World Health Organization
REGIONAL OFFICE FOR Europe

Organisation mondiale de la Santé
BUREAU RÉGIONAL DE L' Europe

Weltgesundheitsorganisation
REGIONALBÜRO FÜR Europa

Всемирная организация здравоохранения
Европейское региональное бюро

Access to new medicines in Europe

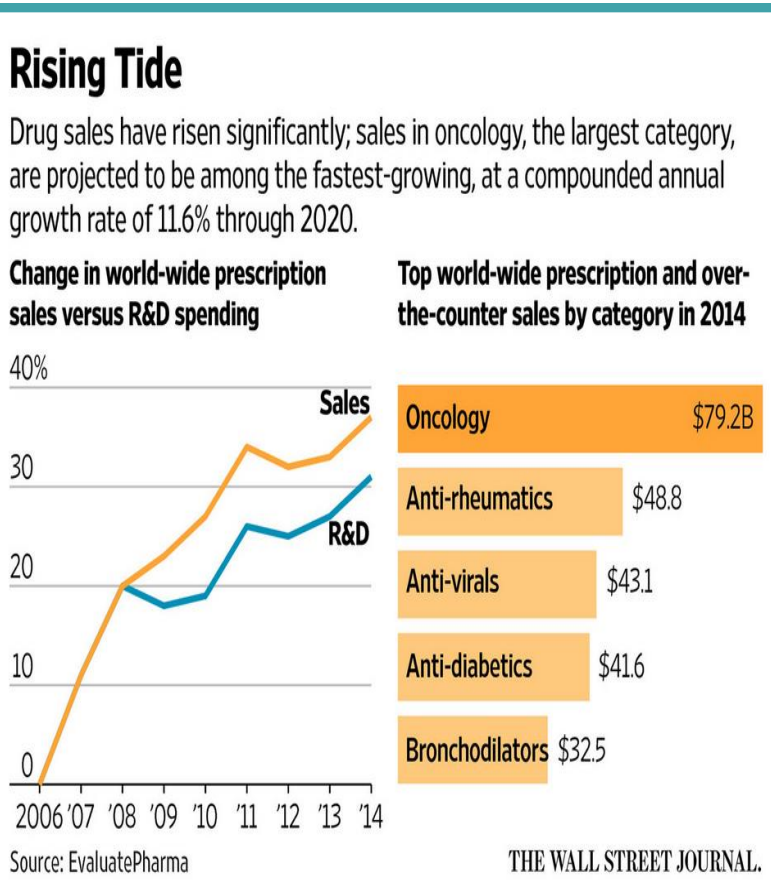
WHO Technical review of policy initiatives and opportunities for collaboration and research

Hanne Bak Pedersen
Programme Manager Health Technologies and Pharmaceuticals
Division of Health Systems and Public Health
WHO Regional Office for Europe

Presentation outline

1. **Current trends and challenges in terms of access to new high price medicines**
2. **Overview of WHO report findings**
3. **Current collaboration and future directions**

