



Promoting Research and Innovation in Life Sciences

The need for a comprehensive framework, 2020 in healthcare and responsible innovation

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17 February 2011

London



Agenda

- EU 2020 and Health
- Pooling the efforts: European Innovation Partnership for Active and Healthy Ageing
- Specific roles of health authorities to promote innovation



Europe 2020 strategy

7 flagship initiatives (EU/national/regional)

- Smart growth

- Sustainable growth

- Inclusive growth

- Digital agenda for Europe

- Innovation union

- Youth on the move

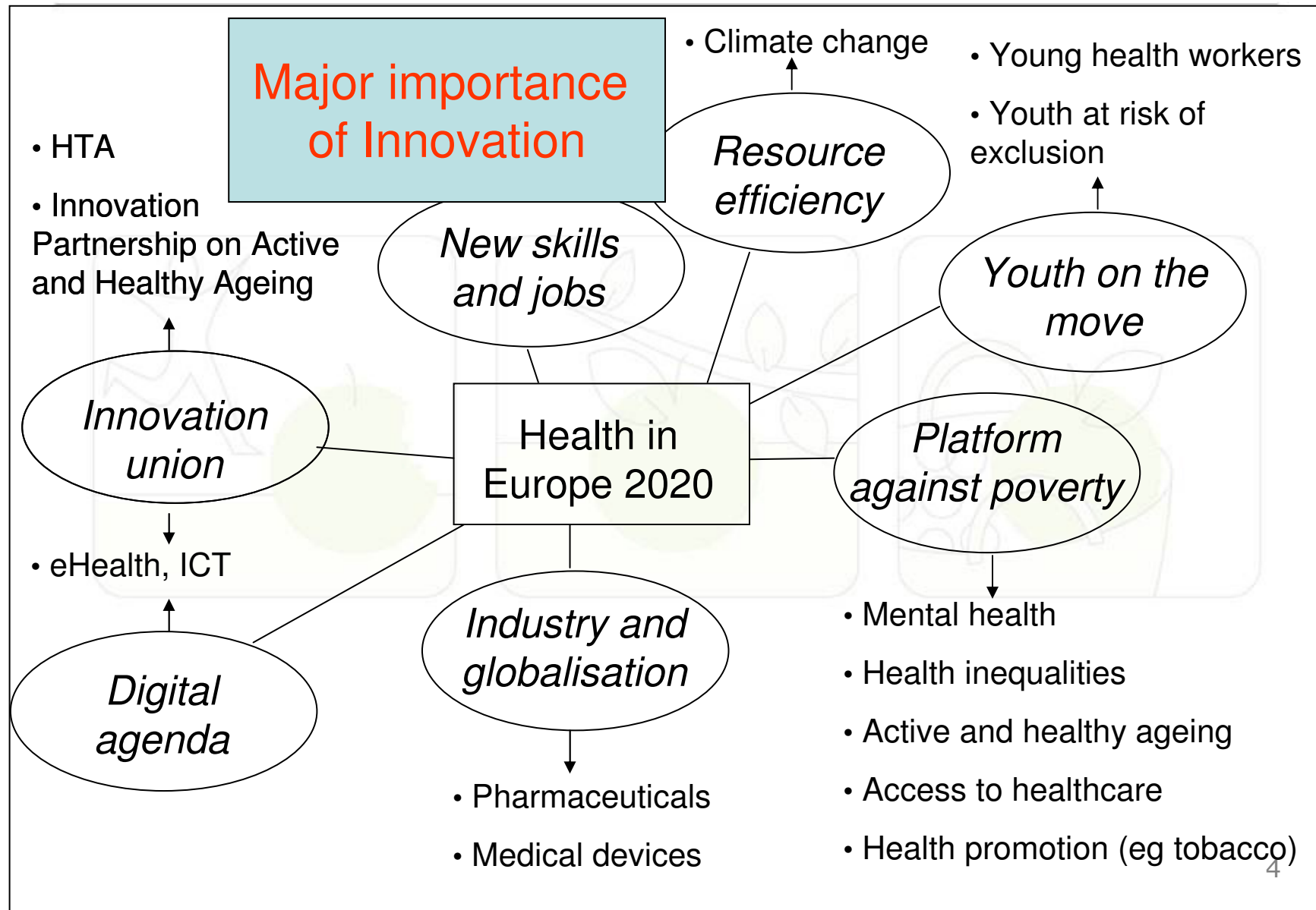
- Resource efficient Europe

- An industrial policy for the globalisation era

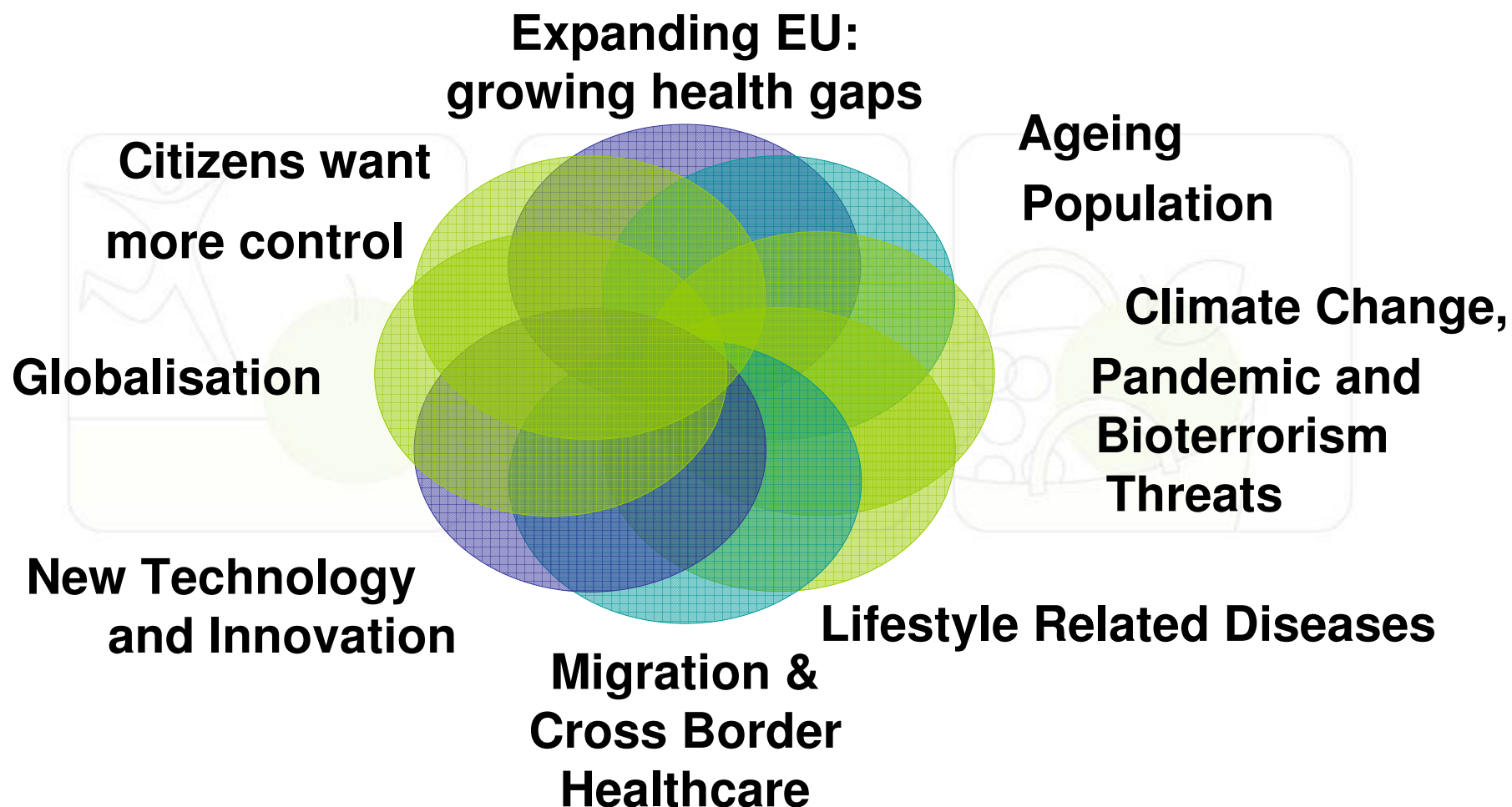
- An agenda for new skills and jobs

- European platform against poverty

Europe 2020 and Health



Why a Strategy: challenges





The EU Health Strategy

Four Principles

1. A value-driven approach
2. Health is Wealth
3. Health in all Policies
4. Global Health

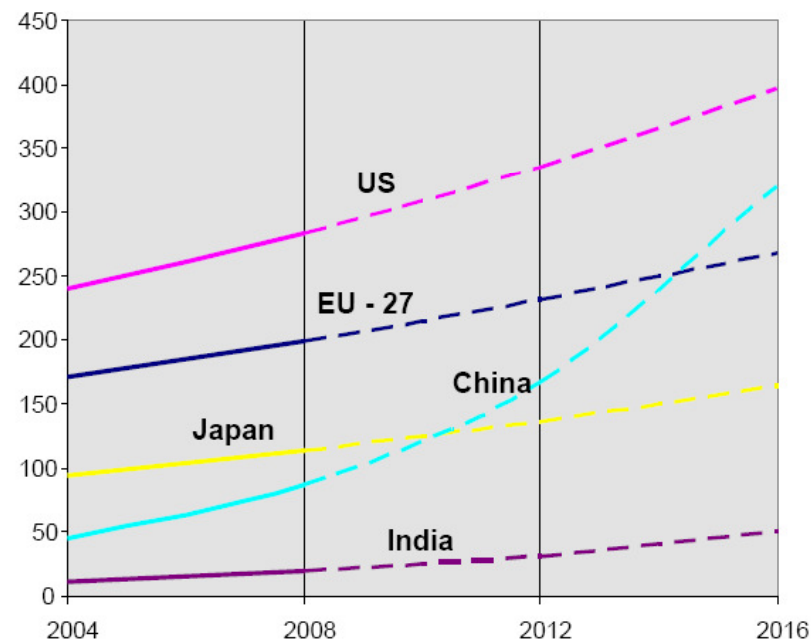
underpins objectives

Three Objectives

1. Foster **Good Health in an Ageing Europe**
2. Protect Citizens from **Health Threats**
3. Support **Dynamic Health Systems & New Technologies**

The EU is slowly falling behind on R&D

Evolution of world R&D expenditure in real terms (in € billion at 2000 prices)





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Innovation Priorities for Europe

Presentation JM Barroso to the Council on 4/2/2011

What's wrong in Europe

- Poor availability of finance
- Costly patenting
- Lack of legal and tax level-playing field
- Outdated regulations and procedures
- Slow standard-setting
- Weak education and innovation systems
- Failing public procurement strategy
- Fragmentation of efforts



