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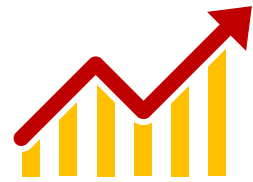
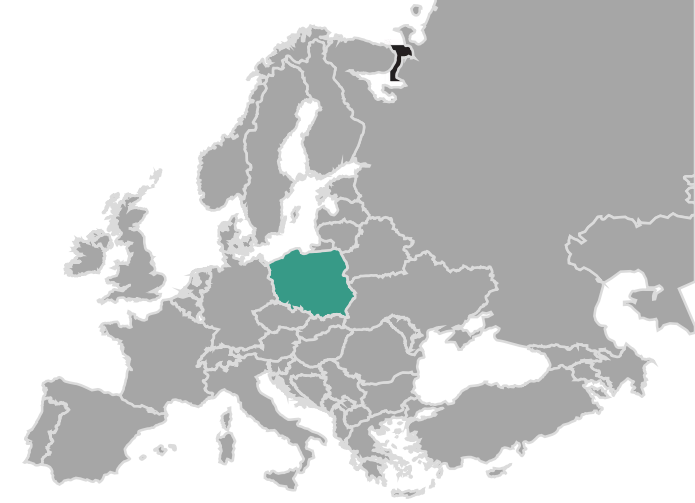
CENTER OF EXCELLENCE IN EVIDENCE SYNTHESIS



POTENTIAL OF THE POLISH MARKET

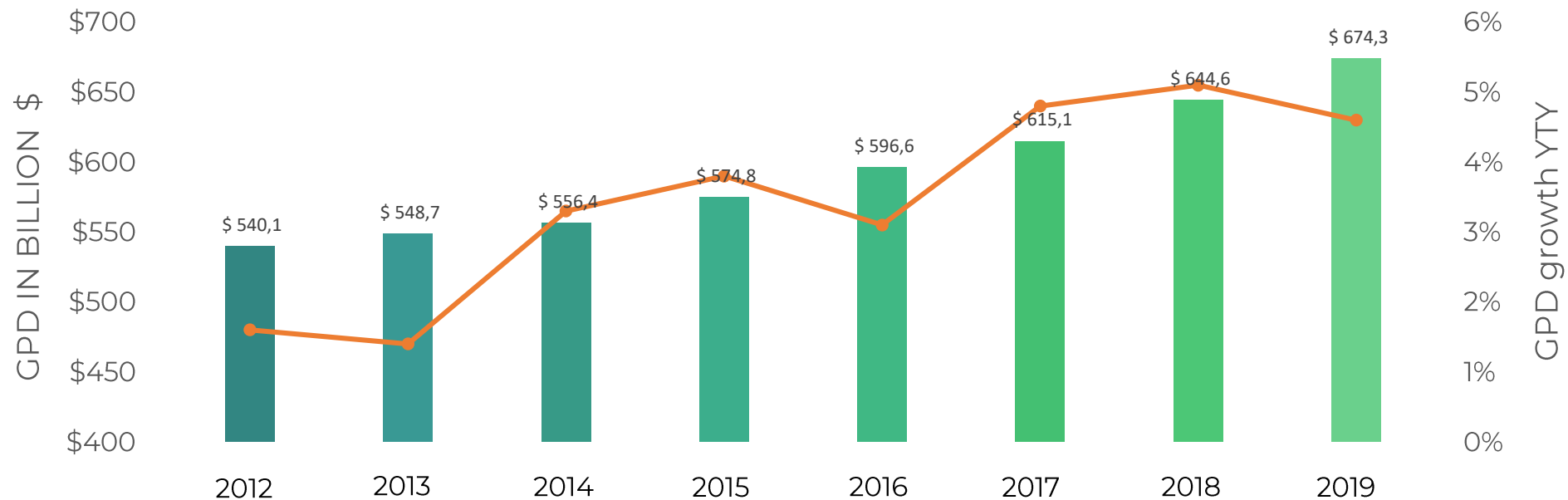
Policy guaranteeing at least **5% of Polish GDP on public health in 2020** increasing gradually up to **6% of GDP from 2024**.

Polish GDP is continuously increasing



4,6% GDP

in the first quarter of 2019 GDP higher than in the corresponding period of the previous year



