

# MEDEV COLLABORATION EU ASSESSMENT FOR REIMBURSEMENT

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Krakow  
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# Some Figures

- Turnover in Europe: € 150,000,000,000.-
- Investment pharma industry
  - Marketing budgets: € 25,000,000,000.-
  - 300 lobbyists Brussels: € 45,000,000.-
- Assessment market (EMEA): € 60,000,000.-
- Assessment reimbursement: € 43,000.-



<http://www.esip.org>

30 EU social security organisations,  
informal  
Rue D'Arlon

## **EuroForum**

12 German Speaking  
social insurance companies,  
informal



[www.aim-mutual.org](http://www.aim-mutual.org)

23 EU social security organisations, 30 other countries,  
formal  
Rue D'Arlon

## **MEDEV**

[www.esip.org](http://www.esip.org)  
Medical Evaluation Committee  
14 countries, informal,  
**Assessment & pricing**  
Rue D'Arlon



DG Enterprise  
DG Sanco  
Workinggroups  
regulations



# World Health Organization

[www.who.int](http://www.who.int)

EU pharma  
Copenhagen

# Participants MEDEV

- Germany
- France
- Austria
- Luxembourg
- Belgium
- Sweden
- Czech Republic
- Latvia
- Malta
- The Netherlands
- Spain
- Portugal
- Slovenia
- Finland
- Denmark
- Hungary
- Norway
- Italy

# Main Tasks

- Represent payers (EU citizen)
- Assessing new drugs
- Developing methodology and criteria
- Review and harmonisation guidelines
- Criteria for reassessment (conditional admittance?)
- Criteria for interchangeability
- Post-listing reviews

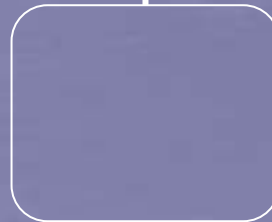
# EU-Commission

Pharmaceutical  
Forum  
(27 ministers)

