Network4Health Meeting

Basics of Health Economics Training
## Agenda – Day 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Day 1 – November 23rd</th>
</tr>
</thead>
</table>
| 09:30 – 10:00 | Welcome and introduction<br>
Andreas Woitsossek, Head of CEE Strategic & Outcomes, Janssen<br>
Vlatka Radić, Patient Advocacy Lead CEE, Janssen |
| 10:00 – 12:00 | Effective patient advocacy in Central Europe<br>
Moderated experience sharing discussion - all |
| 12:00 – 13:00 | Lunch                                                                                 |
|               | **Basics of Health Economics Training led by experts**<br>
*dr. Dávid Dankó, managing director, Ideas & Solutions, research leader, Corvinus University of Budapest<br>
dr. Márk Péter Molnár, partner, Ideas & Solutions, research leader, Corvinus University of Budapest* |
| 13:00 – 13:20 | **Intro to Basics of Health Economics**<br>
(Tools and arguments to support effective communication) |
| 13:20 – 14:00 | **Health Economic data**<br>
(Interpretation, use and collection of health and health economics data – presentation) |
| 14:00 – 14:30 | **Interpretation, use and collection of health and health economics data**<br>
– case discussion |
| 14:30 – 14:45 | **Coffee break**                                                                     |
| 14:45 – 15:30 | **Outlook on international health care systems**<br>
– presentation |
| 15:30 – 16:00 | **Outlook on international health care systems**<br>
– case discussion |
| 16:00 – 17:00 | **Reimbursement policy and health technology assessment**<br>
– presentation, part 1 |
## Agenda – Day 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Day 2 - November 24th</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00 – 10:30</td>
<td>Reimbursement policy and health technology assessment</td>
</tr>
<tr>
<td></td>
<td>- presentation, part 2</td>
</tr>
<tr>
<td>10:30 – 10:45</td>
<td>Coffee break</td>
</tr>
<tr>
<td>10:45 – 12:15</td>
<td>Role-play &amp; message formulation session</td>
</tr>
<tr>
<td>12:15 – 12:30</td>
<td>Conclusions and closing of training</td>
</tr>
<tr>
<td>12:30 – 13:30</td>
<td>Lunch and farewell</td>
</tr>
</tbody>
</table>
TOOLS AND ARGUMENTS TO SUPPORT EFFECTIVE COMMUNICATION
In pharmaceutical policy, things revolve around the Big Trust Gap

PUBLIC AFFAIRS (PUBLIC TALK) LEVEL

PUBLIC AFFAIRS

ESPOUSED VALUES OF OTHER STAKEHOLDERS (MEDICAL AND PATIENT ASSOCIATIONS AND PHARMA INDUSTRY)

Similar problem awareness

Apparent possibility for consensus

PUBLIC AFFAIRS

PAYERS’ ESPOUSED VALUES

FINANCIAL, INSTITUTIONAL AND CULTURAL HURDLES

FINANCIAL, INSTITUTIONAL AND CULTURAL HURDLES

METHODS-IN-USE OF OTHER STAKEHOLDERS (MEDICAL AND PATIENT ASSOCIATIONS AND PHARMA INDUSTRY)

BIG TRUST GAP

Embedded conflict
Old decision patterns and backstage politicking
Payers consider patients and physicians as agents of the pharma industry

METHODS-IN-USE OF OTHER STAKEHOLDERS (MEDICAL AND PATIENT ASSOCIATIONS AND PHARMA INDUSTRY)

PAYERS’ METHODS-IN-USE

OPERATIONAL LEVEL (EVERYDAY ISSUES AND DECISIONS)

OPERATIONAL LEVEL
## Consequences of the trust gap: Payers often think about medical associations and patient organizations in self-contradictory concepts

<table>
<thead>
<tr>
<th>‘Pharmaceuticals target unmet need’</th>
<th>‘Pharmaceutical prices are high, and some products have questionable value’</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘Medical associations, KOLs have clinical knowhow that no-one else has’</td>
<td>‘Pharma industry wants to influence KOL’s and turn them into corporate salesmen’</td>
</tr>
<tr>
<td>‘Patient Organizations have the real life experience of the real patients about the illness and about its consequences’</td>
<td>‘Pharma industry financially supports Patient Organizations, therefore they represent unscrupulous multinationals, not the patients’</td>
</tr>
<tr>
<td>‘Medical and patient organizations offer partnership ideas which sound good’</td>
<td>‘These organizations represent the interest of the pharma industry and all they want is to rip us of our money’</td>
</tr>
</tbody>
</table>

Payers in smaller countries may have weak self-confidence and they fear that their bargaining position is vulnerable and medical & patient organizations are working against them.
Different therapy areas and drugs compete for the same funds...

If funds are not enough to reimburse all value-for-money therapies, these will be prioritized. Middle-income markets often require ‘zero budget impact’.
... and this is why stakeholders must cooperate closely to open up access to new medicines

- Advocacy for alternative funding methods
- Support for HTA recommendation
- Cost-sharing agreements
- Risk-sharing and affordability schemes
- Legal cases
- Health policy issue generation
Communication towards policymakers and payers must observe some sensitivities

**DO...**

- Keep in mind that whoever payers are, they purchase medicines (more than patients)
- Put the emphasis on benefits compared to available therapies
- Use relevant quantitative information to support your argumentation
- Use neutral and general language as payers cannot consider each case separately
- Understand that payers have to deal with several hundreds or thousands of other products
- Be prepared that payers are often procurement-minded who enjoy the process of bargaining itself and are often mistrustful
- Try to look at payers as being housewives in a poor family at the end of the month, who have to make ‘either-or’ decisions about what to buy

**DO NOT...**

- Emphasize product characteristics which serve marketing purposes
- Ask simply for more money, instead try to establish win-win situations
- Use emotional rhetoric showcasing individual patient cases, as payers have to deal with the ‘whole’ and can get frustrated if confronted by the individual
- Use any language that payers might consider as blackmailing
- Move on to the political level before you have done everything to ensure success at technical payer level
- Bend in subserviently to please the payer, instead act as a proud, self-conscious and professional partner
In payer communication, it is safer to refrain from emotional vocabulary

X NO

✓ YES

- „several thousands of people suffer unnecessarily because of poor funding”
- „patients have individual needs that you always have to consider”
- „patient organizations are upset, and if we do not settle this issue, the media may pick it up”
- „several members of parliament are fully aware of the importance of this issue”

- „we understand budget constraints but these should not block the use of the new product by those patients who really need it”
- „we understand that you cannot deal with each patient separately, but if we think together, we may find a better way of defining patient subgroups”
- „higher prices reflect higher quality, and higher quality means that fewer products will be necessary”
In payer communication, you should always look out for resistance

1. Open attack against the proposal
2. Quick questions, many of which irrelevant
3. Moving to the background, keeping silent
4. Confusion and no opinion
5. Directing the dialogue to an abstract level, ideologizing the present
6. Equity debate
7. Previous negative experience
8. Downplaying the need for change
9. Agreeing but referring to external circumstances: „It would work in Germany but...”
10. Quick alternative solution, meaning no effective change
Good example: How many months does an average doctor need to work in order to buy a pack of innovative medicine?


On the other hand an average health care system can buy a doctor for 3,6-17 months time from the cost of an innovative medicine for a month...On this field everything is the perspective...
Key success factors in payer communication in Central Europe: Set vision, uncomplicate & direct-sell

Set a clear vision, based on an understanding of which concepts are suitable for your therapy area, and which are not. Validate the unmet medical needs and better patient outcomes as desired direction.

‘Uncomplicate’ so that it becomes applicable in a dominantly cost-minded environment, where you need to use economic (health-economic) methodology and language.

‘Direct-sell’ your concepts/needs/ proposals to all relevant stakeholders along the decision-making process.
# Approaches to economic evaluation

<table>
<thead>
<tr>
<th>Does the analysis include costs and utilities (input and output) as well?</th>
<th>No</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Only examines outcome</td>
<td>Cost description</td>
<td>Cost and outcome description</td>
</tr>
<tr>
<td>Only examines cost</td>
<td>Efficacy or effectiveness evaluation</td>
<td>Cost analysis</td>
</tr>
</tbody>
</table>

- **Cost-minimization analysis (CMA)**
- **Cost-effectiveness analysis (CEA)**
- **Cost-utility analysis (CUA)**
- **Cost-benefit analysis (CBA)**

*Source: Reproduced from Drummond et al 2005 p.11*
Types of analysis differ in the parameter of outcome comparison

<table>
<thead>
<tr>
<th>Type of analysis</th>
<th>Outcome unit</th>
<th>Cost unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMA</td>
<td>They are the same</td>
<td>Money</td>
</tr>
<tr>
<td>CEA</td>
<td>Natural unit</td>
<td>Money</td>
</tr>
<tr>
<td>CUA</td>
<td>QALY</td>
<td>Money</td>
</tr>
<tr>
<td>CBA</td>
<td>Money</td>
<td>Money</td>
</tr>
</tbody>
</table>

\[
\text{ICER}^* = \frac{\Delta \text{Cost}}{\Delta \text{Health gain}} = \frac{C_2 - C_1}{E_2 - E_1}
\]

*ICER = incremental cost-effectiveness ratio; C = cost of therapy; E = benefit of therapy
Possible inputs and outputs of economic evaluation

**INPUT - Costs**

- **Direct costs**
  - Direct medical costs e.g. drugs, diagnostics, outpatient and inpatient care
  - Direct non-medical cost e.g. travelling, accommodation, home care, special diet

- **Indirect costs**
  - e.g. loss of income, productivity loss

- **Intangible costs**
  - e.g. pain, anxiety

- The perspective of analysis (society, payer) determines which type we should include in the HTA

- Discounting!

