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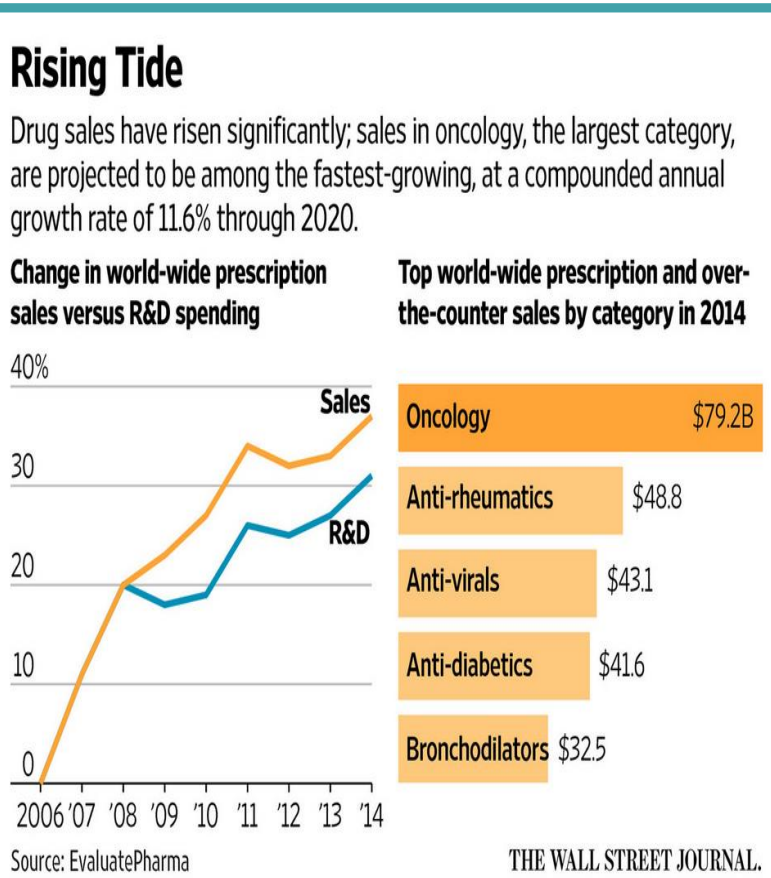
New WHO Report: "Access to new medicines in Europe: Technical review of policy initiatives and opportunities for collaboration and research"

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

Presentation outline

1. **Background - current trends and challenges in terms of access to medicines**
2. **Overview of report findings**
3. **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 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)

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)