The growing possibilities and pressures



Current trends and challenges

Affordability and financing of new medicines

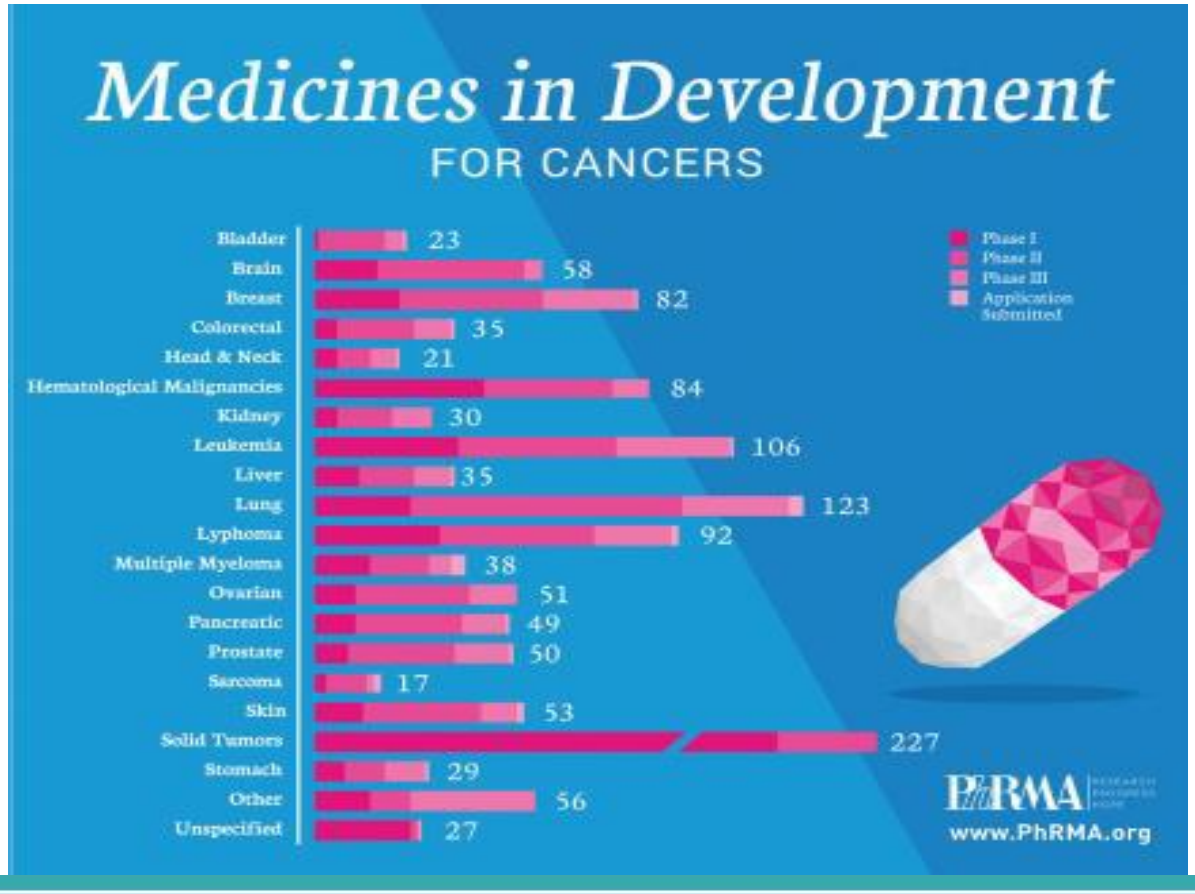
- Pressures on pharmaceutical expenditure
- Increasing demand related to ageing, longer life expectancy, more chronic diseases and cancers

Tension between managing costs and fostering innovation

Pressures on decision-makers inc. payers

- Which medicines to fund / reimburse?
- Which patient populations should be eligible?
- What levels of patient co-payments / out-of-pocket costs?

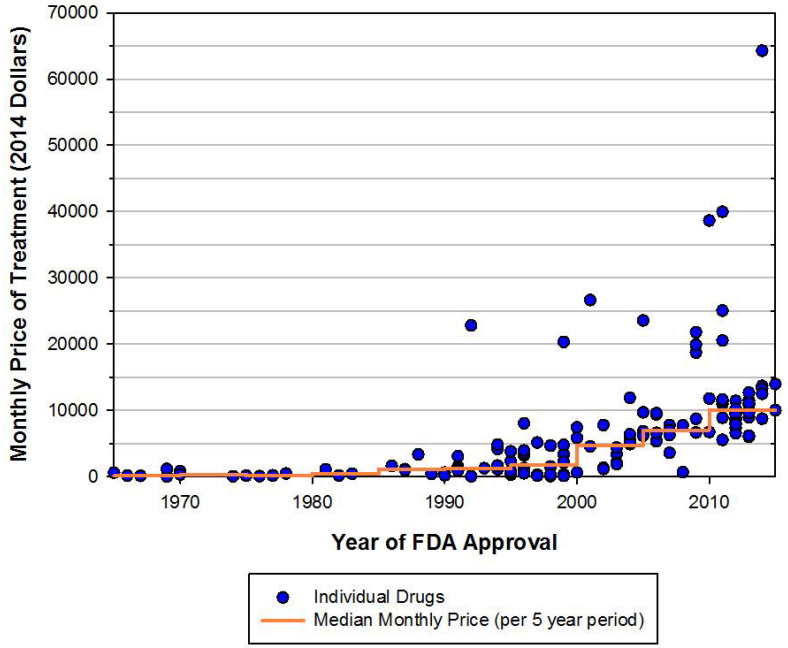
Number of new cancer medicines in development – as an example of a new meds pipeline

