F3: MARKET ACCESS IN CENTRAL AND EASTERN EUROPE: WHAT ARE THE DRIVERS AND CHALLENGES?

Barcelona, Spain
Tuesday 13 November 2018

MODERATOR:
Olha Zaliska, PhD, DSc, Professor, Head of Department of Management and Economy of Pharmacy, Medicine Technology and Pharmacoeconomics, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine

SPEAKERS:
Joanna Lis, PhD, Assistant Professor, Department of Pharmacoeconomics, Medical University of Warsaw, Market Access Director, Sanofi Warsaw, Poland
Oresta Piniazhko, PhD, President, ISPOR Ukraine Chapter, Senior Lecturer, Department of Management and Economy of Pharmacy, Medicine Technology and Pharmacoeconomics, Postgraduate Faculty, Danylo Halytsky Lviv National Medical University, Lviv, Ukraine, Member of Expert Committee of Ministry of Health of Ukraine
Vlad Zah, PhD, Health Economist, CEO, ZRx Outcomes Research Inc., Serbia
Bertalan Németh, MSc, President, ISPOR Hungary Chapter, Senior Health Economist, Syreon Research Institute, Budapest, Hungary
MARKET ACCESS in POLAND
WHAT ARE THE DRIVERS AND THE CHALLENGES?

JOANNA LIS, PHD
Department of Pharmacoeconomics, Medical University of Warsaw, Director of Market Access, Sanofi, Poland

ISPOR Barcelona
November 12, 2018

Current Market Access Drivers & Challenges
Dynamic and robust economy in an unstable environment in Poland

<table>
<thead>
<tr>
<th>Macro environment</th>
<th>Poland KPI</th>
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<tbody>
<tr>
<td>2017-2021 est.</td>
<td>2017 Fund</td>
</tr>
<tr>
<td>GDP growth</td>
<td>3.5%</td>
</tr>
<tr>
<td>Economy ranking in Europe</td>
<td># 8</td>
</tr>
<tr>
<td>Growth GDP vs N-1, %</td>
<td>+ 3.0%</td>
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<tr>
<td>GDP (2016) in USD</td>
<td>$77 bn</td>
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<tr>
<td>GDP growth from 2004</td>
<td>+87%</td>
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<tr>
<td>Currency rate 1 Euro</td>
<td>4.2</td>
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<tr>
<td>% Inflation</td>
<td>1.9%</td>
</tr>
<tr>
<td>Expected regulatory / tax / political environment env, position / stable / negative</td>
<td>Mixed</td>
</tr>
<tr>
<td>Master’s degree or equivalent</td>
<td>21%</td>
</tr>
</tbody>
</table>

Public health and drugs expenditures in Poland are far behind OECD average

Public health expenditures, 2017

Public expenditures on pharmaceuticals, 2017

Sources: OECD Health Data 2018
HC system holds 3 options for drugs reimbursement - public

Drug financing channels:
- Open market
- Drug programs
- Chemotherapy

Internal patient channel:
- Reimbursement
- National programs [FOC: ARV therapy, hemophilia]

Characteristics of reimbursement channels:
Key channel of drugs financing in Poland is open pharmacies

- 4365 SKU within 384 molecules
- Reimbursement indication: full range of SmPC or narrower in some cases (e.g. LAA)
- 4 categories: FOC, lump sum, 30%, 50%, 5% – free for 75+
- Drug dispensed in pharmacies
- Fixed prices and margins, no possibility to discounts
- Groups at ATE 3 or 4 level

- 408 SKU within 127 molecules
- Reimbursement in narrow populations with defined inclusion/exclusion criteria
- FOC for patients
- Drug dispensed in hospitals
- Maximum prices and margins
- Grouping of drugs into limit groups per molecule (few exceptions)