**OUTPUT – Health gain**

1) **Clinical results** – based: e.g. biological parameters

2) **Patient reported outcomes** measured by questionnaires, interviews (multi-dimensional, patient-oriented)

- **QALY** (Quality Adjusted Life Years) expresses the change in mortality and utility in one number → result: a number between 0 (=death) and 1 (=healthy)
  - **Advantage**: different health care technologies can be compared to each other
  - **Disadvantage**: several utility measuring methodologies
How do we decide whether a therapy is cost-effective or not?

![Diagram showing cost-effectiveness analysis with rejection, indifferent, and acceptance zones.]
HEALTH ECONOMIC DATA 2
Health care systems around the world show a large diversity, emerging markets often have parallel systems

<table>
<thead>
<tr>
<th>Health care systems</th>
<th>Universal health care systems (UHC)</th>
<th>Private insurance or out-of-pocket***</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single public payer</td>
<td>Budget systems* (UK model)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>National payer (Albania)</td>
<td></td>
</tr>
<tr>
<td>Multiple public payer</td>
<td>Insurance systems (German model)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>National insurance fund (HU, PL, RO, BG)</td>
<td></td>
</tr>
<tr>
<td>No public payer</td>
<td>Regional payers (Kazakhstan, India, Russia)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regional insurance funds</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Corporatist insurance funds**</td>
<td>Competitive for-profit insurance companies</td>
</tr>
<tr>
<td></td>
<td>Local payers (councils, municipalities)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Competitive health insurers (Slovakia, CZ)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mixed or parallel systems (South Africa, UAE, Saudi Arabia, Morocco)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Out-of-pocket payments (Sub-Saharan Africa)</td>
<td></td>
</tr>
</tbody>
</table>

* Also called NHS (National Health Service) type systems. These systems are typically tax-funded.

** Usually different insurance funds cover different industries or employee groups. It is a logic similar to that of trade unions.

*** Private insurance companies are usually contracted by employers who purchase different insurance policies for their employees and retirees. Families are often covered through the policy of the salaried / wage-earning family member.
Variations for health care systems (1) – examples from high-income and upper middle-income markets

- **Australia** has a budget-funded universal health care system with a centrally defined benefit package.
- **The United States** are normally regarded as a ‘classical’ private insurance system but government programmes such as Medicare and Medicaid cover large population segments. Despite this, more than 10% of the total population is without any coverage.
- **Switzerland** has a private insurance system in which citizens and residents are obliged to take out some form of insurance. Different policies are available from competing insurance companies.
- **Hungary** operates a central insurance system with one national health insurance fund.
- **Slovakia** has a mandatory national health insurance system in which people can choose between 3 competing insurance companies.
- **Sweden** has a budget-funded universal health care system in which a large part of benefits is provided by local municipalities.
- **Turkey** has a universal health insurance supervised by Ministry of Labor and Social Security and financed by Ministry of Finance.

References on the next slide.
Variations for health care systems (2) – examples from emerging markets

Algeria has a national health insurance fund (CNAS) operating under the Ministry of Health.

Israel has a national health insurance system with four competing, non-profit health plans.

Russia has a complex health care system in which most public expenditures are funded from regional budgets. The share of the central budget is growing.

Gulf countries have mixed health care systems in which different sub-systems apply to different populations. Citizens usually benefit from one or more budget-funded national systems while expatriates are typically covered by private insurance.

In India, about 15% of the population has any type of health insurance, primarily through employers. Limited government funding allowed for the unregulated private sector to fill unmet social need.

In most Sub-Saharan countries, there is very limited or no health insurance and out-of-pocket payments dominate.

In South Africa, approx. 20% of the total population is covered by private insurance. Budget-funded state insurance offers a limited service package, which means that out-of-pocket have an important role.

Brazil’s Unified Health System (SUS) provides public access to health care to 202 million people. The system is split between public and private providers.

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In South Africa, approx. 20% of the total population is covered by private insurance. Budget-funded state insurance offers a limited service package, which means that out-of-pocket have an important role.

https://www.idf.org/sites/default/files/attachments/2008_2_Boudiba_Mimouni_EN.pdf
http://www.euro.who.int/__data/assets/pdf_file/0007/85435/E92608.pdf?ua=1
http://content.healthaffairs.org/content/27/4/921.full
Most OECD countries have achieved universal coverage for health care.

In developed universal health systems, medicines are a key component of health benefits.

**Public pharmaceutical expenditures in comparison to public expenditures on hospital care and out-patient care**

**GERMANY**
- Population: 80.1 M (2014)
- GDP per capita: 47,627 USD (2014)
- Hospital care 32%
- Out-patient care 21%
- Pharmaceutical benefits 17%

**FRANCE**
- Population: 66.2 M (2014)
- GDP per capita: 42,736 USD (2014)
- Hospital care 34%
- Other 34%
- Out-patient care 16%
- Pharmaceutical benefits 16%

**KOREA (S)**
- Population: 50.4 M (2014)
- GDP per capita: 27,970 USD (2014)
- Other 30%
- Out-patient care 28%
- Hospital care 22%
- Pharmaceutical benefits 20%

**HUNGARY**
- GDP per capita: 13,903 USD (2014)
- Hospital care 37%
- Pharmaceutical benefits 22%
- Out-patient care 20%
- Other 21%

*Other includes: services of long-term nursing care, ancillary services*

Pharmaceuticals have gained importance both in the hospital and outpatient segments

- Pharmaceutical care offers a strategy in the fight against infectious diseases and chronic conditions.
- Pharmaceuticals treat diseases predominantly in the early stages, increasing the chances of successful treatment and full recovery.
- This also means that pharmaceuticals can save health care resources needed for the treatment of diseases which have reached more severe stages. This way pharmaceutical care can relieve the burden on hospital care.

Pharmaceutical care can be organized in several ways. One way is to integrate it into outpatient care offered by health providers; the other way is to establish a system which is based on community pharmacies.
## Important data sources for public data in onco-hematology

<table>
<thead>
<tr>
<th>Data Source</th>
<th>Data Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>WHO HFA database</td>
<td>- Age-standardized mortality, morbidity by different therapeutic areas</td>
</tr>
<tr>
<td></td>
<td>- Incidence and prevalence data</td>
</tr>
<tr>
<td></td>
<td>- Data for multiple years and countries is available</td>
</tr>
<tr>
<td>OECD database</td>
<td>- Age-standardized mortality, morbidity by different therapeutic areas</td>
</tr>
<tr>
<td></td>
<td>- Incidence and prevalence data</td>
</tr>
<tr>
<td></td>
<td>- Data for multiple years and countries is available</td>
</tr>
<tr>
<td>Central Statistical Offices</td>
<td>- Demographic and morbidity data by sex and age groups and different therapeutic</td>
</tr>
<tr>
<td></td>
<td>areas</td>
</tr>
<tr>
<td>National Cancer Registries</td>
<td>- Cancer incidence data by sex, age groups and counties, from 2001 to 2013</td>
</tr>
</tbody>
</table>

**Source:**
- WHO HFA database: [http://data.euro.who.int/hfadb/](http://data.euro.who.int/hfadb/)
**Central Europe – some selected oncology indicators**

<table>
<thead>
<tr>
<th>Country</th>
<th>Epidemiology</th>
<th>Quality of Life</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Incidence [ASR(W)]*</td>
<td>Mortality [ASR(W)]*</td>
</tr>
<tr>
<td></td>
<td>Men</td>
<td>Women</td>
</tr>
<tr>
<td>Poland</td>
<td>229,6</td>
<td>131,0</td>
</tr>
<tr>
<td>Hungary</td>
<td>285,4</td>
<td>152,1</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>293,8</td>
<td>121,7</td>
</tr>
<tr>
<td>Slovakia</td>
<td>276,9</td>
<td>125,8</td>
</tr>
<tr>
<td>Romania</td>
<td>224,2</td>
<td>127,1</td>
</tr>
<tr>
<td>Slovenia</td>
<td>296,3</td>
<td>125,4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Country</th>
<th>Health care expenditure (share of GDP)</th>
<th>Oncology care expenditure#</th>
<th>Dynamics of expenditure growth (% growth in health care expenditures 2009-2012)***</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>as % of GDP (2011)*</td>
<td>as % of total health care expenditure</td>
<td>Cost per person (€)</td>
</tr>
<tr>
<td>Poland</td>
<td>6,39</td>
<td>6%</td>
<td>37</td>
</tr>
<tr>
<td>Hungary</td>
<td>7,8</td>
<td>5%</td>
<td>39</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>7,36</td>
<td>5%</td>
<td>57</td>
</tr>
<tr>
<td>Slovakia</td>
<td>7,6</td>
<td>5%</td>
<td>57</td>
</tr>
<tr>
<td>Romania</td>
<td>5,51</td>
<td>6%</td>
<td>20</td>
</tr>
<tr>
<td>Slovenia</td>
<td>8,55</td>
<td>4%</td>
<td>72</td>
</tr>
</tbody>
</table>
Mortality vs expenditures on oncology in CEE countries