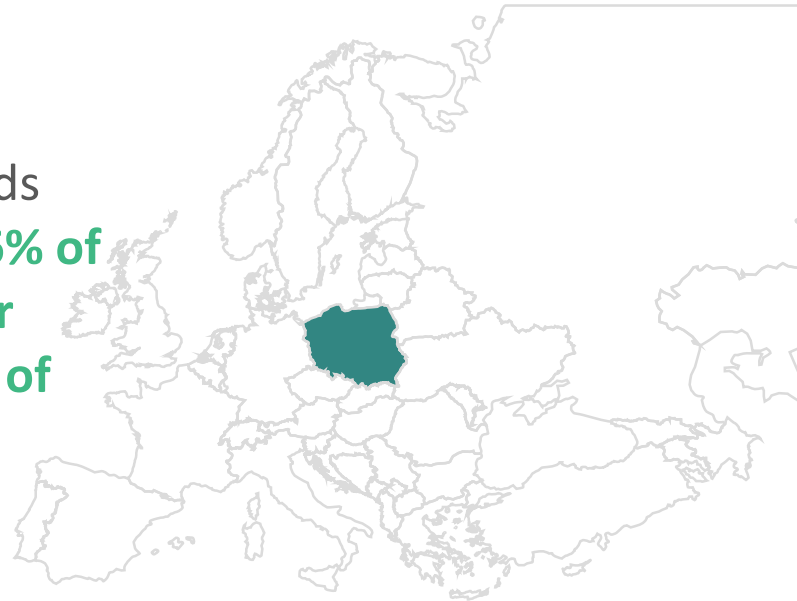
POTENTIAL

OF THE **POLISH** MARKET

4,78%

of GDP spent on healthcare
in 2018

It is planned to increase public funds allocated to health care financing to **6% of GDP** and set the actual **budget for reimbursement at a constant level of 16.5%-17.0%**



Increasing of health spending to 6% of GDP in 2024 may result in a total amount of **health funding of \$218 billion in 2018-2024**

Population of
38,4
million

POTENTIAL OF THE POLISH MARKET



\$ 21 billion

National Health Fund budget
in 2018



\$ 3.4 billion spent on medicines

- \$ 2,2 billion on pharmacy reimbursement,
- \$ 990 million on 91 drug programs (135 985 patients in 2018)
- \$ 198 million on chemotherapy (134 700 patients in 2018)



