



Principles for the appropriate use of medicines and current challenges



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Всемирная организация здравоохранения

Европейское региональное бюро

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Presentation outline

- **Background - current trends and challenges in terms of access to medicines**
- **WHO guidance on principles for the appropriate use of medicines**
- **Future direction and conclusions**

Background - current trends and challenges in access to medicines

Background

- **Affordability and financing** in particular of new medicines pose challenges to governments given increasing pharmaceutical expenditure as well as continued pressure on resources with still unmet need
- These **pressures** mean decision-makers, including payers, must make decisions about what new medicines to fund and in which patient populations whilst still fostering a climate for innovation
- However, for many countries this is a **new or emerging area** in which policies are not yet fully developed and decision-makers remain unsure on how to act

Pharmaceutical expenditure is a continuing concern despite recent falls due to pressures

- Pharmaceutical expenditure **rose** rapidly in recent years - averaging more than 3.5% per year between 2000 and 2009 among OECD countries
- As a result, medicines averaged 18–19% of total health care expenditure in 2009 - typically the **largest or second largest cost component** in ambulatory care
- More recently (2009–2013), there has been a **fall** in pharmaceutical expenditure in some European countries due to price cuts as part of greater emphasis to improve efficiency - including a greater focus on the appropriate use of medicines
- However, **challenges** still exist including the launch of new premium priced medicines and ageing populations. These will pose considerable problems that must be addressed to sustain equitable and comprehensive healthcare

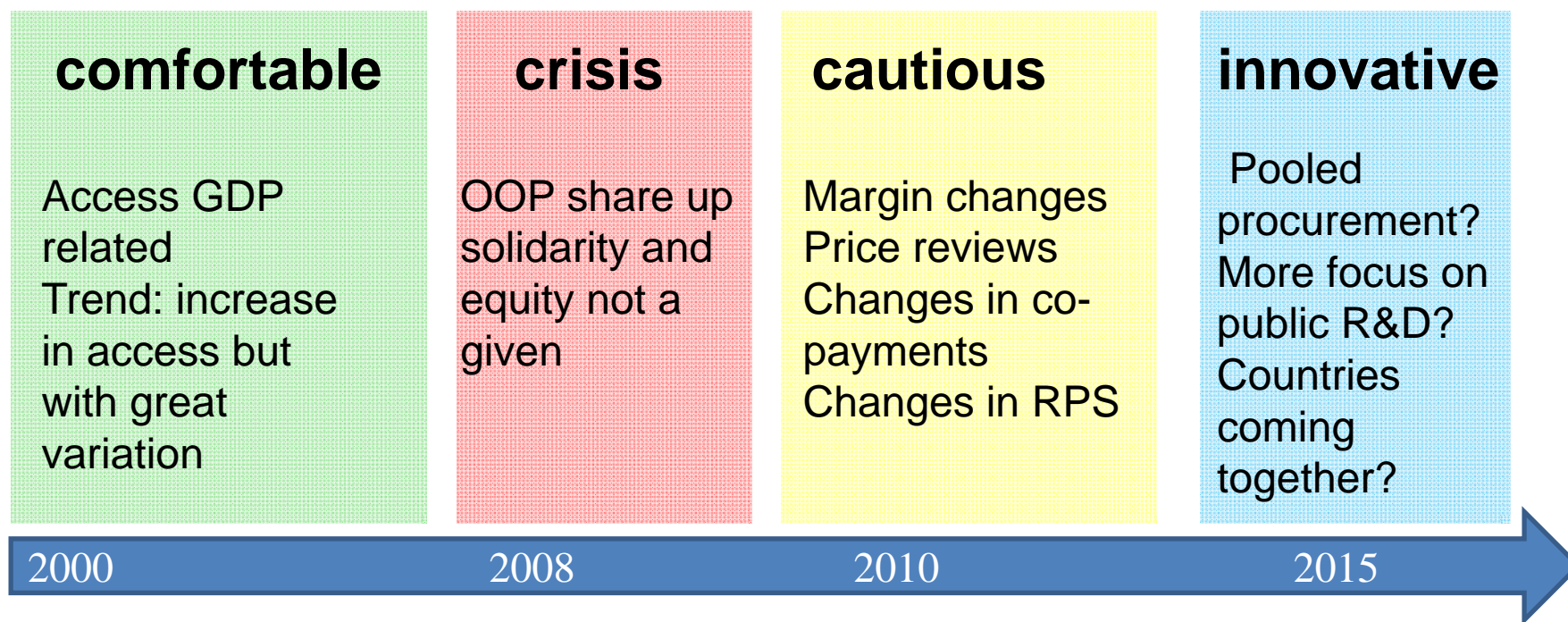
Number of new medicines in development

EvaluatePharma in May 2012 documented an appreciable number of new medicines in development among NASDAQ group of companies