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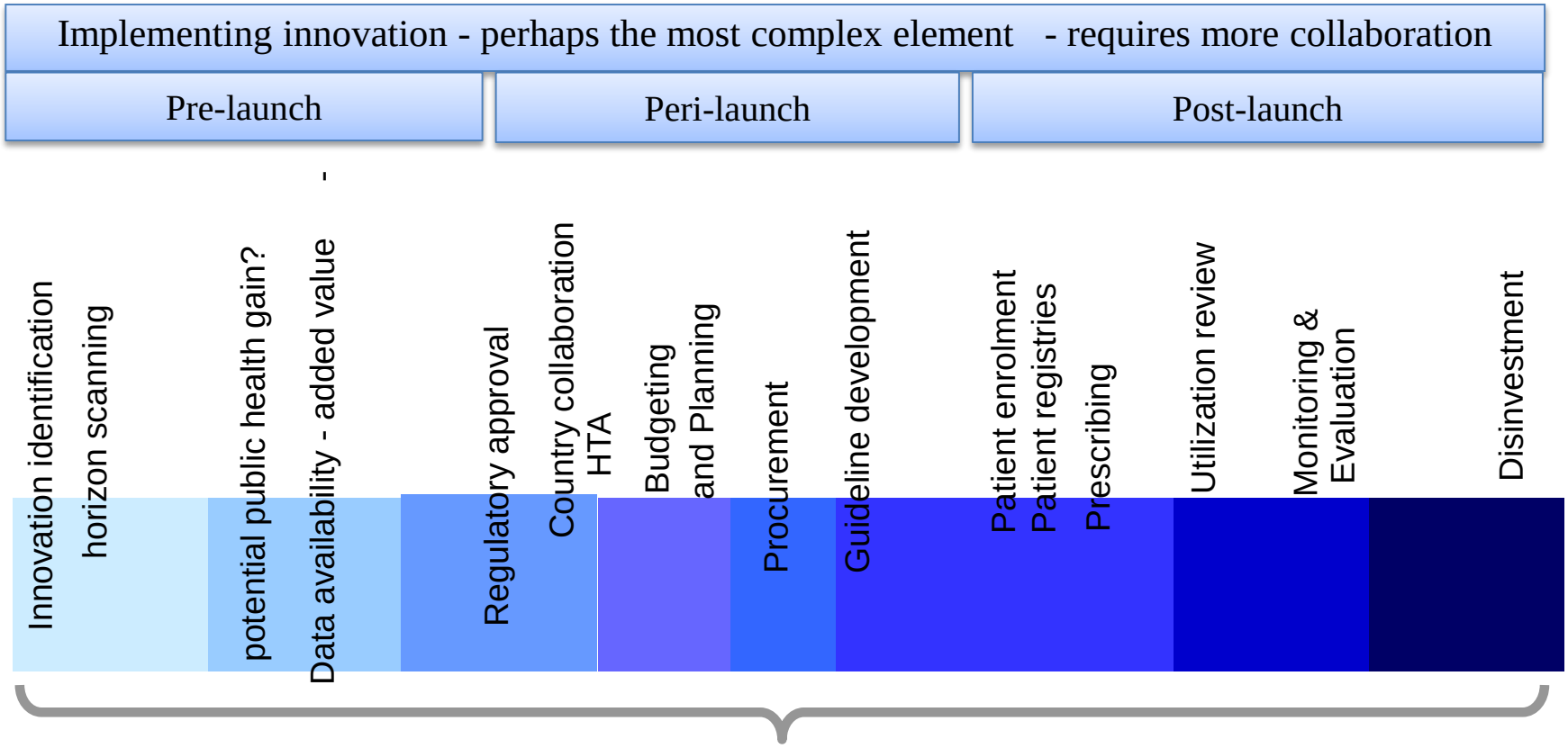
Medicines policy – the continuum from R&D to disinvestment



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

Managing medicines costs

Pre-launch activities

- ►Horizon scanning – know what is coming
- ►Assess impacts on budgets and health service delivery

Peri-launch activities

- ►Health technology assessments (HTA), price negotiations
- ►Risk sharing arrangements of various types

Post-launch activities

- ►Ensuring that medicines are used appropriately / responsibly
- ►Affordable access for patients who need treatment

Responsible use (FIP)