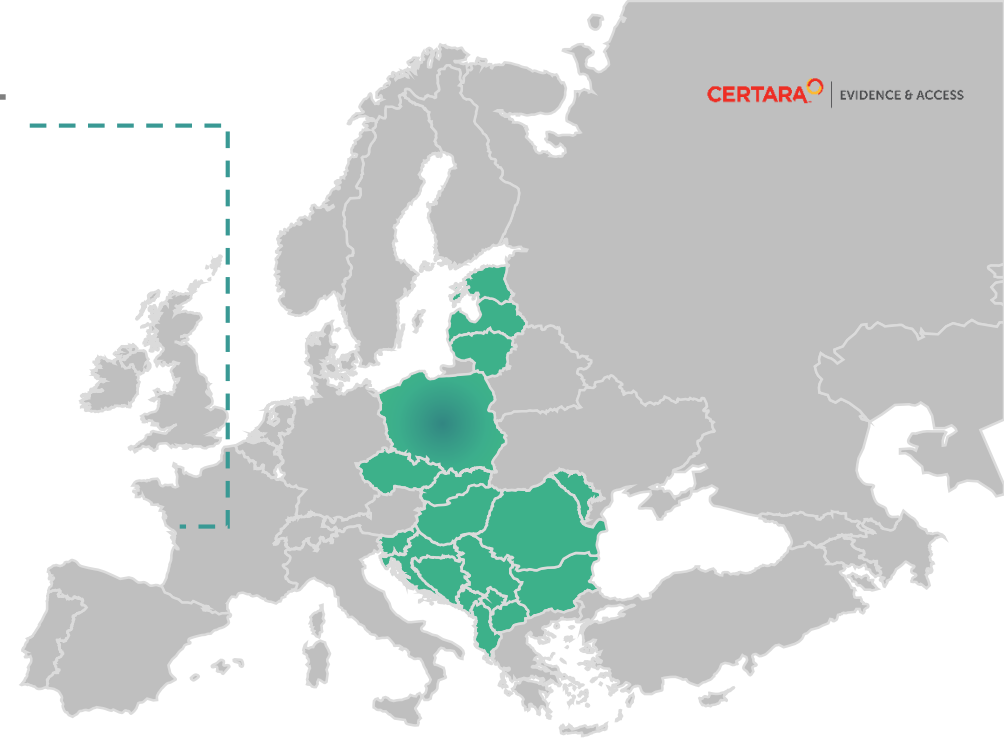
\$ 283 million spent on medical devices

CEE MARKET

16
countries

172 million
people

\$ 92 billion
for healthcare



\$40 000
\$35 000
\$30 000
\$25 000
\$20 000
\$15 000
\$10 000
\$5 000
\$-

Total spendings on health-care in Billion \$



COUNTRY COVERAGE

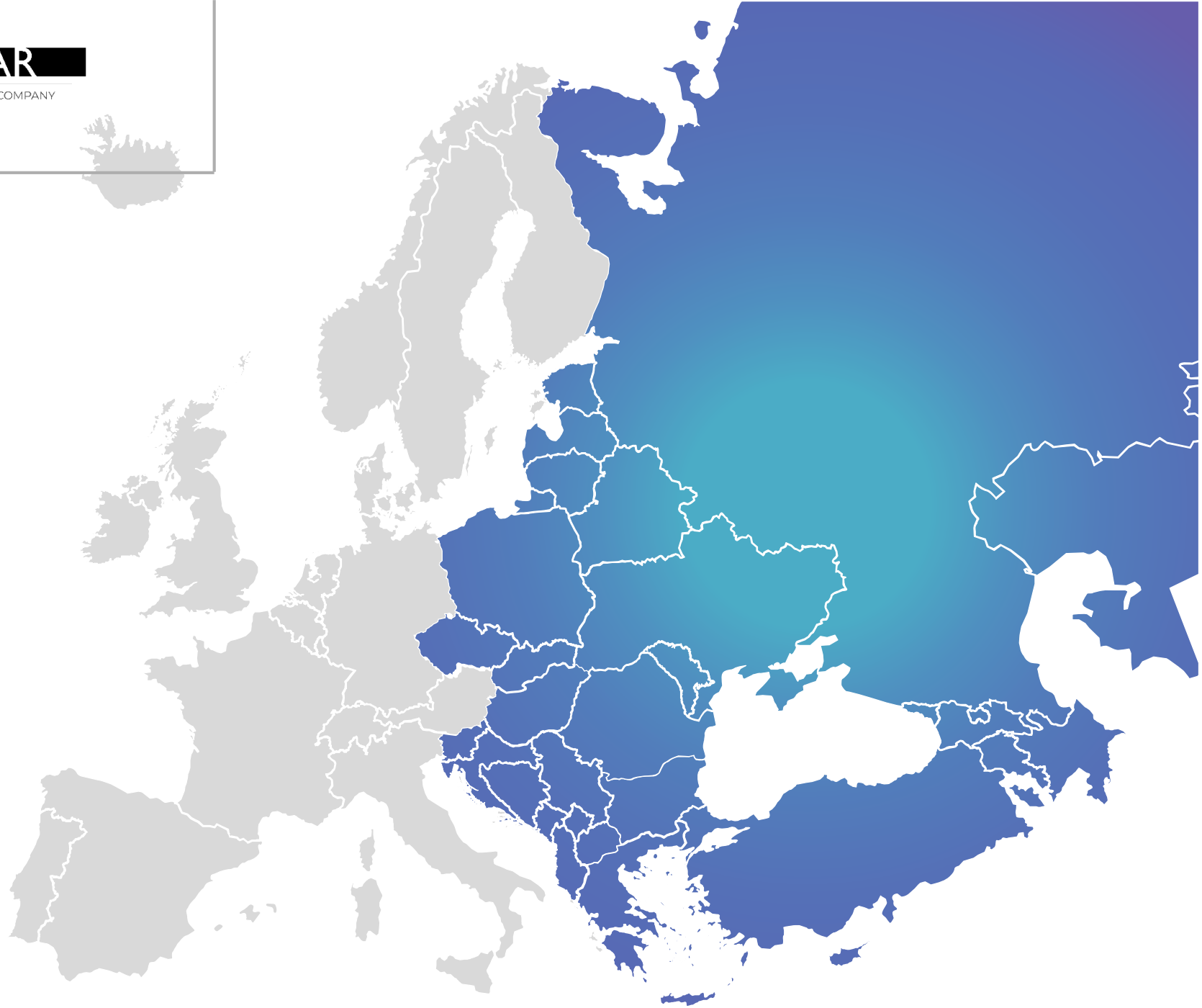


CEE, CIS AND BALTICS

NETWORK OF LOCAL EXPERTS

IN 30 COUNTRIES:

- | | |
|---|-------------------------------------|
| <input type="checkbox"/> ALBANIA | <input type="checkbox"/> LATVIA |
| <input type="checkbox"/> ARMENIA | <input type="checkbox"/> LITHUANIA |
| <input type="checkbox"/> AZERBAIJAN | <input type="checkbox"/> MACEDONIA |
| <input type="checkbox"/> BELARUS | <input type="checkbox"/> MOLDOVA |
| <input type="checkbox"/> BOSNIA & HERZEGOVINA | <input type="checkbox"/> MONTENEGRO |
| <input type="checkbox"/> BULGARIA | <input type="checkbox"/> POLAND |
| <input type="checkbox"/> CROATIA | <input type="checkbox"/> ROMANIA |
| <input type="checkbox"/> CYPRUS | <input type="checkbox"/> RUSSIA |
| <input type="checkbox"/> CZECH REPUBLIC | <input type="checkbox"/> SERBIA |
| <input type="checkbox"/> ESTONIA | <input type="checkbox"/> SLOVAKIA |
| <input type="checkbox"/> GEORGIA | <input type="checkbox"/> SLOVENIA |
| <input type="checkbox"/> GREECE | <input type="checkbox"/> TAJIKISTAN |
| <input type="checkbox"/> HUNGARY | <input type="checkbox"/> TURKEY |
| <input type="checkbox"/> KAZAHSTAN | <input type="checkbox"/> UKRAINE |
| <input type="checkbox"/> KYRGYZSTAN | <input type="checkbox"/> UZBEKISTAN |