Disease area	Number of products
Oncology and immunomodulators	587
Systemic anti-infectives	220
Central nervous system	194
Cardiovascular	88
Musculoskeletal	60
Blood	55
Endocrine	47
Genitourinary	42
Others	104

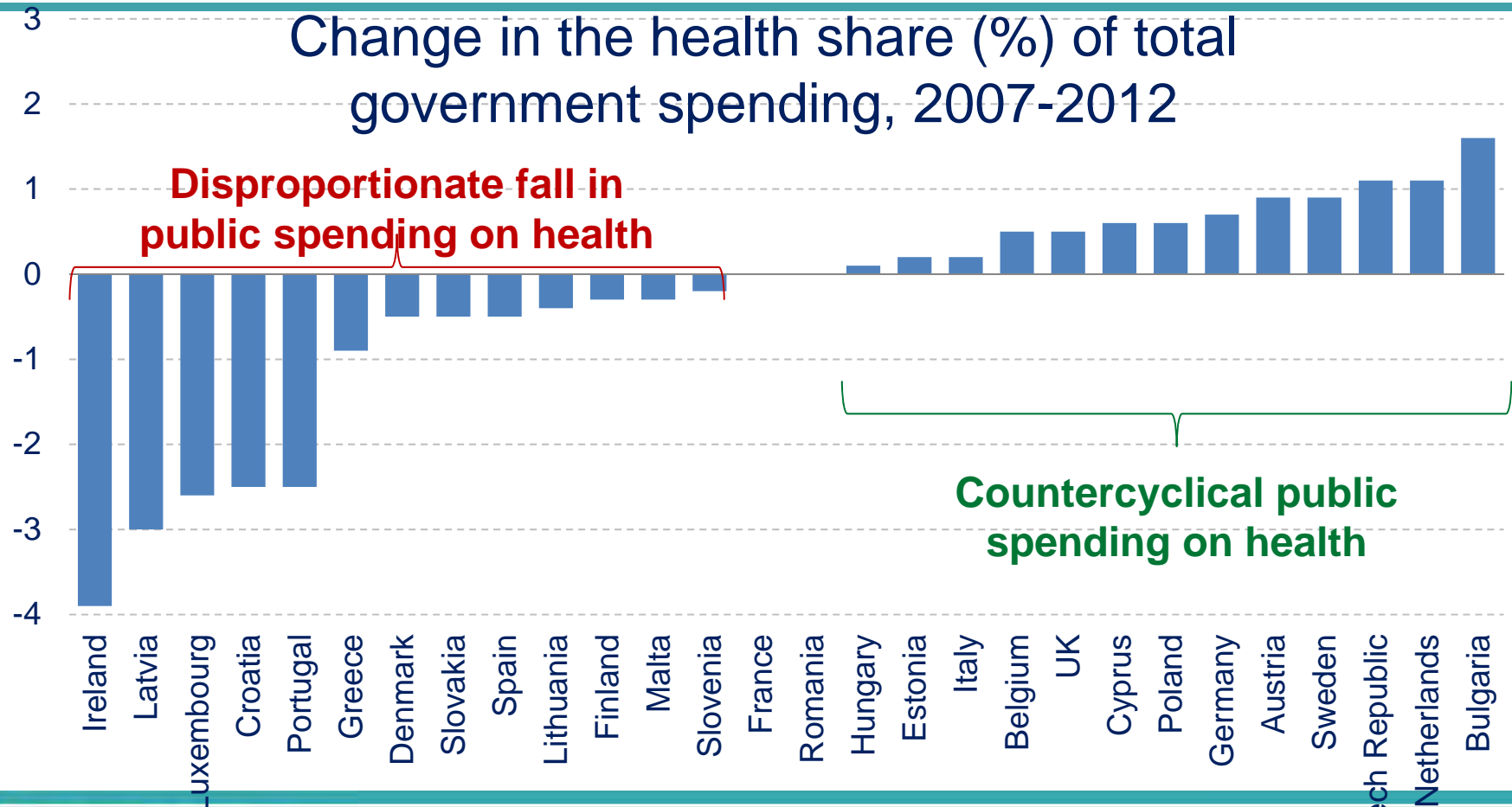
EFPIA believed there were over 16,000 medicines in development in 2011 with the greatest number for patients with cancer (over 6,000)