According to the current trends, mortality rates are the highest where the oncology care expenditures per capita are generally lower (Hungary, Poland, Romania)

* Mortality includes all cancers excl, non-melanoma skin cancer, age-standardised rates per 100,000, GLOBOCAN (WHO) 2012, IARC – 2.10.2014

** Costs are adjusted for price differentials with the purchasing power parity method
### Central Europe – List of useful public pharmaceutical databases by country

<table>
<thead>
<tr>
<th>Country</th>
<th>Database</th>
<th>Link</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><img src="flag.png" alt="Bulgaria Flag" /> First 4 links (Annex 1-4) include files from the Positive Drug List</td>
<td></td>
</tr>
<tr>
<td>Czech Rep.</td>
<td><img src="flag.png" alt="Czech Flag" /> Czech drug list developed by SUKL</td>
<td><a href="http://www.olecich.cz/">http://www.olecich.cz/</a></td>
</tr>
<tr>
<td></td>
<td><img src="flag.png" alt="Czech Flag" /> Reimbursement amount, indication restriction is included</td>
<td></td>
</tr>
<tr>
<td>Hungary</td>
<td><img src="flag.png" alt="Hungary Flag" /> Public list developed by OEP</td>
<td><a href="http://www.oep.hu/felso_menu/szakmai_oddalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/pupha/Vegleges_PUPHA.html">http://www.oep.hu/felso_menu/szakmai_oddalak/gyogyszer_segedeszkoz_gyogyfurdo_tamogatas/egeszsegugyi_vallalkozasoknak/pupha/Vegleges_PUPHA.html</a></td>
</tr>
<tr>
<td></td>
<td><img src="flag.png" alt="Hungary Flag" /> Ex-factory, wholesale and retail prices are also published</td>
<td></td>
</tr>
<tr>
<td>Poland</td>
<td><img src="flag.png" alt="Poland Flag" /> Polish drug list published by Ministry of Health</td>
<td><a href="http://www.bil.aptek.pl/servlet/specjalista_f/list">http://www.bil.aptek.pl/servlet/specjalista_f/list</a></td>
</tr>
<tr>
<td></td>
<td><img src="flag.png" alt="Poland Flag" /> It includes information about retail prices and reimbursement rates</td>
<td></td>
</tr>
<tr>
<td>Romania</td>
<td><img src="flag.png" alt="Romania Flag" /> Drug list published by CNAS</td>
<td><a href="http://www.cnas.ro/page/lista-medicamente-2016.html">http://www.cnas.ro/page/lista-medicamente-2016.html</a></td>
</tr>
<tr>
<td></td>
<td><img src="flag.png" alt="Romania Flag" /> Ex-factory, wholesale and list prices are published</td>
<td></td>
</tr>
<tr>
<td>Slovakia</td>
<td><img src="flag.png" alt="Slovakia Flag" /> Drug list published by MoH</td>
<td><a href="http://www.health.gov.sk/?zoznamy-uradne-urcenych-cien">http://www.health.gov.sk/?zoznamy-uradne-urcenych-cien</a></td>
</tr>
<tr>
<td></td>
<td><img src="flag.png" alt="Slovakia Flag" /> Ex-factory and list prices are published</td>
<td><a href="http://www.sukl.sk/en/servis/search/searching-on-the-database-of-medicinal-products?page_id=410">http://www.sukl.sk/en/servis/search/searching-on-the-database-of-medicinal-products?page_id=410</a></td>
</tr>
</tbody>
</table>
GDP per capita in V4 countries (2010-2015)

- GDP per capita shows a slightly increasing trend in each country.
- Czech Republic has the highest values (15,000 € on average), while Poland and Hungary stay together on the bottom of the figure (10,000-10,300 € on average).

Source: Central Statistical Offices
Health care expenditure as a share of GDP in V4 countries

- Health care expenditure as a share of GDP has been decreasing in all of the V4 countries, except Czech Republic.
- The ratio of private expenditures is outstanding in Hungary (33% on average).

Source: OECD data
A comparison of total net public pharmaceutical expenditure (PPE) across V4 countries shows that expenditures are highest in Poland and lowest in Slovakia and Hungary.

Part of the difference is due to differences in population size: Poland has approx. 40 million inhabitants, while Slovakia has only approx. 5.5 million.

Another part of the difference is more closely related to country policies: although restrictive tools have been applied in both Czech Republic and Hungary, in Czech Rep. the level of expenditures is still higher (+60%) than in Hungary, which is a country with a similar population size.

*In case of Slovakia, longitudinal data about national tendering are not available.

Source: own calculation
If we compare net PPE as a share of GDP, the patterns are similar to that of the per capita analysis:

1. Slovakia (1.55% of GDP on average, total 0% increase during period)
2. Czech Republic (1.26% of GDP on average, total 0% increase during period)
3. Hungary (1.18% of GDP on average, total -0.21% decrease during period)
4. Poland (0.74% of GDP on average, total 0.11% increase during period)

In this analysis, the decrease in Hungarian PPE becomes even more conspicuous. While in Poland, who has the lowest expenditures (both per capita and as a share of GDP), a 0.11% increase can be observed.

*In case of Slovakia, longitudinal data about national tendering are not available.

Source: own calculation
Interpretation, use and collection of health and health economics data
Case discussion – Selling ideas based on regional data

Imagine the following situation:

- You are the head of the leading patient organization in an imaginary average CEE country.
- The country’s all relevant indicators are the average of the CEE countries.
- You accidentally bump into the chairperson of Council for National Medical Schemes (CMS) at a conference. He is responsible for major health politics decisions in the country, and has influence on budgeting issues as well.
- You feel you have a unique opportunity to position health care spending as the most valuable spending using regional data. At the same time, you can’t expect to have more than 1-2 minutes to discuss.
- Of course you want to use this opportunity to make the way for better fiscal parameters for health care and pharmaceuticals.

Prepare for such a scenario.

- You have 10 minutes to prepare for a maximum 2-min chat with the chairperson about health care in general, and oncology/haematology in specifics.
- Try to come up with an interesting and concise story which minimizes the risk of being interrupted or asked.
OUTLOOK ON INTERNATIONAL HEALTH CARE SYSTEMS
Complex system of health quality and safety indicators – the example of New Zealand – a potential best practice

Overview of HTA systems in some European countries

- **Economic evaluation**: UK, Poland, Czech Republic, Hungary, Slovakia, Bulgaria
- **Qualitative assessment without CEA**: France*, Germany
- **Qualitative assessment with complementary CEA in the negotiation process**: Italy, Spain
- **Balanced assessment**: Sweden, Netherlands
- **Checklist-based assessment**: Romania

* Limited cost-effectiveness analyses applied for innovative drugs (indications) claiming high AMSR-rating and high budget impact
Overview of reimbursement submission process

- There is a **formal HTA process** in Poland
- The responsible body for HTA is the **Agency for Health Technology Assessment and Tariff System (AOTMiT)**
- The **AOTMiT recommendation is not binding to the MoH**, the product can be still refused or receive reimbursement
- **National guideline for HTA is in place**

MAH: marketing authorization holder. MoH: Ministry of Health. AOTMiT: Agency for Health Technology Assessment and Tariff System
Overview of reimbursement submission process

- There is a **formal HTA process** in Czech Republic
- The responsible body for HTA is the **State Institute for Drug Control** (SUKL)
- **SUKL is not an independent body**, it belongs to the Ministry of Health
- In case of positive recommendation, the product can still end up without reimbursement, if the sick funds (7 in total) appeal against the proposal of SUKL and the Ministry of Health accepts the argumentation
- Similarly, MAH can also appeal against a negative decision
- **National guideline for HTA is in place**

*SUKL: State Institute for Drug Control*
The HTA process is formal in Slovakia but **there is no dedicated agency to evaluate the submissions**

- The responsible body for HTA is the **Pharmacoeconomic Working Group**, who belongs to the Ministry of Health and is an advisory body to the Reimbursement Committee (within the Ministry of Health)
- The members of the working group are employees of other independent institutions (e.g. health insurance companies or university)
- In case of a negative decision, MAH has a possibility to submit objections against the decision
- **National guideline for HTA is in place**
Overview of reimbursement submission process

- Submission of application, formal control: NHIF

  - Drug evaluation: NIPN
  - Price negotiations: NHIF
  - Determination of reimbursement rate: NHIF

Decision about reimbursement and its publication: NHIF, but legislative amendment may be necessary

**NHIF**: National Health Insurance Fund, **NIPN**: National Institute of Pharmacy and Nutrition

- There is a formal HTA process in Hungary with a dedicated HTA agency
- The responsible body for HTA is the Department of Health Technology Assessment which belongs to the National Institute of Pharmacy and Nutrition
- The recommendation of the HTA body and the NHIF is not binding to the Ministry of Health/Ministry of Finance → the product can be still refused or reimbursed
- National guideline for HTA is in place (currently under revision)
Overview of reimbursement submission process

- Submission of pricing dossier and getting price approval
  JAZMP

- Reimbursement file submission
  HIIS

- Drug evaluation and recommendations
  Drug Reimbursement Committee

- Final reimbursement decision
  HIIS

- Price negotiations
  HIIS

- Drug is added to the reimbursement list
  HIIS

JAZMP: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, HIIS: Health Insurance Institute of Slovenia

- In Slovenia, currently there is no independent body to assess the findings of reimbursement submissions from a methodological aspect
- The entire reimbursement process should be completed within 180 days for new pharmaceuticals. But for innovative products only price approval and Reimbursement Committee approval is completed within this time range.
- The time period necessary for net price negotiations is completely unpredictable
Overview of reimbursement submission process

- **CHIF Drug Reimbursement Committee consists of 13 specialists covering different areas.** If they cannot reach a consensus, an advice is asked from professional societies and/or HTA agency (due to lack of trained staff, HTA agency can take only a limited number of evaluations, and deliver an opinion in time. In practice, the key activity of the Agency is accreditation and quality control of hospitals and there is hardly any activity in the area of HTA.)