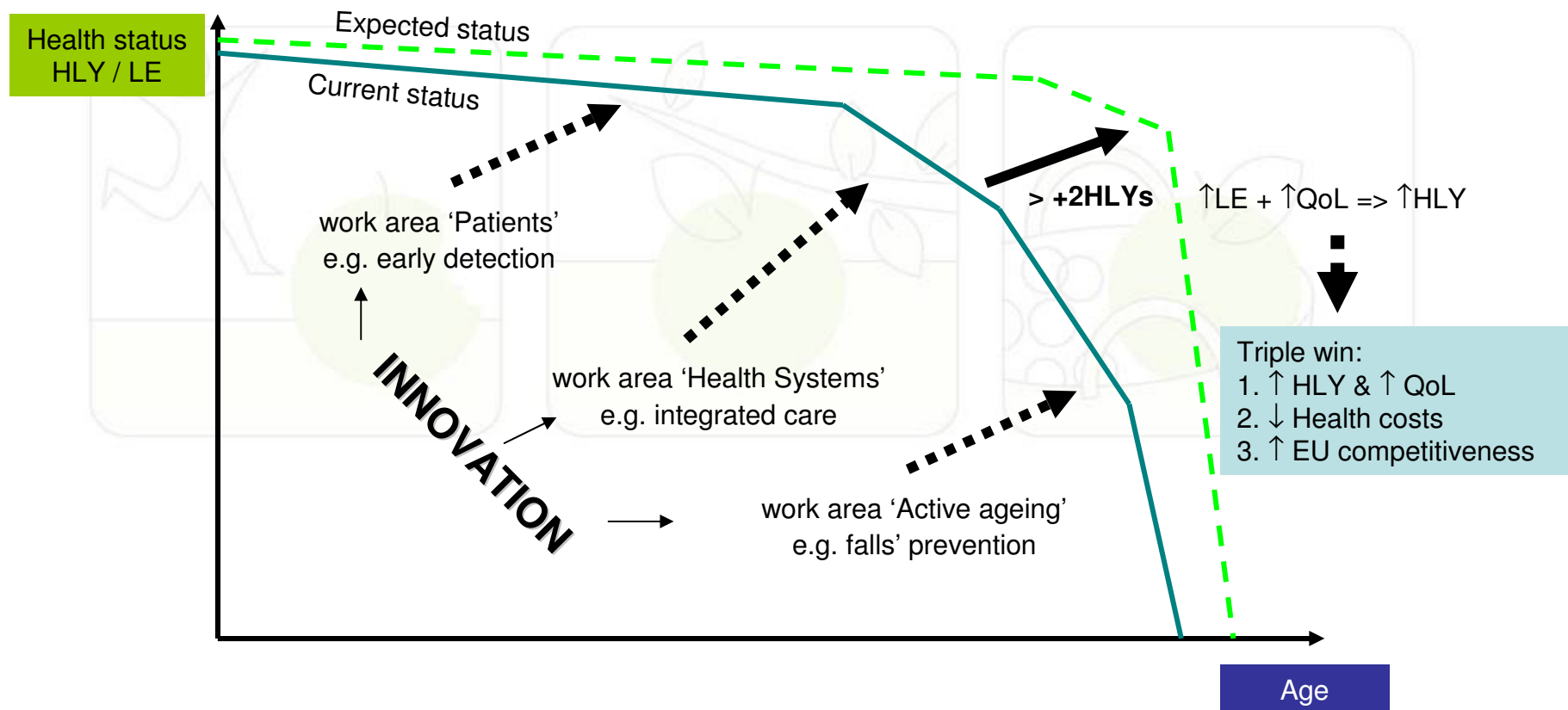
What can we do about it?

- 'Smart' fiscal consolidation
- Improved framework conditions (e.g. pooling)
- Steer and monitor at EU level
- A future-oriented EU budget

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European Innovation Partnership on Active and Healthy Ageing



Three Indicative activity areas

<u>Focus</u>	<u>Barriers (e.g.,)</u>	<u>Potential Activities</u>
1. <i>individuals as patients and consumers</i>	1. Little response to individual demand/needs	1. Personalised medicines
2. <i>social and health care systems</i>	2. Mismatch supply & demand	2. Continuum of care (hospital, home, self)
3. <i>enabling the elderly to lead independent and active lives</i>	3. Fragmented care provision	3. Integrated care including innovative solutions



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Roles for different health authorities to stimulate innovation

Potential Roles

- Define needs for research, set the agenda
- Help address R&D bottlenecks
- Guard safety and quality
- Recognize valuable innovation
- Provide equal access for patients
- Provide for an attractive market
- International collaboration

Example

- Priority Medicines Report (WHO, NL pres.)
- Innovative Medicines Initiative
- SANCO/C8, EMA
- Health Technology Assessment
- Actions on access to orphan drugs
- Pricing, reimbursement, IP, market exclusivity
- US-UE Taskforce_AMR

HTA in Europe: recognizing innovation

EC objectives

- Provide robust scientific evidence
- Support MS/actors with little capacity
- Reduce duplication
- Clear and transparent rules
- Reduce national hurdles
- Promote early dialogue

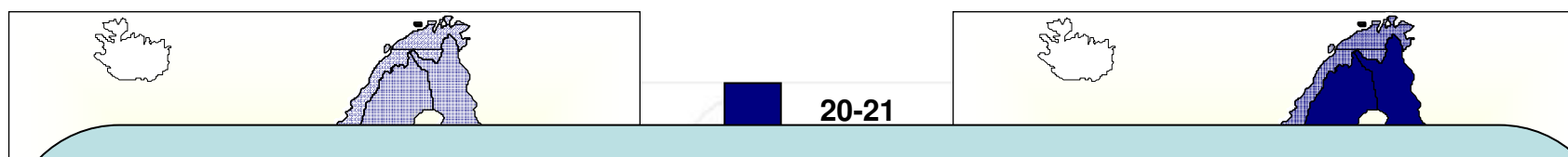
Joint Actions
Cross-Border
HC Directive
(art 14)