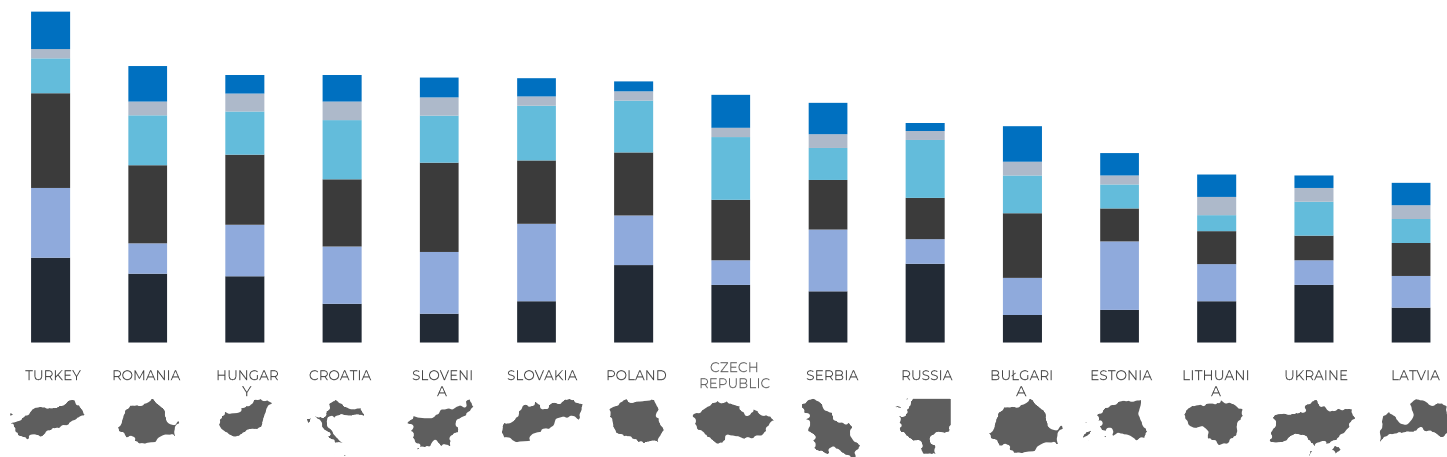


PRICING & REIMBURSEMENT

POTENTIAL ANALYSIS IN CEE EXAMPLE

OVERVIEW FOR ORPHAN DRUG IN 15 CEE COUNTRIES

Overview



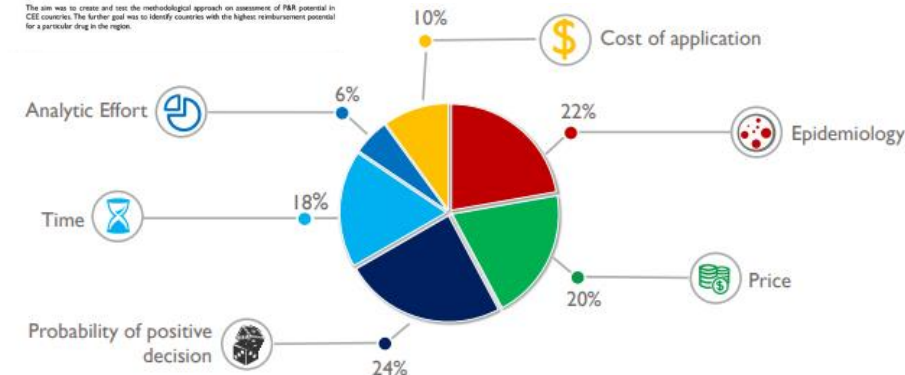
Analytic Effort
 Probability of positive decision
 Cost of application
 Price
 Time
 Epidemiology

Identification of three countries with highest potential for the drug



BACKGROUND
Differences in health systems among Central and Eastern European CEE countries reveal both the opportunities and uncertainties faced during the process of accessing the market with a new drug. The CEE region is characterized by its wide range of approaches to granting public funding for drug – from a “no submission and no HTA” approach up to an extensive HTA with a systematic review and economic evaluation.

OBJECTIVES
The aim was to create and test the methodological approach on assessment of P&R potential in CEE countries. The further goal was to identify countries with the highest reimbursement potential for a particular drug in the region.



Detailed P&R strategy

for the three countries taking into account:

- Current management of disease
- Patient numbers
- KOL mapping
- Patient pathways, guidelines and funding mechanisms
- Orphan drug pricing & reimbursement process and timelines
- Likelihood of achieving an average European list price
- Opportunities to supply drug on basis of Named Patient Programs (NPP)

PRICING & REIMBURSEMENT

POTENTIAL ANALYSIS IN CEE

PROJECTS

P&R SYSTEMS IN 14 COUNTRIES

- Proposition for a Market Access Strategy for 3 drugs in 14 countries in Europe:
Czech Republic, Slovakia, Slovenia, Hungary, Bulgaria, Romania, Russia, Croatia, Turkey, Ukraine, Latvia, Lithuania, Estonia, Serbia
- Submission files were prepared for Czech Republic and Slovakia



ANALYSIS OF LOCAL LEGISLATION IN 14 COUNTRIES

- Analysis of requirements and legislation regarding reimbursement process for manufacturers without local affiliate
- Information provided for 14 countries in Europe:
- **Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Portugal, Romania, Slovakia, Slovenia**
- Recommendations for requirements regarding local affiliate and participation in local reimbursement process



