i>basiliximab</i>	Centralised
Singulair	<i>montelukast sodium</i>	MRP
Sonata	<i>zaleplon</i>	Centralised

<b>Trade name</b>	<b><i>International Non-Proprietary Name (INN)</i></b>	<b>Market authorisation procedure</b>
Starlix	<i>nateglinide</i>	Centralised
Synagis	<i>palivizumab</i>	Centralised
Telfast	<i>fexofenadine hydrochloride</i>	MRP
Uprima	<i>apomorphine hydrochloride</i>	Centralised
Viagra	<i>sildenafil</i>	Centralised
Viracept	<i>nelfinavir</i>	Centralised
Viramune	<i>nevirapin</i>	Centralised
Vistide	<i>cidofovir</i>	Centralised
Visudyne	<i>verteporfin</i>	Centralised
Vitravene	<i>fomivirsen</i>	Centralised
Xeloda	<i>capecitabine</i>	Centralised
Xenical	<i>orlistat</i>	Centralised
Zeffix	<i>lamivudine</i>	Centralised
Ziagen	<i>abacavir sulphate</i>	Centralised
Zometa	<i>zoledronic acid</i>	Centralised