Relative  
effectiveness

Pricing  
Reimbursement

Information  
to patients



# Relative Effectiveness

- New ones compared to best/common alternative
- Clinical relevant

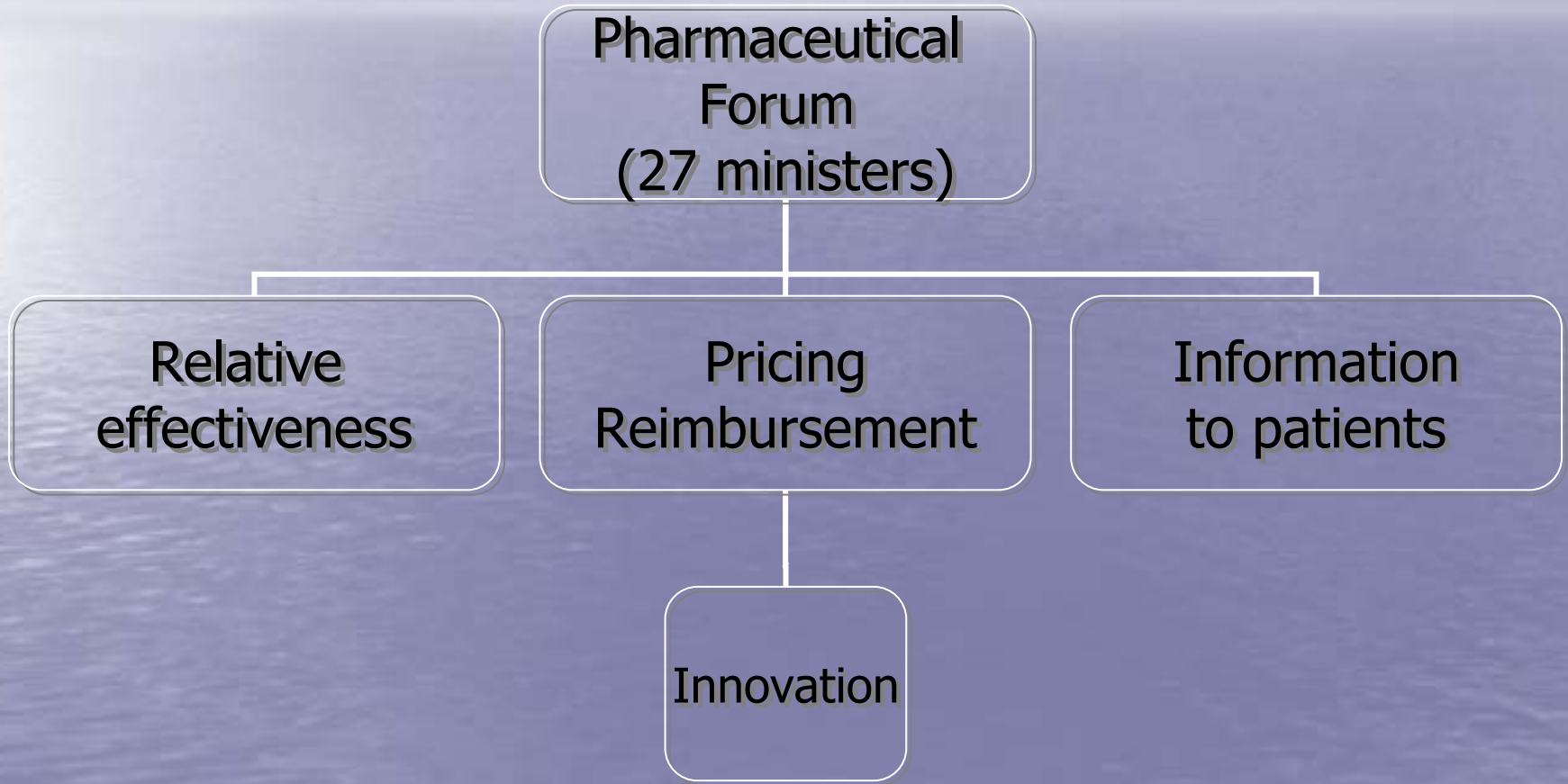
# Pricing & Reimbursement

- Pay for real innovation (not for marketing)
- Societal drive R & D (more acceptance common decisions, public/private)
- Interchangeability
- Transparency (one EU-market)
- No new EU-rules

