IMS Health & Quintiles are now IQVIA™

KSE Kyiv School of Economics

Spending on healthcare and access to treatment

Report of key findings

January 2020

Initiated and supported by ACC AMERICAN CHAMBER OF COMMERCE UKRAINE APRaD

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Glossary

Healthcare indicators' description and metrics used throughout the analysis

Indicator	Description	Unit	Source
GDP	Gross domestic product measured at Purchasing power parity	EUR[1]	IMF
Healthcare expenditures	Health spending measures the final consumption of health care goods and services, including personal health care (curative care, rehabilitative care, long-term care, ancillary services and medical goods) and collective services (prevention and public health services as well as health administration), but excluding spending on investments	EUR[2]	OECD
State healthcare expenditures	Government healthcare expenditures are financed through government spending and compulsory health insurance	%	OECD
Private healthcare expenditures	Private healthcare expenditures are financed through voluntary health insurance and private funds (out-of-pocket payments)	%	OECD
Pharma market	Total market of pharmaceutical products, in Ukraine includes private market (out-of-pocket) and state reimbursement	-	IQVIA, Proxima Research
State reimbursement	State reimbursement includes both hospital purchases and retail reimbursed drugs. In Ukraine state reimbursement includes all types of government purchases, including National programs, regional and local budgets	-	IQVIA, Proxima Research
Co-payment	Patients contribution towards the cost of reimbursed out-patient medicines and towards the cost of their general care	-	-
Clawback tax	Clawback tax referred to obligation of the drug producers to pay contribution for reimbursed medicines	-	-
Original drugs	***Incldues: (1) Innovative (protected) drugs:*** *First on the market products (original) invented by companies running R&D, clinical studies and getting exclusive rights for selling the product for a period of time (~20 years). The newest and the most recent. Subsegment:* ***biological products (including vaccines);*** ***(2) Original non-protected:*** *Original products which lost exclusivity (patent protection) and generics are existent on the market*	EUR[2]	IQVIA
Generics and bioanalogues	***Includes: (1) Generic:*** *Product with the same formula as original product proven for similar effectiveness, safety and mode of action. Can be produced when original products lose exclusivity;* ***(2) Biosimilar (bioanalogues):*** *Biological drugs similar in quality, effectiveness and safety to a reference original biological product*	EUR[2]	IQVIA
Other drugs (non-generic & non-original)	**Includes (1) Food supplements:** Vitamins, minerals, naturally occurring products; **(2) *Traditional and natural:*** *products that are extracted from natural components, traditionally produced (i.e. carvalol)*	EUR[2]	IQVIA

(1) Converted at fixed ex. rate EUR/USD = 1.1438 as of 31 December 2018; (2) Converted at fixed exchange on 31 December 2018

Healthcare indicators' description and metrics used throughout the analysis

Indicator	Description	Unit	Source
Life expectancy	Life expectancy at birth indicates the number of years a newborn infant would live if prevailing patterns of mortality at the time of its birth were to stay the same throughout its life	Years	World Bank
Mortality rate	Crude death rate indicates the number of deaths in general per 1K individuals per year	% per 1K people	World Bank
Birth rate	Birth rate or fertility rate indicates the number of births per woman	# children per woman	World Bank
Infant mortality	Infant mortality indicates the number of deaths of children under one year of age per 1K live births	Cases per 1K live births	World Bank
Mortality from oncology	Indicates the number of deaths per 100 K people caused by oncological diseases (cancer)	Cases per 100K people	WHO, OECD
Mortality from Cardiovascular	Indicates the number of deaths per 100 K people caused by cardiovascular diseases (heart attack and stroke)	Cases per 100K people	WHO
DALYs	DALYs are calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the Years Lost due to Disability (YLD) for people living with the health condition or its consequences	Years per 1 mn people	World Bank
Amenable mortality rate	Amenable mortality is defined as deaths from a collection of diseases, e.g. diabetes and appendicitis, that are potentially preventable given effective and timely health care	Age standardized rate per 100 K people	World Bank
W.A.I.T. indicator: Rate of availability	Rate of availability is a number of new medicines (i.e. medicines including a substance that has not been previously available in Europe) available (having market authorization) to patients in European countries as of 2018	In percent	IQVIA
***W.A.I.T. indicator:* Length of market access delays (average)**	***The average time between marketing authorization and patient access*** *indicates the number of days elapsing from the date of EU marketing authorization (or effective marketing authorization in non-EEA countries) to the day of completion of post-marketing authorization administrative processes*	Days	IQVIA

Healthcare indicators' description and metrics used throughout the analysis

Indicator	Description
Budget excess repayments	• Excess out-patient pharmaceutical spending, i.e. above the annual budget set by the government are repaid by manufactures
Clawback tax	• Sales of reimbursed medicines are subject to a clawback-type tax, charged on the manufacturer's selling price of reimbursed drugs • An additional clawback-type tax can be payed on certain medicines
A fee payable for sales representatives	• Pharmaceutical manufacturers are required to pay a fee for each pharmaceutical sales representative employed
Patient co-payments	• Patients contribute towards the cost of reimbursed out-patient medicines and towards the cost of their general care
Generic pricing rule	• Generics price regulation according to which the price of new and subsequent launches are subject to discounts or caps relative to reference group or branded original drugs
Health Technology Assessment (HTA)	• Systematic evaluation of the properties and effects of new medicines, including evidence regarding clinical effectiveness, safety, cost-effectiveness and others aimed to address the direct and intended effects as well as indirect and unintended consequences

Healthcare indicators' description and metrics used throughout the analysis

Indicator	Description
Financial Based Agreements	• Price level or nature of **reimbursement is based on financial considerations** and is not related to clinical performance
Performance Based Agreements	• Price level or nature of **reimbursement is tied to future metrics** ultimately related to patient performance, outcomes, efficacy, tolerability, dosing, benefit, outcomes, quality of life, or clinical usage
Coverage with Evidence Development (CED)	• Reimbursement decision in which approval is conditional on the **collection of additional population level studies after launch** (with provisional reimbursement) to support coverage or pricing
Price control	• Reference pricing is applied, i.e. the proposed manufacturer's selling price must not exceed the lowest MSP of the same drug in the European Economic Area • Other price control may include a V4 Plus group price discount negotiations and drug reimbursement conditions initiative. An innovative cancer drug and an orphan drug will reportedly be the first drugs to have their prices negotiated by the group
Budget cap	• While not being a preferred option for companies, budget caps have been recently required by payers for most molecules and also for molecules already in the market
Prescribing control	• Government has a number of tools at its disposal to influence doctors' prescribing habits, such as Traffic Light System, Prescribing Quotas, etc.

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Healthcare systems overview

Ukraine is lagging behind benchmarking countries in economic development with GDP per capita 3-4 times lower than in East Europe

Economic environment

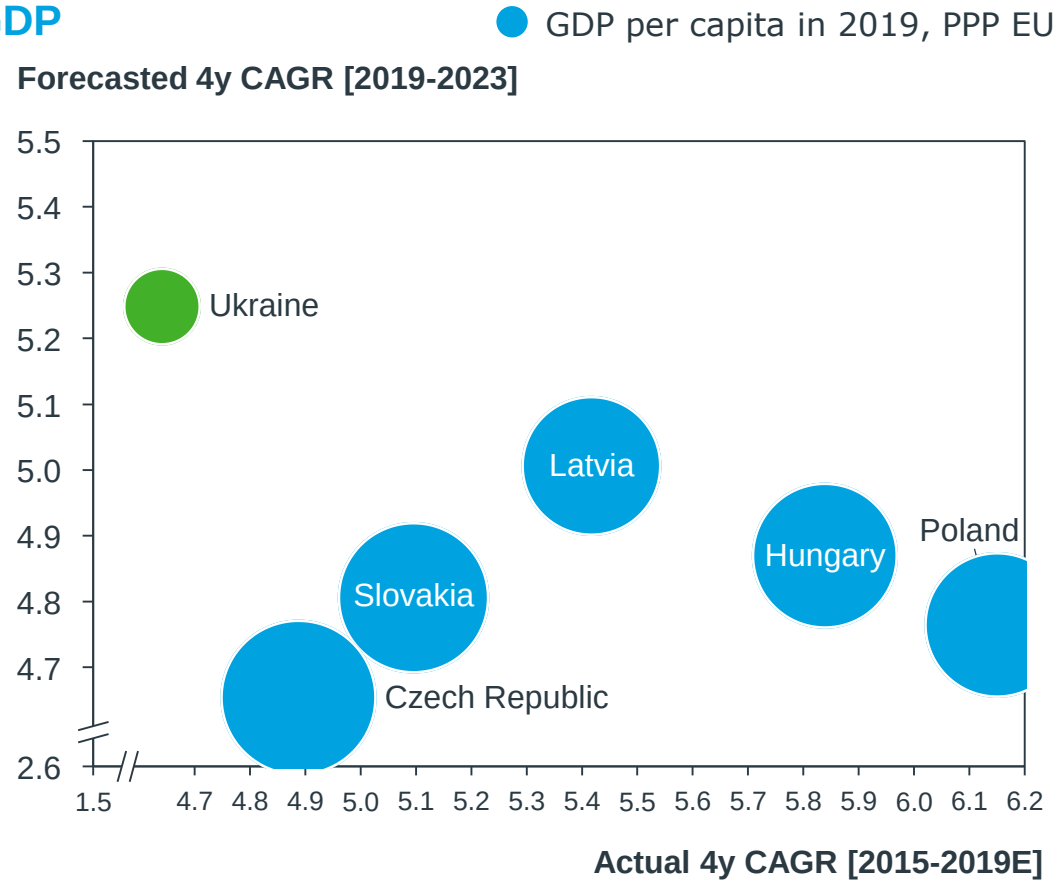
Population

Region	Population [mn, 2019E]	GDP size [PPP bn EUR[1], 2019E]	GDP / capita [PPP bn EUR[1], 2019E]
Czech Republic	10.6	361	34,0
Hungary	9.8	290	29,8
Latvia	1.9	53	27,4
Poland	38.0	1 125	29,6
Slovakia	5.5	175	32,0
Ukraine	**42.2**	**358**	**8,5**

Comments

- **Ukraine has the biggest population** compared to CHLPS countries
- However, **GDP per capita is significantly lower in Ukraine**
- Nevertheless, despite lowest GDP per capita and lowest historical growth of 2% CAGR 2015-2019, **Ukraine is expected to grow with the fastest growth rate in 2019-2023** due to improved business environment and political situation stabilization

GDP



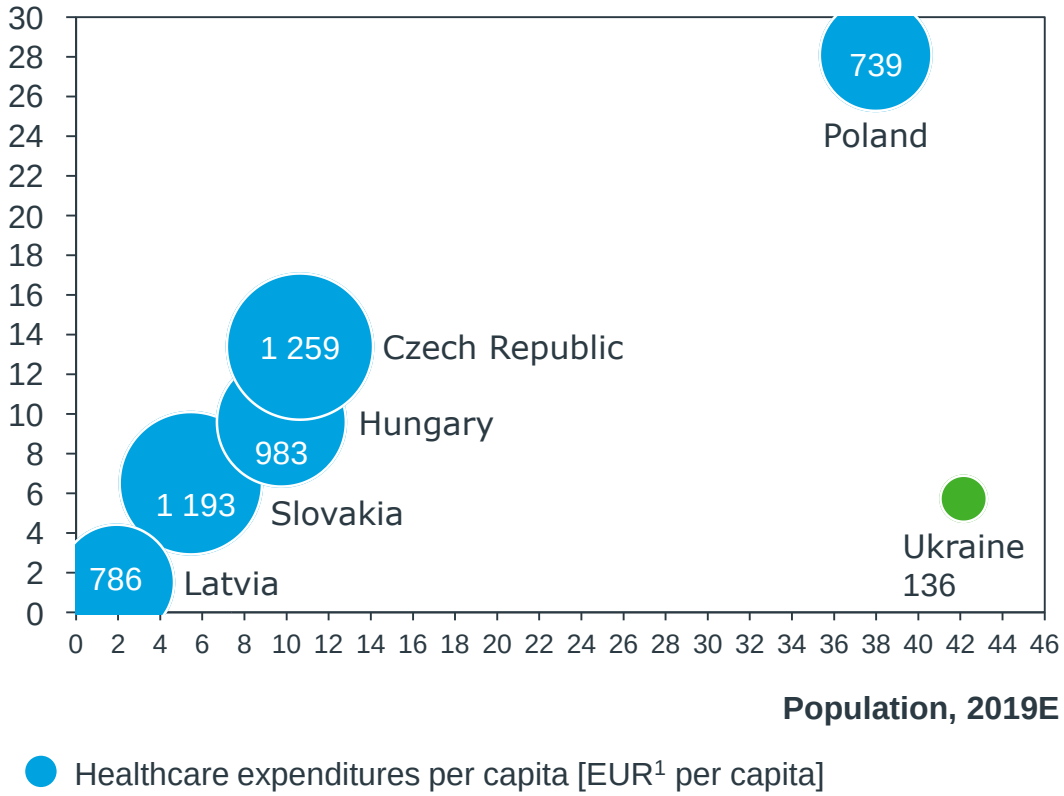
(1) Converted at fixed ex. rate EUR/USD = 1.1438 as of 31 December 2018
Source: IMF, ukrstat.gov.ua

Gap is deepening at healthcare expenditure per capita level with Ukraine five times lower than in Latvia and Poland, 7-9 times lower than in Czech, Hungary

Healthcare provision

Healthcare expenditures

Healthcare expenditures [Bn EUR[1], 2019E]



Comments

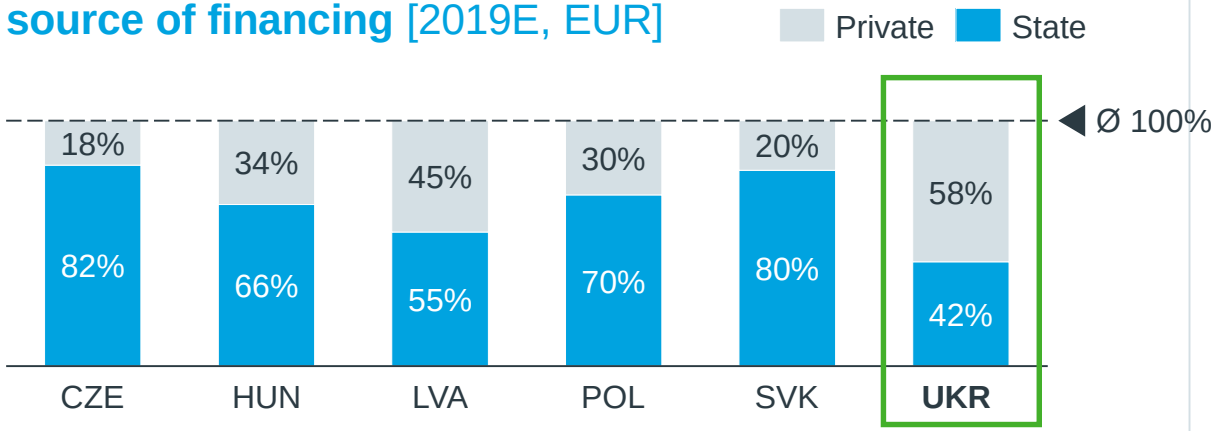
- **Total Ukraine healthcare expenditures** are comparable with Latvia, Slovakia and Hungary. However, Ukraine population is much bigger (x23 Latvia, x8 Slovakia, x5 Hungary)
- **Ukraine healthcare expenditures per capita are the smallest** compared to CHLPS countries
- Healthcare expenditures in Ukraine **amount to 3.6% of GDP** (CHLPS countries range is vary from 5.9% in Latvia to 7.5% in Czech Republic)
- The healthcare sector in Ukraine has been **underfunded for many years** after the demolish of the Soviet Union. The patients have been suffering for years from the **lack of access to the essential medical services and the services** converted in the ghost market in reality. Patients had to pay out of pocket for nominally free and guaranteed services for 80% of the cases
- In February 2017, the Ministry of Health presented reform perspective for 2017-2020. The reform targets include **increase of public funding of patient service**s for state-based guaranteed amount of services and **boost in efficiency** by creating competition for a patient in the sector
- Focus areas include the introduction of **new funding model for primary care, creating a national health service, creation of hospital districts and implementation of medicine reimbursement**

(1) Converted at fixed exchange on 31 December 2018
Source: World Bank, IQVIA

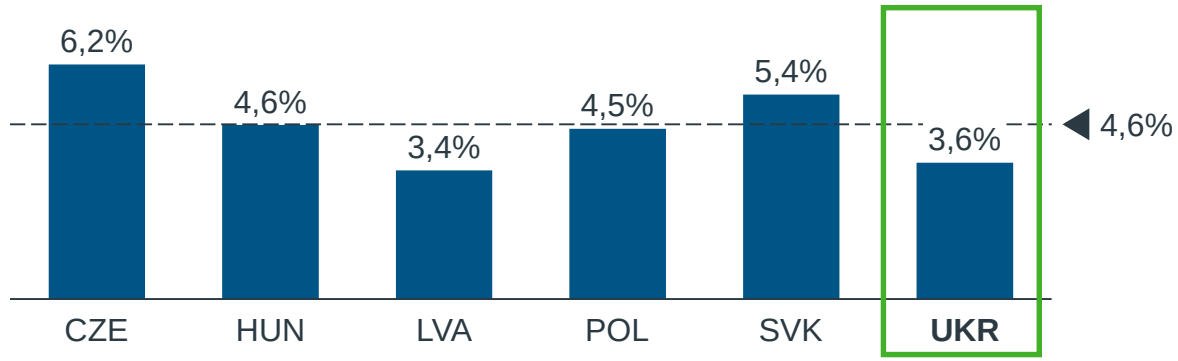
State healthcare expenditures in Ukraine comprise 3.6% of GDP, half of CHLPS countries average of 4.5%

Healthcare provision structure

Healthcare (state and private) expenditures by source of financing [2019E, EUR]



State healthcare expenditures as % of GDP [2019E, %]



Comments

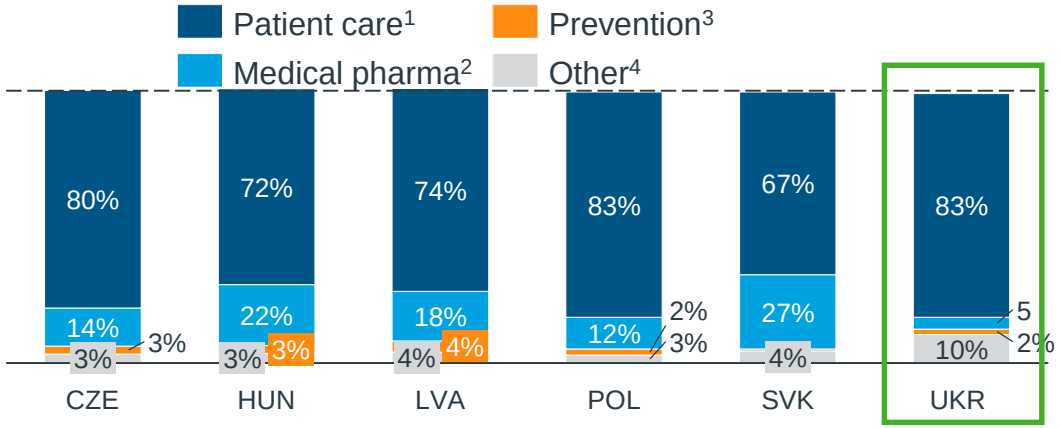
- **Ukrainian** healthcare is driven mostly by **private spending** (~60%), whereas in CHPLS countries private health spending share is not exceeding 18-45%
- Private healthcare contributes is very high in Ukraine as the state is not capable of providing sufficient amount of free healthcare services guaranteed by the law
- **Healthcare reform in Ukraine** is aimed to increase **state spending up to 5%** (of GDP) to reach European countries level (starting from 2020)
- The **state healthcare in Ukraine** is mainly **financed by tax revenues**, while in **CHLPS countries** other funding sources also take place:
  - Main funding is received via **health insurance** (ex: Czech Republic, Hungary, Poland, Slovakia)
  - In Hungary and Poland additional funding is received via **clawback tax**
  - In CHLPS countries there is also a **co-payment system**, when patients partially finance their treatment

Source: OECD, IQVIA

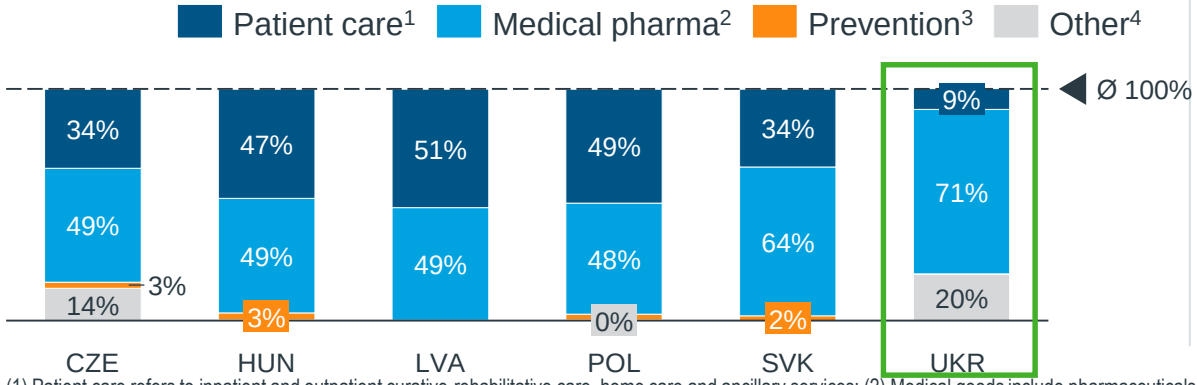
State healthcare expenditure for pharmaceuticals comprises only 4% from state HC expenditure in Ukraine compared to average 20% in CHLPS countries