- **The real length of the procedure: one year**

- **In some cases the drug may be included in a separate list for extremely expensive drugs (regulated by legislation).** The application procedure is the same. In the application MAH needs to state that the drug is a candidate for this list of expensive drugs, with clear guidelines for its use, and a signed risk-sharing contract.
Overview of reimbursement submission process

- Submission of pricing dossier and getting price approval
  - MoH

- Reimbursement file submission as an orphan drug for a rare disease without any other therapy
  - NAMMD

- Negotiations with a Committee for a MEA agreement (only if necessary)

- Reimbursement List update
  - MoH, NHIH, MoF

- Approval and inclusion in the treatment protocol
  - MoH, NHIH

MoH: Ministry of Health; NAMMD: National Agency for Medicines and Medical Devices; NHIH: National Health Insurance House

- HTA process is formal in Romania as well
- The responsible body for HTA is the Health Technology Assessment Department at National Drug Agency which belongs to the Ministry of Health
- The evaluation of the submissions is based on a scoring system
- There are 2 types of positive recommendations: unconditional reimbursement (min. 80 points), meaning that the product is automatically reimbursed, and conditional reimbursement (between 60-79 points), meaning that the reimbursement is conditioned by closing a cost-volume or cost-volume result contracts.
- In case of negative decision, the MAH can appeal against the decision by providing additional information
- National guideline for HTA is in place
Overview of reimbursement submission process

- In Bulgaria, there is a new HTA system in place.
- From this year there is a separate authority - HTA Committee which first evaluates the HTA of the new product. It is independent from NHIF.
- The reimbursement status is re-evaluated in every 3 years.
Outlook on international health care systems
Case discussion – Selling ideas based on regional system settings

Imagine the following situation:

- You are the head of the leading patient organization in an imaginary average CEE country.
- The country is planning to implement a new drug evaluation system, which is based on hard health economic evaluation and declared ICER.
- You accidentally bump into the chairperson of Medical Committee of the National parliament at a conference. He is responsible for major health politics decisions in the country, and has influence on shaping the legal environment.
- You feel you have a unique opportunity to argue that ICER-based decision making is not appropriate for oncology and haematology. At the same time, you can’t expect to have more than 1-2 minutes to discuss.
- Of course you want to use this opportunity to block the way for implementing the new system.

Prepare for such a scenario.

- You have 10 minutes to prepare for a maximum 2-min chat with the chairperson about health care in general, and oncology/haematology in specifics.
- Try to come up with an interesting and concise story which minimizes the risk of being interrupted or asked.
REIMBURSEMENT POLICY AND HEALTH TECHNOLOGY ASSESSMENT
Terminology clarified: public funding, public financing, subsidies, reimbursement

Public funding, public financing, subsidies and reimbursement are all used to refer to the financing of pharmaceutical care from public funds.

**Reimbursement** and **subsidies** both refer to any funds provided to patients by public or private payers in order to cover the price of medicines in full or in part.

It is appropriate to use these words when patients buy the medicine, i.e. for pharmacy drugs.

*literally means 'back to the purse' or 'back to the pocket'*

**Public funding** and **public financing** both refer to any funds used by public payers to purchase pharmaceuticals or reimburse them for patients.

These words have a wider meaning as they cover purchasing of medicines by public payers. At the same time, it is not really appropriate to use these words in the context of private health insurance companies.
Payers need to provide funding for pharmaceuticals to make them affordable for patients (1)

Monthly therapeutic cost of pharmaceutical therapies (INNs) in an upper middle income country (Hungary)

Whether on-patent or generic, chronic therapies pose a continuous financial burden on patients which they would not be able or willing to afford without public funding / reimbursement.

Source: Hungarian National Health Insurance Fund Administration (OEP), www.oep.hu
Payers need to provide funding for pharmaceuticals to make them affordable for patients (2)

The per-patient cost of bringing an innovative pharmaceutical product to the market exceeds the ability to pay of most individuals.

Reimbursement policy means the set of tools to manage public pharmaceutical expenditure

Principles and policy measures by which payers and policymakers influence pharmaceutical expenditure and the way the funding / reimbursement system works
Reimbursement policy originates in the requirement of sustainability

- Limited resources available for health care financing
- „Supply-induced demand“ in pharmaceutical markets*
- Soaring R&D costs of innovative medicines
- High generic margins in some geographies
- Elusive prices of medicines**
- Customer role split into 3 parts: prescriber, consumer, payer

* Payers cannot afford to purchase all new drugs for all patients. They need to make choices and compromises based on prioritization and scientific evidence.
* Payers need to assess and understand the value of medicines, manage prices in on-patent markets and foster competition in off-patent markets.
* Payers need to be mindful of costs as the other two customers are not.

* Supply-induced demand means in the economics of health care that a newly available health technology will generate a demand that leads to its over-utilisation. This is because information asymmetry on patients’ (and physicians’) side leads to excessive value attributions to new technologies. ** ‘Elusive price’ is a term used to refer to the difficulties of capturing the ‘real’ value of a new medical technology.
In the case of publicly funded prescription medicines, the one who pays is not the one who prescribes or consumes.

<table>
<thead>
<tr>
<th></th>
<th>Treating physician</th>
<th>Patient</th>
<th>Payer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decides about the consumption?</td>
<td>YES</td>
<td>NO</td>
<td>NO</td>
</tr>
<tr>
<td>Makes the consumption?</td>
<td>NO</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Pays for the consumption?</td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
</tbody>
</table>

As both the physician and the patient are insensitive to expenditures, the payer needs to implement techniques of price and volume control.

*Source: own compilation*
Reimbursement policy is based on three pillars: price control, volume control and reimbursement (co-payment) regulation

S = P * Q

SPENDING
(public pharmaceutical expenditure)

PRICES

LIST PRICES
List prices are public and they can be affected by various regulations such as price cuts, referencing and HTA assessments.

NET PAYER PRICES
Net prices are usually confidential and they are a result of rebates, discounts and managed entry agreements.

VOLUMES

TOTAL VOLUMES
This type of control aims at preventing any irrational use of medicines by measures that curb supply-induced demand.

PRODUCT MIX
This type of volume control aims at pushing consumption towards lower-priced medicines via generic promotion techniques.

REIMBURSEMENT & CO-PAYMENT
Payers regulate the amount of funding / subsidy they provide to each drug. The remaining part will be co-payment for the patient.

Source: own compilation
Different control tools target different stakeholders

(1) By applying differentiated or regressive fees in hospital payments, payers can simulate reimbursement & co-payment regulation in the hospital segment as well.
Reimbursement cycle: Effective generic policies and managed entry agreements release funds for new therapies

1. Admit new value-added therapies into the formulary based on value assessment
2. Apply managed entry agreements to ensure optimal allocation of available resources
3. Revise public funding based on real-world effectiveness and cost-effectiveness
4. After patient expiry, provide easy and quick access to generic medicines
5. Ensure strong generic price competition
6. Eliminate inefficiencies in expenditure by identifying sustainable cost saving potentials

Outlook: reimbursement policy connects to other areas of health care and pharmaceutical policy
Health technology assessment is a multi-disciplinary activity for the evaluation of new health technologies

Health technology assessment (HTA) covers all methods for

- the systematic evaluation of the comparative value of pharmaceutical products and other health technologies *
- linked to pricing & reimbursement decisions by public and private payers
- preceding to admission to the formulary and during formulary management.

* Mostly: medical devices, diagnostic tests, surgical interventions, vaccination and other public health programmes
HTA provides decision-support to reimbursement policy

Being linked to health policy, HTA is always embedded in the political context of health care decisions.

HTA is usually embedded into a complex decision process which is not independent from political stakeholders and influencers.

* NHS – National Health Service, HI – Health Insurance
HTA potentially means significant improvement in terms of efficiency, transparency and accountability...

