European Federation of Pharmaceutical Industries and Associations

PATIENTS W.A.I.T. INDICATOR

2010 Report – based on EFPIA's database (first EU marketing authorisation in the period 2007-'09)

EXECUTIVE SUMMARY

The **Patients W.A.I.T. Indicator** shows, for new medicines with first EU marketing authorisation in the period 2007-'09:

- The rate of availability, measured by the number of medicines available to patients in European countries;
- The average time between marketing authorisation and patient access, measured by the number of days elapsing from the date of EU marketing authorisation to the day of completion of post-marketing authorisation administrative processes (including pricing and reimbursement processes).

For the purpose of the "Patients W.A.I.T. Indicator", it is considered that Germany and UK allow access to new medicines upon marketing authorisation – in these countries, no pricing / reimbursement process needs to be completed before new medicines can be prescribed to patients. However, other hurdles to access – which are not within the scope of this analysis – may apply in these countries.

"Patients W.A.I.T." stands for *Patients Waiting to Access Innovative Therapies*. The INDICATOR provides a benchmarking analysis of the waiting times registered in 14 European countries[1].

As per mid-2010, depending on the patients' country of residence, doctors would be able to prescribe between 39 and 86% of the new medicines with a valid EU marketing authorisation granted between 1 January 2007 and 31 December 2009. It should be noted that the rate of availability is down in most of the countries included in the survey compared with the previous study-period.

For those new medicines that doctors can prescribe under the national healthcare provisions, average time elapsing between the date of EU market authorisation and the "accessibility" date (i.e. date of completion of pricing / reimbursement procedures) in 14 European countries will vary from 88 to 392 days (not considering Germany and the UK). Delays have most significantly increased in Portugal and Spain compared to the previous study-period.

[1] No updated information received for France (latest input: 2008 Indicator)

BACKGROUND

From 2004 to 2007, EFPIA had requested that IMS Health prepare a database that can be used to analyse delays in market access for medicines in Europe. This database served as a basis to the production of 8 reports issued on a 6-monthly basis, providing a benchmark analysis of time needed for completing pricing / reimbursement processes after marketing authorisation.

In February 2008, EFPIA's "Market Access Delays" ad hoc group agreed that EFPIA would organise its own database needed to produce the next "Patients W.A.I.T. Indicator" Reports.

Data collection is limited to **medicines with an EU marketing authorisations (i.e. "centrally" approved medicines)**. Selection of medicines ("scope" of the analysis) is based on the same definition as that used in earlier reports mandated from IMS Health (from 2004 to 2007), i.e. medicines with an active substance that was not authorised before in the EU (initial marketing authorisation), and which prior marketing authorisation outside the EU dates no more than 10 years back. The selection of medicines within scope was made by H.C.S.; products classified as diagnostics are excluded; products that are classified in the "V" category in the IMS classification are also excluded from scope.

HOW WAS THE DATABASE CONSTRUCTED

EFPIA's database includes medicines authorised from 2005 to 2009 (through the centralised procedure)

H.C.S., mandated by EFPIA, has completed the first part of the database, including information available on the **EMA and Commission websites**. In line with the scope agreed, the database includes information for **117 medicines**. For each medicine, the database includes: (i) the application date; (ii) the CHMP opinion date; (iii) the marketing authorisation date; (iv) the date of notification of the Commission's decision; (v) the active review time; and (vi) the "orphan status", where applicable, as well as any other category (including: "advanced medicines" / "paediatric" review). The database also includes information about the label (therapeutic class and therapeutic indications), and conditions or restrictions with regard to the safe and effective use of the medicinal product.

Member Associations have added the "accessibility" dates for their respective countries. They refer primarily to information available from **official sources**. Where information is not available from official sources, Member Associations take the information **from other sources** (mostly directly from their member companies).

Information relevant to the situation in the countries provided by Member Associations includes: (i) the "accessibility" date, i.e. the first date when doctors can prescribe the medicine to patients, who will be able to benefit from reimbursement conditions applicable in the country; (ii) access to the medicine reserved to patients staying in / visiting a hospital[2]; (iii) any additional comment (such as: special reimbursement conditions, application for reimbursement rejected, pending negotiations, etc.). Member Associations

[2] In a majority of countries, these medicines are not submitted to pricing and reimbursement processes, as is the case for medicines available in ambulatory care. However, in some countries, these products are subject to pricing discussions and / or HTA processes.

have also provided additional comments considered useful for further analysis and interpretation of outcomes.

HOW WAS THE DATABASE COMPLETED

For the purpose of the "Patients W.A.I.T. Indicator", it is considered that Germany and UK allow access to new medicines upon marketing authorisation – in these countries, no pricing / reimbursement process needs to be completed before new medicines can be prescribed to patients. However, other hurdles to access – which are not within the scope of this analysis – may apply in these countries[3].

Information provided by Member Associations was taken from official sources in: Austria, Belgium, Denmark, Finland, Ireland, Italy, the Netherlands, Norway, Sweden, and Switzerland. In Switzerland, medicines are approved following the national regulatory system, and therefore the total number of medicines taken into consideration relates to the number of national MA granted during the study period.