Pharmaceutical expenditure relatively high in Europe and the crisis has created an interest amongst policy makers for new ways of collaborating



Time is ripe for re-thinking strategies to achieve sustainability in intro of innovation in health both in approach and product

Many EU countries viewed health sector as a social equalizer and protected spending



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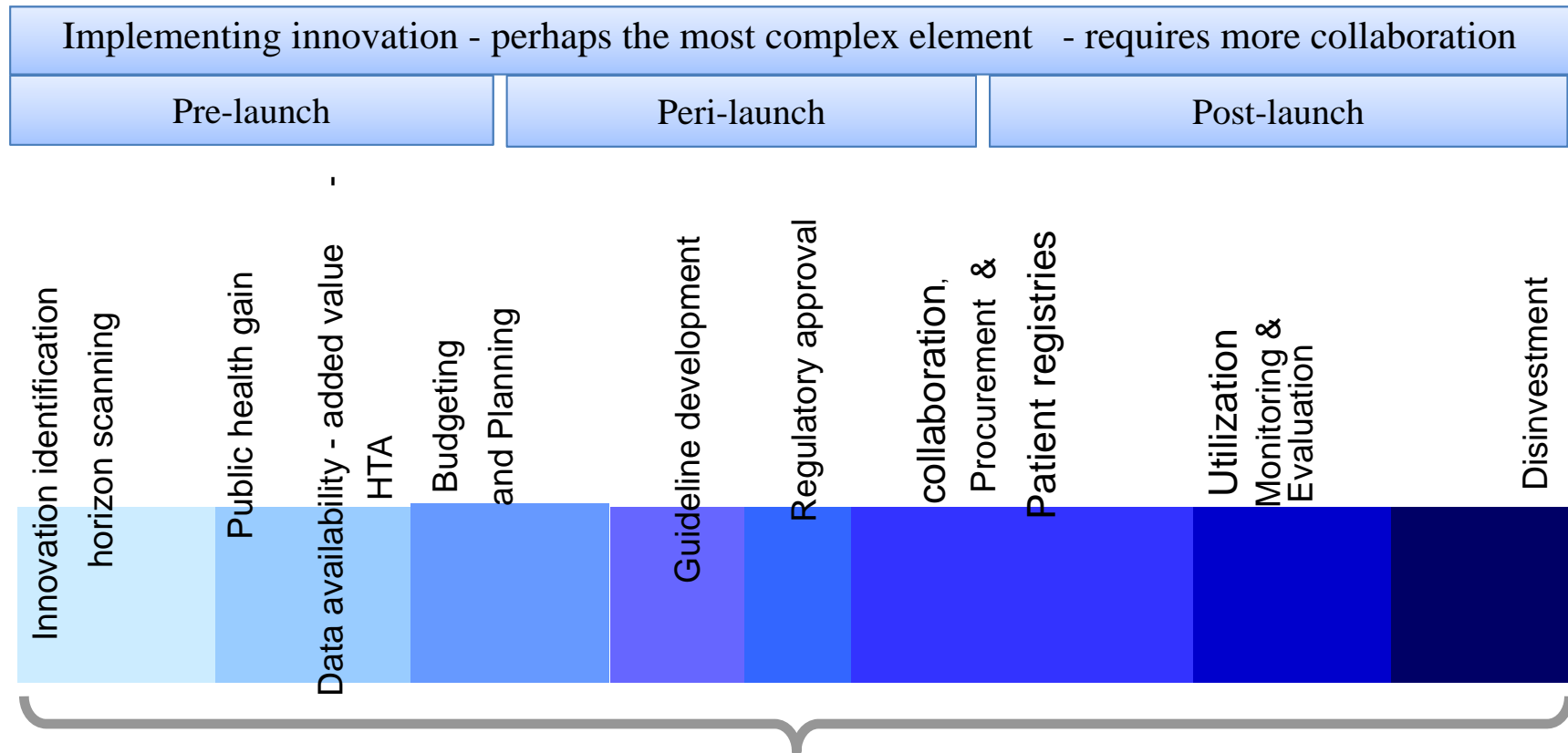
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...but there is no point in pumping money into an inefficient health system