# Information to Patients

- Independant (no advertisement)
- Transparency existing information

# EU-Commission



# EU-Commission

Consultation  
on information  
to patient

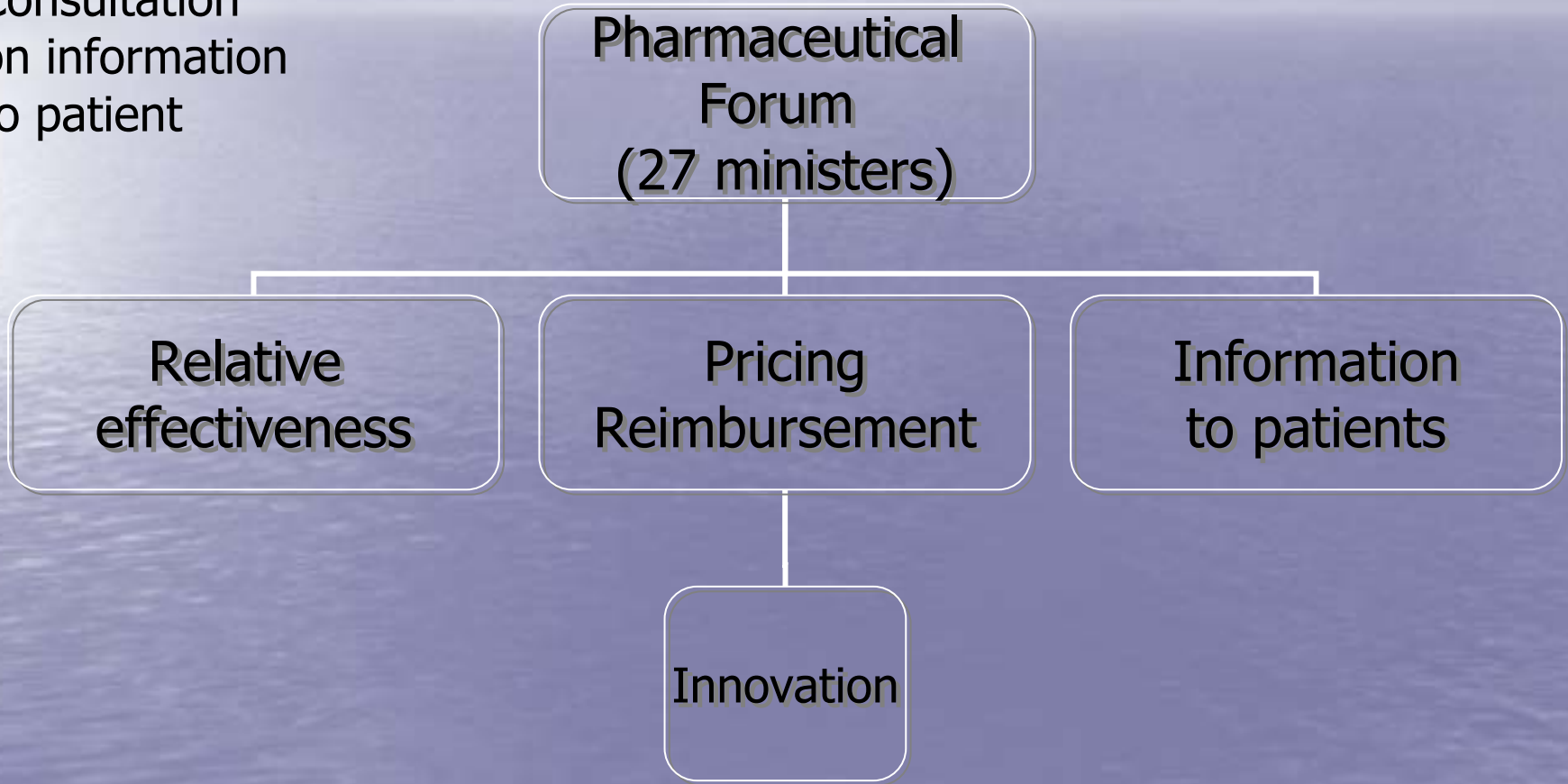
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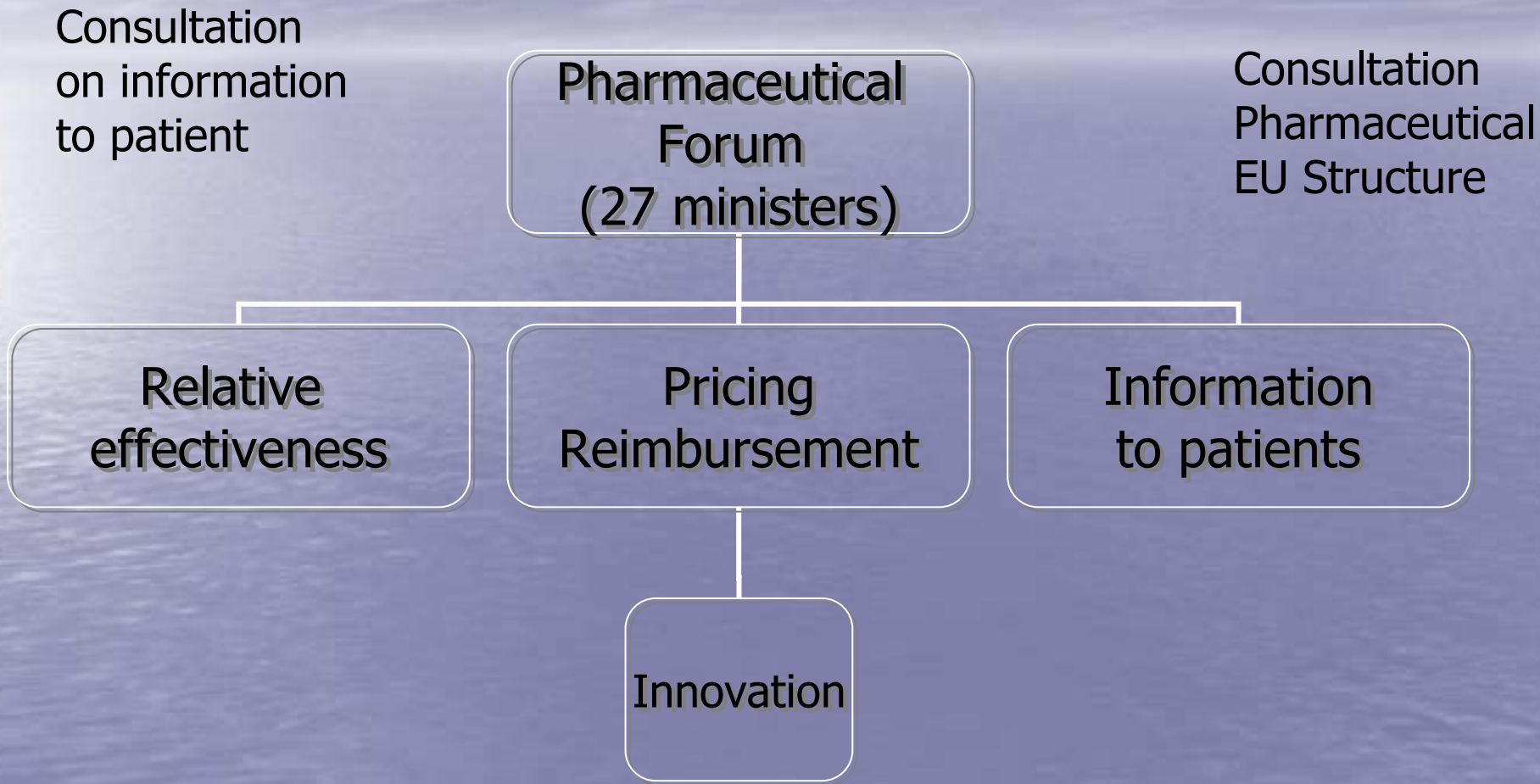
Pricing  
Reimbursement