- 443 SKU within 80 molecules
- Reimbursement in ICD-10 codes (generally no criteria for exclusion of patients)
- FOC for patients
- Drug dispensed in hospitals
- Maximum prices and margins
- Grouping of drugs into limit groups per molecule (few exceptions)
P&R/HTA assessment process is complex and time-consuming

1. Manufacturer P&R/HTA submission
2. Economic Commission
   - Evaluation
   - Cost Risk Sharing Agreement
3. MoH Final decision
4. Price negotiation with Economic Commission
5. Economic Commission
   - Statement
   - formal evaluation of P&R Application
6. Only innovative products (products without equivalents in the reimbursement system)
7. MoH final decision
8. Issue and publication of the decision in the reimbursement list

180 days (240 days for drug programs) but there are often delays

- Stop clocks for formal revisions & required updates

Innovative medicines (without equivalents in the reimbursement system) are subject to HTA assessment by the Polish agency (AOTMiT), therefore it is necessary to prepare an HTA dossier.

**HTA**

Decision problem analysis

- Clinical analysis
- Economic analysis

**Clinical analysis**

- Determination of the scope of the indication of the analysis which will be used in the clinical assessment of the technology
- Primary analysis is done in one of the following ways:
  - ICU
  - RCT

**Economic analysis**

- Determination of the scope and directions of the analyses which are required when applying for financing of a health technology from public funds
- Appraisal of intervention results
- Important for market access strategy

- Rationalization analysis
  - to find the resources in the system to cover the additional costs of a new drug reimbursement

- NCU
- CMA (cost-minimization analysis)
- ICU
- CER

- **BIA and RSA**

- **Rationalization analysis**
  - to find the resources in the system to cover the additional costs of a new drug reimbursement

- **BIA and RSA**
  - to find the resources in the system to cover the additional costs of a new drug reimbursement

- **Rationalization analysis**
  - to find the resources in the system to cover the additional costs of a new drug reimbursement
Reimbursement of new innovative therapies within drug programs grows fastest

**NUMBER OF NEW INNOVATIVE MOLECULES IN REIMBURSEMENT**

**NEW SPENDING ON NEW INNOVATIVE MOLECULES IN REIMBURSEMENT [m€]**

<table>
<thead>
<tr>
<th>Year</th>
<th>Retail</th>
<th>Chemotherapy</th>
<th>Drug programs</th>
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<tbody>
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<td>2012</td>
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<td>2018</td>
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**Innovative molecules included in the reimbursement**

**NUMBER OF NEW INNOVATIVE MOLECULES IN REIMBURSEMENT [m€]**

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<td>2017</td>
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<tr>
<td>2018</td>
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**Sources:** M(01/2012-11/2018), analysis PEX PharmaSequence

**Notes:**
- *Number of innovative molecules included in the reimbursement list by September 2018*
- **Number of innovative molecules including draft of the reimbursement list 1 Nov. 2018.

**Constant exchange rate 1€ = 4,2 PLN**

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**Innovative molecules included in the reimbursement**