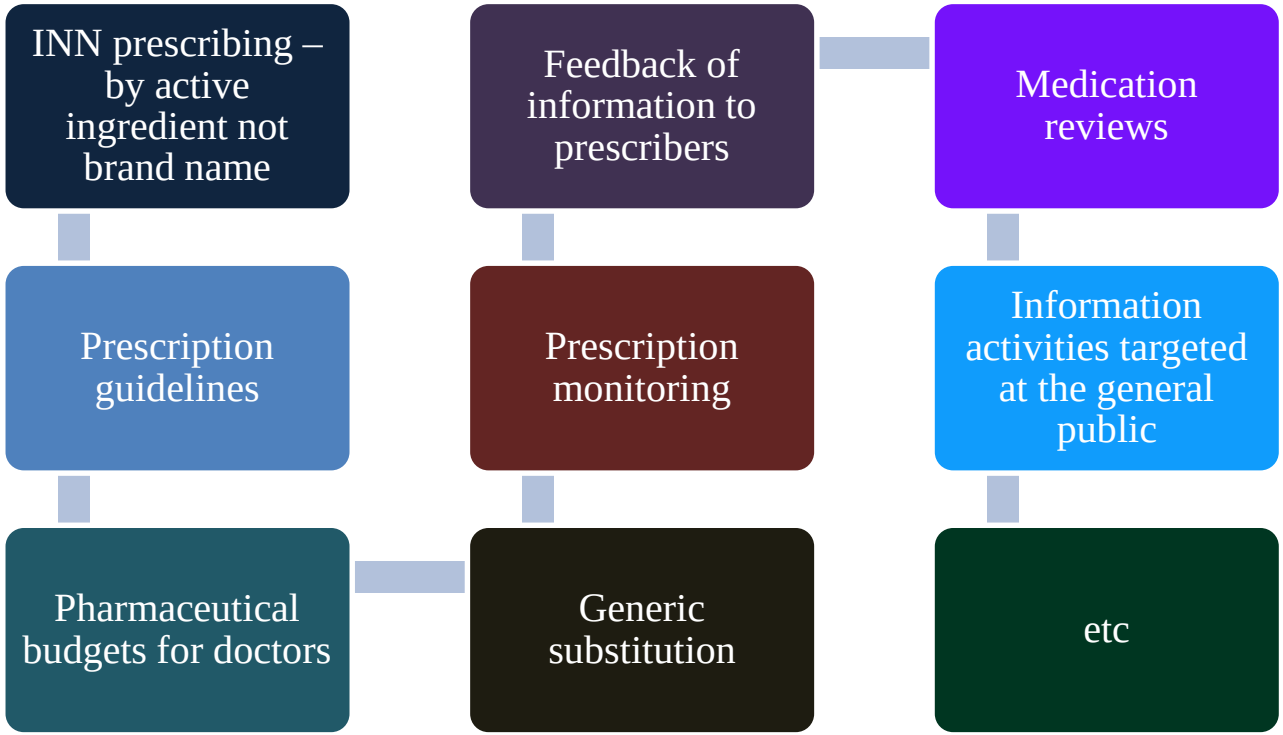
International Pharmaceutical Federation http://www.fip.org/

That a medicine is only used when necessary and that the choice of medicine is appropriate based on what is proven by scientific and/or clinical evidence to be most effective and least likely to cause harm. This choice also considers patient preferences and makes the best use of limited healthcare resources.

There is timely access to and the availability of quality medicine that is properly administered and monitored for effectiveness and safety.

A multidisciplinary collaborative approach is used that includes patients and their families or caregivers.