Healthcare provision structure

State healthcare expenditures by source of financing



Private healthcare expenditures by source of financing



Comments

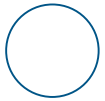
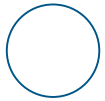
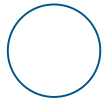
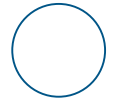
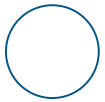
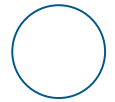
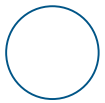
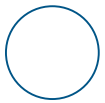
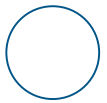
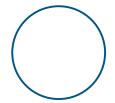
- **Patient care** (medical services) and **medical pharma** (purchasing of pharmaceutical and other medical products) are two **major healthcare components** comprising up to 90% in CHLPS countries
- In Ukraine **medicines are mainly covered out-of-pocket** (~70% of private healthcare expenditures) while patent care covered by state is one of the highest in Ukraine (83% in state HC expenditure structure)
- The government in Ukraine is trying to secure free access to healthcare services as a constitutional right and aiming to make healthcare service universally accessible in the constrained financing environment but in public clinics most of patients are covering required drugs out-of-pocket
- Patient care, prevention and others, including administration and other medical services, as well as part of pharma and medical product purchasing constitute aggregated expenditures of the clinics. The elements are **partially cover CAPEX** for replacement of fixed assets and equipment

(1) Patient care refers to inpatient and outpatient curative-rehabilitative care, home care and ancillary services; (2) Medical goods include pharmaceuticals and other medical durable and non-durable goods; (3) Prevention includes vaccination, early disease detection programmes, disease control programmes; (4) Other includes administration costs, additional medical care services, etc.
Source: OECD, IQVIA

The only source of financing of healthcare in Ukraine is tax proceeds, while all Eastern European countries are using insurance to finance healthcare

Government healthcare provision overview

Public healthare funding sources

Financing sources of state HC spending	Czech Republic	Hungary	Latvia	Poland	Slovakia[2]	Ukraine[3]
Tax revenues						
Compulsory health insurance						
Co-payment						
Clawback tax[1]						

Notes: (1) Clawback tax referred to obligation of the drug producers to pay contribution for reimbursed medicines
(2) Taxes in Slovakia are limited due to high proportion of economically inactive population
(3) Private insurance system in Ukraine is contributing only ~2% (2017) of the total private expenditure and covers mostly corporate employees as a part of social corporate package

Source: IQVIA

Compared to CHLPS countries Ukraine pharma market consumption is lower both in value and volume terms by three and four times correspondingly

Pharmaceutical market

Pharma market size and growth

Country	Pharma value [Bn EUR[1], 2019E]	Pharma value per capita [EUR[1]/ capita, 2019E]	Consumption [SU/ capita, 2019E]	CAGR[2] [EUR, 2015-2019E]
Czech Republic	2.9	271	1 110	11.9%
Hungary	2.9	292	1 307	5.6%
Latvia	0.4	223	1 233	6.1%
Poland	7.5	197	1 242	5.4%
Slovakia	1.6	294	1 233	2.5%
Ukraine	**3.0**	**71**	**479**	**9.8%**
CHLPS average	Ø 3.0	Ø 255	Ø 1 225	Ø 6.3

(1) Converted at fixed exchange on 31 December 2018;
(2) Pharma market annual growth 2015-2019 is calculated in EUR and does not include local currency fluctuations
Source: IQVIA, OECD, Proxima Research

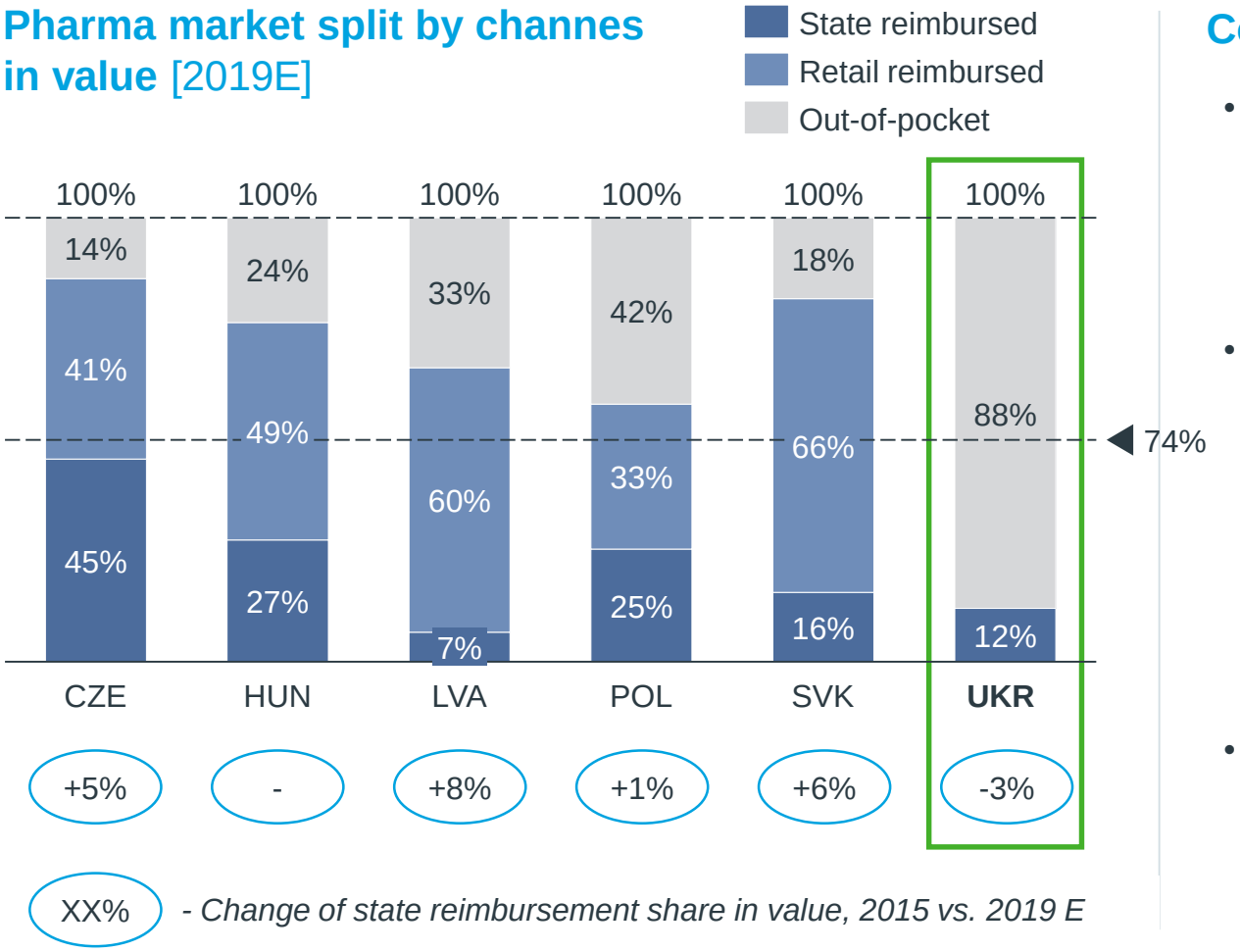
Comments

- Ukraine **total pharma market is comparable** with CHLPS countries
- However, **consumption of pharma products is much lower** in Ukraine:
  - By ~x3 times in units per capita
  - By ~x4 times in EUR per capita
- Nevertheless, **historically Ukrainian pharma market has been growing faster** compared to more developed CHLPS countries except for Czech Republic

In Ukraine government covers 12% of pharmaceuticals (vs CHLPS countries ~74% on average)

Pharmaceutical market structure

Pharma market split by channes in value [2019E]



Comments

- In Ukraine the state funds only **12% of the total drugs expenditures**, which is **significantly below** CHLPS countries. However, the introduced healthcare reform implies raising coverage of population by pharmaceutical products
- **The introduction of state medical reimbursement system** in Ukraine in 2017 for certain drugs (diabetes, cardiovascular, asthma), reference pricing mechanism for a group of medicines, introduction of e-health system targeting the patient are key steps undertaken by the government to **improve patients access to the treatments** in accordance with the modern world's standards
- State reimbursement in Ukraine is comprised of **primary care (e.g. insulins), regional** and **centralized purchases** of the Ministry of Health

Source: IQVIA, Proxima Research

Pharmaceutical products include Original and Biological drugs, Generics and Bioanalogues and Other products

Pharmaceutical market structure

Pharmaceutical market segmentation

Pharmaceutical products

Original drugs	Generics and bioanalogues	Others
Innovative (protected) *First on the market products (original) invented by companies running R&D, clinical studies and getting exclusive rights for selling the product for a period of time (~20 years). The newest and the most recent Subsegment:* ***biological products (including vaccines[1])***	***Generic*** *Product with the same formula as original product proven for similar effectiveness, safety and mode of action. Can be produced when original products lose exclusivity*	***Food supplements*** *Vitamins, minerals, naturally occurring products*
Original non protected *Original products which lost exclusivity (patent protection) and generics are existent on the market*	***Biosimilar (bioanalogues)*** *Biological drugs similar in quality, effectiveness and safety to a reference original biological product*	***Traditional and natural*** *Products that are extracted from natural components, traditionally produced (i.e. carvalol)*

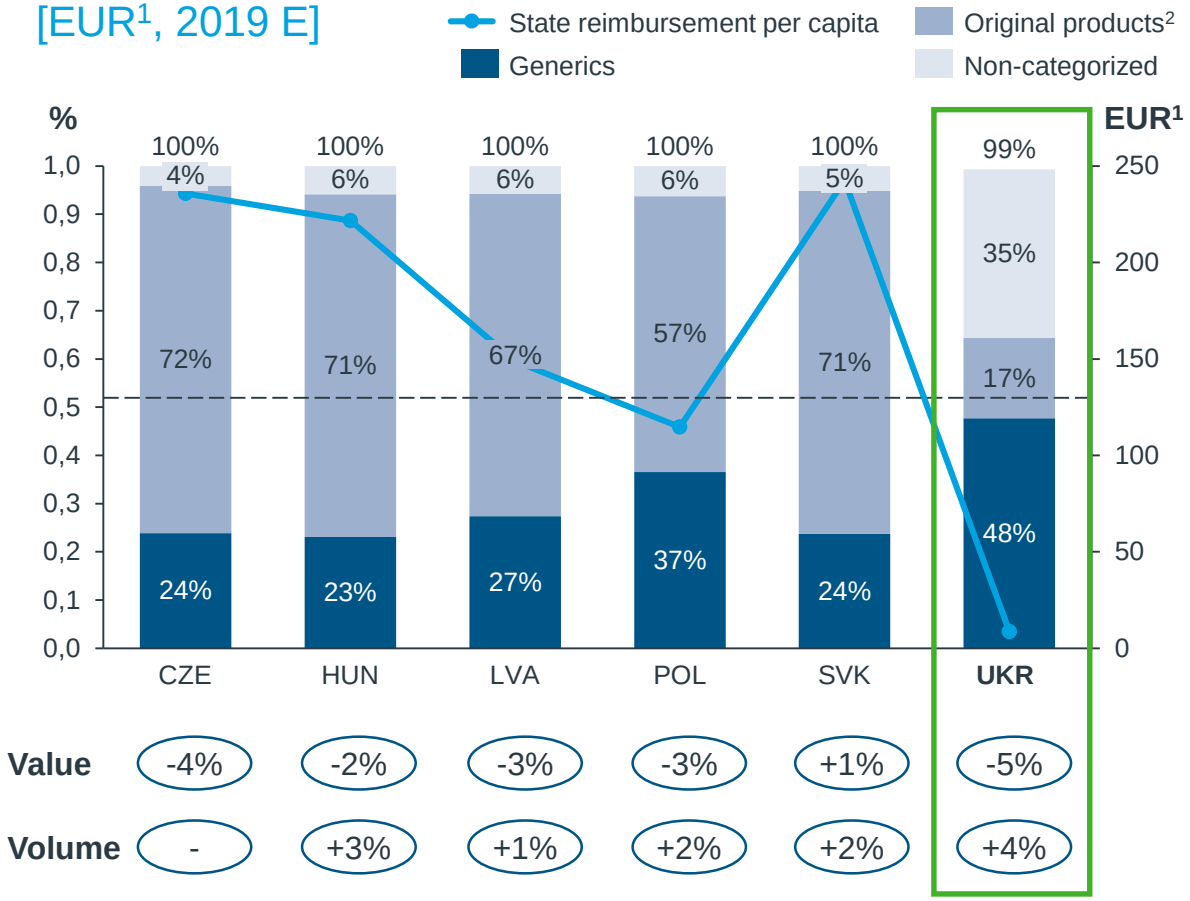
(1) All vaccines are classified as Original drugs as >90% of all vaccines in CHLPS countries are biological
Source: IQVIA

Ukraine has the lowest state spending per capita and the largest Gx and Other drugs share in state reimbursement, which is ~50% higher than CHLPS countries average

Pharmaceutical market structure | State reimbursement

Gx and Original drugs state reimbursement

[EUR[1], 2019 E]



Comments

- **Ukraine** has **the lowest government spending per capita** and **the largest generics share** in government spending
- At the same time ~**36% of Ukrainian state reimbursement** is allocated on **other pharmaceutical products**, i.e. w/o evidence (food supplements, traditional and natural), which is ~30% more compared to CHLPS countries
- As a result, in Ukraine, unlike European countries, **the biggest portion of innovative** treatments is beared by population out of pocket spending
- **In volume terms generics share in government purchases has increased** in all countries
- **Share of generics drugs is expected to increase further** in volume in government procurement structure as a result of increasing accessibility of new medicines available at lower prices of better quality and safety profiles

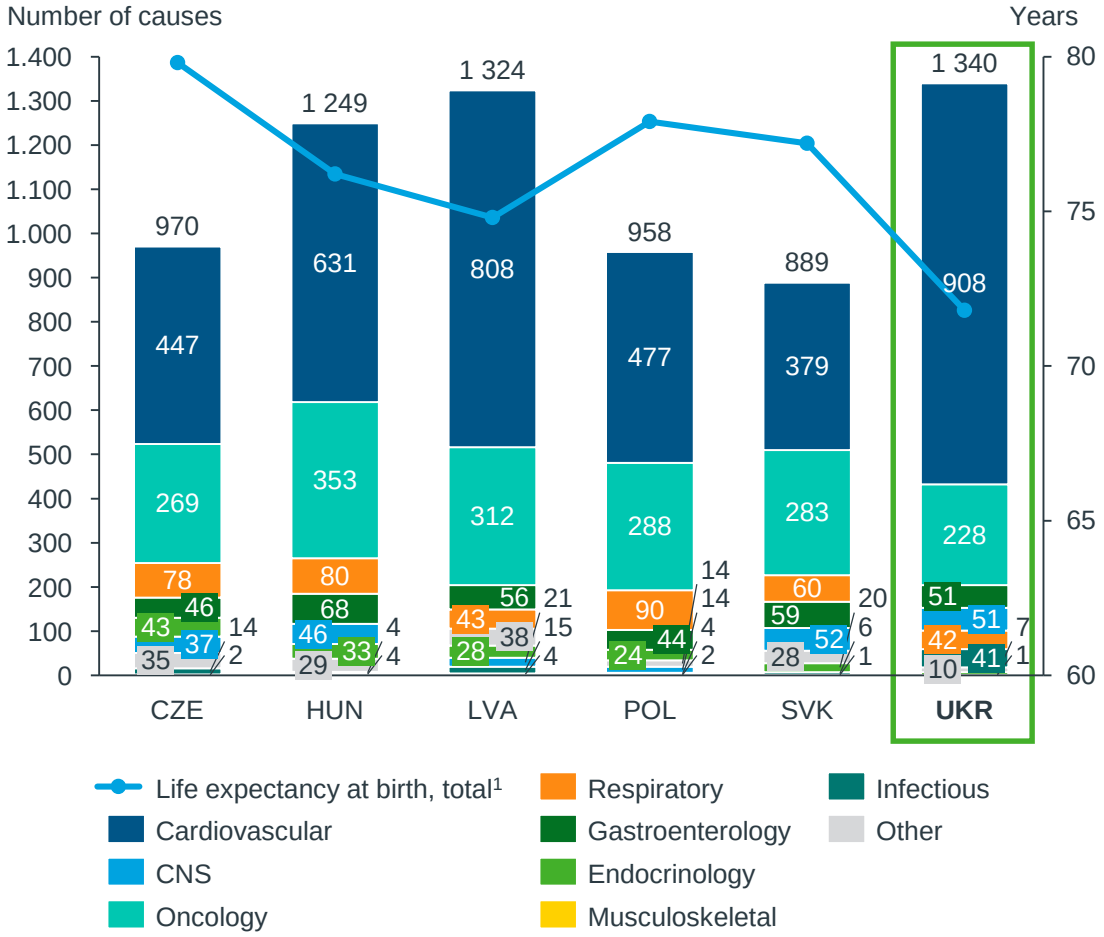
(1) Converted at fixed exchange on 31 December 2018;
(2) All vaccines are classified as Original drugs as >90% of all vaccines in CHLPS countries are biological
Source: IQVIA, Proxima Research

XX% - *Change of Gx share in state reimbursement, 2015 vs 2019*

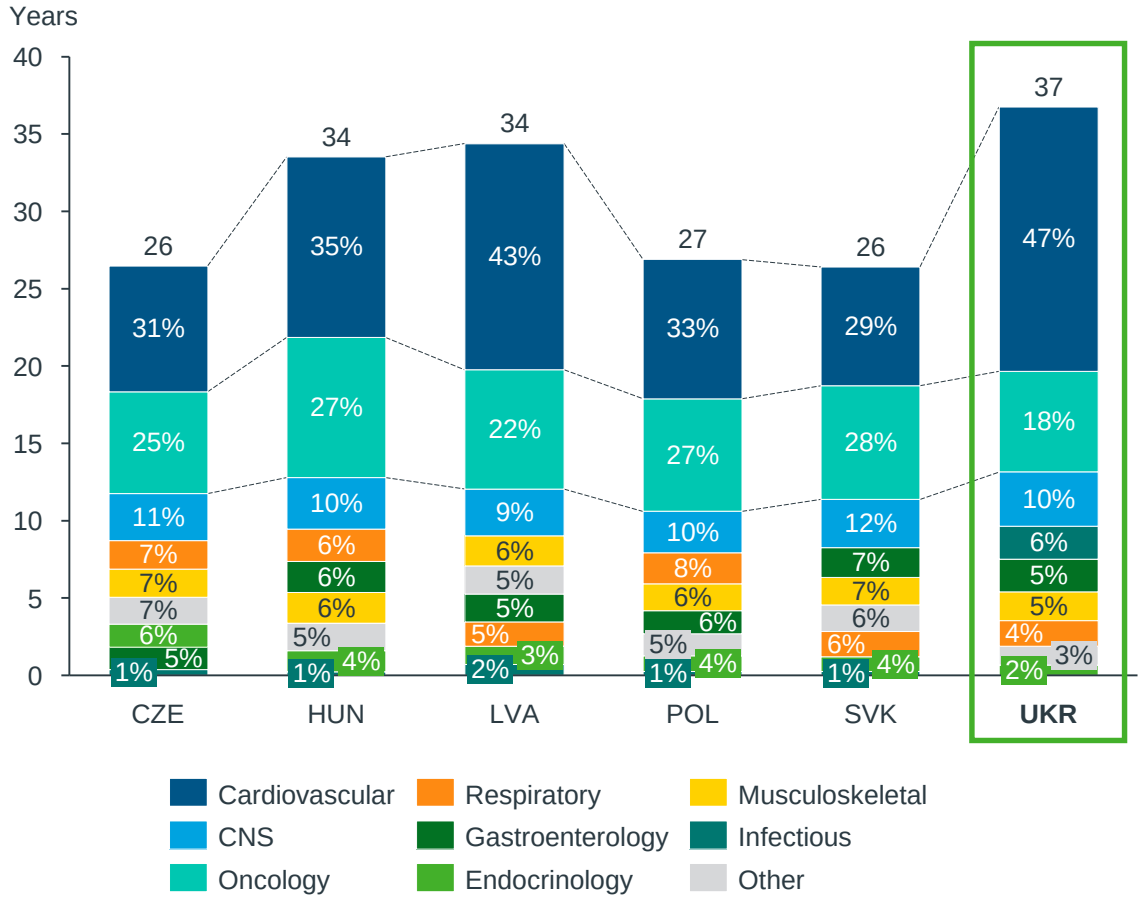
Ukraine has the highest death rate among CHLPS countries with cardiovascular and oncology as primary reasons

Leading causes of death and diseases

Top causes of death [rate per 100 K people]



Top diseases [DALY, years per 100 K people]