Expected outcome

- Fair reward for valuable innovations
- Clearer view on expected value
- Common approaches shared between countries
- NOT: harmonized pricing & reimbursement
- Good collaboration between all actors

AVAILABILITY OF OMPS BY COUNTRY IN 2007

Availability for OMPs approved before 2004 (12 OMPs) & 2006 (22 OMPs)



New priorities: V. Gathering the expertise on rare diseases at European level

Actions to ensure equal access to all EU patients to orphan drugs

The **Commission** should present, a **report** to the Council and EP identifying **bottlenecks on orphan drugs access** (delays, marketing, access, reimbursement, prices, etc.) proposing the necessary legislative modifications in order to guarantee equal access to orphan drugs throughout the EU on the basis of a COMP/EUCERD European collaborative scientific assessment (Commission, EMEA)



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Legal basis for the developments of the EU Public Health Policy on rare diseases

Based on new Article 168 (former 152) of the EU Treaty

- **A Community action programme on Rare Diseases, including genetic diseases, was adopted for the period of 1 January 1999 to 31 December 2003 with the aim of ensuring a high level of health protection in relation to RD. As the first EU effort in this area, specific attention was given to improving knowledge and facilitating access to information about these diseases.**
- **Orphan Medicinal Product Regulation (Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, was proposed to set up the criteria for orphan designation in the EU and describes the incentives (e.g. 10-year market exclusivity, protocol assistance, access to the Centralised Procedure for Marketing Authorisation) to encourage the research, development and marketing of medicines to treat, prevent or diagnose rare diseases.**
- **Rare diseases are now one of the priorities in the Second EU Health Programme 2008-2013. According to the DG SANCO Work Plans for the implementation of the Public Health Programme, main lines of action and priorities are chose every year. **Work Plan for 2011 in process of adoption.****



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Legal basis for the developments of the EU Public Health Policy

- In the current Framework Programme, the FP7, the Health Theme of the "Cooperation" Specific Programme, is designed to support multinational collaborative research in different forms. The main focus of the Health theme in the rare diseases area are Europe-wide studies of natural history, pathophysiology, and the development of preventive, diagnostic and therapeutic interventions.
- Commission Communication COM (2008) 679/2 to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions on Rare diseases: Europe's challenges creating an integrated approach for the EU action in the field of rare diseases. **Adopted 11th November 2008.**
- Council Recommendation on a European action in the field of rare diseases recommending actions at national level to implement the EU action (e.g. National Plans for Rare Diseases). **Adopted 8th June 2009.**
- Decision of the Commission creating a European Union Committee of Experts on Rare Diseases during 2009. To be composed by 51 members representing Member States, patient's organisations, industry, FP Projects, Health Programme projects, etc. **Adopted 30th November 2009.**



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Main priorities in the Commission Communication and the Council Recommendation on rare diseases

I. Plans and strategies in the field of rare diseases

Calls on the MS to elaborate and adopt a plan or strategy by the end of 2013.

II. Adequate definition, codification and inventorying of rare diseases

Evokes the common definition of a rare disease as a condition affecting no more than 5 per 10 000 persons; aims to ensure that rare diseases are adequately coded and traceable in all health information systems based on the ICD and in respect of national procedures; and encourages MS to contribute actively to the inventory of rare diseases based on the Orphanet network.

III. Research on rare diseases

Calls for the identification and fostering of rare disease research at all levels.

IV. Centres of expertise and European reference networks for rare diseases

Asks the MS to identify and facilitate networks of expertise based on a multidisciplinary approach to care, and foster the diffusion and mobility of expertise and knowledge.



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The Commission Communication and the Council Recommendation on rare diseases

V. Gathering the expertise on rare diseases at European level

MS should share best practices, develop medical training relevant to the diagnosis and management of rare diseases, coordinate European guidelines, and, to minimise the delay in access to orphan drugs, MS should share clinical/therapeutic added-value assessment reports at the Community level.