Information  
to patients

Innovation



# EU-Commission



# Assessment for Reimbursement

- Almost all countries assess all medicines
- Transparency guideline 90 days
- Development pharmaco-economic evaluations
- Capacity for evaluations is limited

# Acceleration

- Collaboration on evaluation of medicines
- Creating infrastructure

Final decisions and negotiations are responsibility of national authorities

- Price
- Restriction on indication
- Prescriber(s)?

# Evaluation Criteria

## Therapeutic Value

- Efficacy
- Effectiveness
- Side effects
- Experience
- Applicability
- Ease of use for patient
- Quality of life

**Essential is balance  
between effectiveness and  
side effects**

**Other criteria are less  
important**

# **Efficacy**

A drug is efficacious if its pharmacological action, when used in clinical research, results in a therapeutic effect, usually measured according to a surrogate parameter

# Effectiveness

A drug is effective if  
it is efficacious,  
and research shows,  
measured according to a hard  
parameter,  
that its use in daily practice  
results in achieving the aim of the  
treatment

# Differences

## Efficacy

- Usually surrogate parameter
- Quick to measure

## Effectiveness

- Hard parameter
- Reflects use in daily practice
- Needs costly longterm research

# Limitations Clinical Trials

- No young and old patients
- No chronic use
- Other diseases excluded
- Other drug use excluded
- Better patient compliance
- Surrogate parameters

# Side Effects

- Frequency
- Seriousness
- Duration

Trials too short to show rare side effects

# Experience

- **Limited:**

less than 3 years on market or less than 100,000 prescriptions/20,000 patients

- **Sufficient:**

more than this

- **Considerable:**

after 10 years on the market

# Applicability

- Organ disorders (liver, kidney)
- Older patients and children
- Pregnancy and lactation
- Contra indications
- Resistance (antibiotics)
- Interactions

# Ease of use

- Dose frequency: 1 vs. 3 times daily
- Administration form: Tablet vs. injection
- Taste, packaging etc.

Must have a proven impact on

- Compliance
- Effectiveness
- Side effects

# Quality of life

- Mobility
- Capacity to take care of one's self
- Carrying out daily activities
- Pain/complaints
- Mood

# List of Evaluated Products

- Infliximab and Etanercept
- Leflunomide
- Celecoxib and Rofecoxib
- Imatinib
- Epoietin (EPO) in tumour-related anemia
- Atypical Antipsychotics
- Olanzapin, Quetiapin and Risperidone
- Repaglinide and Nateglinide
- Bonviva
- Rapid acting insulin analogues
- Erlotinab
- Clopidogrel
- Raloxifen
- Orlistat
- Insulin lispro
- Zanamivir and Oseltamivir
- Palivizumab
- Interferon beta and Multiple Sclerosis
- Trastuzumab
- Topical Immunosuppressants - Pimecrolimus Tacrolimus
- Keppra
- Rimonabant

# Recent developments

- Medical devices and advanced therapies
- Orphan drugs: common advice and assessment
- Create sustainable network, formalize MEDEV structure?
- Slovenian/EU network?
- What's in it for industry?