ASSESSMENT OF P&R SYSTEM FOR NEW DRUG

- Assessment of the P&R systems in 7 European countries
Poland, Czech Republic, Hungary, Romania, Bulgaria, Greece, Turkey
- Overall Timing for Assessments
- Required documents and choice of comparator
- Key Value Arguments
- Reference countries
- Other critical components



STRATEGIC ANALYSIS OF MA PATHWAYS TO OBTAIN PUBLIC FUNDING IN 11 COUNTRIES

- 3 Baltic countries and 8 other CEE countries:
Lithuania, Latvia, Estonia, Romania, Bulgaria, Croatia, Slovenia, Hungary, Slovakia, Czech Republic, Poland
- Identification of available market access pathways for particular drug in the treatment of for the cystic fibrosis
- Pathways assessment for outcome (price and other public funding conditions), requirements, operational timelines and probability of success

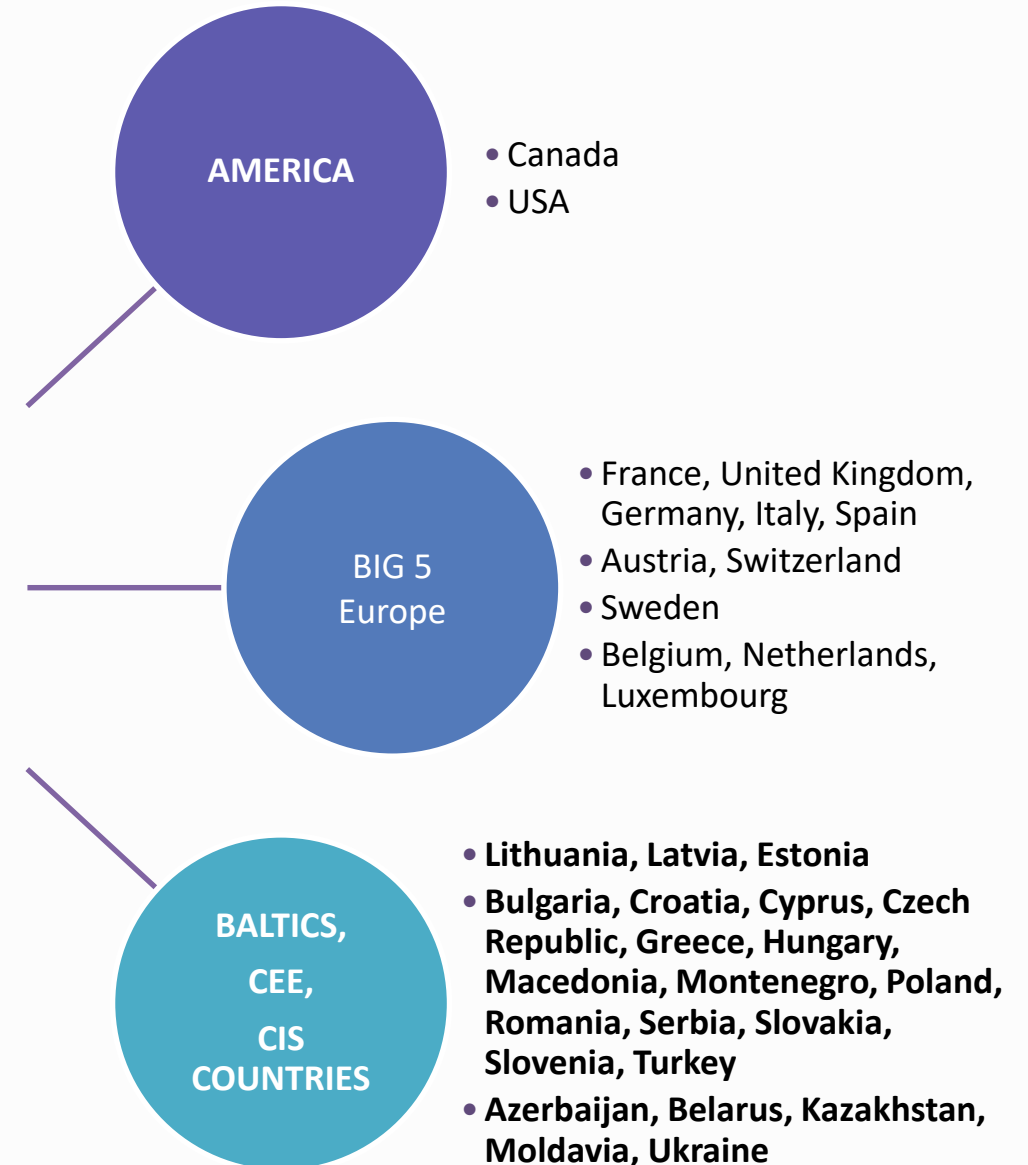


PRICING & REIMBURSEMENT

POTENTIAL ANALYSIS IN CEE

GEOGRAPHIC EXPANSION RETAINER

- To provide International high level market research focusing on selected countries geographic expansion requests
- The Geographic Expansion information will provide a detailed overview supporting the Global Market Access team to determine strategies for opening up market assess including pricing & provide clear direction to the internal stakeholders on entering into a specific geography
- Scope of the project:
 - A country overview
 - Analysis describing the healthcare and reimbursement system in each country (*overview of reimbursement system including type and split of healthcare, possible reimbursement pathways, requirements and HTA guidelines, timelines, costs, price negotiation, innovations*)
 - Analysis of previous decision making-practice for similar medical technologies
 - Reference pricing information
 - Specific information about comparators to the technology
 - Analysis of the reimbursed decision for the competitor