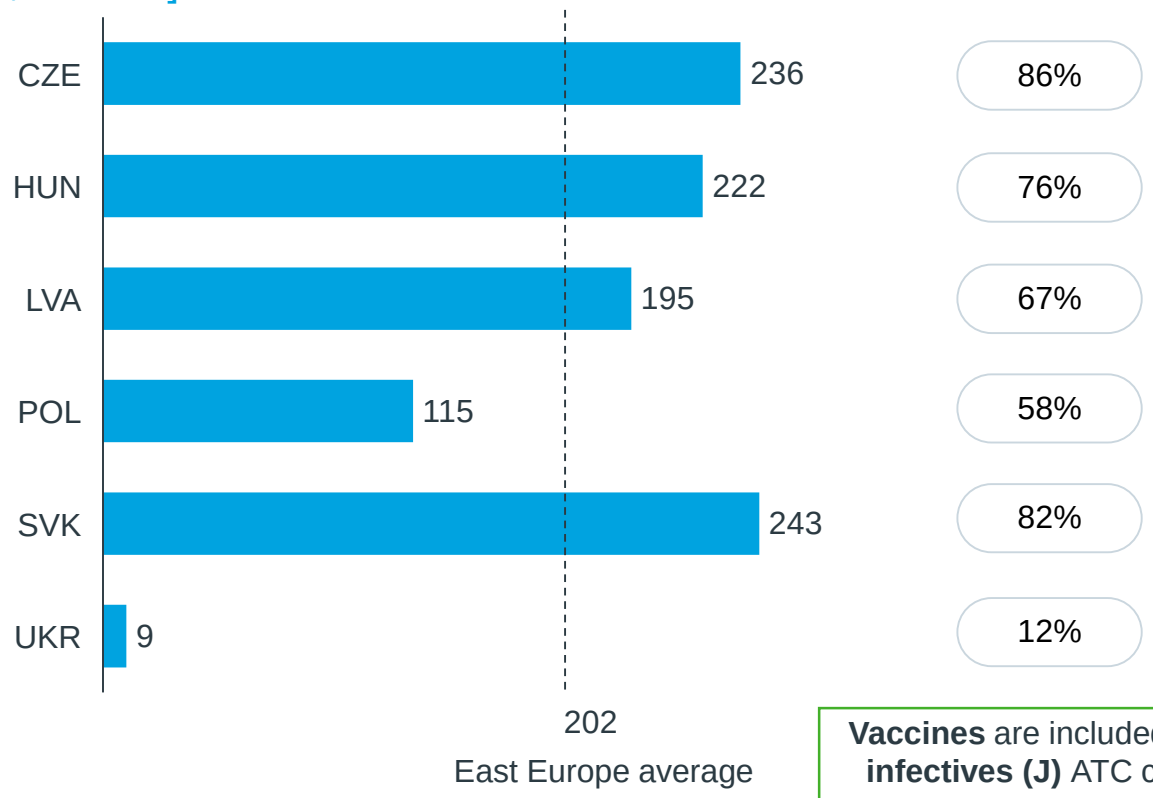


Source: IQVIA analysis, WHO

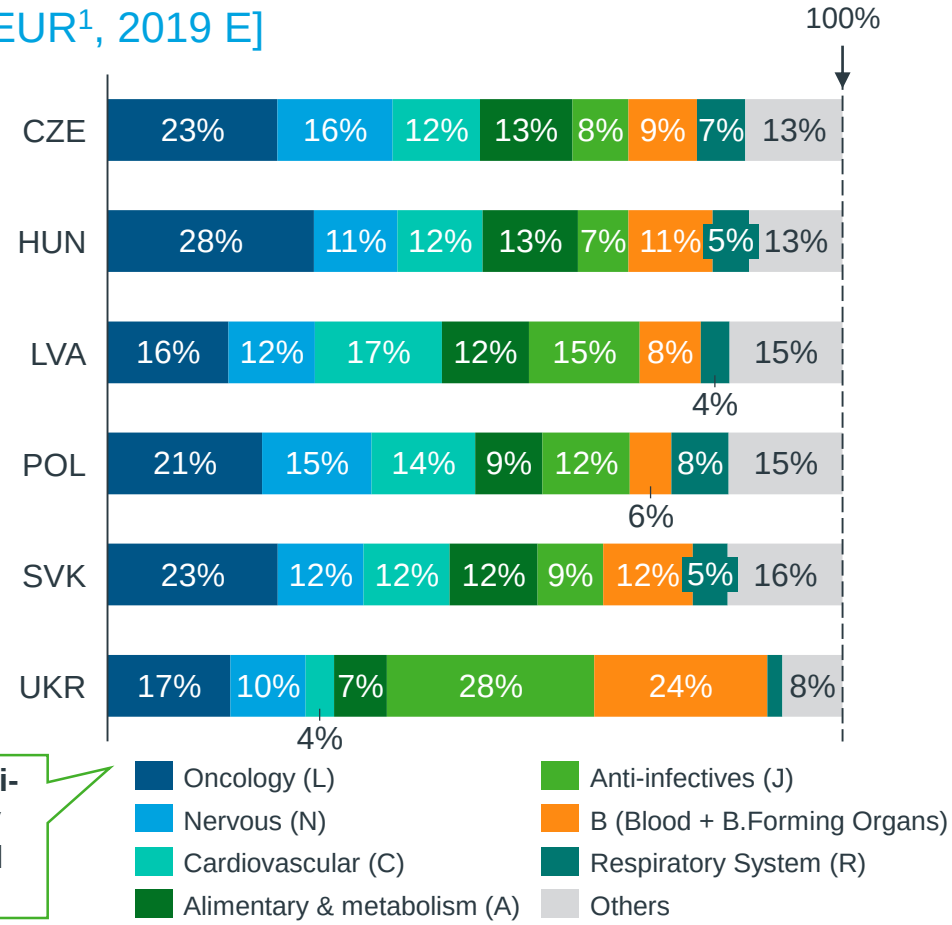
State reimbursement per capita of pharmaceutical products in Ukraine is ~22 times lower than in Easter European countries

State reimbursement structure by therapy (ATC1)

State reimbursement of pharmaceuticals per capita
[EUR[1], 2019 E]



Share of therapy value in state reimbursement
[EUR[1], 2019 E]



Vaccines are included in **Anti-infectives (J)** ATC category (in Ukraine 4% share of total state reimbursement)

(1) Converted at fixed exchange rate on 31 December 2018
Source: IQVIA, Proxima Research

XX - Share of state reimbursement in pharma market

Ukraine is lagging behind East European countries on most of healthcare KPIs

KPIs of Healthcare system (1/2)

KPIs of healthcare system in Ukraine and benchmark countries

Country	Life expectancy, male [years, 2019E]	Life expectancy: female [years, 2019E]	Mortality rate [% per 1K people]	Birth rate [# children per woman]	Infant mortality [cases per 1K live births, 2019E]	Mortality from oncology [cases per 100K people]	Mortality from Cardiovascular [cases per 100K people]	Vaccination per capita [EUR[1], 2019E]
Czech	77	83	10.6	1.6	2.6	269	447	3.9
Hungary	73	80	13.5	1.4	3.6	353	631	4.9
Latvia	70	80	15.0	1.6	3.2	312	808	2.3
Poland	74	82	10.7	1.3	3.7	288	477	1.5
Slovakia	74	81	9.9	1.5	4.5	283	379	6.1
Ukraine	67	77	14.5	1.6	7.5	228	908	0.6
	Ø 73	Ø 80	Ø 12	Ø 1.5	Ø 4.2	Ø 289	Ø 608.3	Ø 3.2

- Have not been included in national health goals

- Have been included in national health goals

Low level of mortality from oncology may be caused by lower life expectancy (as oncological diseases mostly appear in older ages), lower diagnostic level and incorrect codification of death cause

Comments

MoH of Ukraine **established an action plan in 2019** with a number of **healthcare KPIs**:

- **Lower prevalence rate**
  - infectious diseases number decrease - by 20%
  - reduction of cardiovascular diseases in patients of working age - by 10%
- **Faster recovery**
  - average length of hospitalization reduction - by 20%
  - number of cases when a person's working capacity reduced as a result of illness - decrease by 10%
- **Longer life span**
  - mortality rate reduction by 5%
  - life expectancy increase by 5%

Source: IQVIA, World Bank, WHO

Current low funding level of pharmaceuticals and low state coverage do not allow to achieve comparable health outcome results

KPIs of Healthcare system (2/2)

Parameters influencing KPIs

[2019 E]

Country	Economic capacity (GDP / capita) [k EUR[1], 2019E]	State share in healthcare expenditures [value, %]	Share of pharmaceuticals in healthcare [value, 2019E]	State share in pharmaceuticals [value, 2019E]	Share of innovations in state reimbursement [value, 2019E]
Czech	34.0	82%	22%	86%	72%
Hungary	29.8	66%	30%	76%	71%
Latvia	27.4	55%	28%	67%	67%
Poland	29.6	70%	27%	58%	57%
Slovakia	32.0	80%	25%	82%	71%
Ukraine	8.5	42%	52%	12%	17%
	Ø 27	Ø 66	Ø 31	Ø 1	Ø 59

Influenceable parameters

Comments

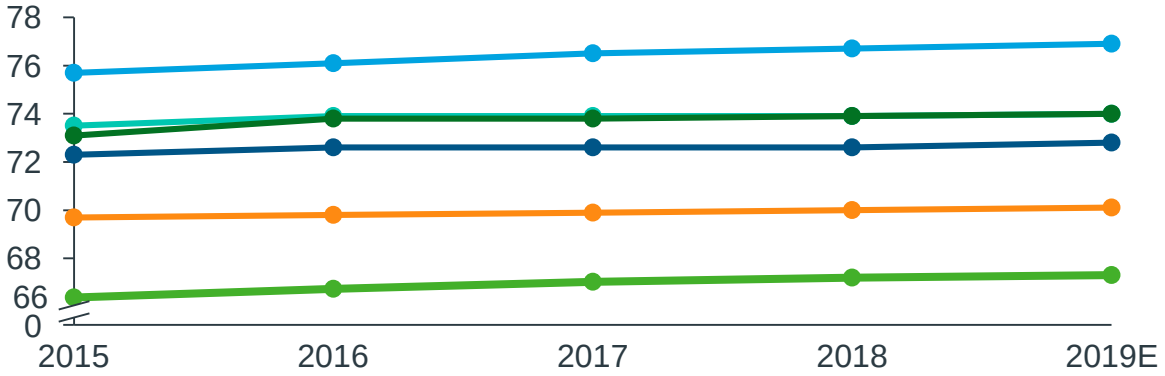
- Ukraine is far behind than CHLPS countries in terms of absolute parameters, such as **economic development**, which **difficult to improve in the short or medium run**
- However, such parameters, as **share of state expenditures on healthcare** or **share of original drugs in state procurement**, are under government control and **can be improved towards European level**
- **In Ukraine some measures have been undertaken to improve the current situation:**
  - **Healthcare reform in Ukraine** is aimed to increase **state spending.** Since 2018 **medical guarantee program** has been implemented: **5% of GDP** should be used to finance the program, however in reality **5% target is not being met**
  - **By 2023 all government medical purchases** should be **included** in the program
  - There are **many targeted MoH programs**, such as oncology or cardiovascular, but they all **do not have quantifiable KPIs**

(1) Converted at fixed exchange on 31 December 2018
Source: IQVIA, OECD, Proxima Research

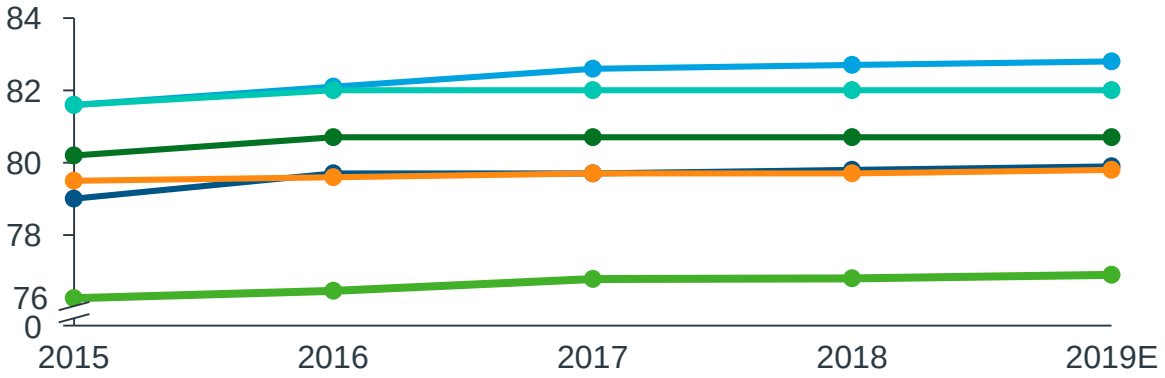
Ukraine has the lowest life expectancy at birth and one of the highest death rates compared to CHLPS countries

Outcomes / KPIs of healthcare system

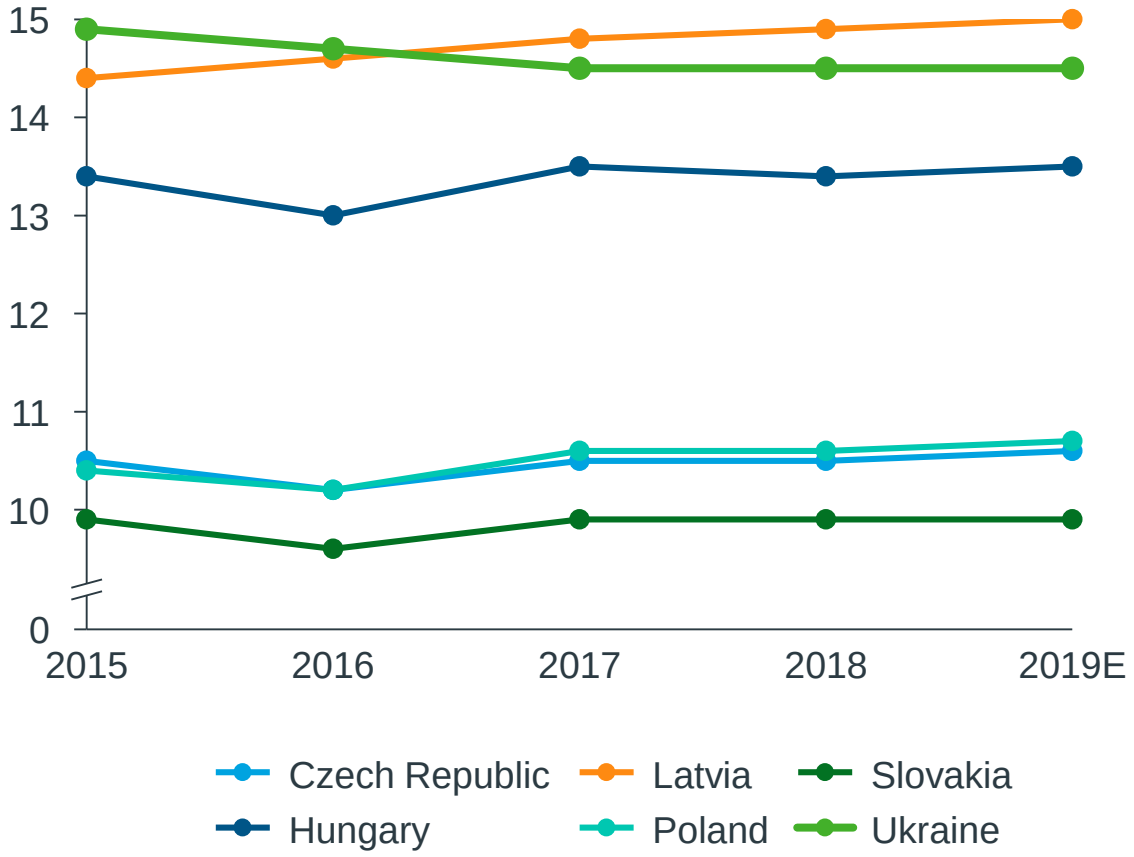
Life expectancy at birth, male [years]



Life expectancy at birth, female [years]



Mortality rate [% per 1K people]

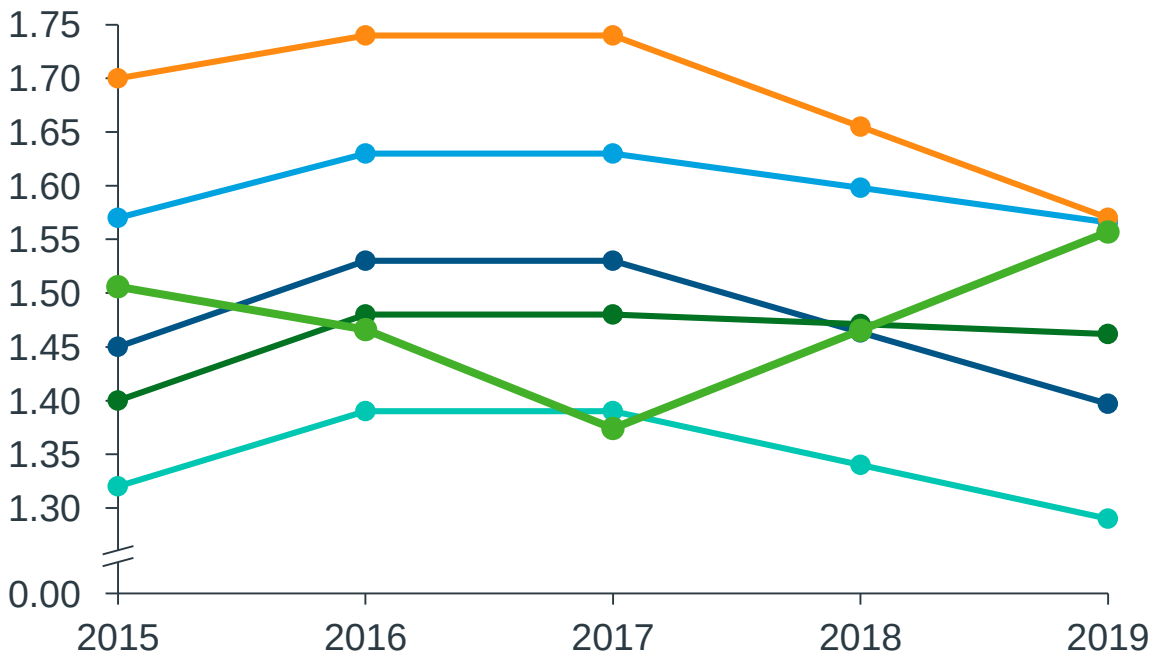


Source: World Bank, IQVIA

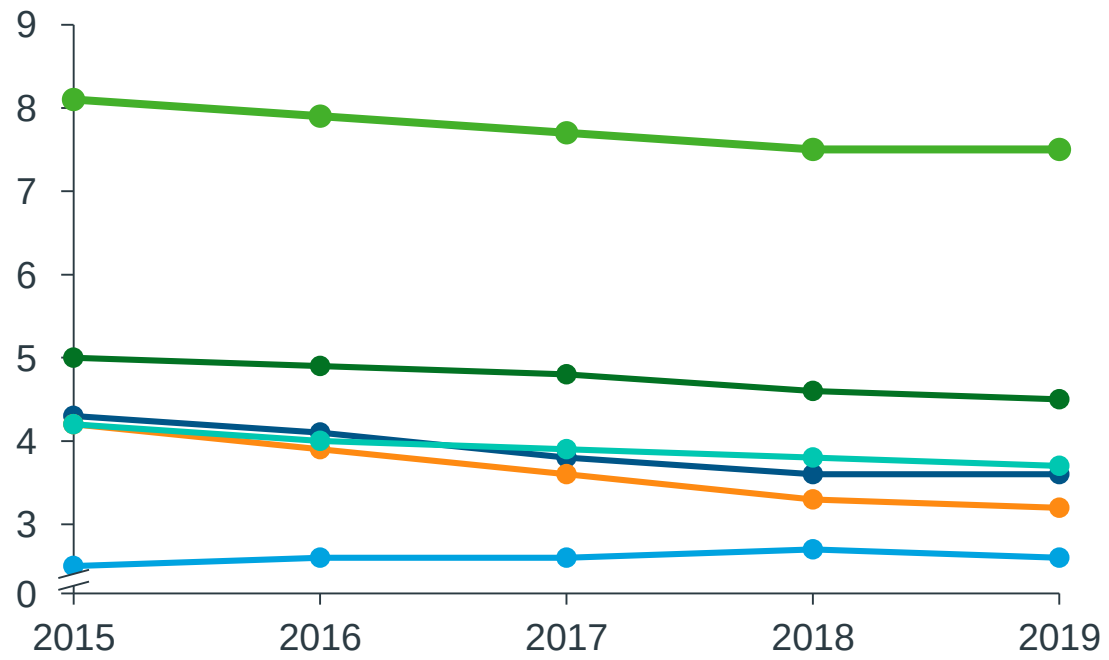
Ukraine has the highest infant mortality rate compared to CHLPS countries, while birth rate is slightly higher than in Hungary, Slovakia and Poland

Outcomes / KPIs of healthcare system

Birth rate [# children per woman]



Infant mortality [cases per 1K live births]



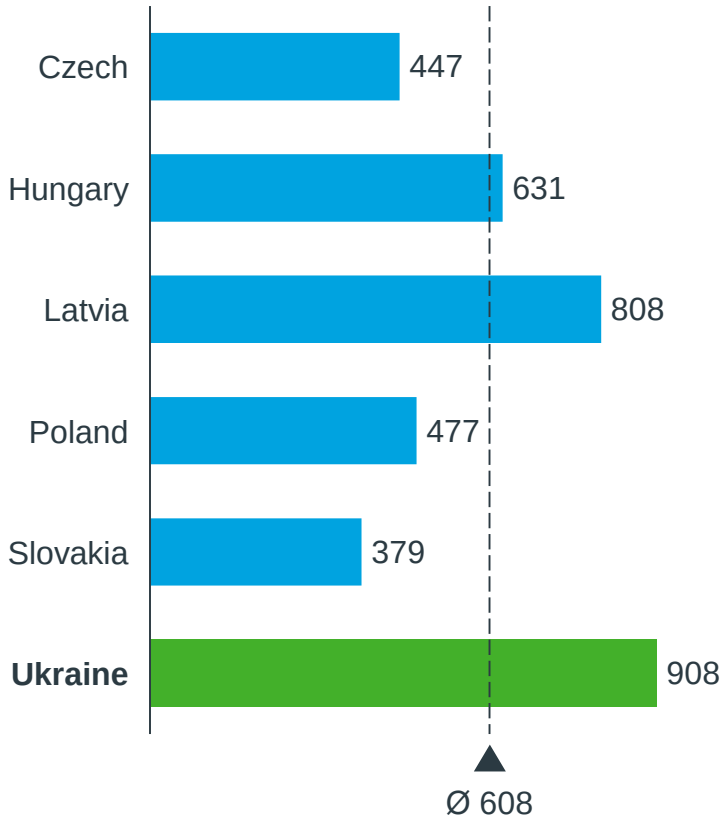
Czech Republic
Latvia
Slovakia
Hungary
Poland
Ukraine