**Pre-HTA health care systems**

- Intransparent and/or arbitrary pricing & reimbursement decisions
- Low efficiency and therefore high opportunity costs
- Limited accountability of decision-makers
- Few formally set procedural deadlines for pricing & reimbursement decisions
- No or few rules for accessibility and traceability of information
- Low level of standardization of pricing & reimbursement submissions (dossiers)

**Health care systems using HTA**

- Chance to minimize opportunity costs
- Chance to link pricing & reimbursement decisions to objective criteria
- Chance to assign institutional and individual responsibilities, deadlines during the pricing & reimbursement process
- Requirement for standardized pricing & reimbursement submissions
- Chance to make part of decision-related information publicly available
... but HTA policy objectives are often not translated properly into actual HTA systems

Main HTA policy objectives

- Provide support to health care decision makers to make their decisions better
- Understand the added clinical benefit and the added cost of new health technologies
- Increase allocative efficiency in public funding systems which are characterized by scarce resources
- Increase transparency and accountability in health care decision-making

Common system failures

- Irrelevant information (l’art pour l’art HTA)
- Information overload
- Pseudo-objectivity: HTA models and assessments represent imaginary health care contexts due to data gaps
- Delay in access to health technologies (HTA as legitimation to postpone decisions or block technologies)
- Parallel access systems
- Reinforcement of fiscal mindset: budget impact as key decision driver
- High running costs of HTA institutions

Source: adapted from Dankó D (2016): Pragmatic value assessment approaches for countries newly implementing HTA. HTAi Annual Meeting, Tokyo, 14/05/2016
Successful HTA systems follow clear policy objectives, take into consideration the institutional context and are properly implemented.

1. CLEAR POLICY OBJECTIVES
2. CONTEXT-BASED DESIGN
3. PROPER IMPLEMENTATION

Beware: poor or failed implementation can discredit good concepts for a long time.
Policymakers need to decide on HTA approach, perspective of assessment, timing of assessment and technology scope

<table>
<thead>
<tr>
<th>Column</th>
<th>HTA APPROACH</th>
<th>PERSPECTIVE OF ASSESSMENT</th>
<th>TIMING OF ASSESSMENT</th>
<th>TECHNOLOGY SCOPE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Economic evaluation</td>
<td>Comparative assessment</td>
<td>Balanced / multi-criteria assessment</td>
<td>Medicines only</td>
</tr>
<tr>
<td>B</td>
<td>Budget holder’s perspective</td>
<td>Societal perspective</td>
<td>Combined analysis (budget holder + societal perspectives)</td>
<td>Proprietary health care interventions</td>
</tr>
<tr>
<td>C</td>
<td>Linked to pricing &amp; reimbursement decision (admission to the formulary)</td>
<td>Linked to formulary (price / reimbursement) reviews</td>
<td></td>
<td>All types of health care interventions</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Choice of approach: we can assess the value of medicines through calculation or categorization or the combination of these

**Calculate**

We can try to quantify *cost-effectiveness and budget impact* by gathering and measuring health benefits and costs.

**Categorize**

We can try to describe the added value of medicines along relevant dimensions (‘sources of value’) and based on this we can classify / rank them.

**Combine**

We can try to combine the previous two approaches to capitalize on their respective strengths while mitigating their weaknesses.
Choice of approach more formally: there are three main paradigms of HTA

**ECONOMIC EVALUATION**
- Builds on health economics and modeling (CUA, CMA, CEA)
- Dossiers and models assessed by an HTA agency
- Key metrics: ICER, budget impact
- ICER threshold to define and judge cost-effectiveness
- Archetype: United Kingdom
- Other markets with cost-effectiveness analysis: South Korea, Thailand, Brazil, Turkey, Poland, Hungary

**COMPARATIVE ASSESSMENT**
- Assesses added clinical benefit against comparator (possibly including some ethical considerations)
- Economic metrics are typically not used as part of HTA / value assessment (but they may be used separately, linked to price negotiations)
- Builds on expert judgment and deliberative decision-making
- Commonly uses value categories and sometimes categorization
- Archetype: France, Italy, Japan
- Emerging market examples: Algeria, Taiwan

**BALANCED / MULTI-CRITERIA ASSESSMENT**
- Multi-criteria analyses, integrating economic evaluation and comparative assessment
- Economic metrics used as inputs to multi-criteria analysis
- Deliberative decision-making, traceability and public accountability of decisions
- Checklists or full-scale models (multi-criteria decision analysis - MCDA)
- Archetype: Canada, Australia
- Other markets: ongoing initiatives in Eastern Europe (Serbia, Slovakia)

### The perspective of analysis can fundamentally influence HTA outcomes

<table>
<thead>
<tr>
<th>Budget holder’s perspective</th>
<th>Societal perspective</th>
<th>Combined analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Costs and benefits are considered only if they are incurred by the payer (budget holder)</td>
<td>Costs and benefits are considered from the whole society’s perspective</td>
<td>Costs and benefits are considered from the payer’s perspective, but wider societal impacts are explicitly included in the assessment</td>
</tr>
<tr>
<td>Indirect costs are usually not considered in the analysis</td>
<td>Fair and insightful approach but may be questioned by the payer who is responsible for public pharmaceutical expenditure</td>
<td>Typically, health care related costs and benefits as well as social benefits (e.g. unemployment benefit, early pensions) are analysed</td>
</tr>
<tr>
<td>Silo-based calculations are fairly common (e.g. drug costs, outpatient costs, hospitalization costs)</td>
<td>Scoping of relevant costs and benefits can be difficult, calculations for indirect costs can be highly probabilistic</td>
<td></td>
</tr>
</tbody>
</table>

In a public funding context, **combined analysis** is arguably the best approach if available competences and resources enable it.
HTA can be used before and after pricing & reimbursement decisions

- **HTA applied to one health technology**
  - Single technology assessment (STA) triggered by manufacturer submission
  - Recommendation is issued for the technology undergoing assessment

- **HTA applied to more health technologies**
  - X
  - Recommendation covers to class of medicines / indication / therapy area / treatment sequence etc.

### Pricing & reimbursement decision (admission to the formulary)
- Single technology assessment (STA) triggered by manufacturer submission

### Formulary (price / reimbursement) review
- Single technology review (STR)
- Multiple technology assessment / review (MTR/MTA)
**HTA programmes usually start with the assessment of medicines and are later expanded to cover other health technologies**

<table>
<thead>
<tr>
<th>Definition</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MEDICINES</strong></td>
<td><strong>HTA only covers medicines, usually including vaccines</strong></td>
</tr>
<tr>
<td></td>
<td><strong>On-patent medicines, biosimilars and non-bioequivalent generics are subject to full assessment with customized methodologies</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Bioequivalent generics are not subject to HTA</strong></td>
</tr>
<tr>
<td><strong>PROPRIETARY HEALTH CARE INTERVENTIONS</strong></td>
<td><strong>Rational approach with important risks related to long time horizons, less robust methodologies and the need to consider technology aspects</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Pharmaceutical assessment methods are only partly transferable to other types of technology</strong></td>
</tr>
<tr>
<td><strong>ALL HEALTH CARE INTERVENTIONS</strong></td>
<td><strong>Comprehensive approach with very significant implementation risks because of huge resource need, scarce methodologies) and long time horizons (with much sensitivity to analysis parameters)</strong></td>
</tr>
</tbody>
</table>

**Comments**

- Can be a good starting point as evidence is usually available, robust methodologies exist, technology aspects are less relevant, time horizons are manageable, intellectual property rights are well-defined
- Minimizes the chances of failure related to „grabbing too much”

**Logical First Step**

**Reasonable Degree of Standardization with Evidence Gaps**

**Possibly Serious Evidence Gaps and Uncertainties**
In a HTA system, the process is as important as the method

1. Submission and technical inspection of reimbursement dossier
2. HTA / Value assessment
   - Report
3. 1st appraisal in Pricing & Reimbursement Committee: decision on reimbursability
   - MEA request to pharma company
4. 2nd appraisal in Pricing & Reimbursement Committee: hearing of pharma company, MEA discussion, decision on reimbursement
   - Assessment Summary
5. Inclusion in reimbursement list
6. Publication of decision

Assessment by HTA / Value Assessment Body

Assessment

EXAMPLE

Appraisal and Decision by Pricing & Reimbursement Committee
The purpose of managed entry agreements is to manage uncertainties and/or to mitigate budget impact.

- Contract between budget holder and pharmaceutical company...
- ...aimed at managing uncertainties related to new medicines...
- ...because of gaps in evidence at the time of listing decision...
- ...based on a standard process...
- ...stipulating confidential discounts or...
- ...adjustments to price or coverage in case of real-world underperformance.

Source: own compilation
Managed entry agreements (MEA’s) are contracts, governed by the Civil Code and industry-specific regulations.

