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

Barcelona, Spain
Tuesday 13 November 2018

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**MARKET ACCESS in
POLAND**
WHAT ARE THE DRIVERS AND THE
CHALLENGES?

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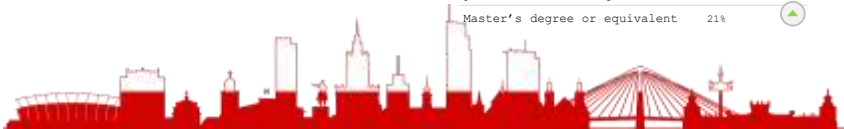
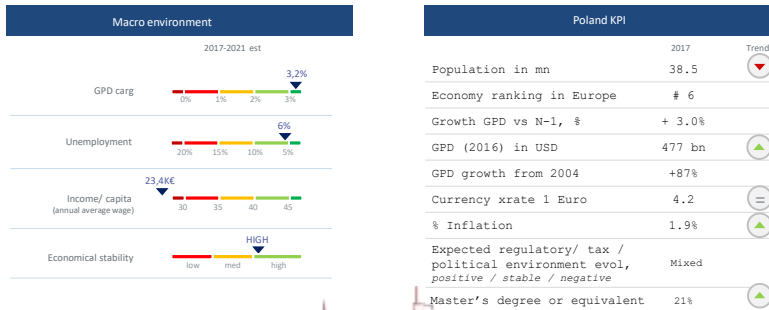
ISPOR Barcelona
November 12, 2018



Current Market Access
Drivers & Challenges

demography analysis ration change access
ispur analysis ration access
healthcare challenges
expenses system comparators
change

Dynamic and robust economy in an unstable environment in Poland



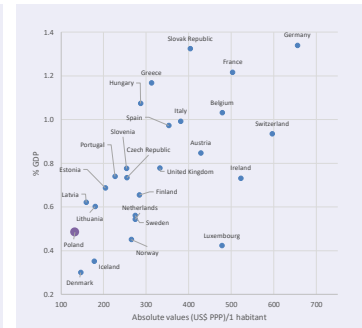
Public health and drugs expenditures in Poland are far behind OECD average