Source: World Bank, IQVIA

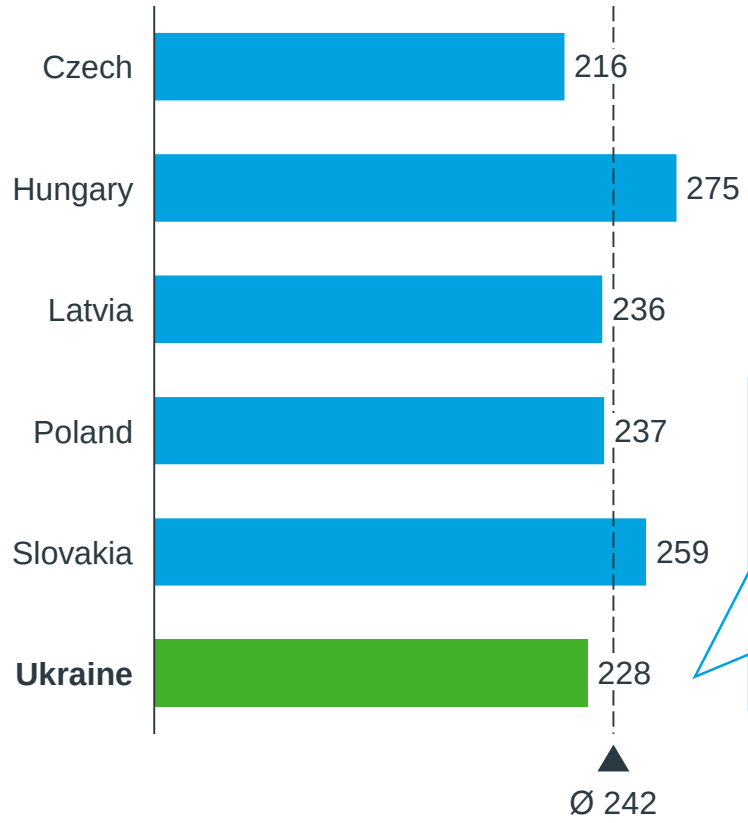
Ukraine has the highest rate of mortality from cardiovascular diseases compared to CHLPS countries, but lower mortality rate from oncology

Outcomes / KPIs of healthcare system

Mortality from cardiovascular diseases [per 100K people]



Mortality from oncological diseases [per 100K people]



Low level of mortality from oncology may be caused by lower life expectancy (as oncological diseases mostly appear in older ages), lower diagnostic level and incorrect codification of death cause

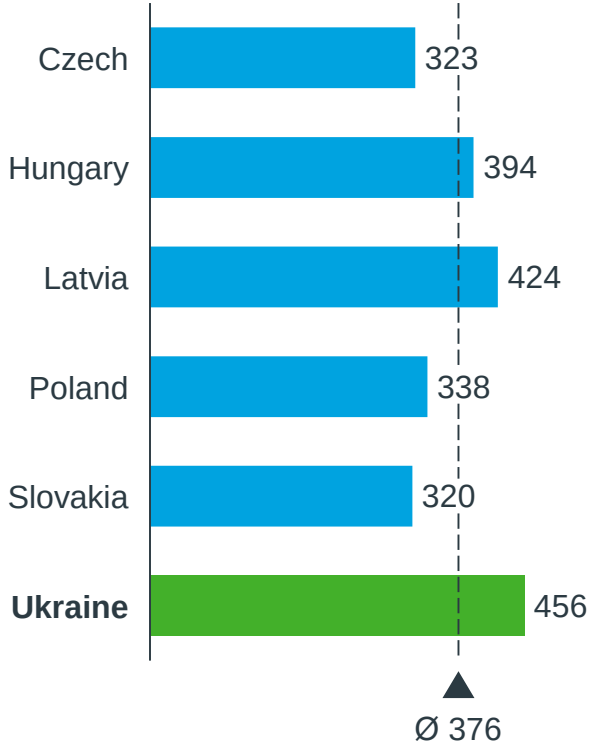
Source: WHO, OECD

Ukraine has highest DALYs and amenable mortality rate compared to East European reference countries

Outcomes / KPIs of healthcare system

DALYs

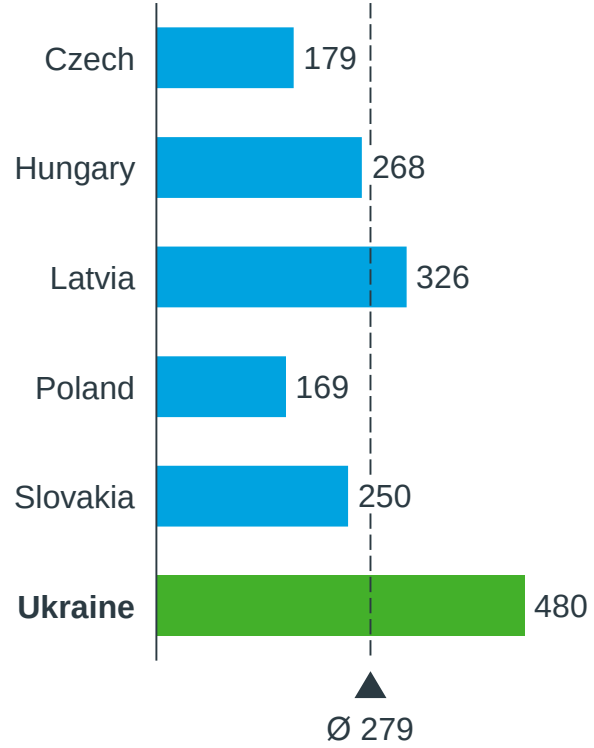
[years per 1 mn people]



*Note: disability-adjusted life year (**DALY**) is a measure of overall disease burden, expressed as the number of years lost due to ill-health, disability or early death*

Amenable mortality rate

[age standardized rate per 100 K people]



*Note: **Amenable mortality** is defined as deaths from a collection of diseases, e.g. diabetes and appendicitis, that are potentially preventable given effective and timely health care*

Source: World Bank, Eurostat

Healthcare systems overview summary

Starting from lower economic ability to fund healthcare (3-4 times lower GDP per capita), the gap (vs Eastern Europe) in funding healthcare by state multiplies

- Ukraine has lower economic capacity (GDP per capita in Ukraine is 3-4 times lower than in Eastern Europe)
- On top of lower economic capacity, the focus is also diluted out of the healthcare: Ukraine healthcare expenditure per capita is five times lower than in Latvia and Poland, 7-9 times lower than in Czech republic, Slovakia and Hungary
- Share of state-funded medicines is half of the level of Eastern European countries (3.6% of GDP**,** vs 4.5% average in Eastern Europe)
- Reason for lowering focus on healthcare of the country and the state is non-targeted sourced of financing of healthcare (tax pool in Ukraine vs dedicated insurance-base in benchmarking Eastern European countries)

Pharmaceutical spending is screwed towards basic generics or other products with no evidence that does not lead to better health outcomes

- Ukraine **pharma market consumption is three times lower** compared to CHLPS countries
- **Only 12% of pharmaceuticals are covered by Government** in Ukraine vs ~74% in benchmarking Eastern European countries
- Ukraine has the **lowest government spending per capita** and **the highest** share of generics in government spending structure
- The measurements of healthcare system quality (life expectancy, mortality, birth mortality, etc) are the lowest for Ukraine
- Treatment of **oncological, cardiovascular, infection and nervous diseases have the highest share** in state procurement budget in Ukraine and CHLPS countries

Ukraine has a vague targets for healthcare which prevents focused spending

- All CHLPS countries have target KPIs to track healthcare system efficiency. However, only action plan by MoH, including three healthcare KPIs: lower disease rate, faster recovery and longer life time, has been established in 2019
- Ukraine is far worse than CHLPS countries in **terms of healthcare outcomes**, which is an indicator of insufficiency of healthcare system
- Ukraine has the **lowest vaccination level** compared to CHLPS countries, which is the priority target of Ministry of Health
- Compared to CHLPS counties Ukraine has **the lowest life expectancy at birth and the highest death rates**, including infant mortality, mortality from cardiovascular diseases, amenable mortality and DALYs

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Instruments for access to innovative therapies

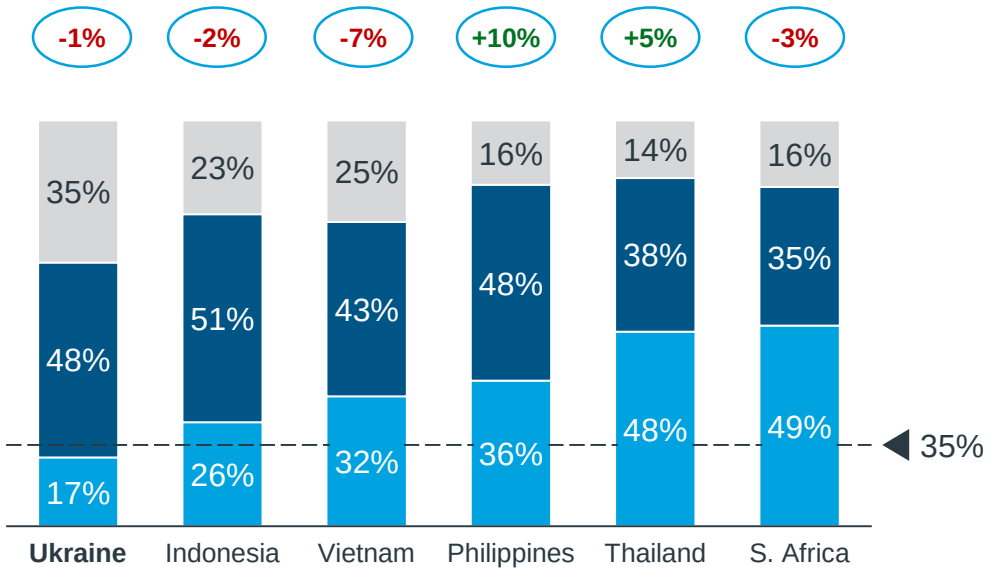
Original drugs share in state procurement is increasing along with economic development. Ukraine is comparable with the lagging countries

Benchmark analysis

Developing countries mainly focusing in generics

- Originals share < 50%
- Generics share ~40%

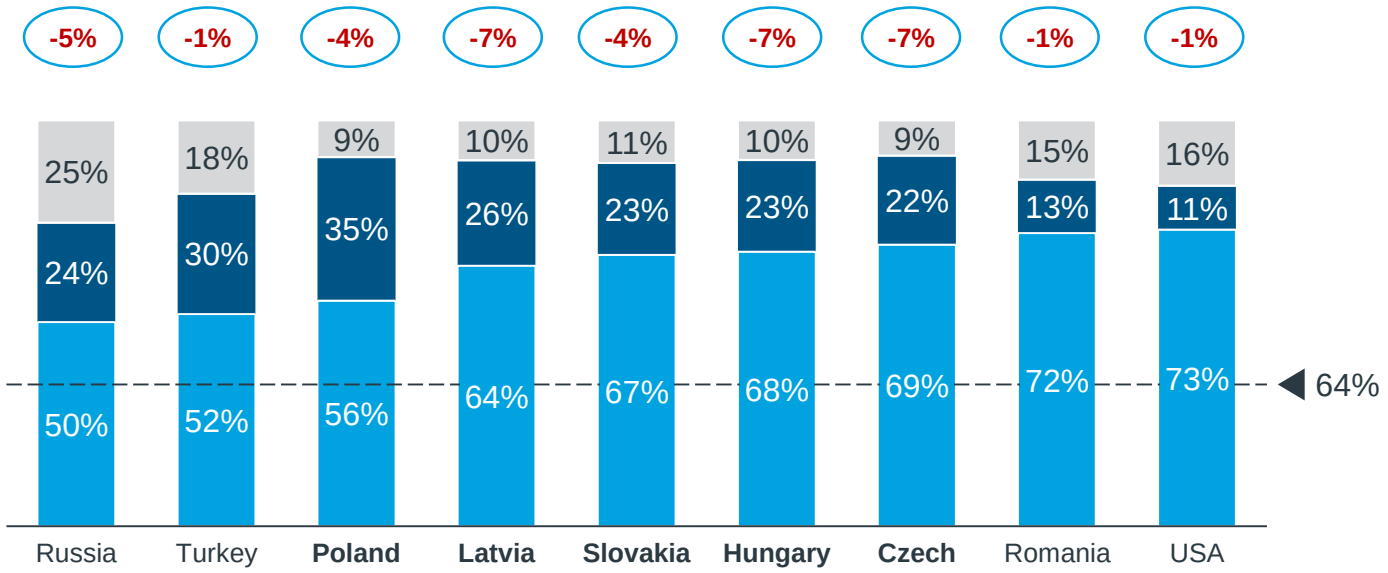
Countries benchmark (2019YTD value split in state reimbursement)



Emerging and Developed countries with more focus on innovative medicines

- Originals share > 50%
- Generics share ~20-25%

Countries benchmark (2019YTD value split in state reimbursement)



XX% Original drugs share in state reimbursement change 2019 YTD vs 2011

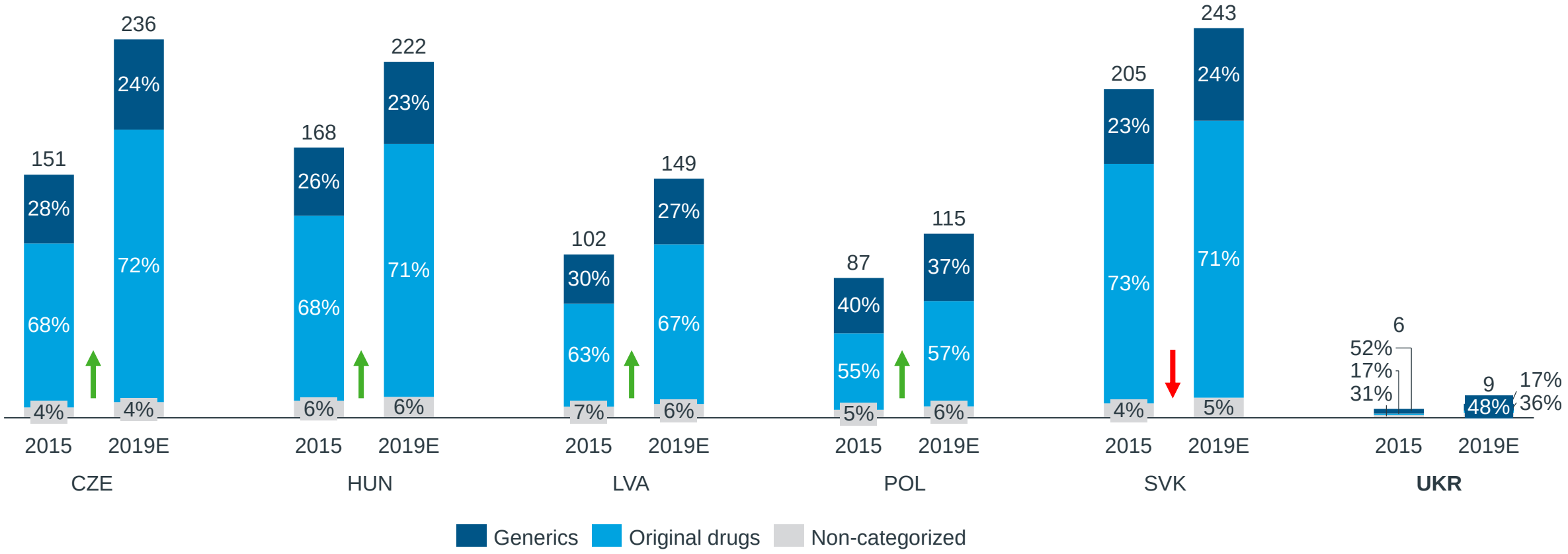
Other Generic Original

Source: IQVIA
Study on spending on healthcare and access to treatment | December 23, 2019

In Ukraine original drugs share in state procurement is the lowest and declining, while in most of benchmarking countries original's share has grown

State reimbursement of Original drugs

Share of original treatments in state reimbursement per capita [EUR[1], 2019]



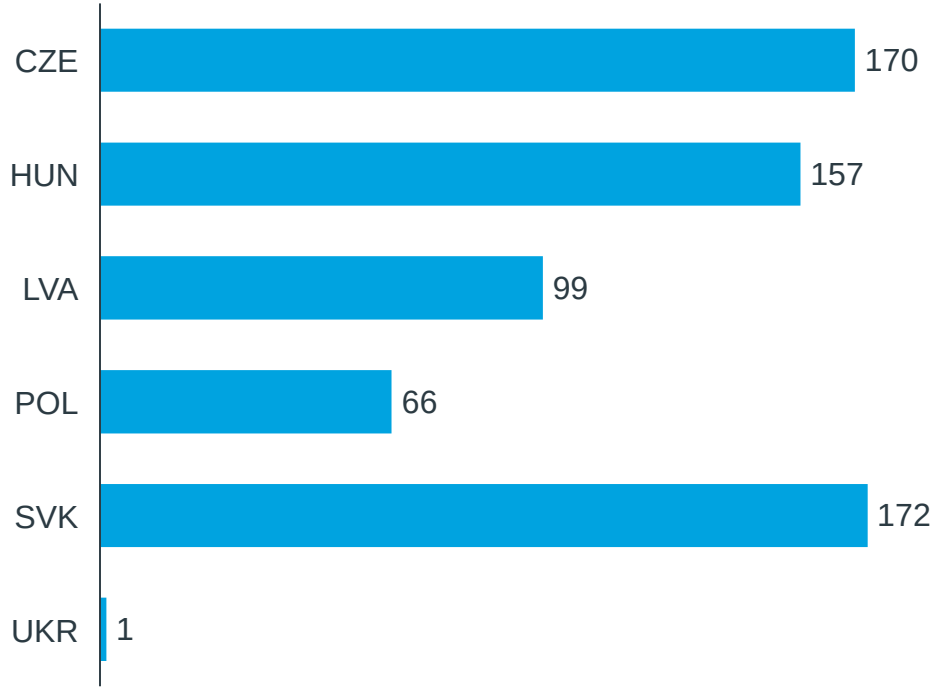
(1) Converted at fixed exchange on 31 December 2018
Source: IQVIA, Proxima Research

- Growth / No change / Decline of Original drugs share in government procurement structure

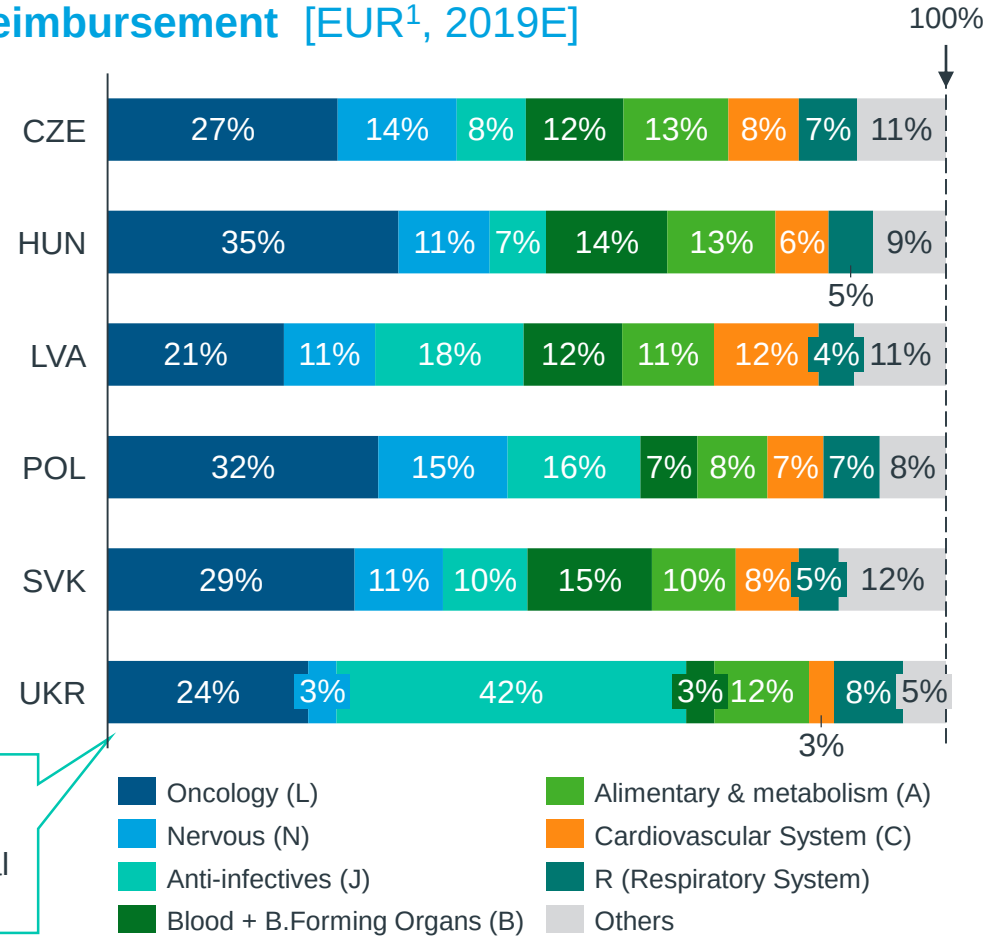
Ukraine state reimbursement of original drugs per capita is ~130 times lower than in CHLPS countries