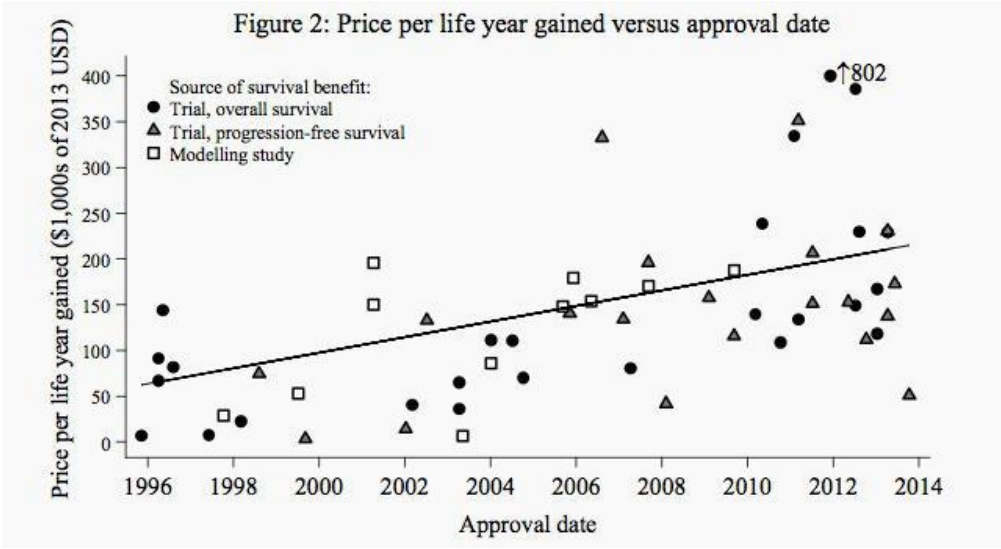


Hanne Bak Pedersen, HTP, WHO/Europe
Nye Metoder
Oslo. Norway 1.February 2016

Monthly & median costs of cancer drugs at US FDA approval 1965-2015 – and prices per life year gained of oncology drugs approved in the US between 1996 and 2014

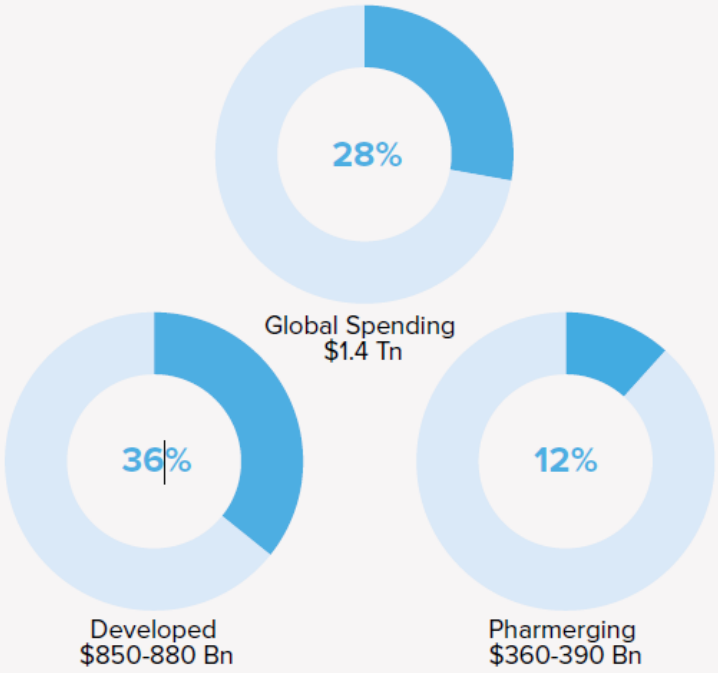
Monthly & median costs of cancer drugs at US FDA approval 1965-2015