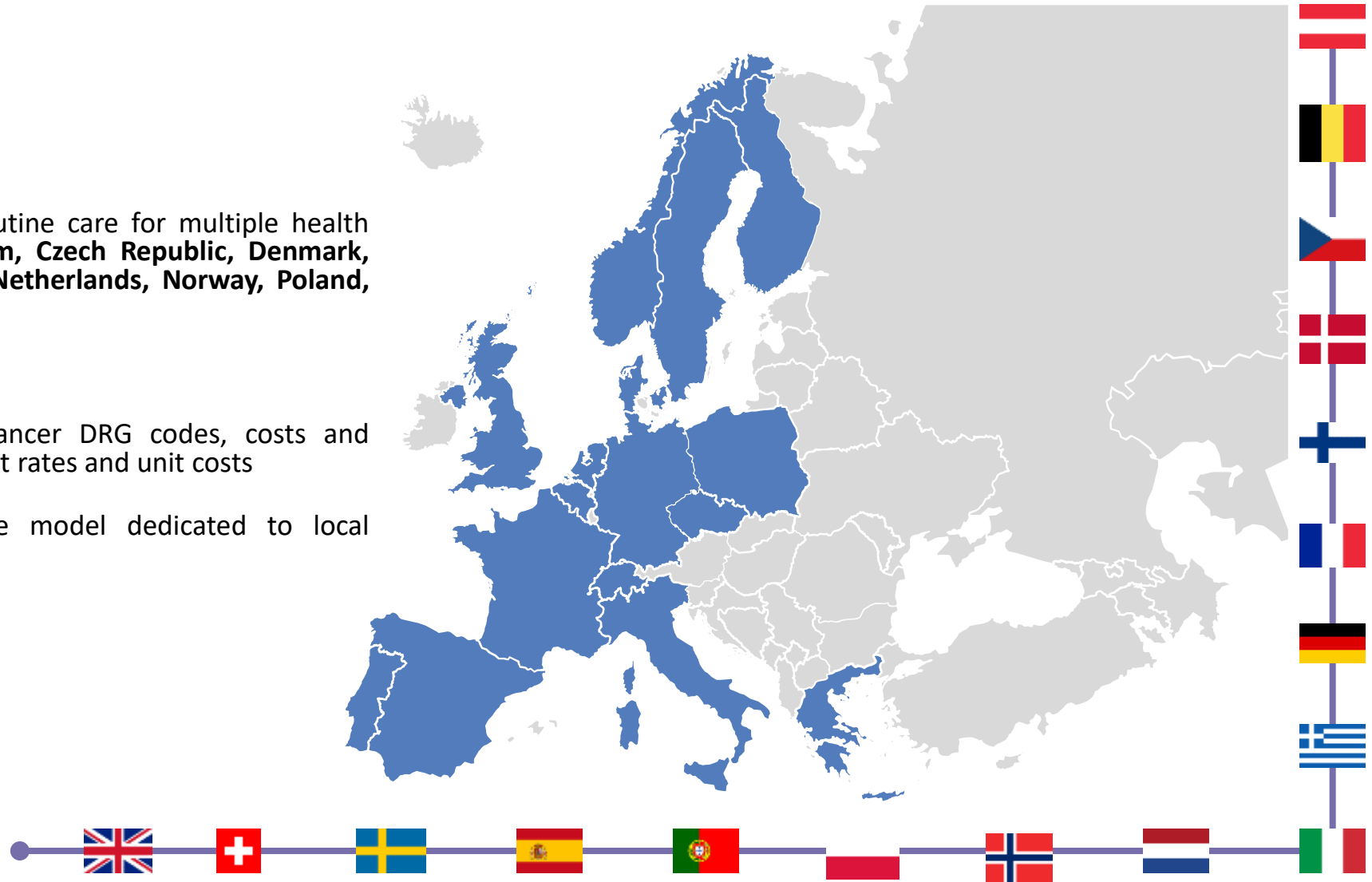
SYSTEMATIC LITERATURE REVIEW

IN 17 EU COUNTRIES

INAR

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- **Systematic literature review** of cancer routine care for multiple health states in EU17 countries (**Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Netherlands, Norway, Poland, Portugal, Spain, Sweden, Switzerland, UK**)
- **Desk research & Gap analysis**
- **Data gathered:** Inpatient routine care cancer DRG codes, costs and resource utilization, market share, treatment rates and unit costs
- **The project aim:** to populate corporate model dedicated to local submissions