In some countries, no official (publicly accessible) sources provide the information required. In these countries, Member Associations have collected information through their membership, i.e.: Greece, Portugal (where information included for non-member companies were taken from the Infarmed database), Slovenia, and Spain. For these countries the database could not be completed for all medicines; the number of medicines for which information is included are shown under "total number of medicines considered" (in orange) – calculation of "average time" is based on the number of medicines for which information could be collected.

France provided data up to 2008 (relating to medicines that received marketing authorisation from 2005 to 2007). The latest data are shown for reference.

[3] EFPIA's "Market Access Delays" Working Group is reflecting on how to benchmark hurdles that result from other than pricing / reimbursement processes.

WHAT THE DATA SHOW

The table below shows the **results** of the data collected – countries are ranked in descending order of "accessibility times". The complete database includes **117 new medicines, of which 84 are considered in the study period covered by this report, i.e. 2007-'09**. For Switzerland, **43** of the medicines included in the EU Medicines Register (i.e. "centrally approved" medicines) have received a national marketing authorisation during the same reference period.

Country *Latest update*	Total number of medicines considered[4]	Number of medicines "available" % rates in *italics* when not referring to all 84 "in-scope" medicines		**Average time elapsed between date of MA and "accessibility" date**	Comments
Belgium *March 2010*	84	36	43% down	**392**	No information available: 31 Pending: 17 – Hospital only: 20
Portugal *October 2010*	60 ➢ Apifarma members: information provided by companies ➢ Non-Apifarma members: Infarmed database, where available	33	55%	**349**	No information available: 24 Not launched / not submitted: 7 Pending: 18 (including all hospital medicines submitted to HTA prior to first acquisition) – NR: 13
Spain *April 2010*	56 Farmaindustria members only	36	*64%* down	**349**	No information available: 4 Pending: 15
Italy *April 2010*	84	36	43% down	**326**	No information available: 41 "Available" with Regional provisions: 15 – 100% reimbursed with restrictions based on pathology & therapeutic plan: 8 – NR: 6

[4] Where member associations have collected data from their membership, the number of medicines considered for calculation average is the number of medicines for which companies provided information.

Slovenia *April 2010*	47 FORUM Members only (11 have responded; 5 did not)	29	*62%* *up*	**255**	No information available: 8 Not available: 8 – Pending: 7
Finland *March 2010*	84	48[5]	57%	**211** H – 0 (18) A – 338 (30)	Not available: 33 – Included in "basic reimbursement" category: 16 – Included in "special" reimbursement category: 6 – Not reimbursed: 8
Sweden *April 2010*	84	656	*77%*	**206**	Not available: 21 NR: 25
The Netherlands *March 2010*	84	54	64% down	**196** H – 200 (4) A/H – 195 (50)	No information available: 30 Pending inclusion in the reimbursement list: 8 – "Expensive medicines" list: 4 – NR: 3
Greece *April 2010*	44 SFEE members only	38	*86%*	**188**	Not marketed: 2 Pending price approval: 4
Norway *March 2010*	84	33 + 21 I	54%	**175** H – 0 (19)	Not available: 19 – Pending: 2 – NR: 3 H: hospital only I: reimbursed on an individual basis
Ireland *May 2010*	84	54	*64%*	**157** H – 0 (22) A – 289 (32)	Not marketed: 3 – Pending: 26 – "hospital only": 22
Switzerland *May 2010*	43 All information from official sources	37	*86%*	**140**	Pending: 1

[5] Finland – calculation of average time intervals exclude 2 medicines, for which the time interval exceeds 2x the average. With inclusion of these medicines, the average time interval would be 243 (instead of 208).

[6] Sweden – "accessibility dates" not communicated for 22 medicines; the average delay was therefore calculated for 43 medicines.

Denmark *April 2010*	84	66	79% down	**125** H – 108 (39) A & A* – 150 (27)	No information: 18 H: reserved to hospital use A: ambulatory A*:

Austria *April 2010*	84	63	75%	**88** GB – 292 (3) YB – 296 (17) NB – 152 (29)	Medicines brought to the market are enlisted in the "red box", providing full reimbursement but restricted prescription[7]. GB: green box (normal reimbursement) YB: yellow box (reimbursed under special conditions) NB: "no" box (taken out of the reimbursement list)

France *October 2008*	63 Leem Members only	42	67%	289	Not available: 16 – Pending: 5 – ex-ATU status: 8 (now accessible under general conditions)

[7] Austria – 63 new medicines were included in the "Warenverzeichnis" within an average 126 days after EU marketing authorisation. As per April 2010: (i) 37 medicines were included in the "red box" (within an average 85 days after EU MA); (ii) 17 were included in the "yellow box" (on average, 296 days after MA); (iii) only 3 benefited from "green box" conditions (on average, 292 days after MA); and (iv) 29 were excluded from reimbursement (being included in the "no box", after an average 152 days).