Promoting responsible use



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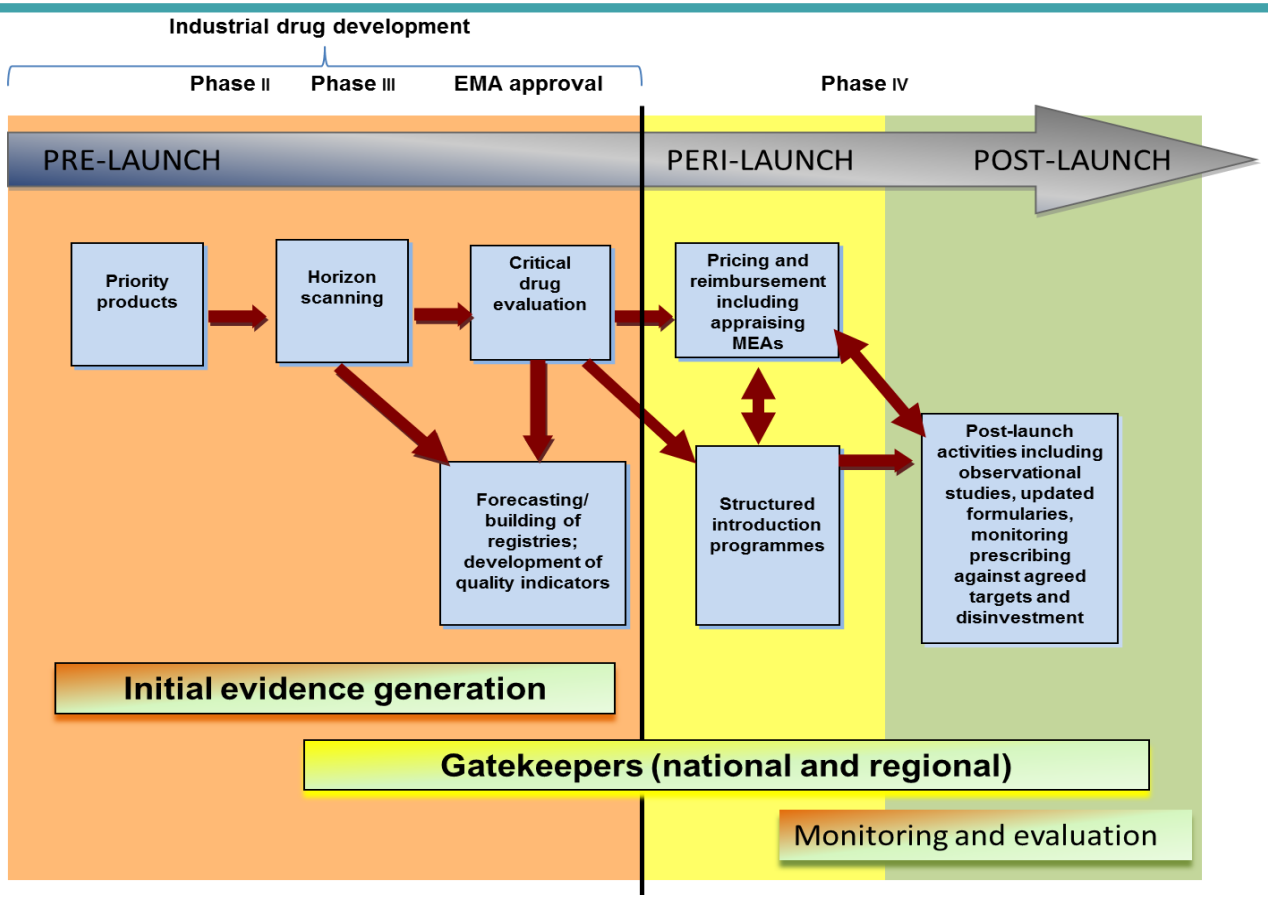
However for new medicines……

- New medicines are mostly patent-protected
  - INN prescribing won't help much and generics are not available
- Guidelines and treatment protocols are still evolving
- The evidence base may be quite limited
  - Patients and doctors have high expectations of new medicines
  - Sometimes information hype - 'breakthrough' medicines
  - Clinical trials may not report the most relevant outcomes – health outcomes may not be clinically meaningful / contribute to overall survival or quality of life that matter to patients

Framework for locating policy interventions



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

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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

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

A 2013 WHO report identified 24 areas for research activities to meet priority health care needs in Europe through addressing treatment gaps, including:

- 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.

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

A number of factors should be considered for the future. These include (2):