State reimbursement of Original drugs by therapy (ATC1)

Original drugs state reimbursement per capita [EUR[1], 2019E]



Share of therapy value in original drugs state reimbursement [EUR[1], 2019E]



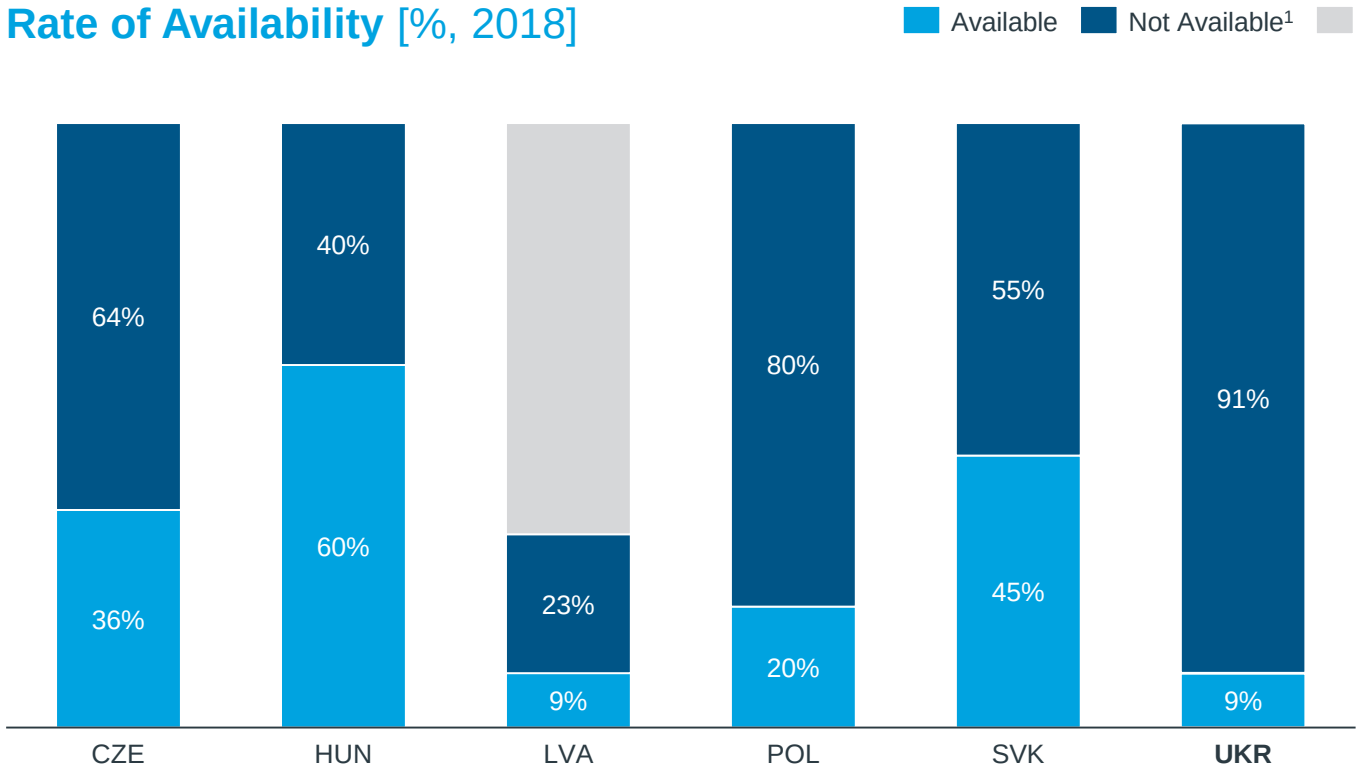
Vaccines are included in **Anti-infectives (J)** ATC category (in Ukraine 20% share of original drugs state reimbursement)

(1) Converted at fixed exchange on 31 December 2018
Source: IQVIA, Proxima Research

Availability to innovative medicines in Ukraine is at the lowest 9% rate of availability in Europe

W.A.I.T. indicator

Rate of Availability [%, 2018]



*Note: **Rate of availability** is a **number of new medicines** (i.e. medicines including a substance that has not been previously available in Europe) **available (having market authorization) to patients in European countries as of 2018***

Comments

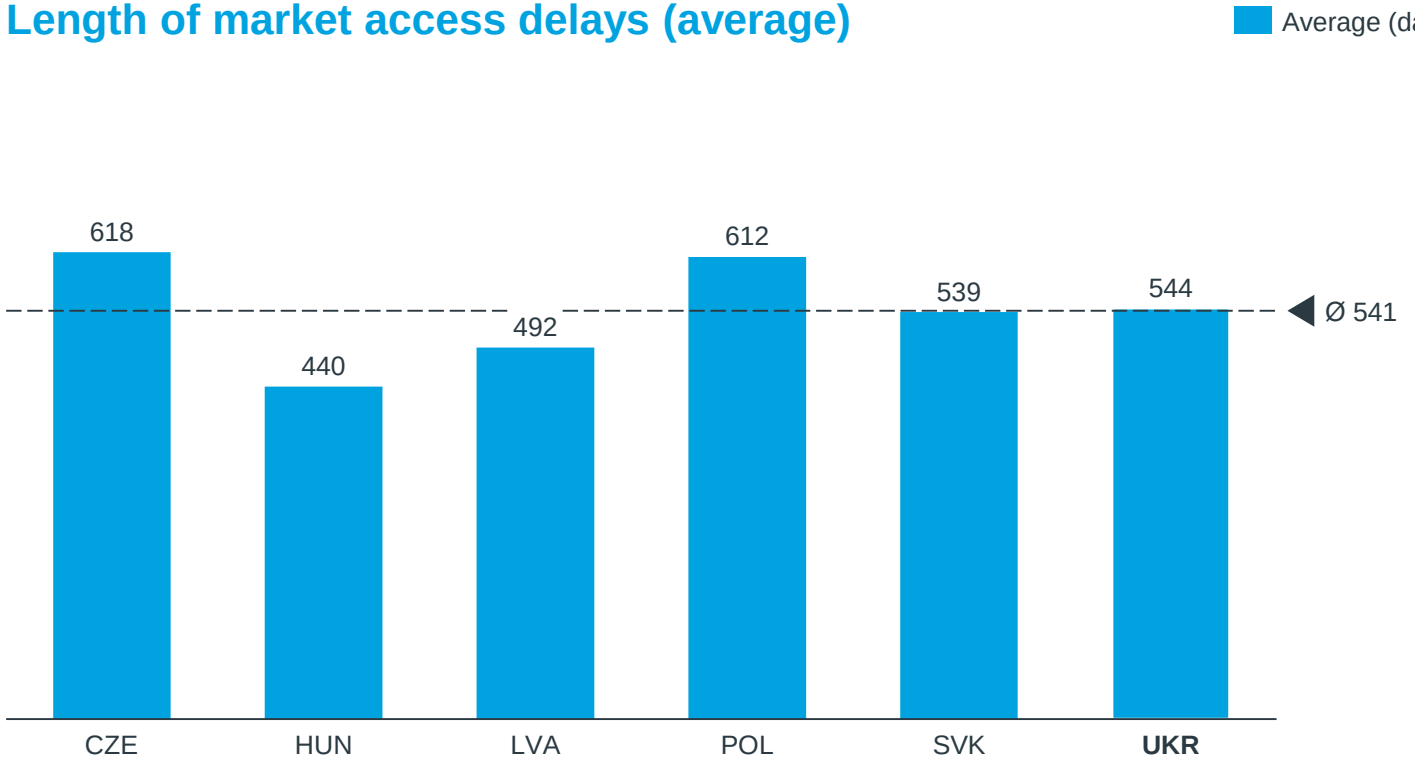
- **Patient access to new medicines is highly varied across CHPLS countries** with the greatest rate of availability in Hungary and lowest in Latvia and Ukraine
- The rate of availability of new medicines heavily depends on **healthcare system performance**: price regulation effectiveness, transparency of healthcare system, barriers to entry and healthcare funding issues

(1) Not available new medicines include drugs w/o market authorization
Source: IQVIA, EFPIA member associations, who either refer to information available from official sources or gather this information directly from member companies

Among CHLPS countries the average delay between market authorization and patient access varies from ~440 days to ~620 days. Ukraine is within the range

W.A.I.T. indicator

Length of market access delays (average)



*Note: **the average time between marketing authorization and patient access** - the number of days elapsing from the date of EU marketing authorization (or effective marketing authorization in non-EEA countries) to the day of completion of post-marketing authorization administrative processes*

Comments

- The average delay between market authorization and patient access **can vary significantly** among countries
- Countries with more products available tend to have faster access to medicines
- Among CHLPS countries patients in Hungary and Latvia accessing new products within **400-500 days** after market authorization, while in Ukraine, Czech Republic, Poland and Slovakia the average time **exceeds 500 days**
- Even **within a country there is a large variation** in the speed of patient access to different products

Source: IQVIA, EFPIA member associations, who either refer to information available from official sources or gather this information directly from member companies

Different instruments and solutions are used to improve access to modern health treatments

Instruments for access to innovative therapies

Funding Solutions

1. Cut of reimbursement of the cheapest generics
2. Generic pricing rule
3. Targeted healthcare budget increase or share (of GDP, state budget etc)
4. Tax on health-damaging products (tobacco / soft drinks)
5. Industry payback mechanisms (ex: clawback tax)
6. Patient co-payment

Process improvement

1. Separate fund for innovative treatments
2. Transparent and efficient process to evaluate innovativeness
3. Simplified registration / EMA & FDA approvals
4. Accelerated / parallel review
5. Stakeholder engagement
6. Health technology assessment (HTA)

Risk-sharing

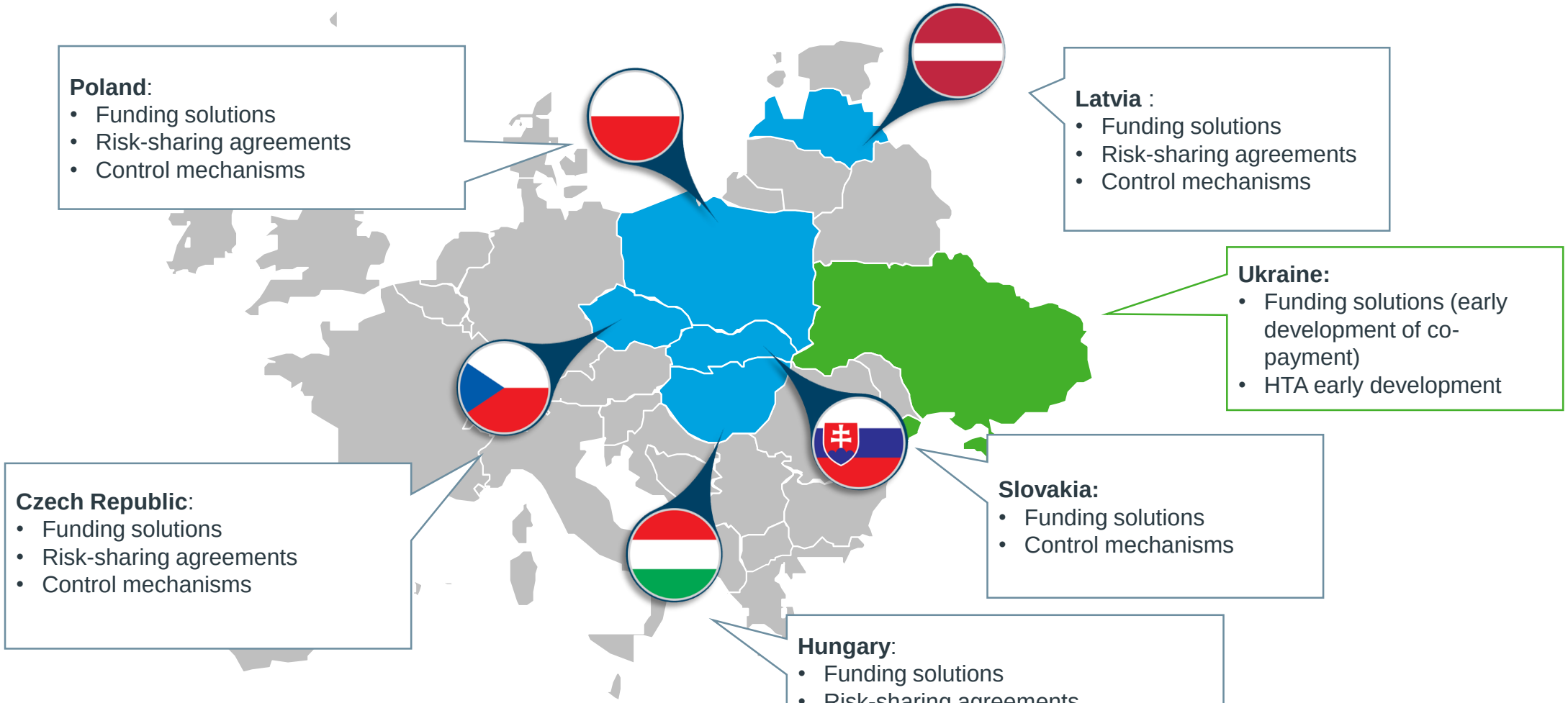
1. Implementation of Managed Entry Agreements: Financial based
2. Implementation of Managed Entry Agreements: Performance based
3. Implementation of Managed Entry Agreements: Coverage with Evidence Development (CED)

Control mechanism

1. Drug re-assessment driven by RWE & value based pricing
2. Phased introduction based on budget impact
3. Patient driven fixed fee per defined diagnosis category
4. Prescribing controls
5. Price / Margin controls

Source: IQVIA

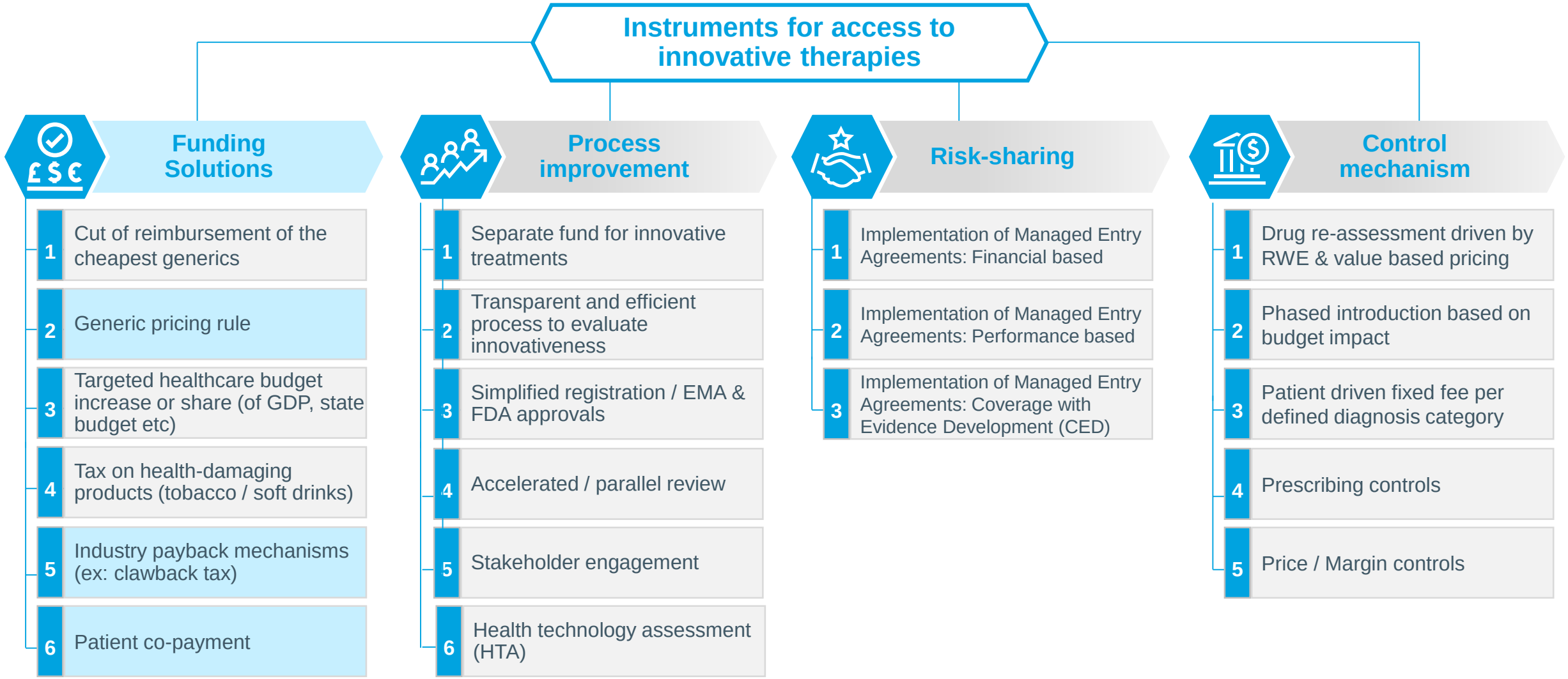
East Europe countries are mainly using risk sharing mechanisms and cost-containment measures, including funding solutions and control mechanisms



Source: IQVIA

Study on spending on healthcare and access to treatment | December 23, 2019

Different instruments and solutions are used to improve access to modern health treatments



Source: IQVIA

Industry payback mechanisms, patient co-payments and generic pricing rule are widely used to fund access to innovative treatments

Funding solutions instruments

Funding solution instrument	Instrument characteristics	Availability in Eastern Europe				
		CZE	HUN	LVA	POL	SVK
Generic pricing rule	• Generics price regulation according to which the price of new and subsequent generics are subject to discounts or caps relative to reference group or branded original drugs	✓	✓	✗	✓	✓
Patient co-payments	• Patients contribute towards the cost of reimbursed out-patient medicines and towards the cost of their general care	✓	✓	✓	✓	✓
Industry payback mechanism: e.g. Clawback tax	• Sales of reimbursed medicines are subject to a clawback-type tax, charged on the manufacturer's selling price of reimbursed drugs • An additional clawback-type tax can be payed on certain medicines	✗	✓	✓	✓	✗

Source: IQVIA

Funding solution instruments are aiming to secure and increase state budget and provide wider access to original more effective drugs

Funding solutions instruments

Funding solution instrument	Scope	Applicability	Impact
Generic pricing rule	• Generics entered market after originator	• Strong competitive market landscape to ensure drug supply security	• Define maximum price of first and subsequent generics/biosimilars by predefined levels e.g. 30% for the 1st generic to enter market.
Patient co-payments	• Outpatients Rx drugs	• Structure of the co-payment levels have to balance financial efficiency with affordability for patients	• Balance budget spending and out-of-pocket spending • Effect depends on difference of price and reimbursement level • Decrease access to health care proportional to the size of the co-payment (1)
Industry payback mechanism: Clawback tax	• Rx drugs	• Applicable in case of highly aggressive price-control measure to secure confidentiality of real agreed/negotiated prices to protect manufacturers' margins on other markets	• Provides funds, risk-mitigation measure in case of overspending • In case of reference pricing secures confidentiality of the real prices for manufacturers

Source: KSE

In CHLPS countries except for Latvia generics are subject to pricing regulations

Funding solutions instruments: Case study

Poland

- **Generics are subject** to the following **pricing regulations**:
  - The manufacturer's selling price (MSP) of the **first generic** is **not permitted to exceed 75%** of the MSP[1] of the **branded original**
  - The MSPs[1] of **subsequent generics** are **not permitted to exceed** the MSP[1] of the **cheapest** therapeutically-**equivalent drug**

Czech Republic

- **Generic prices** in the Czech Republic are among the **lowest in Europe**
- Reimbursement price ceilings for generics and biosimilars were lowered by amendments to the Medicines Act, which were approved in November 2016 and became effective on 1 April 2017
- **Price differential** between the **first generic** and the **original brand must be 40%,** while the **first biosimilar** must be launched at a **price at least 30% below** that of the **reference biologic**

Slovakia

- **First generic** entering the market must have a **45% initial price reduction** compared to the **original**
- **2nd generic** must have an **additional 10% price reduction** compared to the first, and the **3rd generic - additional 5% price reduction** compared to **second**

Generic pricing rule

Latvia

- In Latvia there is **no generics pricing rule**

Hungary

- The price of a generic drug at launch is capped
- If **no reference price reimbursement group** has (yet) been established for a given drug, the **price of a generic** at launch is **capped relative to the price** of the corresponding **off-patent original**. The level of price cap applied depends on whether the drug is the first marketed generic for an active ingredient, or a later version:
  - The MSP[1] of the **first marketed generic** version is **not permitted to exceed 60%** of the (pre-patent expiry) MSP[1] of the **off-patent branded original**
  - The **prices of subsequent generics** are **similarly capped** relative to the price of the preceding generic version until the NEAK forms a new active ingredient-based reference price group
- Once a reference price group has been established, the maximum MSP[1] of any drug, including generics (and the corresponding off-patent original, where applicable), is not permitted to exceed a certain level

(1) MSP – Manufacturer's selling price

Patient co-payment is present in all CHLPS countries, though under different conditions

Funding solutions instruments: Case study

Slovakia

- In June 2003 **patient co-payment of 50SKK/day (1.2 EUR/day) for hospital stay** has been introduced. Maximum days charged are 21.50 % discount applies to 1st and last day of stay
- **Concerning generics**, the **cheapest offer principle is applied:** cheapest generic from a class gets full or almost full reimbursement, other generics of the same ATC group get same reimbursement plus fixed co-payments. Fixed co-payment is the difference between the price/reimbursement of the cheapest offer and the actual offer of other generic concerned
- This practically creates the situation, where **the cheapest generics from a class will have null or very low co-payments**, while others (those who set their prices too high during the time of applications / offer submitting) will suffer from higher co-payments, which disqualifies them from competing in the market place