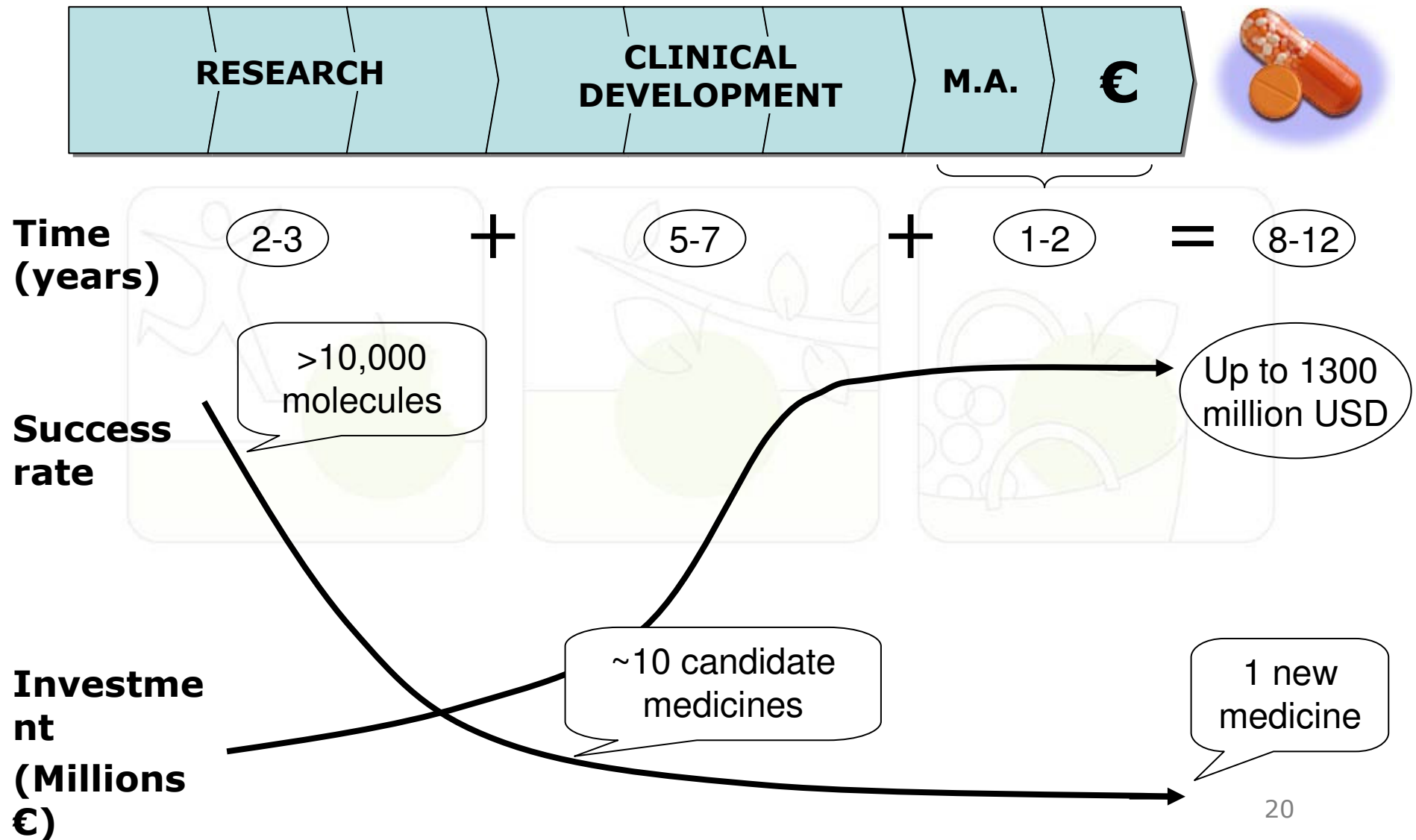
VI. Empowerment of patient organisations

MS should consult patient representatives on policy development; facilitate patient access to updated information on rare diseases; promote patient organisation activities.