- Seeking efficiency gains becomes paramount at times of crisis
- Efficiency in terms of introduction and use of medical product crucial and now a priority in many countries in Europe



Medicines policy – the continuum from R&D to disinvestment



continuum lasts up to 9–12 years depending on the medicinal product

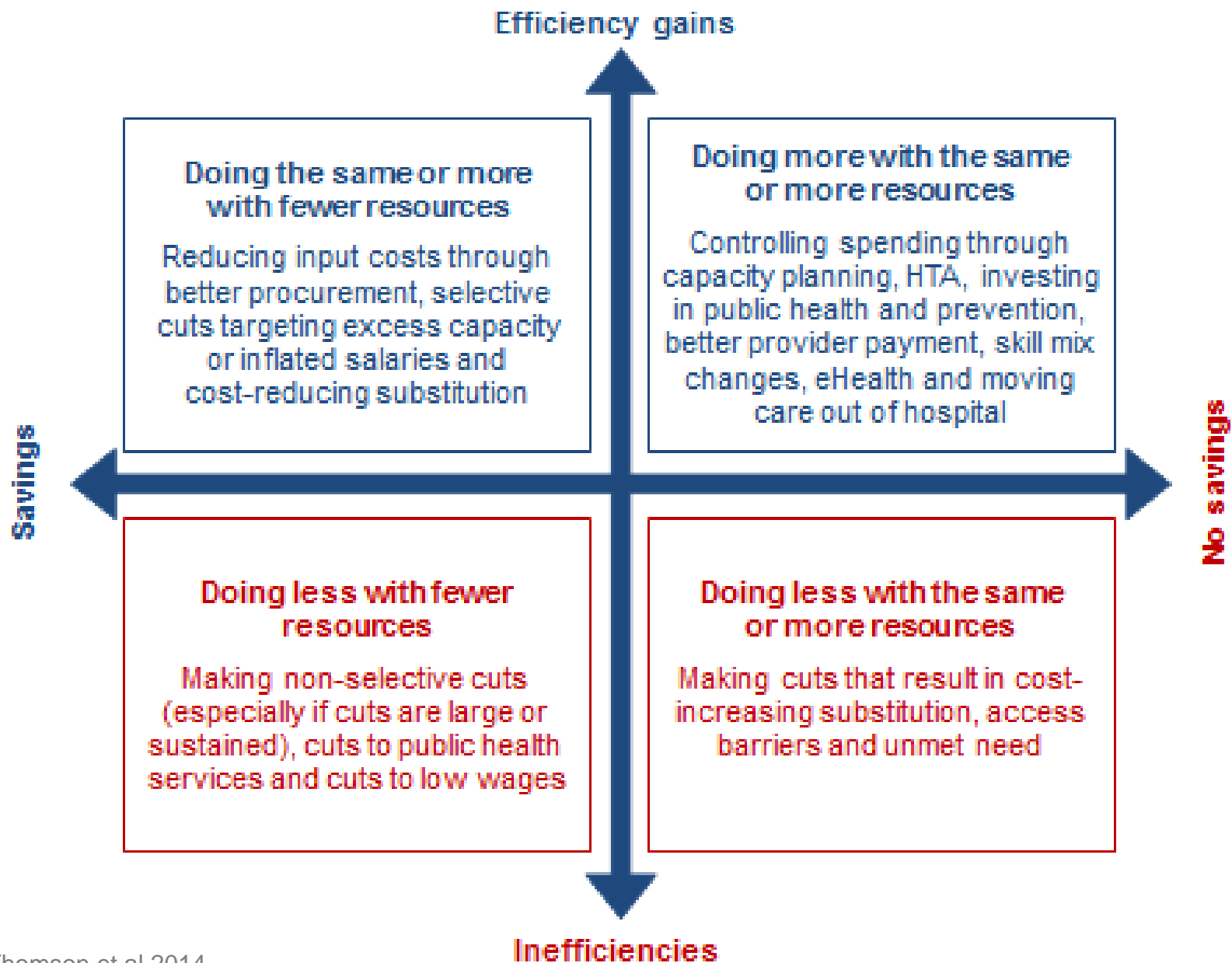
Pre-launch activities

- Identifying and prioritizing therapeutic innovation – horizon scanning - can systematically anticipate and prioritize therapeutic innovation in terms of their likely impact on clinical care, health care systems and patient outcomes
- Forecasting of medicine expenditure is growing to assist health services with future planning
- Pre-launch activities can include educational activities where issues as well as registries
- There are ongoing issues regarding adaptive licensing as this requires careful consideration

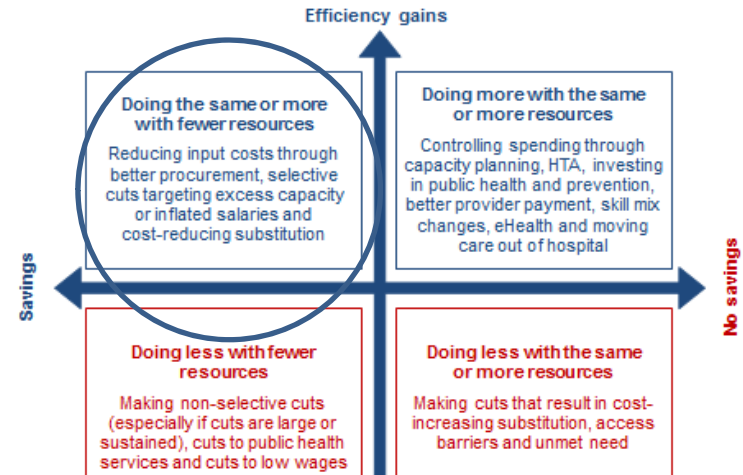
Peri-launch activities

- Include price setting including potentially value-based pricing
- Value-based pricing is growing as a concept across Europe building on existing examples