Poland

- **Patients are required to contribute** towards the cost of many of their **reimbursable medicines**
- **Co-payment** rate varies **from flat free to 50%**
- There are **no patient co-payments** for healthcare services

Patient co-payment

Latvia

- Co-payments include **publicly-provided services**, and payments for privately-provided care (or private insurance)
- The **patient pays the difference between the drug cost** in the pharmacy (Basic Price) **and the compensation sum**
- Concerning the **A list** the **patient pays the difference between prescribed medicine and Reference Price** within pharmaco-therapeutical group. Even if the compensation is 100% the patient pays 0.71 EUR for the prescription. The costs of these drugs are reimbursed (by the sickness funds) if they have been prescribed by a doctor who has an Agreement with a sickness fund

Czech Republic

- Pharmaceutical **co-payments were included in the annual user fee ceiling** unless the level of reimbursement was **lower than 30%** of the maximum price. Under the reference price system, patients must pay the difference between the reimbursement price and the cost of drugs priced at levels in excess of the reimbursement threshold
- In theory, at least **one medicine within each cluster must be fully reimbursed**, requiring no additional co-payment on the part of the patient. In practice, the system is complex, and the large number of products within each cluster (indicated for various diagnoses) sometimes means that a **fully reimbursable product is not available for all indications**

Hungary

- Patients **contribute** towards **the cost of reimbursed out-patient medicines** and towards **the cost of their general care**
- **Normative** Reimbursement: Patients pay **20%, 45% or 75%** of the drug's public price
- **Indication-bound** Reimbursement: Patients pay **0%** (subject to a HUF300 'pack fee'), **10%, 30% or 50%** of the drug's public price
- For **biological** drugs included in the reference price reimbursement system, **separate fees** may apply
- In the **active ingredient-based** or **therapeutic reference pricing systems**, the applicable **level of co-payment** is calculated based on the **price of the reference product**

In Ukraine there are no exemptions for poor people and outpatient prescribed medicines are fully payed by patients

Funding solutions instruments: Case study

Patient co-payment by country

Country	Outpatient visits	Outpatient prescribed medicines	Inpatient care	Exemptions	Cap
Czech Republic	FC	FC	FC	Yes, including poor	No
Hungary	No charges	FC + PC + RP	FC+PC	Yes, including poor	No
Latvia	FC	FC + PC + RP	FC	Yes, including poor	Outpatient visits + inpatient
Poland	No charges	FC + PC + RP	No charges	Yes, but not for poor	No
Slovakia	No charges	FC + RP	No charges	No	Rx
Ukraine	No charges	No formal charges but all pay	No charges	No	No

Note: FC - fixed co-payment, PC - percentage co-payment, RP: reference pricing, Rx - prescribed outpatient medicine

Comments

- Co-payment design is a key factor influencing financial protection
- **Exemptions for poor people** are the single most effective co-payment design feature in terms of access and financial protection
- **Caps** also protect people if they are applied to all co-payments over time rather than narrowly focused on specific items or types of service – and if they are low enough
- In contrast to low fixed copayments, **percentage co-payments** shift financial risk from purchasing agency to households and expose people to health system inefficiencies
- Co-payment policy should pay attention to all three design features (exemptions, caps and type of co-payment) and be as simple as possible to minimize confusion and enhance transparency

Source: OECD

Industry payback policies are widely used and powerful tools for cost-containment and generation of additional funding

Industry payback

- Clawback tax
- Fees for sales representatives
- Budget excess repayments

Hungary

- **A 20% clawback on all reimbursed drug sales:**
  Sales of reimbursed medicines are subject to a clawback-type tax, charged at 20% on the price of reimbursed drugs. However, manufacturers can reduce their liabilities under the clawback scheme. Furthermore, manufacturers of drugs granted beneficiary reimbursement status are exempt from payment
- **Additional 10% clawback on branded prescription drugs:**
  An additional clawback-type tax is payable on certain medicines: branded prescription drugs meeting all of the following criteria: 1) have been reimbursed for at least six years 2) have no reimbursed generic equivalents in Hungary 3) are priced at HUF1,000 or more (at MSP[1])
- **Excess budget repayments:**
  Manufacturers must cover any excess out-patient pharmaceutical spending (i.e. above the annual budget set by the government) incurred by the National Health Insurance Fund (NEAK) in a given year. Repayments are allocated according to each manufacturer's share of reimbursed drug spending
- **Fees for sales representatives:**
  Pharmaceutical manufacturers are required to pay a HUF10 million fee to the NEAK for each pharmaceutical sales representative employed

Latvia

- **Excess budget repayments:**
  Latvia sets an annual pharmaceutical budget in order to control spending and to allocate a fixed share of health expenditure to pharmaceuticals
- An annual pharmaceutical expenditure cap is set: if the National Health Service detects an annual increase of more than 10% in the sales volumes of particular reimbursed medicines or medical devices that have been listed for at least three years, a **rebate is mandated** (except where a sales volume contract has been previously signed or prescription conditions have changed)
- Thus, **industry pays only part of the consumption excess**

Czech Republic

- There are **no mandatory industry payback** arrangements. However, introduced prescribing limitations and back-bonus limitations were introduced with the objective to achieve cost containment
- **Budget caps** have been recently required by payers for most molecules and also for molecules already in the market

Poland

- **17% ceiling:**
  - Applied if annual prescription drug reimbursement budget exceeds plans, ultimately capped at 17% of the total annual healthcare budget
- **50% clawback tax:**
  - 50% of any National Health Fund (NFZ) expenditure in excess of the ceiling. The payback sum is obtained by multiplying the number of packs necessary to meet patient needs (as estimated based on average monthly demand when there is full supply) by the MSP[1], proportional to the length of time and quantity for which the supply commitment was not fulfilled

(1) MSP – Manufacture selling price
Source: IQVIA

Different instruments and solutions are used to improve access to modern health treatments

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1. Drug re-assessment driven by RWE & value based pricing
2. Phased introduction based on budget impact
3. Patient driven fixed fee per defined diagnosis category
4. Prescribing controls
5. Price / Margin controls

Source: IQVIA

Health Technology Assessment of new medicines is a required stage prior reimbursement in all CHLPS countries

Process improvement

Process Improvement	Instrument characteristics	Availability in CHLPS countries				
		CZE	HUN	LVA	POL	SVK
Health Technology Assessment (HTA)	Systematic evaluation of the properties and effects of new medicines, including evidence regarding clinical effectiveness, safety, cost-effectiveness and others aimed to address the direct and intended effects as well as indirect and unintended consequences	✓	✓	✓	✓	✓

Source: IQVIA

HTA implementation helps to ensure value for money in original and innovative drugs spending and minimize use of ineffective technologies

Process improvement

Process improvement	Scope	Applicability	Impact
Health technology assessment (HTA)	• Original or innovative drugs	• Implemented in a setting where there are other pricing policies and where there is sufficient technical capacity and legal framework	• No substantial evidence of HTA on prices • Minimise the use of ineffective or harmful technologies • Contribute to value for money investments in health technology in finite budgets • Provide clear information to stakeholders

Source: KSE

Health technology assessment is implemented in all CHLPS countries, however, only in Hungary and Poland a separate agency is established

Czech Republic

- The establishment of a formal body responsible for performing HTAs on costly pharmaceuticals is unlikely in the near future. The State Institute for Drug Control (SÚKL) will continue to employ cost-effectiveness and budget impact calculations during the Pricing and Reimbursement assessment process
- The MoH and the SÚKL have worked on the establishment of comprehensive manuals for the conduct of HTAs, based on methodologies employed by authorities in other western European countries
- Existing rules require manufactures to provide a pharmacoeconomic analysis and clinical effectiveness and budget impact analysis along with other clinical information in application dossiers, and this information appears sufficient for reimbursement decision making for the moment. There is no separation of the appraisal and decision-making stages within SÚKL

Latvia

- In Latvia the NHS is responsible for assessing and approving medical technologies
- Cost–effectiveness, safety aspects (risks and potential side-effects), potential impact and efficiency, influence of the technology on the patient's health and quality of life are assessed by the Unit of Health Economics, Technology and Clinical Guidelines within the NHS
- Since 2002, every new medicine is evaluated according to the Common Baltic Guidelines on Economic Evaluation of Pharmaceuticals prior to being entered into the positive list of NHS reimbursed medicines

Health Technology Assessment

Poland

- **The Agency for Health Technology Assessment and the Tariff System (AOTMiT)** is responsible for carrying out health economic evaluations of **new** drugs that have no reimbursed therapeutic alternatives
- Manufacturers of new drugs without any reimbursed therapeutic alternatives are required to provide the following information:
  - Budget impact analysis (required for all new drugs)
  - Evidence of the drug's clinical effectiveness
  - An analysis of the economic impact of the drug from the payers' perspective
  - A rationalization analysis, providing reimbursement solutions to free up public funds, if the BIA shows an increase in reimbursement costs for the NFZ
- The clinical and economic analyses are evaluated by the AOTMiT before a final decision is taken on whether or not the drug should be reimbursed

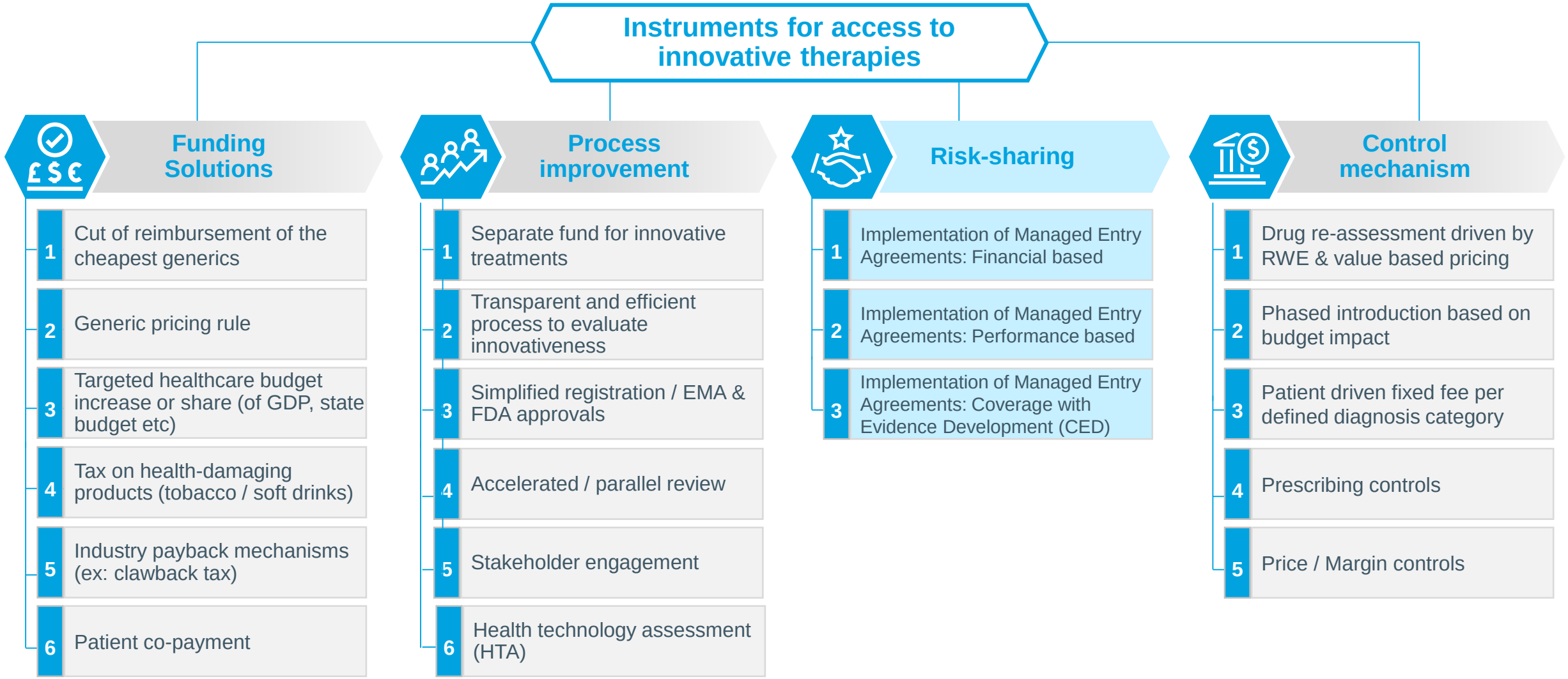
Hungary

- Pharmacoeconomic data of new drugs submitted by manufacturers are passed by the National Health Insurance Fund (NEAK) to the Department of Health Technology Assessment (HTA), part of the National Institute of Pharmacy and Nutrition (OGYÉI)
- The HTA Department **evaluates the drug's efficacy/safety, cost-effectiveness and budget impact**, among other factors. The outcome of this assessment is then taken into consideration by the NEAK's Technology Appraisal Committee (TÉB) when making a reimbursement recommendation
- HTA department also has a number of other responsibilities: defining the scope of the HTA process, the development of pharmacoeconomic guidelines, the development of policy designed to encourage the rational use of healthcare resources and is required to work in co-operation with other HTA bodies in Europe

Slovakia

- There is no special state institution in charge of HTA in Slovakia
- The HTA is still in a relatively early stage of implementation
- Participation within the European Network for Health Technology Assessment has significantly improved the quality of the process of HTA in Slovakia

Different instruments and solutions are used to improve access to modern health treatments



Source: IQVIA

Study on spending on healthcare and access to treatment | December 23, 2019

All CHLPS countries arrange innovative market access agreements with manufactures of new medicines

Risk-sharing agreement

Risk-sharing agreement	Agreement description	Availability in CHLPS countries				
		CZE	HUN	LVA	POL	SVK
Financial Based Agreements	Price level or nature of **reimbursement is based on financial considerations** and is not related to clinical performance	✓	✓	✓	✓	✗
Performance Based Agreements	Price level or nature of **reimbursement is tied to future metrics** ultimately related to patient performance, outcomes, efficacy, tolerability, dosing, benefit, outcomes, quality of life, or clinical usage	✓	✓	✓	✓	✗
Coverage with Evidence Development (CED)	Reimbursement decision in which approval is conditional on the **collection of additional population level studies after launch** (with provisional reimbursement) to support coverage or pricing	✓	✗	✗	✗	✗

Source: IQVIA

Study on spending on healthcare and access to treatment | December 23, 2019

Risk sharing agreements are aimed to secure state budget in case of original and innovative drugs usage with uncertain consumption and clinical risks

Risk-sharing agreement

Risk-sharing agreement	Scope	Applicability	Impact
Financial Based Agreements	• High-cost drug with high budget impact and low clinical uncertainty	• Dealing with new and often expensive technologies, which are characterised by significant levels of uncertainty • Simple to apply tool, requires negotiation capacity and legal framework	• Limit budget expenditures for drugs with uncertain/volatile consumption
Performance Based Agreements	• High-cost drug with uncertainty of effect / population or high budget impact	• Dealing with new and often expensive technologies, which are characterised by significant levels of uncertainty • Implemented in a setting where there are other pricing policies and where there is sufficient technical capacity and developed infrastructure	• Facilitate earliest possible access for patients • Reduces budget impact of risk clinical uncertainty
Coverage with Evidence Development (CED)	• High-cost drug with uncertainty of effect / population or high budget impact	• Applicable in cases with low evidence but high-therapeutic need(lifesaving conditions) • Requires pre-launch activities(collecting data on existent clinical trials, pre-approved drugs, etc.)	• Facilitate earliest possible access for patients

Source:KSE

CHLPS countries implement different types of risk-sharing agreements to facilitate access to new medicines

Slovakia

Types of risk-sharing agreements

- No agreements yet implemented

Rationale for future implementing

- The possibility of **introducing MEAs is currently being discussed** as an instrument, together with other changes in the reimbursement legislation, to improve access to new medicines

Poland

Types of risk-sharing agreements

- **Financial-based**
  1. Discounts
  2. Price-volume agreements
  3. Payback
  4. Bundle agreements
- **Health outcome-based**

Rationale for implementing

- **Better-controlled introduction** of new and costly medicines into the reimbursement system
- Increasing and improving **patients' access** to medicines and other products
- Enhancing **financial sustainability** of the reimbursement system
- Increasing **flexibility** of pricing and reimbursement policy

Latvia

Types of risk-sharing agreements

- **Financial-based**
  1. Discounts
  2. Price-volume agreements
  3. Payback
- **Health outcome-based**

Rationale for implementing

- Risk-sharing agreements are intended for the **reimbursement of expenditures for the acquisition** of medicinal products and medicinal devices for outpatient medical treatment
- **The aim** of agreements is **to mitigate** the impact of **high prices**, **uncertainties** around **cost effectiveness**, and **added value**

Czech Republic

Types of risk-sharing agreements

- **Financial-based**
  1. Discounts
  2. Price-volume agreements
  3. Payback
- **Health outcome-based**
- **Coverage with Evidence Development (CED)**

Rationale for implementing

- Increasing **access to new therapies**, while containing expenditure Law on statutory health insurance. It does not contain specific provisions on Managed Entry Agreements, but recognizes that sustainability of health care financing is an integral part of public interest in health care
- Same law introduces **provisions on coverage with evidence development for 'highly innovative medicinal products'** ('VILPs)

Risk-sharing agreements

Hungary

Types of risk-sharing agreements

- **Financial-based**
  1. Discounts
  2. Price-volume agreements
  3. Free doses
  4. Payback
  5. Bundle agreements
- **Health outcome-based**

Rationale for implementing

- Mitigation of **budget** impact
- Mitigation of **uncertainty** about clinical value
- **Confidential** way to manage price

Different instruments and solutions are used to improve access to modern health treatments

Instruments for access to innovative therapies

Funding Solutions

1. Cut of reimbursement of the cheapest generics
2. Generic pricing rule
3. Targeted healthcare budget increase or share (of GDP, state budget etc)
4. Tax on health-damaging products (tobacco / soft drinks)
5. Industry payback mechanisms (ex: clawback tax)
6. Patient co-payment

Process improvement

1. Separate fund for innovative treatments
2. Transparent and efficient process to evaluate innovativeness
3. Simplified registration / EMA & FDA approvals
4. Accelerated / parallel review
5. Stakeholder engagement
6. Health technology assessment (HTA)

Risk-sharing

1. Implementation of Managed Entry Agreements: Financial based
2. Implementation of Managed Entry Agreements: Performance based
3. Implementation of Managed Entry Agreements: Coverage with Evidence Development (CED)

Control mechanism

1. Drug re-assessment driven by RWE & value based pricing
2. Phased introduction based on budget impact
3. Patient driven fixed fee per defined diagnosis category
4. Prescribing controls
5. Price / Margin controls

Source: IQVIA

All CHLPS countries use control mechanism instruments, which include price control, budget caps and prescribing control measures

Control mechanism instruments

Control mechanism instruments	Instruments main characteristics	Availability in CHLPS countries				
		CZE	HUN	LVA	POL	SVK
Price / margin control	• Reference pricing is applied, i.e. the proposed manufacturer's selling price (MSP) must not exceed the lowest MSP of the same drug in the European Economic Area • Other price control may include a V4 Plus group price discount negotiations and drug reimbursement conditions initiative. An innovative cancer drug and an orphan drug will reportedly be the first drugs to have their prices negotiated by the group	✓	✓	✓	✓	✓
Prescription control	• Government has a number of tools at its disposal to influence doctors' prescribing habits, such as Prescription by INN, Traffic Light System, Prescribing Quotas, etc.	✓	✓	✓	✓	✓

Source: IQVIA

CHLPS control mechanism instruments allows to decrease and control drug prices and scale patients coverage with treatments

Control mechanism instruments

Control mechanism instruments	Scope	Applicability	Impact
Price / margin control	• Might be applied for all drugs / specialized lists (e.g.EDL) or other drugs	• The impact of reference pricing is only efficient when there are large differences in the prices of drugs in a given pool of comparators • Used for both multisource and single-source products and is also used as part of a series of price setting mechanisms. • Efficient and easy to use price control mechanism	• Median relative reduction in cumulative drug expenditures of -18% after first year (-50% - +3%) (5)
Prescribing control	• Rx drugs	• Applicable when highly standardized treatment guidelines in place • Due high resource demand for implementing – most efficient and important for highly cost treatment	• Minimize overprescription, overutilization or unappropriated prescriptions, thus controlling spending (-10% on State programs KSE-MoH 2019)

Source: KSE

CHLPS countries use control mechanism instruments, which include price control, prescribing control and budget caps

Price control

Poland

- **Reference pricing:** Fixed MSPs[1] are established for all retail sector reimbursed prescription drugs through price negotiations between MoH and the manufacturer. For innovative drugs, the price is negotiated taking into account factors such as the price in other EU states, budget impact, and cost-effectiveness. The prices of new drugs with at least one reimbursed therapeutically equivalent alternative on the market cannot exceed 75% of MSP of the alternative; or, where there are several alternatives, the price cannot exceed the MSP[1] of the reference rug in the same reference price reimbursement group
- **Price negotiations:** Regular price cuts are implemented via updates to the reimbursement list. In the hospital sector, the MSP is negotiated between the MoH and the manufacturer: hospitals can (and do) negotiate discounts with suppliers on this maximum MSP[1]
- Poland is participating in a Central European joint price discount negotiations and drug reimbursement conditions initiative – along with Hungary, Lithuania and Slovakia (the so-called V4 Plus group). **An innovative cancer drug and an orphan drug** will reportedly be the first drugs to have their prices negotiated by the V4 Plus group