**Budget Holder** (payer / institution)

**Pharmaceutical Company** (supplier)

**Civil Code**

**Pharma Law**

Source: own compilation
Managed entry agreements can be of three major types

- **Cost-sharing schemes (CSS)**
  - Discount or rebate schemes without any uncertainty involved

- **Risk-sharing schemes (RSS)**
  - Management of clinical, health economic or budget-related uncertainty

- **Affordability schemes**
  - Distribution of payer budget burden across several periods and/or
  - Engagement of alternative sources of funding

*Source: own compilation*
### A simple matrix typology of managed entry agreements

<table>
<thead>
<tr>
<th>Financial agreements</th>
<th>Performance-based agreements</th>
<th>Affordability schemes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population level schemes</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flat discounts*</td>
<td>Population-level outcome guarantee</td>
<td>Population-level deferred payment schemes</td>
</tr>
<tr>
<td>Tiered discounts / rebates*</td>
<td>Coverage with evidence development</td>
<td></td>
</tr>
<tr>
<td>Patient number caps / Budget caps</td>
<td>Population-level adherence guarantee</td>
<td></td>
</tr>
<tr>
<td>Fixed price-volume contracts</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| **Patient level schemes** |                          |                        |
| Cycle capping             | Reimbursement for responder patients only | Deferred payment schemes based on patient registries |
| Free initiating cycles    | Money back guarantee for non-responders** |                          |
| Dose capping              | Pre-initiation companion diagnostics*** |                          |

* Purely cost-sharing agreements (no uncertainty element included), ** may take the form of payback, free packs or credit notes, *** at the pharma company’s cost

Source: own illustration
Risk-sharing: some major uncertainties related to new medicinal therapies from the payer’s perspective

<table>
<thead>
<tr>
<th>CLINICAL UNCERTAINTIES</th>
<th>HEALTH ECONOMIC UNCERTAINTIES</th>
<th>POPULATION-RELATED UNCERTAINTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Real-life effectiveness falls behind clinical efficacy</td>
<td>• Therapy duration is longer than expected</td>
<td>• Number of patients enrolled into therapy is higher than expected</td>
</tr>
<tr>
<td>• Clinical benefit differs across patient subgroups</td>
<td>• Average dose is higher than expected</td>
<td></td>
</tr>
<tr>
<td>• Clinical benefit is limited by patient behaviour (mainly: adherence to treatment)</td>
<td>• Cost-effectiveness deteriorates by changes in comparator or price structures</td>
<td>• Higher utilization of the new medicine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Higher reimbursement outflow (public expenditure)</td>
</tr>
</tbody>
</table>

Risk-sharing schemes can often address more types of interrelated uncertainties.

Source: Dankó – Molnár (2013, modified)
Population-level financial schemes – examples for tiered discount agreements

Example 1: progressive discount scheme

The pharmaceutical company offers 10% discount on every pack sold with reimbursement up to 1,000 packs. The discount increases to 15% per pack for each unit sold above 1,000 packs.

Example 2: conditional rebate

The pharmaceutical company offers 10% rebate on every pack sold, retrospectively and prospectively, as soon as the purchased volume reaches 1,000 packs.
Patient-level financial schemes – the difference between cycle capping and free initiating cycles

**CYCLE CAPPING**

<table>
<thead>
<tr>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payer</td>
<td>Manufacturer</td>
<td></td>
</tr>
</tbody>
</table>

Cycle capping may be cost-sharing (if the number of cycles is pre-defined) or risk-sharing when it is linked to the effectiveness of the therapy.

**FREE INITIATING CYCLES**

<table>
<thead>
<tr>
<th>Cycle 1</th>
<th>Cycle 2</th>
<th>Cycle n</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturer</td>
<td>Payer</td>
<td></td>
</tr>
</tbody>
</table>
Patient-level performance-based schemes – Simplified process for a hospital product with evidence development

- Manufacturer
- Payer
- Hospital/pharmacy
- Patient

Flow diagram:
- Manufacturer pays Original pricing & reimbursement decision reinforced
- Invoice
- Product delivery
- Clinical review
- Data reporting
- Dispensing
- NEGATIVE
- Manufacturer pays
- POSITIVE
- Original pricing & reimbursement decision reinforced
**Stakeholder benefits and hurdles related to managed entry agreements**

### PAYER

- Innovative therapies become accessible without delay, thus reaching political / societal objectives
- Budget impact will be plannable and manageable
- In some agreements, real-world evidence will be generated

### PHARMA COMPANY

- Marketing and sales of innovative medicines can start without delay
- Strategic / international pricing considerations can be ensured via confidential agreements
- Stepwise launch approaches will become possible
- MEA’s may offer an opportunity for expert-level co-operation with payers

### PATIENTS / SOCIETY

- Sustained access to innovative therapies becomes quicker (as opposed to no access or highly bureaucratic individual approvals)
- MEA’s may increase general allocative efficiency in the reimbursement / public funding system, which means that there will be budget for more therapies

### BENEFITS

- For more complex schemes, transactional and monitoring costs may become high
- Data availability may be limited
- Further re-assessment and changes in reimbursement may become limited
- There may be a trade-off between the ‘fairness’ of a scheme and its potential for budget mitigation

### HURDLES

- For more complex schemes, transactional and monitoring costs may become high
- Data availability and IT factors may limit the viability of certain schemes
- Some schemes may pose significant admin burden on treating physicians
- First movers may be faced with free-rider effects from competitors
- MEA’s may become institutionalized and mandatory

### Source:

Dankó – Molnár (2013), amended
Possible links between managed entry agreements to health technology assessment (HTA)

- **Economic evaluation**
  - In some countries (e.g. UK, Poland, Slovakia) managed entry agreements are used to improve the incremental cost-effectiveness ratio (ICER) of the new medicine by decreasing costs from a payer perspective.
  - Managed entry agreements are widely used to mitigate the budget impact of a new medicine.

- **Comparative assessment & Balanced assessment**
  - In some countries using comparative / qualitative assessment (e.g. France, Italy), MEA’s are used to mitigate the budget impact of a new medicine in function of its therapeutic value added.
  - In some cases (e.g. Italy, Spain), MEA’s are used as confidential discount techniques.

Source: own compilation
Managed entry agreements can be embedded into the HTA process

- MEA’s can be incorporated into the pricing & reimbursement decision-process
- MEA discussions always follow economic & clinical assessment and are based on the results of this assessment
International experience with managed entry agreements

Selected examples

Population-level schemes

Financial schemes

Performance-based schemes

Patient-level schemes

Financial schemes are more commonly population-level approaches.

Source: Ferrario A. – Kanavos P. (2013), modified
In Czech Republic, risk-sharing schemes (RSS) are not embedded in legislation. Instead, they are subject of individual and confidential negotiation among MAH’s and payers (VZP = general health insurance, SZP = association of 6 smaller insurance companies). There are no restrictions/recommendations for RSS. Risk-sharing schemes are seen as cost containment tools: proven cost-effectiveness does not prevent the application of different caps if budget impact is significant.

Mostly used techniques:

- Financial agreements (paybacks, discounts → not real RSS)
- Performance-based RSS (e.g. payment for responders)
- Combined contracts

Source: own analysis
Poland

- Risk-sharing schemes are **confidential** in Poland therefore there is **no precise data available**
- **Financial agreements are quite common for new drugs** and uncommon for established drugs
- At the same time, cost- and risk-sharing contracts may be accepted by payers to **avoid reference pricing**
- **Patient number caps per period** are common for drugs reimbursed in drug programmes (oncology, rheumatology, haematology)
  - In most cases the cap is rigid, it does not allow flexibility if circumstances change
- **Portfolio agreements** are applied for almost all new drug programs, some chemotherapy and about 20-30% of new entrant products in outpatient care
- **Free of charge initiating cycles** were used before 2012, mainly in rheumatology
- **Cycle capping and outcome-based schemes** (e.g. reimbursement for responders only) are rather uncommon

Source: own analysis
Slovakia

- Cost- and risk sharing contracts are **usually agreed for drugs not included in the central reimbursement list** → via these schemes patients gain some access to innovative but expensive medicines.

- **No official information available** about exact conditions of agreement between manufacturers and payers (insurance companies).

- **Insurance companies prefer simple contract-based rebates and patient number caps** because they do not have resources to monitor complicated schemes.

- In the case of expensive medicines (e.g. oncology drugs), patient number caps follow a **yearly basis**.

- There is only one example of **published 'innovative' agreement** related to **Multaq (dronedarone)** but it is no longer in force: if Multaq budget cap was exceeded during FY 2011-2012, MAH undertook to decrease other drug prices in order to compensate additional expenditures (→ **PPRS connotation**).

- **Conditional reimbursement** is also available officially by MoH but currently there is only one example (prostate cancer).

- **Free of charge initiating cycles**: only for one innovative drug.

- For drugs not included in reimbursement list, **biomarker-linked reimbursement** is possible at the company's cost.

- Reference pricing rules cannot be circumvented by cost/risk sharing contracts.

**Source:** own analysis
Applicable types of risk-sharing schemes are **defined by regulation** (Law 298/2006) and a **list** of existing agreements is available on the sick fund website (MAH, brand, contract type).

Agreement details are **confidential** (incl. details on combined or portfolio contracts).

Cost / risk sharing is **mandatory for all new INN’s and indications** in order to decrease financial burden of the payer.

In **outpatient care, simple financial agreements** are preferred between payer and MAH (several caps):

- Until 2011, multi-tier schemes were common, now payback is typically 100% above the cap.
- Caps are usually monetized, i.e. patient numbers are converted into reimbursement outflow.
- Advance payment may be required with annual closing of accounts and financial settlement.

**Outcome-based elements** are incorporated into **itemized hospital payments** and individual patient applications.

**Particularities:**

- Patient motivation (reimbursement of adherent patients): a type of conditional reimbursement came into force for insulin analogues in 2012: if the patient is non-adherent, and this lowers the real-life effectiveness of treatment, reimbursement will decrease from 100% to 50% or the patient has the option to switch back to conventional human insulin therapy at 100% reimbursement.
- Population-level schemes (for LMWH and oral anticoagulation therapies): experiment in 2009-2010 to define outcome-linked payback based on aggregated payer databases.