- Achieving fair pricing and sustainability of health care systems are key future considerations
- ERP is widely used across Europe to help regulate pharmaceutical prices but concerns
- There are ongoing development to improve reimbursement decision making to include multiple-criteria decision analysis (MCDA)
- Ongoing dialogue between HTA agencies and pharmaceutical companies is being encouraged
- Ongoing developments include budget impact analysis to help with future planning
- New models are needed to optimize the managed entry of new medicines

Savings vs efficiency



The holy grail: savings & efficiency gains?



Policy response

Countries (n°)

Hospitals: lower prices and investment

28

Drugs: lower prices, more generics

22

Cuts to overhead costs

22

Health workers: lower pay and numbers

22

Hospitals: closures or mergers

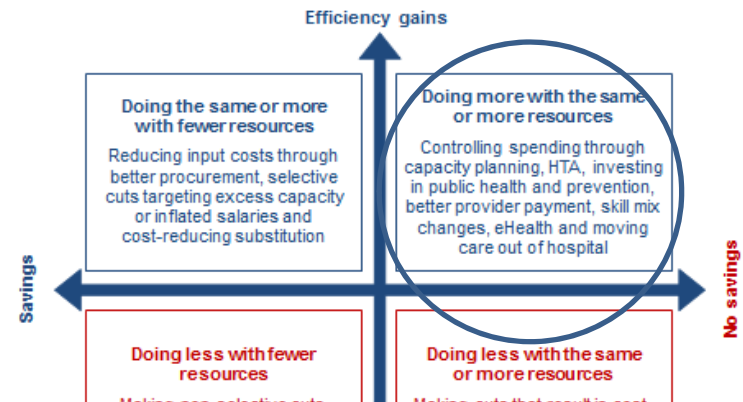
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Abolishing tax subsidies for richer people

2



Longer-term thinking: efficiency gains without immediate savings?