Czech Republic

The State Institute for Drug Control (SÚKL) is responsible for reimbursement decisions and HTA assessment including calculating the cost-effectiveness of drugs. In May 2017, the union of health insurance companies published a methodology in agreement with the SÚKL to revise the threshold of incremental cost-effectiveness ratio (ICER) to CZK1.2 million (decreeing from EUR1.38m). Manufacturers may not be willing to lower their prices to levels required by the new methodology, which causes delays. However, temporary reimbursement can be granted via Section 16 for highly expensive drugs. Individual hospitals have the authority to decide on the budget that is directed towards usage of drugs

Slovakia

- Pharmaceutical prices are b**eing reduced almost continuously,** which makes the Slovak market to be one of the cheapest in Eastern Europe and we believe in Europe as such
- **Reference pricing:** The reimbursement committee during the reimbursement process (1-2 times a year) evaluates the health benefit/pharmaco-economic profile of a product and decides on the level of reimbursement. With regards to innovative products, the reimbursement committee bases its reimbursement decision on EBM (evidence based medicine) facts
- Slovakia is participating in a Central European joint price discount negotiations and drug reimbursement conditions initiative (within V4 Plus group)

Latvia

- For drugs included in the positive list, prices are negotiated between the Medicines Pricing and Reimbursement Agency and the manufacturers. For drugs not included in the reimbursement system, prices are based on manufacturer's price with limited mark-ups for wholesalers and pharmacies

Hungary

- **Reference pricing:** The proposed MSP[1] must not exceed the lowest MSP[1] of the same drug in the European Economic Area. Drugs for hospital use are subject to the same pricing and reimbursement procedures as reimbursed retail drugs, but actual prices are determined by negotiations between suppliers and NEAK[2]/hospitals (either individually or as part of the government's centralised procurement initiative). Generics, biosimilar prices are capped relative to the price of the off-patent original
- Hungary is participating in a Central European joint price discount negotiations and drug reimbursement conditions initiative (within V4 Plus group)

(1) MSP – manufacturer's selling price; (2) National Health Insurance Fund in Hungary
Source: IQVIA

CHLPS countries use control mechanism instruments, which include price and prescribing controls and budget caps

Prescription control

Hungary

- There are no prescribing budgets for physicians. However, the National Health Insurance Fund (NEAK) has a number of tools at its disposal to **influence doctors' prescribing habits**: Traffic Light System, Prescribing Quotas
- **Traffic Light System:** Physicians' prescribing software is reported to include a 'traffic light' color coding system to encourage doctors to prescribe the lowest-cost and/or 'preferred' medicines in a given reference price reimbursement group
- **Prescribing Quotas:** Prescribing quotas apply for biological medicines, according to which physicians must prescribe a minimum percentage of 'preferred' (i.e. lower-cost) biological medicines
- INN prescribing is possible in Hungary (as a pilot for statins)

Czech Republic

- **Budget caps** have been recently required by payers for most molecules and also for molecules already in the market
- There is no penalties for doctors who deviate from the prescribing formulary. Hospitals are open to negotiations for price-volume agreements with manufacturers. As part of agreements with companies, hospitals expect to receive a payback that will cover the penalties they face if they exceed their annual drug budget
- **Cost capitation per patient:** Well perceived especially by smaller payers – market potential remain unaffected and company is not exposed to higher than expected prevalence risk
- INN prescribing is **obligatory** in Czech Republic

Poland

- Doctors can prescribe a maximum of five different medicines per prescription. However, prescribing controls are weak, there are no physician prescribing budgets or official prescribing guidelines
- INN prescribing is possible in Poland

Slovakia

- INN prescribing is **mandatory** for selected substances in Slovakia and prohibited for the others

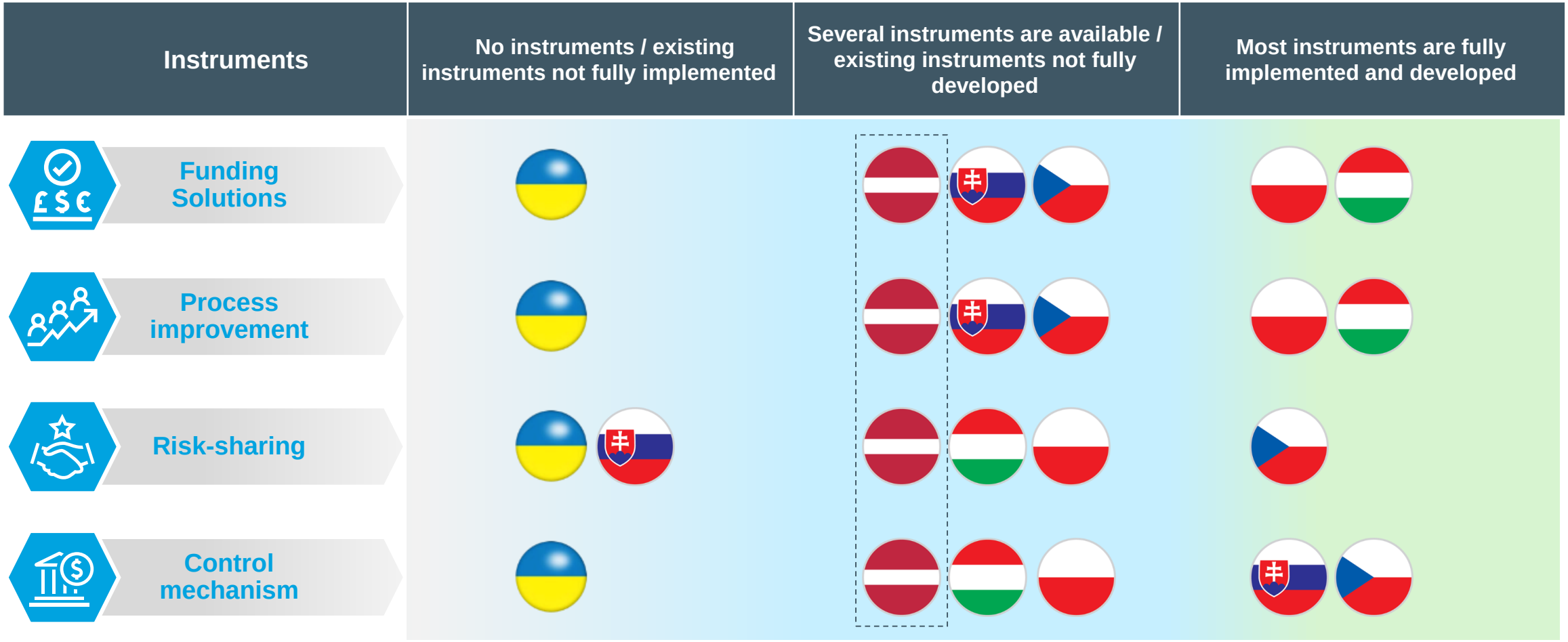
Latvia

- INN prescribing is Possible in Latvia
- According to Regulation No. 899, INN prescribing is mandatory for naive patients when the physician prescribes list A reimbursable medicine

(1) MSP – manufacturer's selling price
Source: IQVIA

Poland and Hungary are ahead of CHLPS countries in using instruments for access to innovative therapies, Latvia is on the way for further development

CHLPS countries' instruments for access to innovative therapies overview



Source: IQVIA

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Recommendations for Ukraine

Available instruments are applying to both original and generic drugs aiming to ensure budget savings, increase access to innovative therapies and improve health outcomes

Instruments for access to innovative therapies

	Risk-sharing	Process improvement	Control mechanism	Funding Solutions
Product group	Original drugs		Generic drugs	
Types of instruments	• Financial based • Performance based	• Health Technology Assessment (HTA)	• Price / margin control • Prescribing control	• Generic pricing rule • Patient co-payment
Key benefits	• **Budget savings for drugs for drugs** with uncertain/volatile consumption • **Ensure** earliest possible **access to advanced therapies** • **Minimize risks** and **reduce budget impact** in case of **clinical uncertainty**	• **Minimize the use of ineffective or harmful technologies** • **Contribute to value for money investments** in health technology in finite budgets • Provide clear information to stakeholders	• **Reduction** in cumulative **drug expenditures of -18% after first year (-50% - +3%)** of pricing control • Minimize overprescription, overutilization or unappropriated prescriptions, thus **controlling spending** • **Costs savings in short-time period**	• **Increase budget** by lowering current spending to be allocated to innovative therapies, thus improve health outcomes for population • **Increase access to innovative therapies** • **Provides funds, risk-mitigation measure** in case of overspending

Instruments applying to generics will allow to get additional budget by lowering prices and implementation of control mechanism to be allocated to highly effective innovative therapies

Source: IQVIA, KSE

Recommended instruments will help to address current gaps in Ukraine healthcare and increase access to innovative therapies

Limiting factors for access to innovative therapies in Ukraine

Limiting factors / gaps	Current state / description	Recommended instruments to fulfill gaps

1 **Low funding level**	▪ **Only 12%** of pharmaceuticals are **covered by Government** in Ukraine vs ~**74% in CHLPS**
	▪ **Ukraine** has the **lowest government spending per capita**, **extremely low for original drugs** while other products take ~40%
	▪ **Non-targeted sourced of financing** of healthcare (**tax pool in Ukraine** vs dedicated insurance-base in CHLPS)
		▪ **Generic pricing rule, price/margin controls, prescribing control** are aiming
		  ▪ To create fiscal space **within current budget** to increase innovative therapies use
		  ▪ To minimize overprescription, overutilization or unappropriated prescriptions, thus **controlling spending**

2 **Non targeted spending**	▪ **Current state spending** is focusing on the **cheapest generics** with **no link to health outcomes**
	▪ Narrow scope of existing HTA department (**no economic evaluation**, only medical aspect)
	▪ **Availability to innovative medicine**s in Ukraine is at the lowest **9%** rate of availability in **CHLPS (up to 60%)**
		▪ **Risk sharing agreements** will allow
		  ▪ To increase access to innovative therapies
		  ▪ **Minimize risks** and **reduce budget impact** in case of **clinical uncertainty**
		  ▪ **Budget savings for drugs** with uncertain/volatile consumption

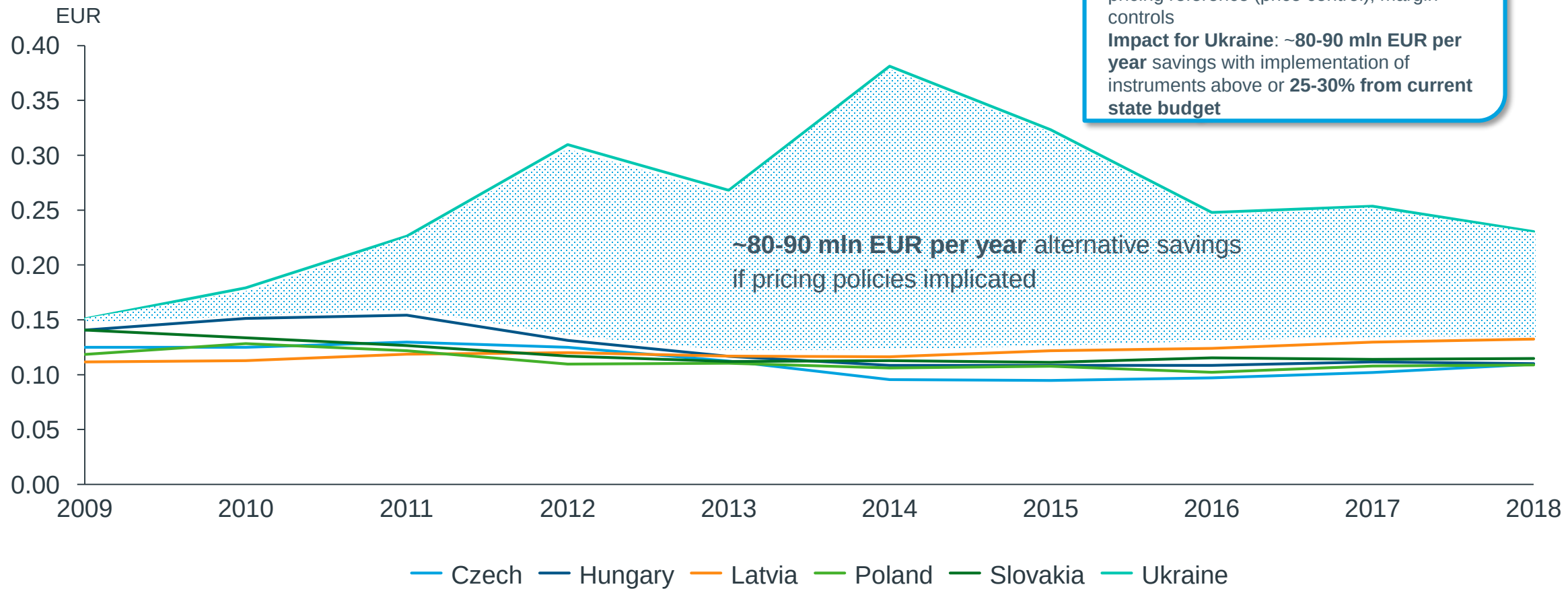
3 **Lack of KPIs**	▪ The **measurements of healthcare system quality** (life expectancy, mortality, birth mortality, etc) are the **lowest** for Ukraine ▪ CHLPS countries have standard healthcare system KPIs while Ukraine most of them are not implemented that leads to worse health outcomes of population ▪ **Lack of KPIs leads to poor health outcomes** (life expectancy 67 male vs 73* / 77 female vs 80*, infant mortality 7,5 vs.4,2*, mortality from cardiovascular 908 vs.608* etc.)	▪ **Health technology assessment (HTA)** will help to **ensure access to innovative therapies** ▪ **HTA** considers **evidence** regarding clinical effectiveness, safety and cost effectiveness that should includes various **KPIs impact**

* Average indicator among CHPLS countries
Source: IQVIA, KSE

Implementation of pricing policy instruments will allow to save up to 90 mln EUR per year within current state budget which equals 25-30% from current state budget

Average generic price* per SU in state reimbursement

Instruments: Generic pricing rule, External pricing reference (price control), margin controls
Impact for Ukraine: ~**80-90 mln EUR per year** savings with implementation of instruments above or **25-30% from current state budget**



* Based on all generics covered by Government in CHLPS countries and available on Ukrainian market

Source: IQVIA, KSE

Up to 40% in current state budget might become available after pricing policies and prescription control implementation

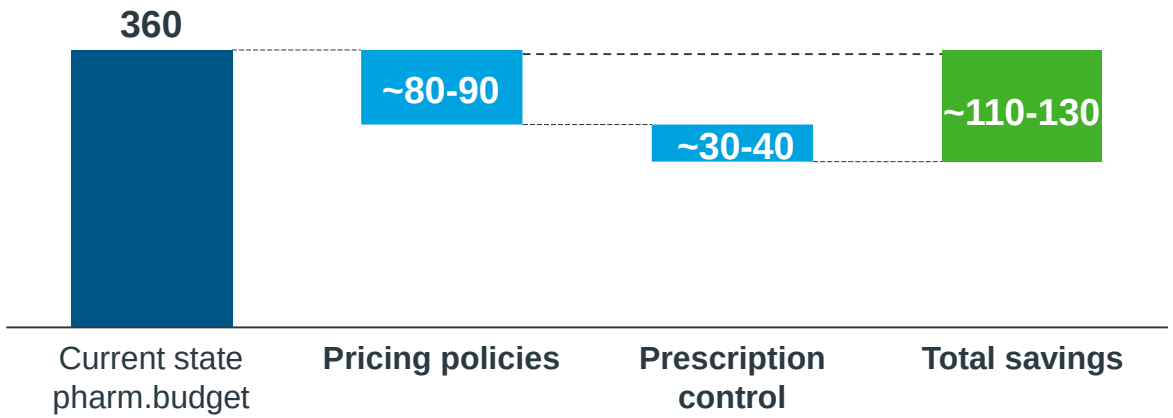
High level state pharma budget impact estimations

Current state pharma budget impact

3.6% of GDP

[mEUR]

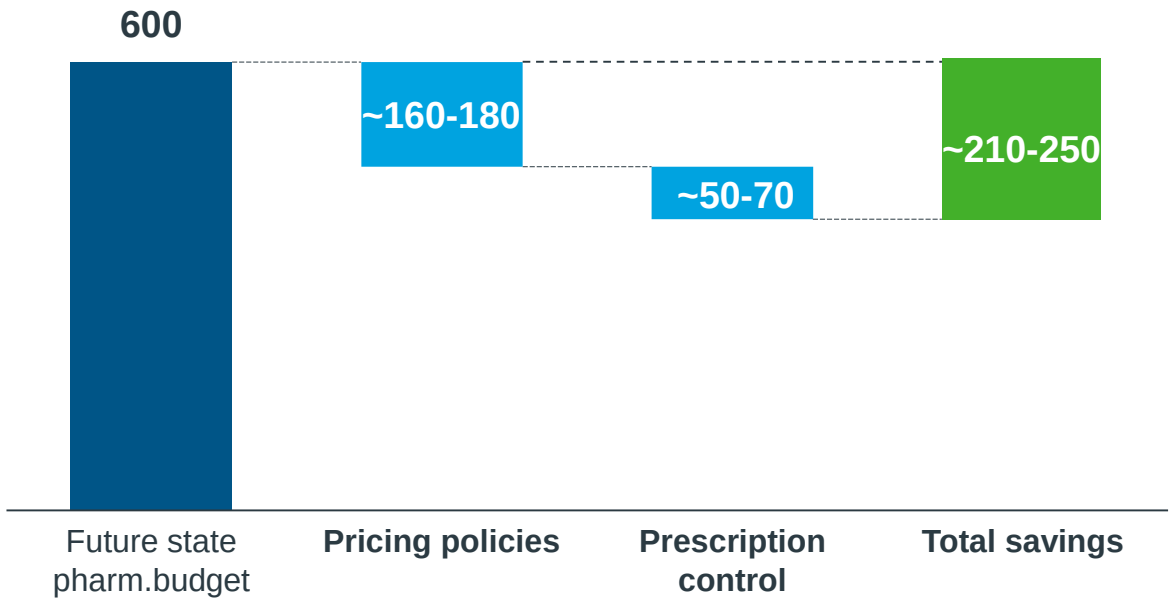
Pricing policies implementation will give **~25-30% savings** from current budget, **prescription control ~5-15%**



Future state pharma budget impact

5% of GDP

[mEUR]

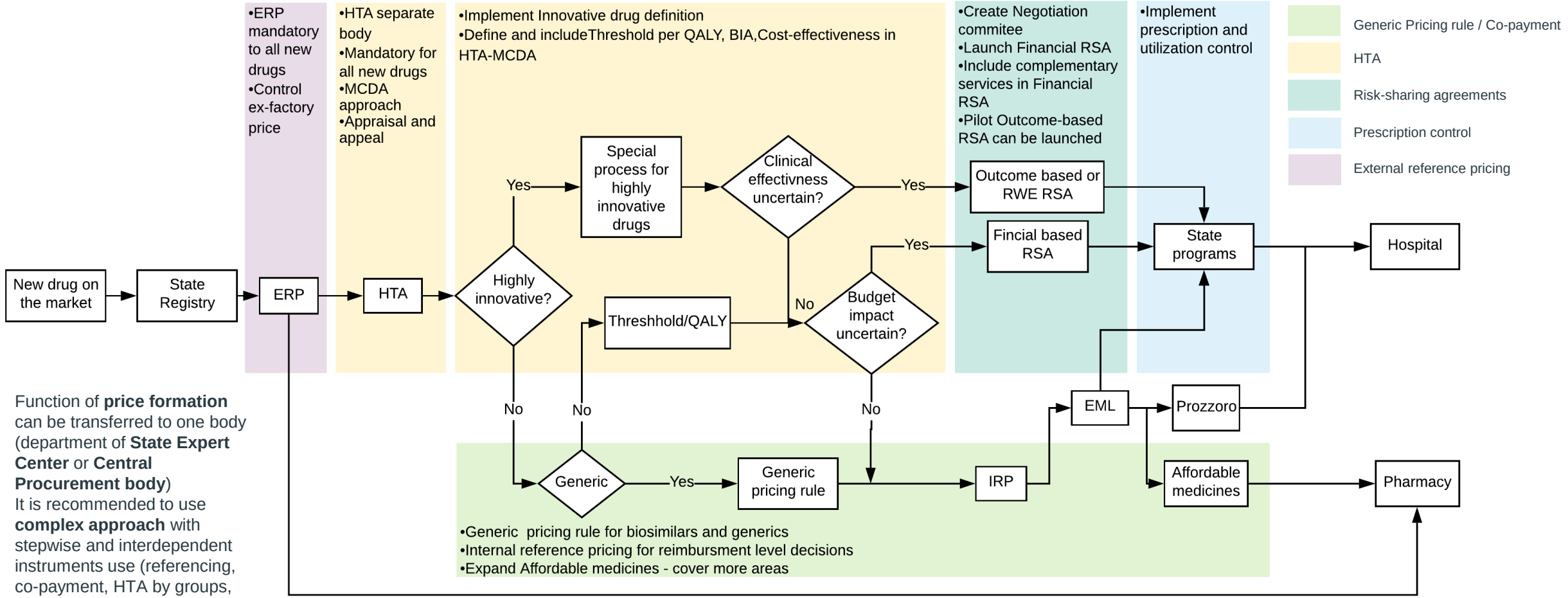


- Pricing policies instruments assume implementation of generic pricing rule, external price references, margin control
- Based on expert estimation we evaluated potential impact from prescription control implementation at 5-15% level
- Other recommended instruments (HTA, RSA) financial impact might be evaluated separately (no direct impact)