- Bevacizumab
- Darbepoetin alfa
- Filgrastim alfa
- Insulin detemir
- Insulin glargine
- Latanoprost
- Omalizumab
- Pegfilgrastim
- Menotropin
- Oxycodone hydrochloride
- Naloxone hydrochloride
- Posaconazole
- Pregabalin
- Urofollitropin
- Lipegfilgrastim
- Plerixafor
- Afatinib
- Axitinib
- Cysteamine bitartrate
- Golimumab
- Velaglucerase
- Ikatybant
- Plerixafor
- Aflibercept
- Dabrafenib
- Daklatasvir
- Dasabuvir
- Epoprostenol
- Ledipasavir + Sofosbuvir + Paritaprevir + Ritonavir + Ombitasvir
- Pembrolizumab
- Pertuzumab
- Symproicog
- TGF-beta
- Ezetimibe + Atorvastatin
- Indacaterol + Glycopyrronium + Vilanterol + Olodaterol + Tiotropium
- Netupitant + Palonosetron
- Alemtuzumab
- Anakinra
- Bosutinib
- Enzalutamide
- Elbasvir + Grazoprevir
- Ibrutinib
- Kobimetinib
- Levodopa + Carbidopa
- Mepolizumab
- Nonoxynol-9 (rDNA)
- Osimertinib
- Pirfenidone
- Pentoxifylline
- Radium dichloride Ra223
- Teriflunomide
- Trametinib
- Wismodegib
- Quadrivalent vaccine against influenza
- Paliperidone Bitartrate + Haloperidol
- Cotrimoxazole + Buprenorphine + Naloxone
- Eftolivirapine + Alimemazine + Pimozide
- Protamine sulphate
- Timolol maleate
- Ketobsalate
- Bilirubin
- Calcium gluconate 10% (rDNA)
- Bupivacaine
- Fentanyl
- Feosol
- Krobicidinum
- Piroxicam
- Terbutaline
Cost-containment mechanisms in HCS used to keep limited budget for drugs in Poland

HCS management within the limited resources in the context of reimbursement system

**Statutory tools and mechanisms**

- Price erosion
- HTA and RSA/MEA tools

**Cost-cutting approach of the MoH**

- Limited access to treatment for very narrow patient populations
- Delayed & time-consuming introduction into the reimbursement system
- Important therapies excluded from the system (full co-payment)

**Example**: NOACs are reimbursed in VTE prevention but not reimbursed in stroke prevention (in non-valvular AF)

**Example**: Incrtins (GLP1, DPP4, NOACs, SGLT2) are not reimbursed in diabetes treatment

**Example**: Sakubitryl/walsartan in heart failure treatment still in the P&R process (since 2015)

**Temporary reimbursement decisions**

- External Reference Pricing
- Internal Reference Pricing (for innovative R&D/BIO) Mandatory prior for the first 90/120/180 days

**HTA - Guidelines with the strict rules for HTA**

- C/E Threshold = 3 GDP/QALY (€100k/PLN100k)
- MOH (conditions defined in HTA process & agreed with MoH)
- Mandatory price capped & can be adjusted

**Capping - full reimbursement cost returned by MAH above agreed threshold**

**New Market Access Drivers & Challenges**

- HTA: Guidelines with strict rules for HTA
- C/E Threshold = 3 GDP/QALY (€100k/PLN100k)
- MOH: conditions defined in HTA process & agreed with MoH
- Mandatory price capped & can be adjusted
- Capping: full reimbursement cost returned by MAH above agreed threshold
Main MA drivers and challenges in Poland in 2018 and beyond

- 6% of GDP as healthcare expenses
- Price re-negotiations
- V4 group negotiations
- Hospital purchasing groups

- Public drug policy
- Agency for medical studies
- E-prescriptions & internet patients’ account
- Medical registries

MA drivers and challenges in Poland in 2018 and beyond

- 6% of GDP as healthcare expenses
- Price re-negotiations
- V4 group negotiations
- Hospital purchasing groups

- 6% of GDP as healthcare expenses
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Healthcare budget to reach 6% of GDP in 2024

Increasing resources to improve:
- Outpatient special care
- Inpatient services
- Medical rehabilitation
- Dental services
- Drug programs

EU countries healthcare budget as GDP %, 2016

Poland falls short in comparison with EU countries

<table>
<thead>
<tr>
<th>Year</th>
<th>Poland (current)</th>
<th>EU average</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>4.78%</td>
<td>5.80%</td>
</tr>
<tr>
<td>2019</td>
<td>4.86%</td>
<td>5.55%</td>
</tr>
<tr>
<td>2020</td>
<td>5.03%</td>
<td>5.86%</td>
</tr>
<tr>
<td>2021</td>
<td>5.30%</td>
<td>6.03%</td>
</tr>
<tr>
<td>2022</td>
<td>5.55%</td>
<td>6.28%</td>
</tr>
<tr>
<td>2023</td>
<td>5.80%</td>
<td>6.55%</td>
</tr>
<tr>
<td>2024</td>
<td>6.03%</td>
<td>6.80%</td>
</tr>
</tbody>
</table>