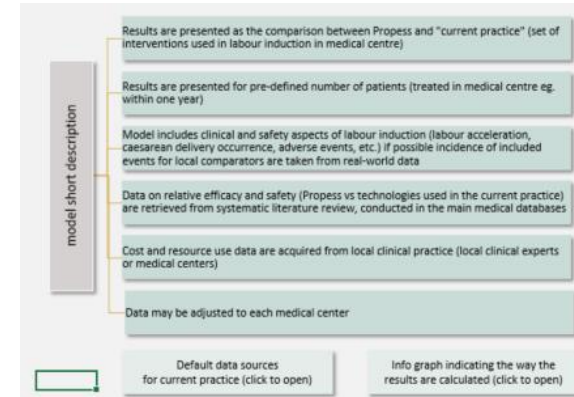
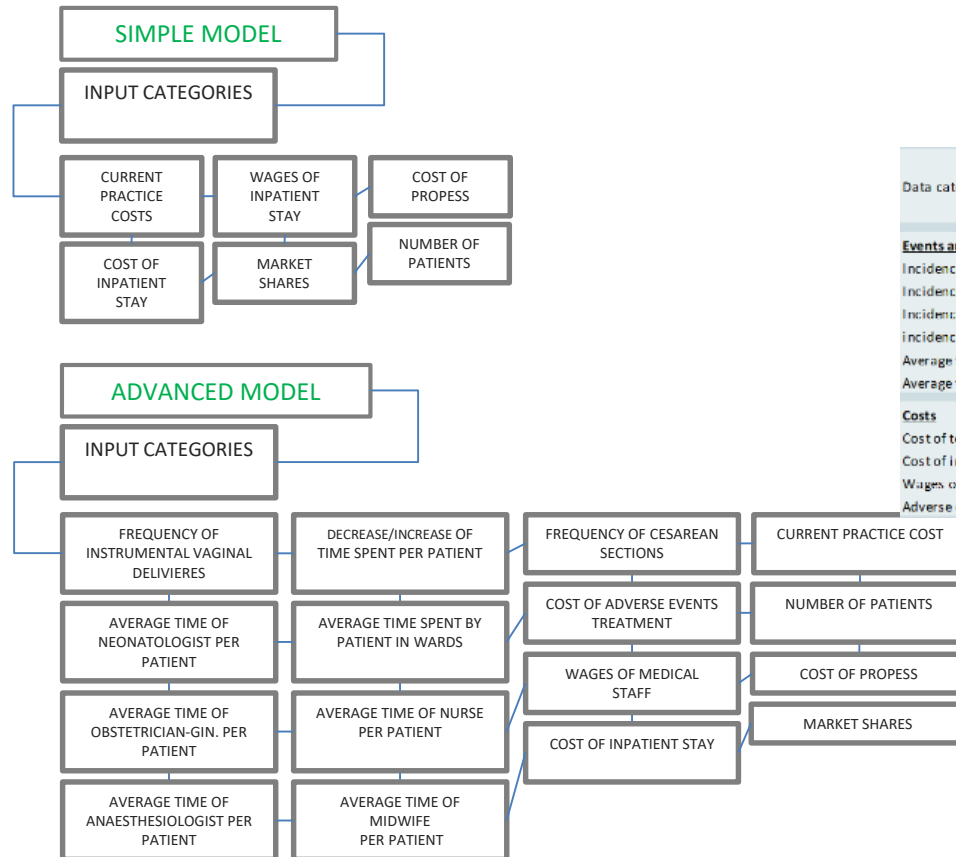
SUPPORTING PRODUCT LAUNCH

IN CEE, CIS AND BALTICS

ECONOMIC MODEL CASE

The model was adapted to conditions of 11 countries:

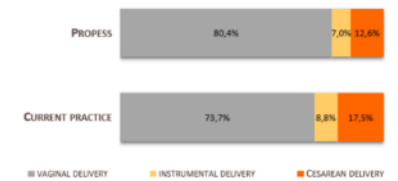
- Croatia
- Czech Republic
- Estonia
- Hungary
- Poland
- Romania
- Russia
- Serbia
- Slovakia
- Slovenia
- Ukraine



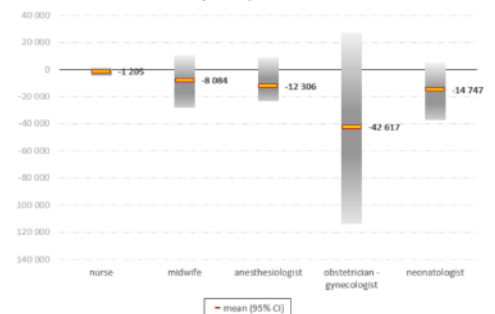
Data category	Local practice (from questionnaires)	Local practice in other countries	Randomized controlled trials
Events and resource use			
Incidence of Cesarean deliveries	<input checked="" type="checkbox"/>		
Incidence of instrumental vaginal deliveries	<input checked="" type="checkbox"/>		
Incidence of additional oxitocin administration			<input checked="" type="checkbox"/>
incidence of adverse events			<input checked="" type="checkbox"/>
Average time spent by patient in wards	<input checked="" type="checkbox"/>		
Average time spent by medical staff per patient	<input checked="" type="checkbox"/>		
Costs			
Cost of technologies used in labour induction	<input checked="" type="checkbox"/>		
Cost of inpatient stay in wards	<input checked="" type="checkbox"/>		
Wages of medical staff	<input checked="" type="checkbox"/>		
Adverse events costs	<input checked="" type="checkbox"/>		