Public health expenditures, 2017

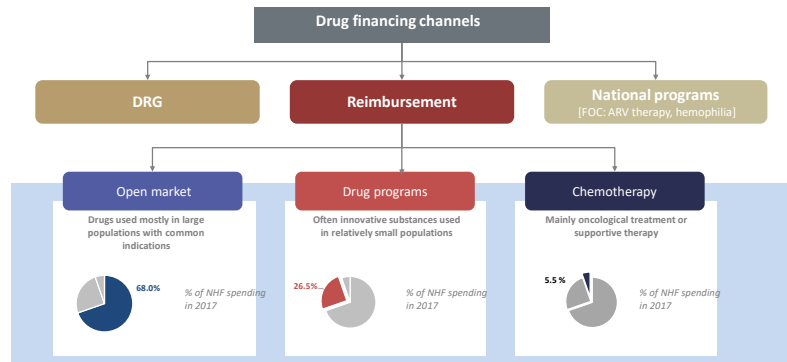


Source: OECD Health Data 2018

Public expenditures on pharmaceuticals, 2017

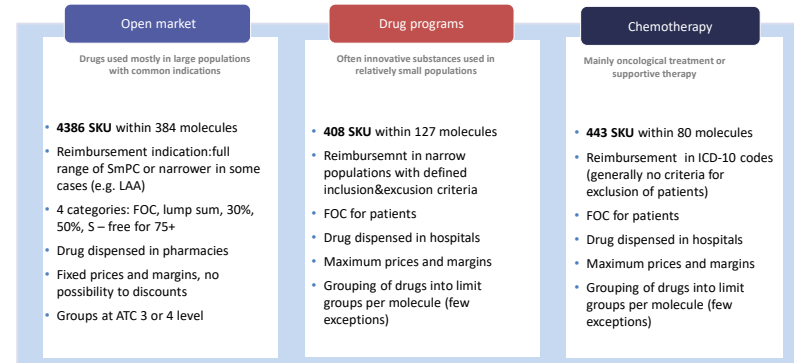


HC system holds 3 options for drugs reimbursement - public



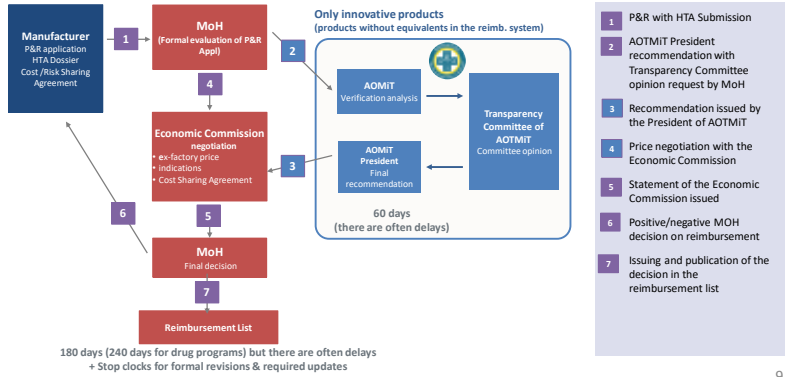
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**Characteristics of reimbursement channels:
Key channel of drugs financing in Poland is open pharmacies**



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P&R/HTA assessment process is complex and time-consuming

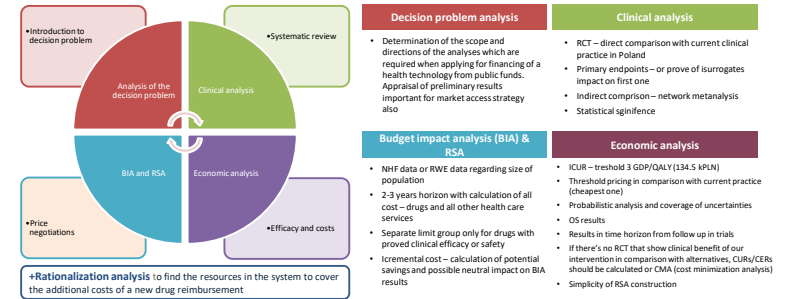


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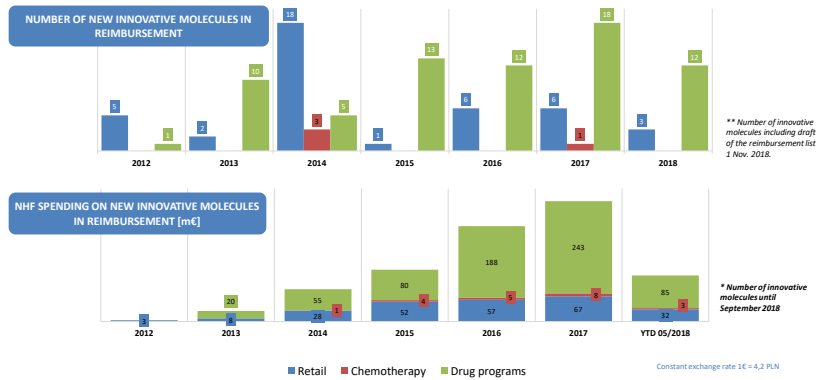
HTA



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.