Expected growth to 6% of GDP will improve HCS situation

Public health expenditures, 2017 and simulation of 6% GDP for Poland

Public expenditures on pharmaceuticals, 2016 and simulation of 6% GDP for Poland

Source: OECD Health Data 2018
Price decrease expected due to decision renewal negotiations

General reimbursement principles in Poland:
- Reimbursement decisions are valid for 2y for the first two applications and 3y for next applications
- Each decision is preceded by price negotiations with MoH
- The next price can not be higher than the last one

Cumulation of renewals starting January 2019 will cover more than 45% of all reimbursed SKUs!

A new option of extending access under joint pricing negotiations within the EU collaboration

Fair & Affordable Pricing (FaAP) initiative by Visegrad (V4+) Group

• Memorandum of Understanding dated 3 March 2017, signed by the MoHs of the V4+ Group countries - Lithuania, Poland, Slovakia, Hungary & the Czech Republic and Latvia with an observer status

• THE OBJECTIVE of the FaAP is to improve and facilitate access to the cost-effective therapies as well as to develop methods & principles of cooperation and pricing negotiations at the regional level
  - Value based pricing
  - Scale effect

• 3 areas of ACTIVITIES to achieve the intended goals are:
  - expert meetings
  - exchange of information
  - organization of pilot negotiations at the regional level
Hospital’s purchasing groups as a new cost-containment mechanisms

General reimbursement principles in Poland:
- Hospitals are provided with drugs through tenders with a price level as the main criterion.
- Prices of reimbursed products on the hospital market are determined by the MoH.
- The MoH decision sets maximum prices + 5% maximal wholesale margin.
- NHF funds hospital drugs up to the TRP limit (set within the reimbursement limit group). If the purchase price is:
  - lower than the limit, the NHF finances the entire cost of the drug,
  - higher than the limit, NHF finances the cost of the drug up to the limit.
- Additional incentives to purchase the cheapest drugs were introduced — for selected therapies NHF uses correction factors that increase the value of returned funds to the hospital in cases of buying the cheapest equivalents.

Central tenders for drugs reimbursed in hospital at the level of voivodship NHF office (change of law in October 2018)

MA drivers and challenges in Poland in 2018 and beyond

Spendings on health

Health law/policy

Evidences for better management

- State drug policy
The aim is to provide a wide patients access to EFFECTIVE AND SAFE MEDICINES as well as a transparent and rationally operating drug reimbursement system that supports investment activities in Poland and the development of the Polish economy.

Prevention
Reducing the incidence of infectious diseases through safe and effective prophylaxis of infections

Improving the market availability of medicines
Providing safe and effective medicines, available at the right place and time

Reimbursement
Systematic improvement of the population’s health status, thanks to optimization of public expenditures ensuring the widest possible access to effective, safe and cost-effective therapies

Developing potential of the pharmaceutical sector
Strngthening and successive development of the potential of the pharmaceutical sector located in Poland

Role of health care professionals
Obtaining the best possible health effect by rationalizing the pharmacological treatment based on scientific evidence and clinical guidelines, effective supervision and effective cooperation between doctors and pharmacists

Digitalization
Systematic improvement of the effectiveness of the HCS in Poland and achievement of additional health results thanks to the use of information systems

State Drug Policy for Poland 2018-2020

MA perspective in „State drug policy for 2018-2020”

STABLE FUNDING
- Establishing a reimbursement budget at a stable level of 16.5%-17.0% of total NHF spending on HCS (in 2017: 15.6%)  
- Including savings from the MEAs to the drug budget for innovation