Percentages of patients by mode of delivery



Medical staff salaries
Proppss vs current practice: additional RUB saved (-)/induced (+)
per 100 patients



REMOVABLE DINOPROSTONE VAGINAL DELIVERY SYSTEM: COST-CONSEQUENCES MODEL FOR CENTRAL AND EASTERN EUROPE COUNTRIES

Pacocha K¹, Pieniżek I¹, Stelmachowski J¹, **Walczak J¹**, Bierut A², Sajdak S³, Wilczak M⁴, Jaworowski A⁵, Rokita W⁶, Młodawski J⁶, Baev OR⁷, Bila J⁸, Pitko V⁹, Zhemela O¹⁰, Chorna O¹¹, Lohinova O¹²

¹Arcana Institute a Certara Company, Cracow, Poland, ²Ferring Pharmaceuticals Poland, Warszawa, Poland, ³Clinic of Surgical Gynecology, University of Medical Sciences, Poznań, Poland, ⁴Department of Maternal and Child Health, Gynaecology and Obstetrics Hospital of the Medical University in Poznań, Poznań, Poland, ⁵Clinical Department of Obstetrics and Perinatology The University Hospital in Cracow, Poland, ⁶Clinic of Gynecology and Obstetrics, Provincial Integrated Hospital in Kielce, Poland, ⁷National Medical Research center obstetrics, MOSCOW, Russian Federation, ⁸Clinic of Obstetrics and Gynecology, Yalta, Ukraine, ⁹The Government hospital Obstetrics, Gynecology and Perinatology, Lviv, Ukraine, ¹⁰The Obstetrics and Gynecology Hospital, Cherkassy, Ukraine, ¹¹The Obstetrics and Gynecology Hospital, Cherkassy, Ukraine, ¹²The Obstetrics and Gynecology Hospital, Cherkassy, Ukraine

to assess the savings and health benefits of induction of labor instead of alternative technologies in local European hospital settings.

in current practice, including time to vaginal delivery, vaginal delivery and adverse events. Efficacy and safety in medical databases. Cost and resource use data came from medical centers. Data was collected from the

literatures used in IOL indicated by local experts and clinical guidelines. Preliminary results for Russian conditions indicated that the use of DVDS is cost-saving for the following categories of costs: labor, hospitalization, and additional expenditures in the treatment of

patients. This study joins real life data from local practice with experimental data to inform on treatment standards and costs of IOL in



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Authors Affiliations: 1. Arcana Institute a Certara Company, Cracow, Poland 2. Ferring Pharmaceuticals Poland Sp. z o.o., Warsaw, Poland
Presenter name: Izabela Pieniżek, MSc

Abstract title: Effectiveness of removable Dinoprostone Vaginal Delivery System used in induction of labour: Systematic review of randomized controlled trials followed by data synthesis
Brief Introduction: The aim of the systematic review was to compare clinical effectiveness of Dinoprostone Vaginal Delivery System (DVDS) with other prespecified alternative technologies/devices used in induction of labour (IOL) in Central and Eastern Europe countries, including i.a. Balkans, Baltics, Hungary, Poland, Romania, Russia, Ukraine. The systematic review and data synthesis were preceded by local market recognition with regards to clinical practice used in induction of labour in the countries of interest.
Materials and Methods: An electronic search in Medline and The Cochrane Library was undertaken to identify randomized controlled trials comparing effectiveness of DVDS and

Effectiveness of removable Dinoprostone Vaginal Delivery System: Systematic review of randomized controlled trials

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⁸Clinic of Obstetrics and Gynecology, Clinical Center of Serbia, Belgrade, Serbia,

TARGETED DAILY MONITORING

FOR MEDICAL TECHNOLOGY IN CEE, CIS AND BALTICS

STEP I:

Targeted continuous monitoring of publicly available information with CASE ALERTS

Country Coverage – all **CEE, CIS, Baltic states and globally** (e.g. Big 5 EU, Canada, USA, Australia, New Zealand)

We monitor:

- Information from **CEE**, CIS, Baltics Ministries of Health and other relevant sources
- Reimbursement recommendations, not only **CEE/CIS/Baltics** but also from other well-recognized agencies
- Information on changes in legal provisions regulating the financing of health technologies from public funds
- News on technology safety, new marketing authorizations, variations in registered and reimbursed indications published by EMA, HMA, FDA, MHRA, European Commission and other national institutions
- Other valuable information which may impact reimbursement, published in mass-media and sectoral press

STEP II:

Tailored monthly update of information gathered by local experts (from **CEE**, CIS, Baltic states)

Local experts opinion and insight (focused on medical technology reimbursement status and other relevant Market Access and Regulatory Affairs information gathered through a customized questionnaire.)

Sample questions:

- Is the technology registered?
- Is the technology reimbursed under 'normal conditions' (standard procedure)?
- Is the technology reimbursed (available for patients) under any special condition
- Is the technology during/after the preparation of reimbursement application or during the negotiation process?