"In 1995 patients and their insurers paid USD 54,100 for an additional year of life. A decade later, in 2005, they paid USD 139,100 for the same benefit. By 2013, they paid USD 207,000." (Howard et al, 2015)

Specialty medicines and leading therapy areas in 2020



Leading Specialty Therapy Areas	*Sales in 2020	CAGR 2016-2020
Oncology	$100-120Bn	9-12%
Autoimmune	$55-65Bn	11-14%
Viral Hepatitis	$45-55Bn	7-10%
Immunosuppressants	$20-30Bn	11-14%
HIV Antivirals	$20-30Bn	1-4%
Immunostimulants	$15-18Bn	2-5%
Interferons	$7-9Bn	1-4%
Erythropoietins	$7-9Bn	0-3%
Macular Degeneration	$6-8Bn	6-9%

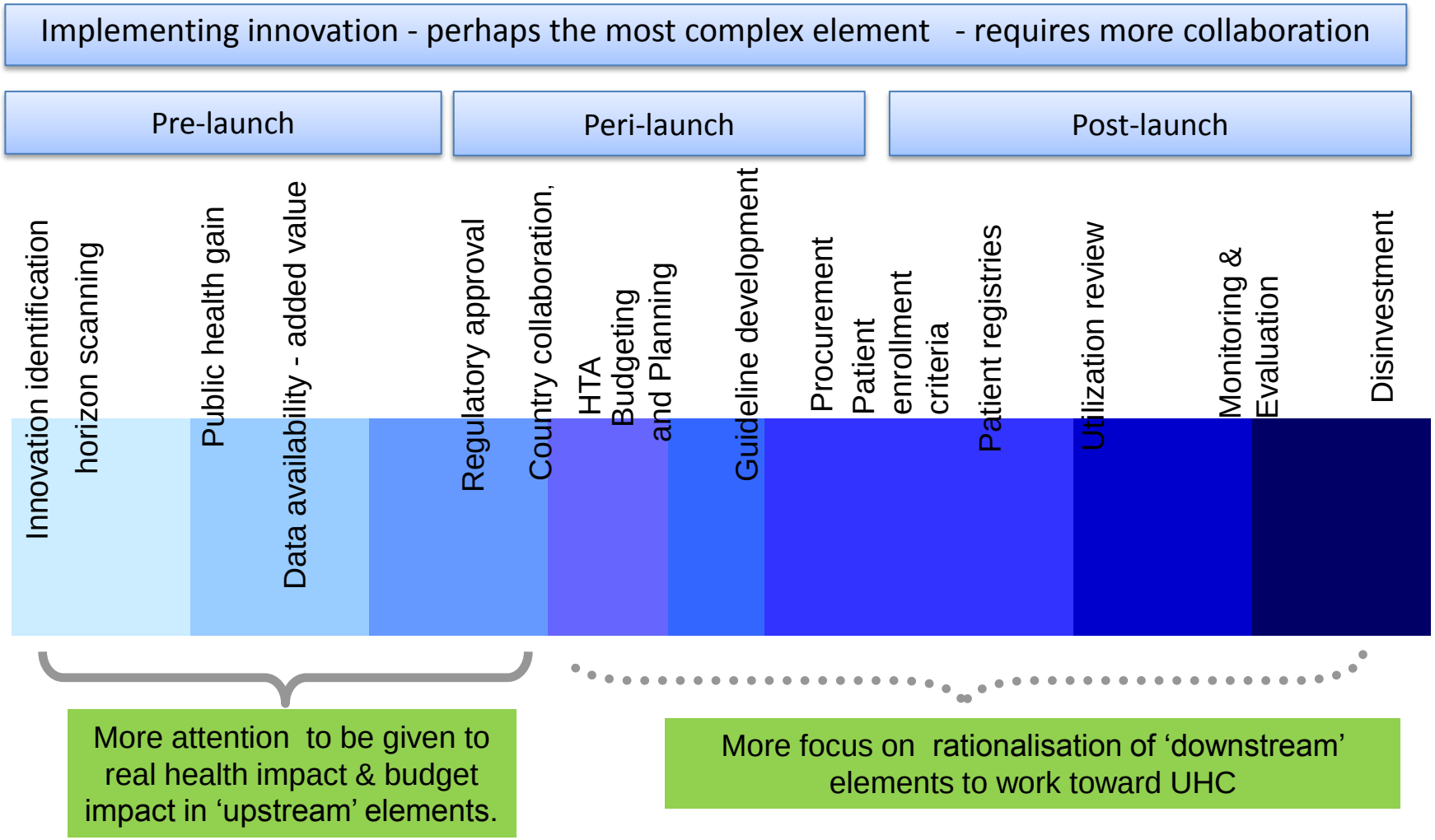
*Sales represented in constant US dollars.
Source: IMS Health, IMS Therapy Prognosis, Sept 2015; IMS Institute for Healthcare Informatics, October 2015
Note: Leading traditional therapy areas shown for 8 developed countries and 6 pharmerging countries (see Definitions & Methodologies section).