VALUE BASED ACCESS
- Systematic extension of reimbursed drugs with documented evidence of effectiveness  
- Declaration on introduction of outcome-based MEAs (based on medical registries)

DISINVESTMENT
- Announcement of the review of reimbursement lists and removal drugs from reimbursement

ACCESS EXTENSION
- Declaration on introduction of a free drug program for pregnant women  
- Declaration of co-payment category verification & financing support for poor & chronically ill people, children, people with disabilities

DECREASING PATIENTS’ CO-PAY
- Monitoring ordination & developing an incentive system for physicians leading to the rational use of drugs  
- Increasing price competitiveness by launching cheaper generics
MEAs - one of the most effective tool to ensure access to innovative drug in Poland ... with unused potential

Introduction of MEAs in Poland by Act on Reimbursement in 2012

- Making the applicant’s total sales amount dependent on the drug’s outcomes (PAYMENT-BY-RESULT)
- Making the price dependent on the applicant’s assurance to supply the drug at a reduced price (DISCOUNTS/REBATES)
- Making the price dependent on the drug’s sales (PIVA)
- Making the price dependent on partial repayment of the reimbursed amount to the public payer (PAYBACK)
- Arrangement of other conditions improving access to or reducing cost of healthcare services (OTHER)

| Source: NHF data, PEX PharmaSequence analysis |

<table>
<thead>
<tr>
<th>Refund due to RSAs (mln €)</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
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<tbody>
<tr>
<td>30</td>
<td>45</td>
<td>38</td>
<td>58</td>
<td>58</td>
<td>84</td>
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</tr>
</tbody>
</table>

Refund due to MEAs as % of NHF’s reimb. expenditures

- Outcome based schemes
- Price discounts
- Price volumen agreement
- Payback
- All others (free stock)

Implemented RSS Proposals - RSS

- Outcome based schemes
- Price discounts
- Price volumen agreement
- Payback
- All others (free stock)

In practice mostly financial based exists in Poland – as preferred one by Polish payer:

- Only 20% of them are more complex (2-3 mechanism or/and with cap)
- App. 50% to open care and 30% for drug programs

MA drivers and challenges in Poland in 2018 and beyond

- E-prescriptions & internet patients’ account
- Medical registries
- Agency for medical studies

Spendings on health
Health law/policy
Evidences for better management

New organizational and IT solutions for evidences generations and resource optimization in HCS
Digitalization in HCS: evidences generation for better HCS management

E-prescription and Internet Patient Account:
- Advanced implementation stage of drug prescription digitalization process and consolidation of patient data
- Effects:
  - Increasing the possibility of analyzing patient journey (real-life data)
  - Limiting polypharmacy and drug waste and increasing the scale of substitution
  - Monitoring ordination & developing an incentive system for physicians leading to the rational use of drugs

Medical registries:
- Currently, there are only a few registers dedicated to selected diseases (e.g., National Cancer Registry, National Registry of Acute Coronary Syndromes)
- Launching the new registry by MoH requires a legislative process (e.g., Register of Family Dyslipidemia treatment is at the stage of legal consultations)
- MoH plans assume implementation of medical registries as standard tools for measuring therapy process
- Started as social initiative, currently at the stage of consultations and discussion with decision-makers

ABM (Agencja Badan Medycznych = Medical Research Agency):
- ABM is scheduled to launch in 2019
- Goals: Funding research and innovation in medicine, as well as increasing the effectiveness of HCS in Poland
  - The Medical research Agency will serve non-commercial clinical research.
  - The project for the new institution, which is currently undergoing public consultations, aims to financially support new technologies, products and procedures.

Summary: Market Access Drivers & Challenges
- Cost-containment mechanisms due to limited spendings on health
- Plans for increasing health spending, including drug spending
- Developing of optimal management in HCS to ensure rational spending for prevention and treatment
- E-Health & evidences generation as a tool for better health decision making processes
THANK YOU