Reimbursement of new innovative therapies within drug programs grows fastest

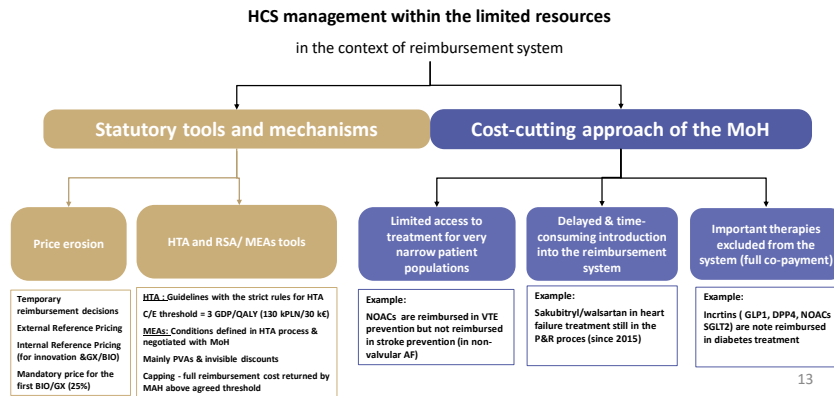


Innovative molecules included in the reimbursement

2012	2013	2014	2015	2016	2017	2018
AO Degarelixum	AO Konestat alfa	AO Apixabanum	AO Ikatybant	AO Agomelatium	AO Dieta kompletna zawierająca TGF-beta	AO Quadrivalent vaccine against influenza
AO Denosumabum	PL Retigabium	AO Cetrorelixum	PL Afibercept	AO Calcipotriolum + Betamethasonum	AO Esetimibum + atorvastatinum	PL Paliperidonum
AO Insulinum detemirum	PL Ambrisentanum	AO Follitropinum alfa	PL Dabrafenibum	AO Febuxostat	AO Indacaterolum + Glycopyrronii bromidum	PL Betametazonum + salicylic acid
AO Insulinum glargine	PL Boceprevirum	AO Follitropinum beta	PL Daklatasvirum	AO Styrypentol	AO Olodaterolum + Tiotropii bromidum	PL Apomorphini hydrochloridum
PL Tafuprostum	PL Certolizumabum pegol	AO Ganirelixum	AO Dasabuvirum	AO Tapentadolum	AO Umeclidinii bromidum + Vilanterolum	PL Cabozantinibum
	PL Deferazyroxum	AO Indacaterolum	AO Ledipasavirum + Sofosbuvirum	PL Umeclidinii bromidum	PL Netupitantum + Palonosetronum	PL Efmoroctocog alfa
	PL Fingolimodum	AO Indapamidum + Amlodipinum	AO Metyctentan	PL Brentuximabum vedotinum	PL Anakinra	PL Etrrombopagum
	PL Natalizumabum	AO Inhibitor G1-esterazy	AO Nitisinonum	PL Crioitinibum	PL Dimethylis fumaras	PL Glesaprevirum + Pibrentasvirum
	PL Tadalafilum	AO Koryfollitropina alfa	AO Omibatavirum + paritaprevirum + ritonavirum	AO Nivolumabum	PL Ebinastivum + Grazoprevirum	PL Nintedanibum
	PL Telaprevirum	AO Lakozamid	AO Ritonavirum + paritaprevirum + ritonavirum	AO Obinutuzumabum	PL Ibrutinibum	PL Pasireotidum
	PL Ustekinumabum	AO Lipegfigrastimum	AO Ramibzumab	AO Olaparibum	PL Peginterferonum beta-1a	PL Vedolizumabum
	PL Wemurafenib	AO Menotropinum	AO Rocogastum	AO Pembrolizumabum	PL Simtoltokog alfa	PL Pomalidomidum
		AO Oxycodoni hydrochloridum + Naloxoni hydrochloridum	AO Symeprevirum	AO Pertuzumabum	PL Tensirolimusum	PL Sekukinumabum
		AO Posaconazolom	AO Sofosbuvirum	AO Turoctocog alfa	PL Turoctocog alfa	PL Isekitumabum
		AO Pregabalinum				PL Ailrokumabum
		AO Urofollitropinum				
		KCN Lipegfigrastimum				
		PL Plerixaferum				
		AO Posaconazolom				
		PL Afatinib				
		AO Axitinibum				
		AO Cysteamini bitartras				
		AO Galinimabum				
		AO Velaglucerasum alfa				

Sources: MoH (01/2012-11/2018), analysis PEX PharmaSequence

Cost-containment mechanisms in HCS used to keep limited budget for drugs in Poland



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Main MA drivers and challenges in Poland in 2018 and beyond



Spendings on health

additional resources in HCS & cost optimization tools (new launches and verification of existing ones)

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



Health law/policy

update of the government's operational strategies for the pharmaceutical market in Poland

- Public drug policy



Evidences for better management

new organizational and IT solutions for evidences generations and resource optimization in HCS

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

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MA drivers and challenges in Poland in 2018 and beyond



Spendings on health

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Health law/policy



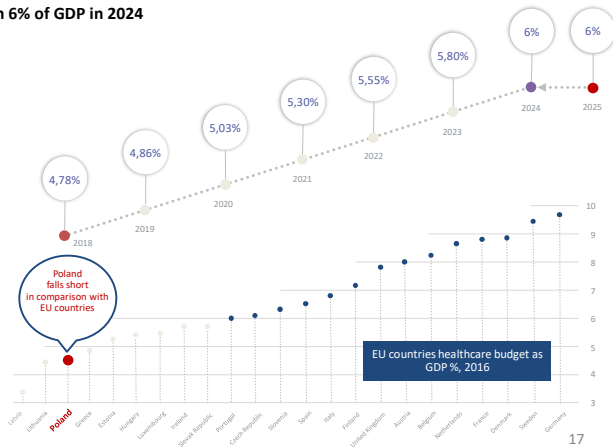
Evidences for better management

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Healthcare budget to reach 6% of GDP in 2024

Increasing resources to improve:

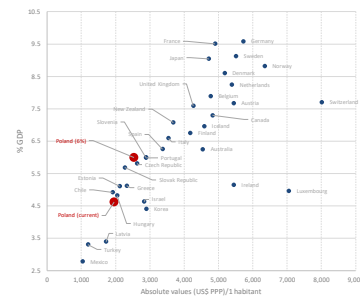
- Outpatient special care
- Inpatient services
- Medical rehabilitation
- Dental services
- Drug programs



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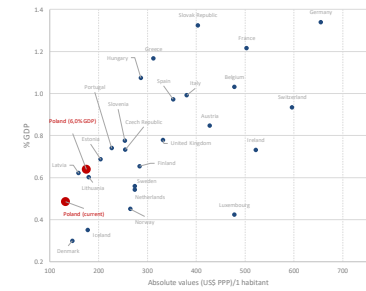
Expected growth to 6% of GDP will improve HCS situation

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



Source: OECD Health Data 2018

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



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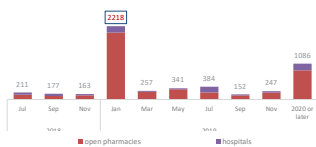
Price decrease expected due to decision renewal negotiations

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

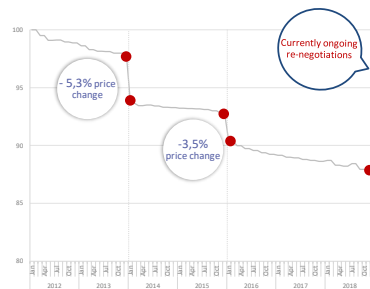
Cumulation of renewals starting January 2019 will cover more than 45% of all reimbursed SKUs!

Number of SKUs reimbursed in by date of decisions' renewal



Source: MoH reimbursement lists, PEX PharmaSequence analysis

Average weighted price index of reimbursed products in open pharmacies
[100 is the price level in January 2012]



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

Fair & Affordable Pricing (FaAP) initiative by Visehrad (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



Preparations for 1st negotiations are underway

„The object of our interest is a drug used in the epidemiologically disseminated oncological disease. For now, we have had a technical dialogue with the producer and we are planning further meetings“.

- Undersecretary of State Marcin Czech /press interview dated October 21, 2018/

Cross-country Initiatives (CCIs):

- BeNeLuxA
- Valletta
- Nordic Procurement
- FINOSE
- Visegrad

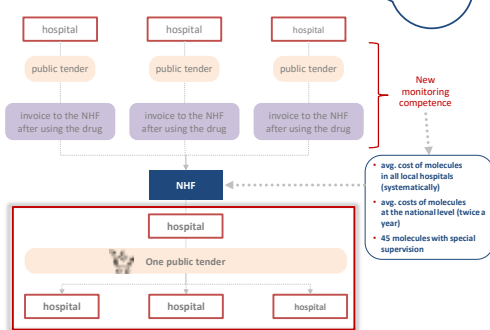
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Hospital's purchasing groups as a new cost-containment mechanisms

General reimbursement principles in Poland:

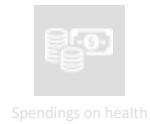
- Hospitals are provided with drugs through tenders with a **price level as the main criterion**
- Prices of reimbursed products on the hospital market are determined by the MoH
- The MoH decision sets **maximum prices + 5% maximal wholesale margin**
- NHF funds hospital drugs up to the TRP limit** (set 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)



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MA drivers and challenges in Poland in 2018 and beyond



update of the government's operational strategies for the pharmaceutical market in Poland

- State drug policy

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State Drug Policy for Poland 2018-2020

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 he 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

Strengthening 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 pharmacist

Digitalization

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

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

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

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

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



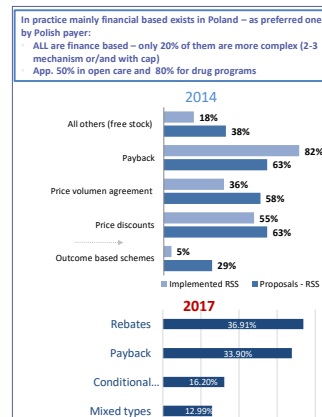
MEAs - one of the most effective tool to ensure access to innovative drug in Poland ... with unused potential

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 (PVA)
- 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)

	2012	2013	2014	2015	2016	2017
Refund due to RSAs (mln €)	30	45	38	58	58	84
Refund due to RSAs as % of NHF's reimb. expenditures	1.4%	2.0%	1.6%	2.2%	2.1%	2.9%

Source: NHF data, PEX PharmaSequence analysis



MA drivers and challenges in Poland in 2018 and beyond



Spendings on health



Health law/policy



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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 date)
 - limiting polypragmasy 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 tool 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.

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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