Access to new medicines in Europe – Technical report

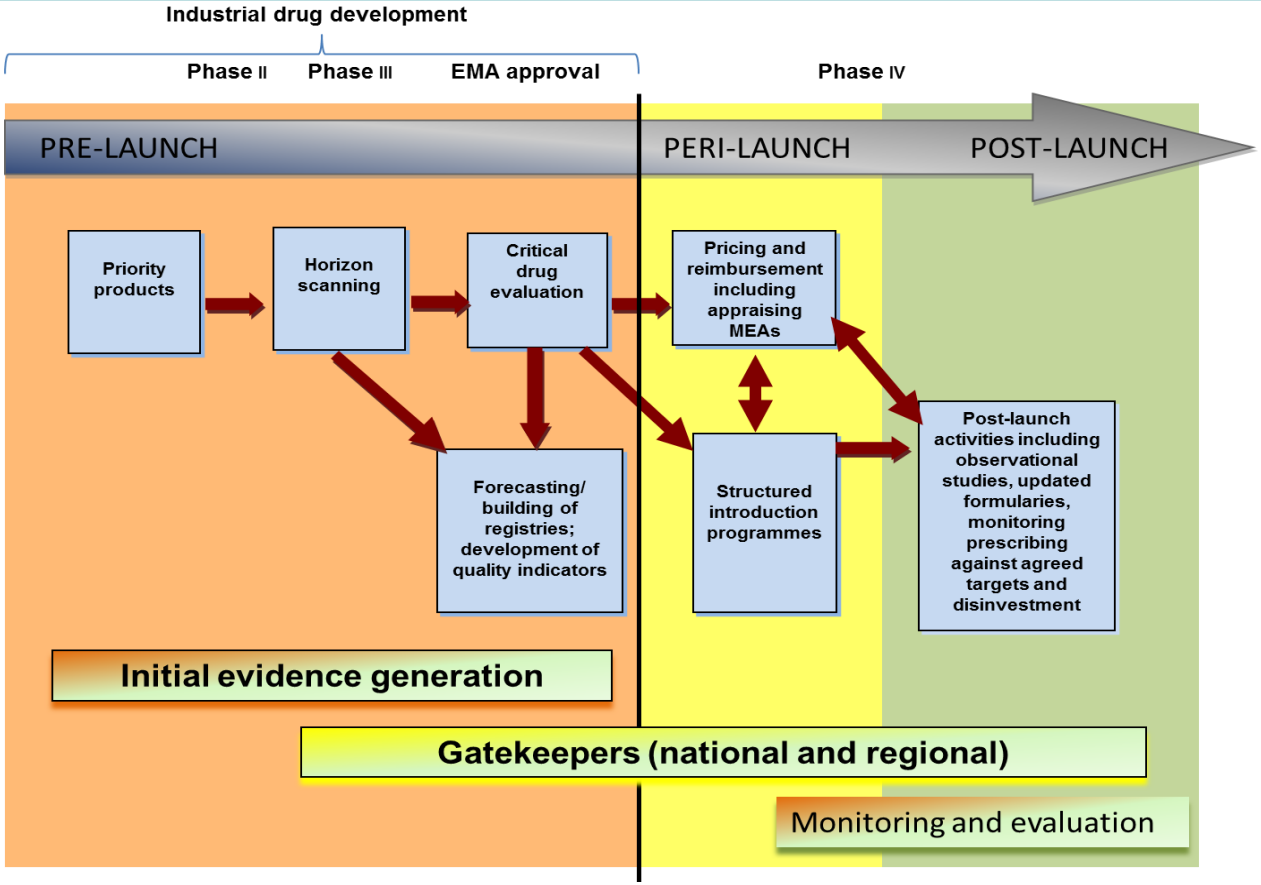
- WHO Collaborating Centre for Evidence-Based Research Synthesis and Guideline Development, Emilia-Romagna Health and Social Care Agency (Italy)
- WHO Collaborating Centre for Pharmaceutical Pricing and Reimbursement Policies, Gesundheit Österreich GmbH (Austria)
- WHO Collaborating Centre for Health Policy and Pharmaceutical Economics, LSE Health, London School of Economics and Political Science (United Kingdom)
- Karolinska Institute (Sweden)
- Organisation for Economic Co-operation and Development (OECD) (France)
- WHO Regional Office for Europe (Denmark)
- WHO headquarters (Switzerland)
- Government of Norway (Directorate of Health)