- 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

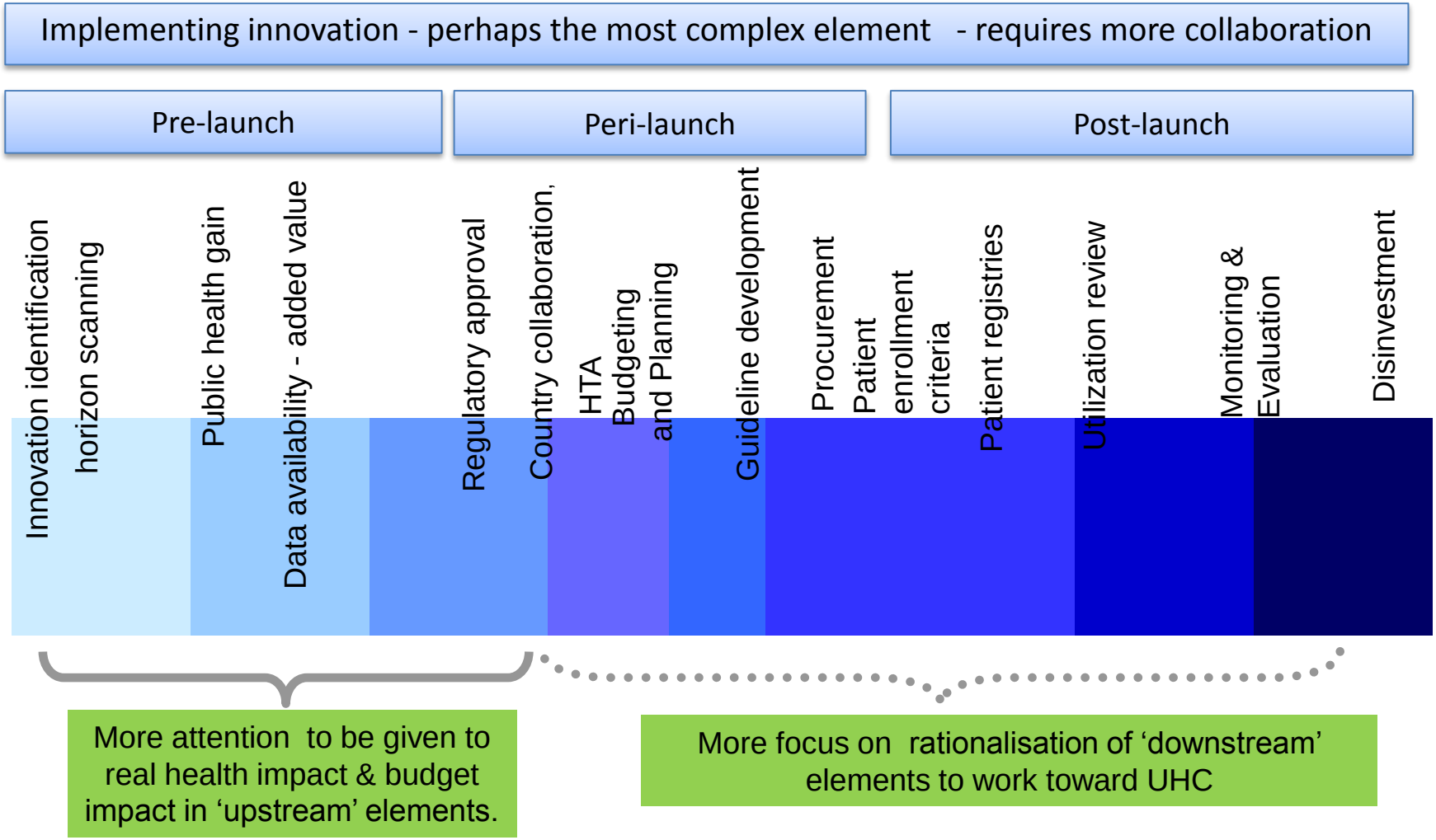
- Collaboration among regional or subregional health systems might benefit from including a particular focus on chronic care, specialty medicines and rare diseases

The future

- New medicines and high prices will require action
- Solutions must involve all stakeholders
  Regulators, payers, clinicians, patients and the community
- How to prioritize when resources are finite and limited
- 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

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



WHO ongoing activities

- HTA - WHO guidance consultations and WG created
- Country consultation for Europe in Copenhagen early September to define priority actions and opportunities for collaboration between countries on new high-prices medicines
- The WHO Pricing and Financing information keep evolving see http://www.who.int/medicines/areas/access/en/

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

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