**Source:** own analysis
ROLE-PLAY
Four common payer personality types

<table>
<thead>
<tr>
<th>KEYWORD</th>
<th>GOAL /MOTIVATION</th>
<th>TYPICAL BEHAVIOUR</th>
</tr>
</thead>
</table>
| Political Bureaucrat | • Switch into politics  
• Maximise political support or votes  
• Get sellable ideas                                                               | • Mostly socialized in state bureaucracy  
• Knows bureaucratic processes but has weak business understanding  
• Ready to liaise and small-talk, egocentric                                       |
| Technical Bureaucrat | • Keep the job  
• Avoid all conflicts & risks  
• Follow all legal rules                                                          | • Socialized in state bureaucracy  
• Avoids personal contacts as these may increase vulnerability  
• No regulation means risk (not opportunity)                                       |
| Scientist           | • Reach conceptual clarity  
• Ensure evidence-based decision-making  
• Professional dialogue                                                              | • Often has university / research background  
• Appreciates academic concepts, but performs low on pragmatic problem-solving  
• Process is more important than decision                                             |
| Sourcing Guy        | • Pride in every cent saved  
• Economise on time  
• Maximum pragmatism inside bureaucracy                                             | • Prefers quick pragmatic solutions  
• Dislikes small-talk and l’art pour l’art meetings  
• Likely has an understanding of business                                            |
What to say, what not to say? (1) – Political bureaucrats and technical bureaucrats

**Political bureaucrat**
- Ask for timeframe, plan accordingly
- Find cosier environment for (informal) discussion (e.g. café, restaurant)
- Align your messages with public messages, formulate simple messages
- Think in quick wins, political cycles
- Play on ego, vanity, self-esteem, then switch to your subject
- Use “PR-words”

**Technical bureaucrat**
- Ask for timeframe, plan accordingly
- Use formal office locations
- Send short, technical pre-reading (problem analysis OK, detailed proposal not OK!)
- Keep your messages very simple
- Insist on written statements
- Use legal references, show that there are no legal difficulties
- Always respect formal processes

**DON’T SAY / DON’T DO**
- Propose academic or complicated concepts with long-term return
- Use technical argumentation
- Use marketing speech or argumentation
- Use too many numbers
- Spend much time on process details (instead concentrate on outcomes)
- Send any pre-reading
- Seem cynical about politicians / politics

- Refer to Mr X (name-drop)
- Create a situation where the decision-makers feels responsibility or work burden
- Ask about personal preferences, opinion
- Push for an imminent deal
- Use uncertain statements („maybe”, „we have to see”, „I can’t assure you”) 
- Use „emotion-words”
- Be ironical, cynical or critical about bureaucratic decision-making
What to say, what not to say? (2) – Scientists and sourcing guys

**SAY / DO**
- Define topic clearly and manage the whole negotiation (to keep focus)
- Use office as location for negotiations
- Provide latest academic update, refer to up-to-date guidelines, pre-reading
- Ask frequently about preferences, include regular wrap-ups
- Stress advantages to patients, society, ethical considerations
- Carefully show more alternatives
- „Use evidence-words”

**DON’T SAY / DON’T DO**
- Indulge in long introduction and small-talk
- Propose out-of-office meeting locations (other than scientific venues)
- Use marketing argumentation instead of clinical argumentation
- Simplify or distort academic evidence
- Use „emotion words”

**Scientist**
- Use straightforward negotiation style
- Use office as location for negotiations
- Structure your arguments / talk
- Use „fact-words”
- Clearly refer to financials (budget impact, savings, financial offer)
- Propose clear deal and solution, playing on mutual interest
- Be smart, circumventing bureaucracy

**Sourcing guy**
- Indulge in small talk
- Ask about personal opinion
- Use „emotion words” and expressions which reveal uncertainties, weak points
- Refer to unmet need, media and social pressure, supporting innovation
- Over-emphasize clinical value
- Spend time on scientific models or fill your presentation with academic data
- Send long or academic pre-reading
Role-play I.

- We are in Baltavia that is a middle-income member country of the European Union (EU) with approx. 6.0 million inhabitants. The country is organized into 4 regions and the capital city. The regions are subdivided into counties. The population has been on a slow decrease for a decade because of low birth rates and high emigration in the 20-30y age group, and ageing is becoming a major concern for government. Rural population still constitutes a considerable part (35.0%) of the nation’s total population.

- Baltavia’s economic performance was characterized by fast growth in the 90’s, followed by an export-related crisis in 2006-2007 when the economy plummeted by 5.4%. Since 2008, GDP has grown at a minimal rate above zero. This stagnation prevents governments from increasing public spending on health care. In fact, public health expenditures have accounted for 7.4-8.1 per cent of GDP over the past years, with severe budget cuts.

- Baltavian health care is organized into primary care provided by general practitioners (GP’s), community health care units (HCU’S) which provide ambulatory services in towns and cities, county hospitals with limited acute services, regional hospitals with comprehensive services, and national clinics specialized in different medical professions. GP’s have a gatekeeper role: it is mostly them who refer patients to hospitals and national clinics. Almost all health care providers are state-owned. Political parties generally agree that health care is a subsystem of the state, and almost all prominent political figures are against privatization of health service providers.

- Health care funding is ensured through mandatory health insurance. There are three sick funds which together cover the whole population: the first one provides coverage for state employees (including civil servants and everyone working in public sector jobs), the second one caters for inactive people (including pensioners, students and the unemployed), and the third one includes everyone else, i.e. mostly private sector employees. Sick funds work independently from each other but there are centralized procedures for listing new technologies (drugs, surgical procedures, currently also medical devices) into reimbursement as well as setting reimbursement rules and conditions. These tasks are carried out by the Reimbursement Committee jointly run by the Ministry of Health and the Ministry of National Wealth.

- The Reimbursement Commission has 7 members: 2-2 representatives of the ministries, and 1-1-1 representative from the three sick funds. Physician and patient organizations are regularly consulted, but the Reimbursement Commission is not obliged to follow their opinions when taking its decisions. The Reimbursement Commission is assisted by the Bureau for Medical Technology Evaluation, which is a satellite entity of the Ministry of Health and performs, as required by law, an economic and clinical assessment of health technologies. Its role is mostly technical but a negative recommendation from the Bureau makes it unlikely that the technology will be admitted to reimbursement. There are no formal protocols that govern the functioning of the Bureau, although law requires that recommendations should be issued within 60 days of the receipt of the dossier. There is no such regulation for the Reimbursement Commission itself, which in fact can make reimbursement decisions very lengthy in time.
Role-play II.

- The Baltavian government decided to reform the drug evaluation system in the country for three main reasons:
  - Joining EU means that the national regulation needs to be harmonized with the European regulation, and it is necessary to implement a transparent drug evaluation system.
  - There is a huge backlog in the country in terms of registered but not reimbursed drugs.
  - WHO published a review on European health care system, and it turned out, that Baltavia is one of the worst systems in the region.

- The Baltavian government plans to implement a system based on health-economics and a hard ICER threshold set in the law. No drugs will get the reimbursement above the formal threshold and no listing will take place until the new HTA body will be set up.

- Ministry of Health organizes a public hearing to collect the feedback from all relevant stakeholders. This is the last public opportunity for everyone to influence the new system that will affect all patient’s life in the near future in Baltavia.

- You have been invited to the public hearing (consultation session) at the Ministry of Health. You represent the organization which is described in your role sheet (given to you separately). Your goals, personality traits as well as some background information are described in the role sheet, too.

- Please use the next 35-40 minutes to prepare for the public hearing according to the instructions and suggestions you find in your role sheet. Try to identify yourself with the personality of your role-play character as closely as you can. It is going to be important during the public hearing.
## Public hearing at the Ministry of Health – participants

<table>
<thead>
<tr>
<th>Name</th>
<th>Title and Association</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ms. Elsa Hildebrandt</td>
<td>State Secretary, Ministry of Health (MoH)</td>
</tr>
<tr>
<td>Mr. Frank Frattoni</td>
<td>Head of Pharmaceutical Department, Ministry of Health (MoH)</td>
</tr>
<tr>
<td>Ms. Rita Jovovic</td>
<td>State Secretary, Ministry of Finance (MoF)</td>
</tr>
<tr>
<td>Mr. Andrea Grandi</td>
<td>Deputy Director-General, National Insurance Fund (NIF)</td>
</tr>
<tr>
<td>Ms. Claire McKinley</td>
<td>President, Association of People Living with Cancer (APLC)</td>
</tr>
<tr>
<td>Ms. Judith Legrand</td>
<td>Secretary-General, National Platform of Physicians (NPP)</td>
</tr>
<tr>
<td>Mr. Paul Smith</td>
<td>President, Association of Innovative Pharma Manufacturers (AIPM) Country Manager, Pfizer</td>
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</tbody>
</table>
### Role sheet: Ms. Elsa Hildebrandt, State Secretary, Ministry of Health (MoH)

**Goal**
- You are not fully aware of the current status in the reimbursement of drugs. You tend to believe that there are inefficiencies, and the idea of a new evaluation system may not come from the devil, but you are not able to tell the right methods.
- You believe that the economic evaluation can bring the expected result. You know that the National Insurance Fund (NIF) strongly supports this method, and this is fine with you. However you have a second thought that economic evaluation will affect oncology patients negatively, may be less acceptable from a social (and media) perspective.

**Personality**
- You feel you are a person who is more interested in the big picture, however you also have the patience to deal with small details, when this is necessary.
- You have never had a problem with understanding how finance people think. You acknowledge their role, and your experience with physician key opinion leaders makes you think finance people may be the only balance against the irrational way physicians tend to go.