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



Framework for locating policy interventions



Source: adapted from Wettermark et al. *(14);* Malmström et al. *(15)*; Godman et al. *(16)*.

Horizon scanning

- Early intelligence on new drugs and technologies
- Medicines expected to become available in the near future with the potential for moderate/high net impact on drug budget and/or significant implications for service delivery.
- Budget impact estimates take account of anticipated costs and savings associated with the new medicine and may included cost offsets with reduced use of existing medicines.
- Identifies system changes needed to support the use of the new medicine or technology

Why is it useful?

- Patients benefit from earlier introduction than might otherwise occur and it may improve uptake of the new medicine or technology
- Aligns with industry objectives of early and rapid uptake of their products
- Allows earlier decision making and budget allocation
- Facilitates planning for guideline development, training of staff, education of prescribers to ensure appropriate use of the new medicine or technology

When and what

- Pre-launch activity; programs vary in processes, scope
- Typically begins during phase II/III trials – allows time for planning and prioritization work, budget allocations, HTA processes and decisions before / around product launch
- Dynamic process; must respond to environmental changes e.g. launch dates, other products, trial evidence
- Often relies on information that is commercial-in-confidence – need mechanisms to respect and protect that confidentiality

Some examples – Country level

- UK Pharmascan
  - developed by Department of Health (DoH) and the Association of British Pharmaceutical Industry (ABPI), funded by DoH and NHS horizon scanning bodies; hosted by NICE (National Institute for Health and Care Excellence); operating since 2010
  - pharmaceutical companies enter data in UK Pharmascan data base; information assessed by horizon scanning bodies
  - after identification and profiling as well as filtering and prioritization, information is forwarded to HTA organizations whose decisions flow into NICE guidance and costing templates

Some examples – Country level

- France “Comité de Prospective des innovations médicamenteuses” (CPIM)
  - Launched in 2015
  - Operates at the pricing committee level (CEPS)
  - In collaboration with the pharmaceutical industry (Association of French Pharmaceutical Industry)
  - Monitoring of molecules to come and regular discussions with industry in order to present their pipeline of new medicines

Some examples – European level

- EuroScan
  - members from European and several non-European countries
  - exchange information on new medicines, devices, procedures
  - some assessments are publicly available, others confidential
  - data sources vary - pharmaceutical companies, financial analysis companies, international scientific societies, meetings (including conference abstracts), documents and websites produced by regulatory agencies, health information websites, medical–scientific literature, experts in their field and pharmaceutical companies' press releases

Health technology assessment (HTA)

- HTA is a process - "*systematic evaluation of properties, effects and/or impacts of health technologies and interventions*"
  - to inform policy and decision-making, especially on how best to allocate limited funds to health interventions and technologies
  - e.g. including a new medicine into a reimbursement scheme, rolling-out public health programmes (immunization, screening), priority setting in health care, identifying health interventions producing greatest health gain and offering value for money, setting medicine prices based on their cost–effectiveness, and formulating clinical guidelines.

