EFPIA Mission

* The aim of the European Federation of Pharmaceutical Industries & Associations, which has no profit-making purpose, is to promote pharmaceutical discovery and development in Europe and to bring to the market medicinal products in order to improve human health worldwide.

* EFPIA pursues a mainly scientific aim, ensuring and promoting the technological and economic development of the pharmaceutical industry in Europe.

* EFPIA’s represents the pharmaceutical industry operating in Europe. Its direct membership includes 40 national associations and 39 leading companies. Two specialised groups within EFPIA represent vaccine manufacturers – Vaccines Europe (previously EVM), with 9 member companies and emerging bio-pharmaceutical companies – EBE with approx. 60 member companies.
Our aspiration for EU citizens

- Our common goal should be that patients around Europe have equal access to modern healthcare, regardless of medical, social and economic vulnerability.

- This includes that regulatory processes (pre- and post-MA) should be efficient and streamlined.

- Patients should not suffer undue delays in accessing new therapies.
The Patients W.A.I.T. Indicator

- Patients W.A.I.T. stands for patients waiting to access innovative treatment

- Scope of the Indicator includes medicines with active substance that has not been approved before
The EFPIA Database – publicly available information

Information Relating To The Marketing Authorisation Process –

source: HCS

• **Scope:** medicines with an active substance that did not receive an EU MA (i.e. First MA in Europe) – diagnostics and V-class products are excluded; vaccines are included

• **Information for each medicine** includes:
  - Identification – *name of product and MAH*
  - Dates – *each step in the MA process*
  - Category – *legal status and therapeutic class*
  - Label – *indications and prescription recommendations*

★ **for Europe** – taken from EMA and Commission websites
★ **for the US** – taken from the FDA website

EFPIA’s database of **new medicines** includes **169 medicines** (from 2004 to 2012-s1) and **15 vaccines**
Country-specific data

Information Relating To The Administrative Processes In The Countries – collected from Member Associations

• **Accessibility dates** – the first date when doctors can prescribe the medicine to patients, who will be able to benefit from reimbursement conditions applicable in the country

• **Access to medicines**
  - Ambulatory or Hospital-only
  - Ambulatory, but initiated in hospital
  - Additional conditions, such as: special reimbursement conditions
  - Any other information, such as: application for reimbursement rejected; pending; etc.

Data taken from official sources, where available; other sources (mostly directly from member companies of the national associations)
Patient availability depends on different pricing & reimbursement processes in each country

We have defined availability as completion of the regulatory processes required for patient access at a basic level of reimbursement.

Date of marketing authorisation

Date of price approval

Date of reimbursement approval

Date of patient access

Pricing & reimbursement approval may take place simultaneously

Is price approval required in this country?

Is reimbursement approval required in this country?

Is any form of publication required in this country?

Official publication of the decision may be required
What does the Indicator measure?

- **The rate of accessibility** measured by the number of medicines available to patients in each country, compared to number of medicines with EU MA granted in the reference period.

- **The average time between MA and patient access** measured by the number of days elapsing from the date of EU MA to the day of completion of post-MA administrative processes (including pricing and reimbursement processes).

These are not the delays as meant in the “Transparency” Directive.
## Delays increase

<table>
<thead>
<tr>
<th>Country</th>
<th>% 2011</th>
<th>% 2012</th>
<th>Average 2011 days</th>
<th>Average 2012 days</th>
<th>Increase days</th>
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<tbody>
<tr>
<td>Portugal</td>
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</table>
Portugal – average delay increasing year-on-year

<table>
<thead>
<tr>
<th>Period</th>
<th>Average Delay</th>
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<tr>
<td>2005-2007</td>
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<td>2006-2008</td>
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<td>2007-2009</td>
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<td>2008-2010</td>
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<tr>
<td>2009-mid-2012</td>
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</table>
Expectations of citizens and patients

- Modern medicine shows that prevention, early diagnosis, and early treatment improves the prognosis

- Citizens and patients rely on their governments to ensure that they have access to the care they need

- Governments are under popular pressure to reduce waiting times and remove obstacles to access healthcare products and services
Budgettary Orthodoxy

Continuous Violation of Maastricht Criteria in Europe (2011, Q4/11)

Demographic pressures on budgets

Projected Increases in Public Health Spending, 2011-2030

Source: Global Trends in Public Health Spending and the Outlook, International Monetary Fund (IMF), 2011.
Exploiting efficiency gains would allow to improve health outcomes further…

Source: OECD Health Data 2009; OECD calculations.
...and help to contain future health care spending

Source: OECD Health Data 2009; OECD calculations.
Total costs per asthma patient

Source: STAKES statistics and treatment record database, STAKES publications, expert interviews, Statistics Finland, KELA publications and Statistics, Finnish Centre for Pensions, Finnish publications, NHG calculations
Innovation has delivered value-for-patients

Development of 5 year survival rates in cancer

Source: VfA; RKI, 2009.
Policy makers becoming increasingly concerned about health expenditure and cost of innovation

Debate too much focused on cost and not on efficiency

Growing concern over possible ineffective (or harmful) use of untested technology

Need for enlightened tools for assessing value of health care services
Seminal report from BE Presidency

Sales of innovative products (launched 2005-2009) per 100,000 inhabitants in 2009 per country

• SOURCE: IMS MIDAS; analysis for INAMI
Economic challenges have had a dramatic effect on the growth of healthcare expenditure

Average OECD health expenditure growth rates in real terms, 2000 to 2010, public and total

Recommandations

★ Focus on value not on cost

★ Deliver sustainable funding mechanisms

★ Support science and strengthen the science base

★ Keep talking, with the determination to address the issues whatever difficult they are, and aim for workable solutions