**Background**
- You are a lawyer by profession. You have been working in state administration for 8 years, but this position is your first job in the Ministry of Health. Previously you held positions in the Ministry of Justice and Ministry of Economy.
- You are not entirely satisfied with how your team in the Ministry of Health works. You feel they are a bit old-fashioned and want to get rid of decisions as long as they can. You are seriously contemplating a quality upgrade at the middle management level.
- The President of the Association of People Living with Cancer (APLC), who is also a lawyer, is your ancient roommate from university times. You have managed to keep fairly close contact, and every two months you find time for a coffee. You think that her perceptions concerning the general contexts are often relevant, however, you do not really like to discuss your forthcoming decisions with her.
### Role sheet:
**Mr. Frank Frattoni, Head of Pharmaceutical Department, Ministry of Health (MoH)**

| **Goal** | Although you have been part of the joint-task force which came up with the idea of economic evaluation of drugs, you are still not convinced whether there is a real need for this. However, you understand the main point: the decision has been taken at a higher level and it has to be followed.  
| | You are firmly convinced that the Ministry of Finance will have the final word to say, and because of this you do not want to take the responsibility of any decision. You think that economic evaluation and other methods are feasible but you also like to add that ‘they won’t change the world’. |
| **Personality** | You are said to be shy and tending to avoid open conflicts with anyone. You would sooner say that your top priority in life is not mediating between conflicting interests and parties, but rather staying with your wife and two young children.  
| | You do not like it when your boss, the Secretary of State, asks you technical questions in plenary sessions and uses you as her aide-de-champ. The reason is that you do not like being in the spotlight.  
| | You normally stay in the background, but when National Insurance Fund (NIF) representatives play the ‘important’, you sometimes interrupt them to show that the Ministry of Health takes decisions. |
| **Background** | You are a physician (pulmonologist) by profession, but you have been in the state administration for twelve years. You believe that finance people always tend to interfere with clinical practice and physicians’ freedom.  
| | You do not trust industry because you think they simplify clinical problems, and want to sell the same stuff for all conditions. On the other hand, you like to rely on patient groups.  
| | You see the National Insurance Fund (NIF) as overplaying their role and trying to shift competences to themselves which normally belong to the Ministry of Health. In the joint task force you always felt that NIF people wanted to dominate you. |
Role sheet:
Ms. Rita Jovovic, State Secretary, Ministry of Finance (MoF)

<table>
<thead>
<tr>
<th>Goal</th>
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<tbody>
<tr>
<td>■ Your only real concern is that savings should be achieved due to the new economic evaluation system, and the austerity plan may not be watered during the public consultations.</td>
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<tr>
<td>■ You strongly support economic evaluation, where the new and unrealistically expensive drugs can be rejected easily.</td>
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<td>■ You would only see other methods acceptable if the MoF was able to veto all products based on budget impact.</td>
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<tr>
<th>Personality</th>
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<tbody>
<tr>
<td>■ You are a straightforward, down-to-earth person who does not like small-talk and gets directly to the point. You have even received feedback that you are impatient and not ‘political’ enough.</td>
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<tr>
<td>■ You hate lobbyists because they kill easy solutions and argue for complicated ones to maintain their own manoeuvring room.</td>
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<tr>
<td>■ You have recently been mentioned as possible Minister of Finance, following the cabinet reshuffling which is due to take place at the end of summer.</td>
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<tr>
<td>■ You are an economist by profession. You are convinced that there are many savings opportunities in health care, and incontinence care is no exception. You believe that doctors cannot think at system-level, and this is the main reason for inefficiencies in health care.</td>
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<tr>
<td>■ Up to eight years ago, you used to work for the National Insurance Fund (NIF). You left that job and moved on to the Ministry of Finance because you felt that bureaucratic decision-making blocked every intelligent initiative at the NIF. In general, you don’t have nice memories about the NIF. You consider the current management of the NIF quite poor.</td>
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<td>■ You have a neutral but good relationship with the State Secretary of the Ministry of Health.</td>
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Role sheet:  
Mr. Andrea Grandi, *Deputy Director-General*, National Insurance Fund (NIF)  

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<tr>
<td>- You personally do not agree that the new evaluation system is needed in the reimbursement of drugs, but you understand that the austerity plan is a government decision that has to be followed.</td>
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<tr>
<td>- Together with your colleagues at the NIF, you have actively been involved in the joint task force which developed the plan of economic evaluation, and you believe that it is differentiated enough to be a relatively acceptable restriction.</td>
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<tr>
<td>- You are a straightforward, down-to-earth person who does not like small-talk and gets directly to the point. You have even received feedback that you are impatient and not ‘political’ enough.</td>
</tr>
<tr>
<td>- You hate lobbyists because they kill easy solutions and argue for complicated ones to maintain their own manoeuvring room.</td>
</tr>
<tr>
<td>- You always tell your bosses and colleagues about your opinion, no matter who they are.</td>
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<th>Background</th>
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<tbody>
<tr>
<td>- You are a pharmacist by profession. You believe that there are savings opportunities in health care but politics and lobbying always prevent that intelligent and well-founded restructuring actions could be implemented.</td>
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<tr>
<td>- You do not like higher-level decision processes which you see influenced by short-sightedness and particular interests.</td>
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<tr>
<td>- You do not trust industry because you think prominent figures of absorbent product manufacturers are pushy and greedy, and even those who are not, are also pressed by their headquarters to profiteer.</td>
</tr>
<tr>
<td>- You believe that the Ministry of Health is not pragmatic enough in health care financing. In the joint task force, their Department of Medical Devices had little added value. You have the impression that the Ministry of Finance is much better prepared and supportive.</td>
</tr>
</tbody>
</table>
### Goal
- You consider everything unacceptable which would increase the financial burden of patients or make the waiting time longer.
- Your goal is to protect the system and keep it as it is.
- You feel that the economic evaluation is only a trojan horse against oncology and haematology.

### Personality
- You are said to be a tactical person who really feels when to listen, and when to speak. However, you would rather say that you have a fairly good understanding of social situations.
- You do not like entering into personal discussions. You like to say your opinion at critical moments only. You like to use numbers to support your arguments.
- The only type of person you cannot stand is bureaucrats who always want to seem the cleverest.

### Background
- You are a lawyer by profession. You have come into contact with cancer because of your mother who, unfortunately, has a fairly serious condition.
- You have a good working relationship with all major suppliers of drugs (in education and patient training), and you have managed to build a trust-based relationship with them.
- You are annoyed with the bureaucratic and cynical way decisions are taken at the National Insurance Fund (NIF) regarding incontinence. You do not think that social problems can be managed from a financial perspective.
- The Secretary of State at the Ministry of Health is your ancient roommate from university times. You have managed to keep fairly close contact, and every two months you find time for a coffee. However, you have not had the opportunity to discuss the issue of incontinence personally yet.
### Role sheet: Ms. Judith Legrand, Secretary-General, National Platform of Physicians (clinical association, NPP)

<table>
<thead>
<tr>
<th>Goal</th>
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<tbody>
<tr>
<td>- You consider everything unacceptable which would restrict prescription rights of physicians or decrease the impact of NPP on the final decisions.</td>
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<tr>
<td>- You go to the public hearing to make it clear that the medical profession is not going to accept any changes to the reimbursement procedure.</td>
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<tr>
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<td>- According to your friends, you always say what is on your heart. You are said to be an emotional person who does not like to conceal her opinion if it is about patients or vulnerable people.</td>
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<tr>
<td>- You cannot stand bureaucrats who always want to seem the cleverest. You have a particularly poor opinion about finance people who sit behind their desks and take decisions without seeing the problems of patients and their carers.</td>
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<tr>
<td>- You are a geriatrist by profession. You come into contact with cancer patients day by day in your work as head of ward in a large county hospital.</td>
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<tr>
<td>- You have never really accepted that there are restrictions on the reimbursement of drugs.</td>
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<tr>
<td>- You feel you have a good relationship with all major suppliers of drugs, however you cannot accept that profit considerations can be more important than the interests of patients and doctors.</td>
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</table>
Mr. Paul Smith, *President*, Association of Innovative Pharma Manufacturers (AIPM)  
*Country Manager*, Pfizer

**Goal**
- As president of the AIPM, you go to the public hearing to strongly protect the reimbursement of innovative drugs.
- However, if changes are inevitable, you are against economic evaluation, because it will block access to the majority of new products with quite high ICER ratio.
- You are for alternative evaluation methods that has special ways of assessment for oncology/haematology.

**Personality**
- You have never considered yourself to be particularly good at lobbying, and yet you have to deal with this type of activity in your role as president of AIPM. You feel you have already learnt what to say and what not to say, but you still prefer technical discussions to politicking.
- You feel you get along well with physicians and patient organizations, because you understand their motivations. It is in line with your strategy which is focused on long-term sustainability.

**Background**
- You are a salesman by profession. You have been managing Pfizer for 12 years, but the last 3 years have turned out to be more difficult than the previous period, because of struggle to get listed with the new products.
- You know that if the economic evaluation does come true, you will have a long and bad time explaining to your boss (the head of region) why you could not prevent it, although you are president of AIPM.
- You believe that if something is bad for patients, it is your responsibility to stand up and argue against it with decision-makers.
- You feel you have a good working relationship with both ministries (Health and Finance) but you do not feel much trust coming to you from the National Insurance Fund (NIF).