HTA assessments

- identifying evidence on benefits and costs of health interventions
- synthesizing research on effectiveness of interventions
- evaluating economic implications and analysing cost and cost–effectiveness of the intervention
- appraising social and ethical implications of the introduction and use of health technologies
- assessing the potential impact on medical practice and health systems' organization

Use of HTA within WHO

- WHO-CHOICE (**CHO**osing **I**nterventions that are **C**ost **E**ffective) [http://www.who.int/choice/en/]
- WHO Expert Committee on the Selection and Use of Essential Medicines uses HTA principles in developing the WHO Model List of Essential Medicines
- WHO's Guidelines Review Committee applies evidence-based medicine principles and HTA approaches for guideline development; considers values, preferences and resource use with guideline implementation.

Using HTA evidence

- HTA not a ‘magic bullet’ solution
- Makes the trade-offs between benefits and costs clearer
- Considers implementation issues, resource implications
- Informs the decision-making process
- Only one of the strategies available to help manage pharmaceutical costs – e.g. reference pricing, generic substitution, control of supply chain mark-ups

WHA 67.23 Resolution on HTA

- raise awareness, foster knowledge, encourage practice and use of HTA in evidence-based decision-making
- integrate HTA concepts/principles in relevant WHO work
- provide technical support to Member States to strengthen capacity for HTA
- support exchange of information, sharing of experiences, capacity-building in HTA through networks and collaborative mechanisms at the global, regional and country level

National/ regional use of HTA to make coverage decisions for pharmaceuticals

Use of HTA to make coverage decisions for pharmaceuticals	Countries
Systematically	Belgium, Finland, France, Hungary, Ireland, Israel, Italy, Luxembourg, Netherlands, Norway, Poland, Slovenia, Sweden, Switzerland
In some circumstances	Austria, Denmark, Portugal, Spain, United Kingdom
Determine reimbursement level or price	France, Hungary, Ireland, Norway, Poland, Sweden, Hungary,

HTA collaborations

- EUnetHTA (http://www.eunethta.eu/)
- Advance HTA Program (http://www.advance-hta.eu/)
  - Funded by the European Commission's Research Framework Programme (FP7)
  - Complementary streams of research that aim to advance and strengthen the methodological tools and practices relating to the application and implementation of HTA
  - Partnership of 13 Consortium members (international organizations, HTA agencies, universities etc.)
- HTA forum in Russia

Conclusion on methods

- Horizon scanning and HTA are tools for decision-makers
  - Horizon scanning helps with planning
  - HTA provides a framework / systematic process for evaluating medicines and technologies and the impact of their introduction
- Promotes transparency, helps make trade-offs explicit
- Not a new process, there is a long history and expertise of HTA in Europe (NICE, HAS, TLV, IQWiG etc.)
- Room for collaboration and knowledge sharing; start by building on existing systems and capacity

The report summarize the challenges and indicate that developments are needed

- 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

Report conclusions: a number of factors should be considered for the future:

- 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 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

Conclusions

- New medicines and high prices will require action
- Solutions must involve all stakeholders
  Regulators, payers, clinicians, patients and the community
- Use prioritization and transparent decision making
- Need for collaboration and information sharing
- The challenge is finding a reasonable balance between rewarding meaningful innovation, equitable and affordable access and sustainable health systems

WHO ongoing activities

- Horizon scanning and HTA – a focus area for WHO to strengthen country collaboration
- Strategic procurement – a Country Working Group is being set up

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

The WHO Pricing and Financing information keep evolving see http://www.who.int/medicines/areas/access/en/

Contact, questions and queries:
Hanne Bak Pedersen
hba@euro.who.int