Policy response

Countries (n^o)

Investing in promotion and prevention	12
Moving care out of hospital	11
More HTA to inform delivery	9
More HTA for coverage decisions	7
More eHealth	4
Increased funding for primary care	3
Primary care skill mix changes	3

WHO Essential Medicines List can be used for selection of medicines and adapted to the country context

WHO MOVES TO IMPROVE ACCESS TO LIFESAVING MEDICINES FOR HEPATITIS C, MDR-TB AND CANCERS

In April 2015 the WHO Expert Committee on the Selection and Use of Essential Medicines met and reviewed more than 70 applications

2015 WHO Model List of Essential Medicines (EML) includes ground-breaking new treatments for hepatitis C, a variety of cancers and multi-drug resistant tuberculosis (TB), among others. The move opens the way to improve access to innovative medicines that show clear clinical benefits and could have enormous public health impact globally

The EML can be used as a guide for selection of medicines and can adapted at national level to fit the individual country context

WHO recommendations for the increasing use of HTA include:

Countries should use HTA as a tool to support reimbursement, price setting and negotiations as well as combine HTA with other policies and strategies

Countries should consider the following when using HTA:

- review the applicability and adaptation of reports from other countries
- review reports submitted by pharmaceutical companies
- conduct assessments based on local information and local data

Countries could take a stepwise approach to develop legislative and technical capacity to take full advantage of the potential utility of HTA in pharmaceutical price setting. This should clearly define the roles and responsibilities of decision-makers and other stakeholders, and the process of decision-making

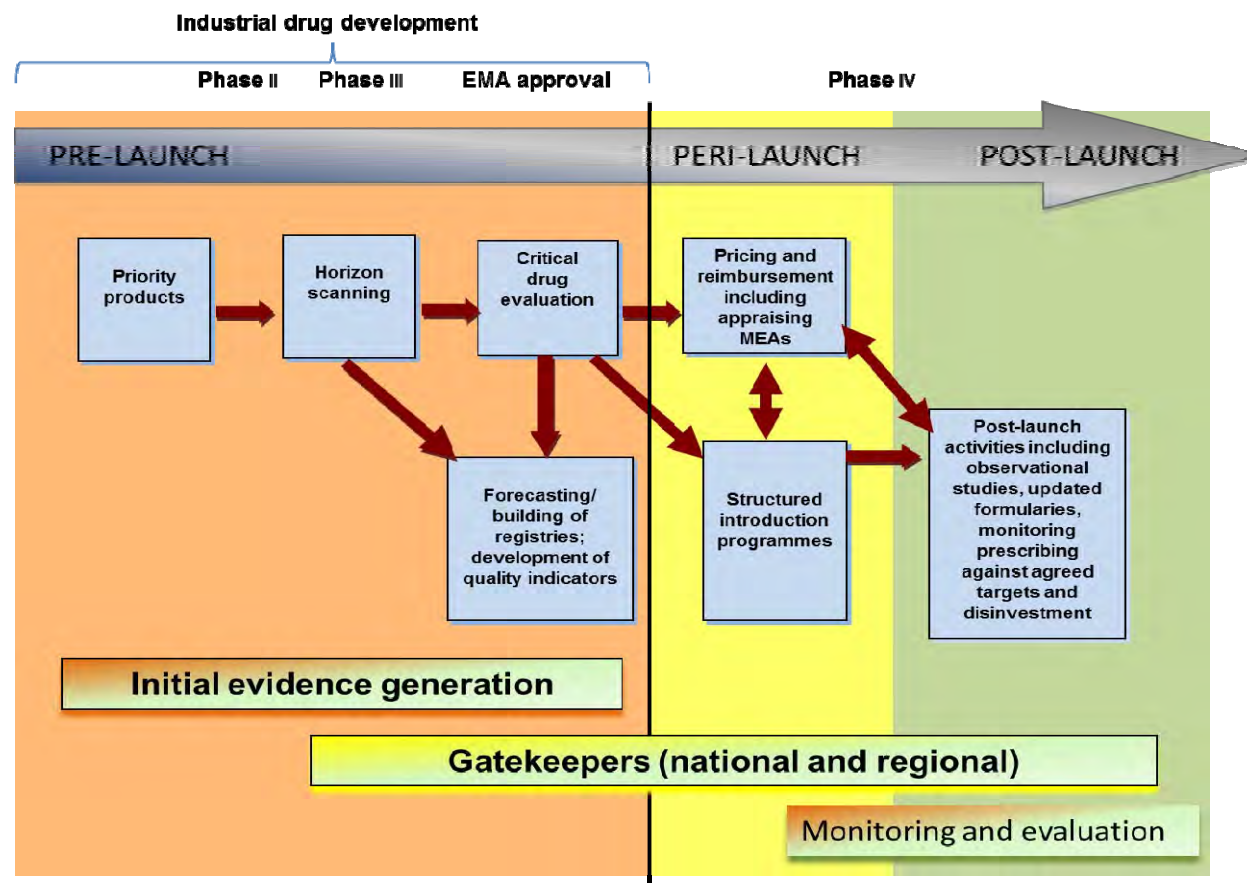
Countries should ensure that HTA processes are transparent and that the assessment reports and decisions are made publicly available and effectively disseminated to stakeholders.