VII. Sustainability

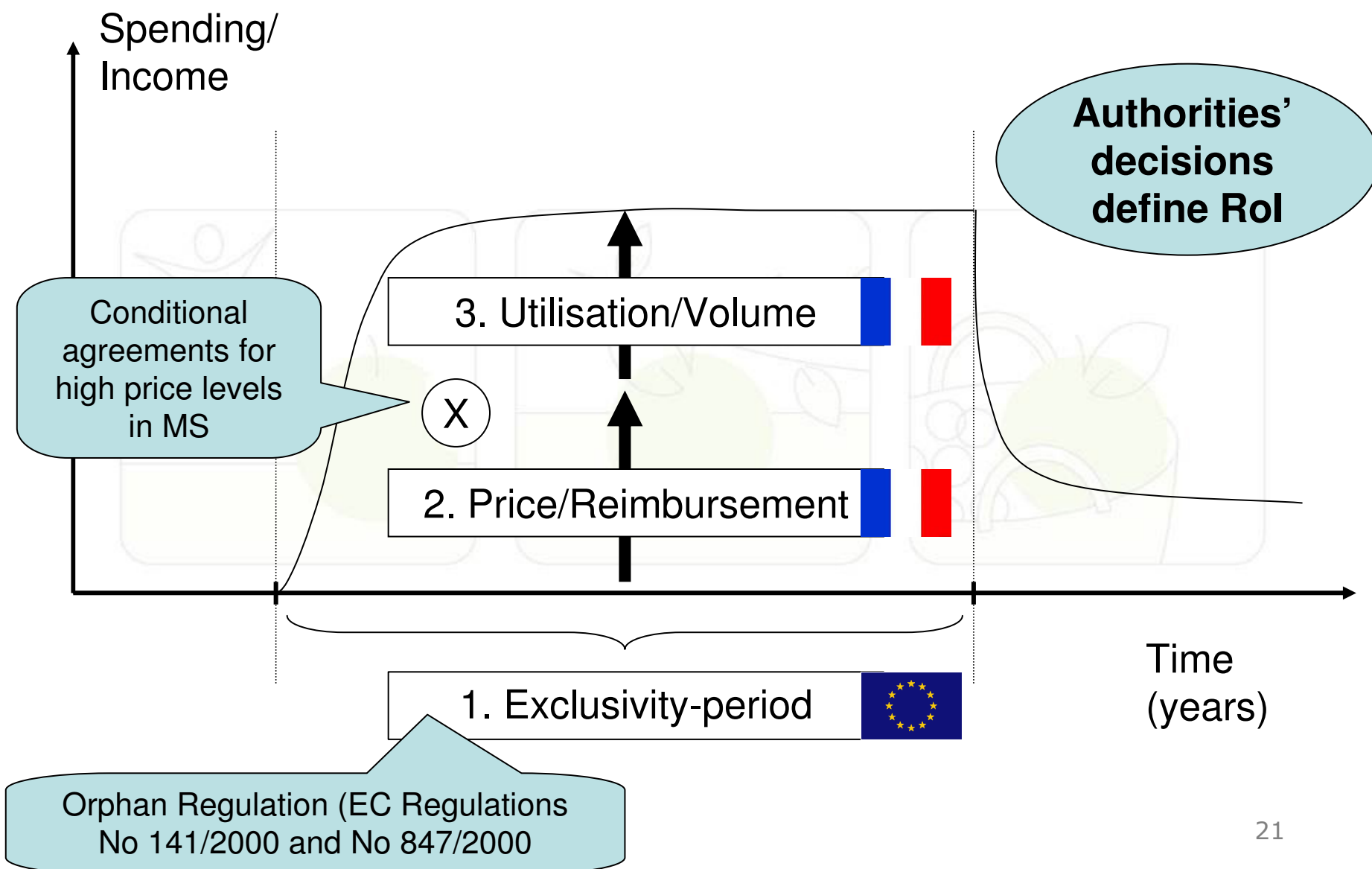
Long-term sustainability in the field of information, research and healthcare of infrastructures must be ensured.

Creating an innovative therapy requires significant upfront investment (e.g. pharma)



Return on Investment

EUROPEAN COMMISSION





Conclusions

- Innovation and healthcare are high on the European Agenda
- Much value lies in bringing the efforts together
- There are many levers authorities can and have to pull to promote innovation in healthcare