Countries should collaborate to promote exchange of information and develop common requirements for HTA.

Post-launch

- Activities should be tailored to the local context to improve medicine utilisation
- There may also be a need to improve medicine use at the Interface given dual funding systems
- Clinical Program Guidelines are important information tools aimed at enhance appropriate treatment of patients
- Methods for developing CPGs have evolved and now include the GRADE methodology
- Many organisations are involved with guideline development. Less research on implementation
- Committees can assist in selections and enhancement of appropriate use of medicines

Framework for locating policy interventions



The WHO Technical Review Report describe policy option in detail

Objective

- To articulate the challenges, policy options and tools in the management of high/premium-priced new medicines in Europe through the provision of an overarching review of experiences so far from European countries
- Published on 26 March 2015 on WHO Europe website



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Future direction and conclusions

Current trends include the pace of innovation in recent years. Further developments are needed

- **The current rapid pace of therapeutic innovation, particularly NCDs, is extremely positive from a patient perspective**
- The introduction of new medicines is adding both to therapeutic complexity and higher costs putting pressure on European health systems. However, balanced against unmet need
- Transparent systems and processes will be necessary to improve the use of new medicines
- **Further development of systems and processes** are needed to optimize the entry of new medicines across Europe to address these challenges - applying both to countries with well developed medicine policies and those with less mature systems
- **Key steps should include methods to distinguish and reward meaningful clinical innovation**, as well as continual evaluation assessing the actual benefit of new medicines in clinical practice and their impact on health systems and budgets

A number of research activities are needed to address priority healthcare areas in Europe

A recent WHO report identified 24 areas for research activities to meet priority health care needs in Europe through addressing treatment gaps. These included:

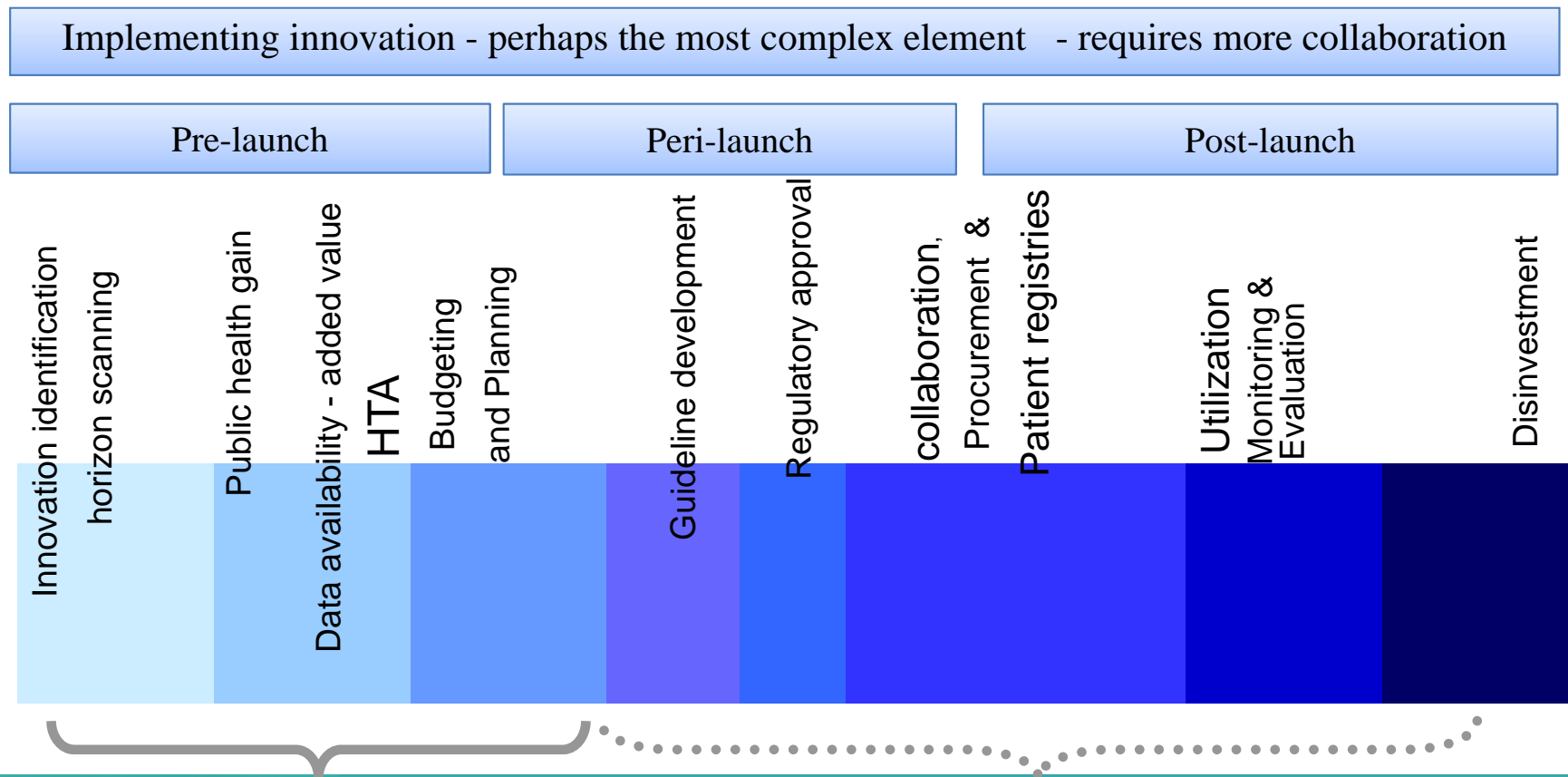
- ❑ Gap 1: Treatments exist but will soon become ineffective, e.g. antibiotics with increasing resistance development
- ❑ Gap 2: Pharmaceutical delivery mechanisms/ formulations not optimal, e.g. HIV/AIDS, cancer, depression, diabetes, pneumonia and postpartum haemorrhage
- ❑ Gap 3: Treatments do not exist/ not sufficiently effective, e.g. acute stroke, osteoarthritis, Alzheimer's disease and other dementias, chronic obstructive pulmonary disease and rare (including orphan) diseases.
- ❑ Gap 4: Global risk factors exist with no or insufficient pharmaceutical treatment, e.g. obesity and alcohol-related diseases

A number of factors should be considered for the future. These include:

- Decision-makers are increasingly faced with difficult choices and are required to make informed decisions
- This involves **greater use of information technology (IT)**, better steering of medical practitioners to comply with clinical evidence and better targeting of national drug policies to those using resources more intensely
- **Prioritization processes** will increasingly be required for introduction of new medicines and should incorporate principles of collaboration and transparency
- **There is also the need for greater cooperation between countries and stakeholders** on what constitutes a fair reward for industry innovation while preserving access and sustainability. This should involve better balancing of the value of innovation with equitable, affordable patient access
- **Collaboration among regional or subregional health systems might benefit from including a particular focus on chronic care**, specialty medicines and rare diseases

Medicines policy – covering the continuum from R&D to disinvestment

Future: increased focus in Europe on products that enable health gain – have impact on patient health and of value to society



More attention to be given to real health impact & budget impact to 'upstream' elements.

More focus on rationalisation of 'downstream' elements to work toward UHC

May 2015

Thank you for your attention!



<http://www.euro.who.int/en/health-topics/Health-systems/medicines/publications2/2015/access-to-new-medicines-in-europe-technical-review-of-policy-initiatives-and-opportunities-for-collaboration-and-research>

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