Source: IQVIA, KSE

Recommended instruments are allocated within product flow to ensure effective implementation in Ukraine

Product flow and instruments implementation



- Function of **price formation** can be transferred to one body (department of **State Expert Center** or **Central Procurement body**)
- It is recommended to use **complex approach** with stepwise and interdependent instruments use (referencing, co-payment, HTA by groups, RSA in the case of high budget impact)

RWE – real-world evidence
EML – Essential Medical List
MCDA - Multiple-criteria decision-making
ERP – external(international) price referencing
IRP – internal price referencing
RSA – risk-sharing agreements
BIA – budget impact analysis

Source: KSE

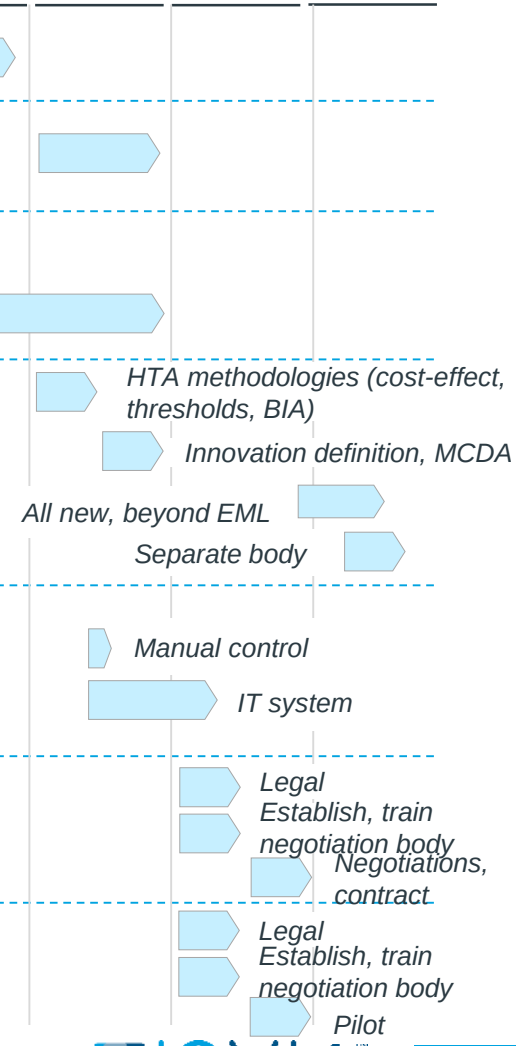
Each of recommended instrument has specific aspects to be considered for implementation that reflected in the table…

Instruments		Recommendations details
Funding Solutions	▪ Generic pricing rule ▪ Patient co-payment	❑ **Generic pricing policies and instruments** are efficient funding solution and have to be implemented to start sustaining drug cycle ❑ **Generic pricing rule**, should be implemented for the purposes of **generic price control** ❑ In case of reimbursement list growth **Internal (therapeutic) reference pricing** for Affordable Medicines program can go beyond INN (ATC 4) referencing to stimulate intra-/intergroup competition ❑ **Affordable Medicine reimbursement program** already use elements of co-payment and reference pricing but it **have to cover more therapeutic areas** and include far more INN of different groups
Process improvement	▪ Health Technology Assessment (HTA)	❑ **HTA department** that is already part of State Expert Center **should be separate body** with self-sustained financing ❑ **HTA process** have to be implemented **beyond EML** and have to be **mandatory**(may be with different approaches simple/normal) for all drugs that apply for reimbursement, central or hospital procurement ❑ **HTA appraisal** have to be **public** for better transparency, **appeal procedure** has to be developed ❑ HTA have to include clinical, cost-effectiveness, budget impact analyses and define financial threshold. It is recommended to include **MCDA approach** in HTA evaluation and appraisal procedures ❑ Legal definition and methodology to define **highly innovative drug** should be created and included in MCDA approach to secure access to **highly-innovative drug/drugs with unmet need**
Risk-sharing	▪ Financial based agreements ▪ Performance based agreements	❑ **Financial-based Risk sharing agreements** can be launched **with minimal infrastructural changes** for drugs with **high budget impact** ❑ Include **complementary services** in **Financial RSA** to facilitate infrastructural development ❑ Create **medium** to start **systematic** and **transparent business-government interactions** ❑ **Outcome-based RSA** can be launched in **pilot** for centrally procured **high-cost drugs** with feasible outcome and registry in place
Control mechanism	▪ External pricing control ▪ Price / margin controls ▪ Prescription control	❑ Implement **prescription control for high-cost treatments (State programs)** to mitigate irrational use of medicines. **Incentive/penalties system** should be developed to enforce **prescription control.** ❑ **External reference pricing** have to be used as **mandatory mechanism** for price formulation for both hospital and retail sales(all Rx drugs) ❑ As Ukraine already have predefined distribution margin control it is recommended for Authorities to control **ex-factory/wholesale prices** and use **Registry of wholesale-retail prices**, but with **improvements (regularly revised (6-12 month), prices have to be included after ERP evaluation)**

Source: IQVIA, KSE

… with detailed timeline for the next three years

Instruments	Measure		Level of legislation	Duration (months)
Co-payments	• Implement protection caps for threatened population - create dynamic calculations		• Constitution • Law • Orders	12
Generic pricing rule	• Define percentage for 1st, 2nd, 3rd generics/biosimilars entering market after originator		• Orders	12
External pricing reference	• Implement ERP caps in Prozorro • Implement ERP during authorization procedure for all drugs entering the market		• Law • Orders	6 18
HTA	• Separate body • Beyond EML • Mandatory for all new drugs funded by state • Public appraisal (public methodology and guidelines)	• Appeal • Cost-effect, BIA, threshold • Innovation definition • MCDA approach	• Law • Decree • Orders	6 6 24 6
Prescription control	• System for demand and prescription calculation for State programs • Penalties/incentives system		• Orders	3 12
Financial based PSA	• Medium for business govt. interaction	• Financial RSA for high-cost, budget impact drugs • Complementary services in State programs	• Law • Decree • Orders	6 6 6
Performance based RSA		• Pilot outcome-based for high-cost drug with known effectiveness in State programs	• Law • Decree • Orders	6 6 6



Source: IQVIA, KSE

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Appendix

Ukraine key indicators per capita are far behind CHLPS countries with the lowest GDP per capita, HC expenditure and government spending per capita

Key figures for country comparison

Key facts of Ukraine and benchmark countries (1/2)

Country	GDP size [bn EUR[1], 2019]	Population [mn]	GDP/capita [k EUR[1], 2019]	Healthcare spending value [bn EUR[1], 2019]	Healthcare spending per capita [EUR[1], 2019]	Public healthcare spending as % of GDP [2019E]	Pharma market value [bn EUR[1], 2019E]	Pharma market value per capita [EUR[1], 2019]	Pharma market value as % of GDP [2019E]
Czech	361	10.6	34.0	13.4	1 259	6.2%	2.9	271	0.8%
Hungary	290	9.8	29.8	9.6	983	4.6%	2.8	292	1.0%
Latvia	53	1.9	27.4	1.5	786	3.4%	0.4	223	0.8%
Poland	1,125	38.0	29.6	28.1	739	4.5%	7.4	197	0.7%
Slovakia	175	5.5	32.0	6.5	1 193	5.4%	1.6	294	0.9%
Ukraine	358	41.9	8.5	5.7	137	3.6%	3.0	71	0.8%
	Ø 394	Ø 18	Ø 27	Ø 11	Ø 850	Ø 4.6	Ø 3	Ø 225	Ø 1

(1) Converted at fixed exchange on 31 December 2018
Source: IQVIA, World Bank

Ukraine key indicators per capita are far behind CHLPS countries with the lowest GDP per capita, HC expenditure and government spending per capita

Key figures for country comparison

Key facts of Ukraine and benchmark countries (2/2)

Country	Healthcare spending value [bn EUR[1], 2019]	Pharma market value [bn EUR[1], 2019E]	Pharma market share in healthcare [%, 2019E]	Reimbursed market[2] share in total pharma market [%]	Reimbursed value per capita [EUR[1]]	Original reimbursed market per capita [EUR[1]]	Original drugs market share in reimbursed [%]
Czech	13.4	2.9	22%	86%	236	163	69%
Hungary	9.6	2.8	30%	76%	222	152	68%
Latvia	1.5	0.4	28%	88%	195	105	54%
Poland	28.1	7.4	27%	58%	115	64	56%
Slovakia	6.5	1.6	25%	82%	243	159	66%
Ukraine	5.7	3.0	52%	12%	9	1	10%
Ø	11	3	30	0	170	107	54

(1) Converted at fixed exchange on 31 December 2018; (2) Reimbursed market includes both hospital and retail reimbursed segments
Source: IQVIA, World Bank

Compared to CHLPS Ukraine consumption in Rx segment is also lower both in value and volume terms by four and three times correspondingly

Pharmaceutical market. Rx segment

Rx segment size and growth

Country	Pharma value [Bn EUR[1], 2019E]	Pharma value per capita [EUR[1]/ capita, 2019E]	Consumption [SU/ capita, 2019E]	CAGR[2] [EUR, 2015-2019E]
Czech Republic	2.6	244	773	11.2%
Hungary	2.4	246	813	6.9%
Latvia	0.3	157	532	7.1%
Poland	6.0	159	742	6.8%
Slovakia	1.4	258	747	2.2%
Ukraine	**1.8**	**42**	**218**	**19.0%**
CHLPS average	Ø 2.4	Ø 184	Ø 638	Ø 8.9%

(1) Converted at fixed exchange on 31 December 2018;
(2) Pharma market annual growth 2015-2019 is calculated in EUR and does not include local currency fluctuations
Source: IQVIA, OECD, Proxima Research

Comments

- Ukraine **Rx pharma market is comparable** with CHLPS countries
- However, **consumption of pharma products is much lower** in Ukraine:
  - By ~x3 times in units per capita
  - By ~x4 times in EUR per capita
- Nevertheless, **historically Ukrainian Rx pharma market has been growing faster** compared to more developed CHLPS countries except for Czech Republic

Innovative market access agreements fall into three main buckets

Types of managed entry agreements

Terms	Description
Financial Based Agreements	Price level or nature of **reimbursement is based on financial considerations** and is not related to clinical performance
Performance Based Agreements	Price level or nature of **reimbursement is tied to future metrics** ultimately related to patient performance, outcomes, efficacy, tolerability, dosing, benefit, outcomes, quality of life, or clinical usage
Coverage with Evidence Development (CED)	Reimbursement decision in which approval is conditional on the **collection of additional population level studies after launch** (with provisional reimbursement) to support coverage or pricing

Source: IQVIA

Study on spending on healthcare and access to treatment | December 23, 2019

Financial-based agreements are focused on financial and economic metrics, not clinical ones

Examples of financial based agreements

Terms	Examples

Financial Based Agreements	• **Price-volume agreements**
	  - Price is reduced as the total volume of product sold increases
	• **Total cost cap**
	  - Manufacturers provides patients with free treatment after are the first X treatments
	  - Payers total liability is capped at a pre-determined amount
	• **Net price discounts**
	  - Discounts on initial therapy for a preset amount of time
	• **Rebates**
	  - Fixed percent rebate from list price
	• **Non-price discounts/ free goods**
	  - Additional bonus products with minimum purchase

Performance Based Agreements	
Coverage with Evidence Development (CED)	

Note: Net price discounts and rebates are considered IMAAs if additional data needs to be gathered for the payer to realize the discount or rebate

Source: IQVIA

Performance-based agreements are focused on clinical metrics

Examples of performance-based agreements

Terms	Examples
Financial Based Agreements	
Performance Based Agreements	• **Outcomes guarantee** - Manufacturer provides rebates, refunds, or price adjustments if their product fails to meet the agreed upon performance criteria • **Compliance monitoring** - Manufacturer and payer jointly works to increase compliance/use to drive drug use and increase patient benefit • **Pattern or process of care** - Reimbursement is tied to the impact on clinical decision making or practice patterns
Coverage with Evidence Development (CED)	

Source: IQVIA

Study on spending on healthcare and access to treatment | December 23, 2019

CED is when reimbursement approval is conditional on the collection of additional population level studies after launch

CED overview

Terms	Description
Financial Based Agreements	• **Rationale** - Some medicines or technology may show significant indication of clinical benefit based intermediate endpoints, but performing additional clinical trials may be difficult or ethically unacceptable - The objective of CED is to provide reimbursement while further evidence is collected, giving patients access to promising new technologies sooner • **Data collection** - Typically, patients will need to enroll in a registry or clinical trial to have access to the medication, but the CED arrangement should specify how to collect the additional evidence and the criteria for making subsequent decisions on the basis of this evidence • **Exceptions** - Payers in the Netherlands and in the U.S. (e.g. Kaiser Permanente) use the term CED when evaluating all high cost medicines independent of the level of uncertainty; these evaluations are not considered true CED
Performance Based Agreements	
Coverage with Evidence Development (CED)	

Source: IQVIA

12 out of 414 experts interviewed

414 Interviewers were identified in CHLPS-countries

Type	Contact list / Contacted / Interviewed				
	Czech republic	Hungary	Latvia	Poland	Slovakia
Policy	13 / 13 / 0	18 / 15 / 0	36 / 30 / 0	31 / 28 / 2	50 / 20 / 0
Academia	1 /1 / 1	17 / 13 / 2	-	3 / 3 / 1	15 / 12 / 2
Patients	-	5 / 0 / 0	-	6 / 5 / 0	3 / 1 / 0
Business	31 / 30 / 1	29 / 19 / 0	10 / 10 / 2	37 / 37 / 1	65 / 47 / 0
Total	**44 / 14 / 2**	**69 / 47 / 2**	**46 / 40 / 2**	**77 / 73 / 4**	**133 / 80 / 2**

Interview guide:
This interview aimed at stakeholders involved in the decision-making process for innovative drugs market access in the CEE region. The scope of this interview is to collect information on experience in the implementation of different instruments and approaches to improve market access and financing of innovative drugs. The interview will be semi-structured and has the next parts:

Prerequisite questions:

1. Does your country have a definition of innovative drugs?
2. Does your country have a definition of high-/very high- price drug?
3. What mechanisms to increase patient access to innovative therapies are used in your country? (rank)
4. Are those measures used only for selected groups of drugs? (innovative, generics, biosimilars, etc)
5. What factors forced the consideration of instruments?

Main questions:
Who:
1. Who initiated considerations of cost-saving or risk-sharing measures?
2. Who proposed instruments/measures (schemes) to consider? (pharmaceutical company, patient organization, governmental body, professional organization, academia)
3. Name stakeholders and their roles in decision making?

Decision process:
4. Is there any legal framework or procedure for evaluating and introducing new cost-saving methods?
5. How the process of selection was held? (describe)

Reasons
6. What issues those instruments were aimed to address? (efficacy, a quantity of patients population, etc)
7. What factors were considered in the decision making? (rank)

Requirements:
8. Were any changes in infrastructure, policies, financing required for implementing of instruments? (specify)
9. What main steps/milestones had to be taken for instrument implementation? (describe)
10. Did the implementation of the instrument require collaboration between institutions and authorities (specify)?
11. How long did it take to implement it?

Barriers:
12. What were the barriers and problems in the process of implementation? (rank)
13. How the performance of the instrument was evaluated or compared?

Advantages/Disadvantages
14. What are the main country-specific advantages/disadvantages? (rank)

Future directions:
15. How do you see the future of cost-saving measures?

Source: KSE analysis 2019

Semi-structured interview guide

Different bodies (MoH, HTA, NHS) responsible for reimbursement and pricing decisions

Country	Business	Policy	HTA	Payer	Professional organizations	Patients organizations	Stakeholders committees	Insights
Czech Republic	Manufacturer start process submitting application	Ministry of Health	State Institute of Drug Control(SUKL)	Several private and Governmental insurance companies	-	-	-	• Strict pricing regulations – delayed access to innovative therapy • Transparent system of drug regulation - greater **rights of appeal** to companies • **General Health Insurance Fund** covers 60% of market. Other **6 funds** have joint negotiations as **association** which **simplifies** price negotiations • 2020 – new pricing legislation will be implemented with involvement of **Patients organizations** to decisions
Hungary		State Secretary of Health	HTA office at National Institute of Pharmacy and Nutrition (OGYÉI)	National Institute of Health Insurance Fund Management	Medical Professionals Board	-	Technology assessment committee	• **Complex** price and reimbursement process (7+ steps, stakeholders, governmental bodies) • In case of **high political impact**, even **Prime-Minister** involved in decision
Latvia		Ministry of Health	State Medicine Agency, Department of Drug evaluation	National Health Service	-	-	-	• **No legal framework** for implementation of different cost-saving measures • 2020 **new regulation** will be implemented • 2018 - **more** innovative drugs entered market due to **additional funds** in NHS • **No negotiation structure** and **procedure** • Experts and patients organizations **opinions gathered informal**
Poland		Ministry of Health	HTA Agency(AOTMiT)	National Health Fund(NFZ)	Transparency Board at HTA agency	-	Economic Committee by MoH	• **Frequent changes** to the reimbursement list - numbers of **cheaper products added** frequent • Strong patients organization, but only **informal influence** • **Changes** to reimbursement law will be implemented in 2020 • **Economic committee** made by best practices from **France, Netherlands**
Slovakia		Ministry of Health	HTA expert group by MoH	Several private and Governmental insurance companies	ATC experts group	Reimbursement committee	Reimbursement committee	• **Patient advocates** involved in reimbursement committee but w/o voting rights. • **4 Healthcare insurance companies** dominates market(2 state and 2 private) • The Healthcare Surveillance Authority (ÚDZS) gov. body to **oversee health insurance sector**
Ukraine		Ministry of Health	Department of HTA at State Expert Center	National Health Service	-	-	-	• National Health Service “pay” for drug included in Affordable Medicines reimbursement program(23INN) and insulins

– process overseeing, final decision

Source: KSE analysis 2019

Cost reduction is a main driver of instrument implementation

What bodies starts the instrument implementation in CHLPS-countries

Country	Body	Drivers	Insights
Czech republic	• State Institute for Drug Control	• **Cost reduction** • Control of Healthcare budget	• **Pre-launch** activities - **Horizon scanning** provide government with data on drug that soon will enter market • All possible measures arise after 2008 **Health Insurance law** • **Political decisions** influence measures initiation
Hungary	• Ministry of Finance • NIH insurance fund	• **Cost reduction** • Control of Healthcare budge • Improvement of coverage • Introduction of new therapies	• Cost saving measures appeared mainly after **budget restrictions**
Latvia	• NHS	• **Cost reduction**	• There is **no strict legal framework** for new method implementation – decisions dominated by Pharmaceutical companies
Poland	• Ministry of Health	• **Cost reduction** • Control of Healthcare budge • Improvement of coverage • Introduction of new therapies	• 2012 Reimbursement law gives possibility to **implement whole spectrum of risk-sharing agreements** • Australian, Scotland and Netherlands pricing and reimbursement systems serve as **frameworks** for nowadays system • Manufacturers drive drug program initiation and expand
Slovakia	• Ministry of Health	• **Cost reduction** • Control of Healthcare budge • Improvement of coverage • Introduction of new therapies	• Slovak Society for Pharmacoeconomics and ISPOR Chapter Slovakia used to be engaged in the process of formulation of the rules, however, recently the **process is driven mainly by the Sick Funds** to their short-/mid- term orientation towards financial sustainability

Source: KSE analysis 2019

The most common instruments are: co-payments, generic substitution, financial RSA, reference pricing and HTA

Instrument type	Instrument	Czech republic	Hungary	Latvia	Poland	Slovakia
Co-payments		✓	✓	✓	✓	✓
Generic substitution		✓	✓	✓	✓	✓
Generic Pricing rule		✓		✓	✓	✓
Price Cuts		✓				✓
Reference pricing	Internal (therapeutic)	✓	✓	✓	✓	✓
	International (external)	✓	✓	✓	✓	✓
HTA		✓	✓	✓	✓	✓
Prescription control		✓	✓		✓	
Risk-sharing agreements	Financial-based	✓	✓	✓	✓	✓
	Performance-based		✓	✓	✓	
	Coverage with Evidence Development (CED)	✓				
Claw-back tax			✓		✓	

- Generics/biosimilars instruments

- Essential instruments

Source: KSE analysis 2019

Funding solution instrument: Non of the above countries except Ukraine have dedicated drug funds

Funding solution instrument	Strengths	Weaknesses
Generic substitution	• Highly effective cost cutting measure **(up to 40%) CZ, HU, PL, SV** • **Doctors tools** with price information **CZ** • **Pharmacist/doctor tools** to **incentivize** generic prescription **HU** • 2020 law include pharmacist obligation to substitute drug with cheap generic **LV** • High willingness to uptake **biosimilars PL** • **Brand prescription** have to be justified by physician **PL** • **Payers control** prescription in centralized manner by IT system **SV**	• Poor compliance **CZ, HU, SV** • **Additional monitoring tools** required **CZ** • **Additional incentive system for doctors HU** • No clear regulation for biosimilars **PL** • **Price monitoring system for patients SV**
Price cuts:	• Effect with extern. on the whole market **(2008 and 2011, ~30% reimb. list) CZ** • **Stepwise cost-cut** for generics, biosimilars **LV**	• Used as **crisis tool** during certain period (2009) **CZ**
Clawback tax	• **Clawbacks** and **paybacks as a function of volume HU** • Not used with risk sharing thus **doesn't affect innovative therapies PL**	• Due to **high tax** limits the access to innovative therapies **HU**
Co-payment	• **Fixed co-payments** led to quick financial results **CZ** • In every therapeutic group there is **fully reimbursed** drug **CZ** • **Protective limits** for elderly **CZ, SV** (for patients of different ages and social status) • Flexible (reviewed **yearly**), different levels/rates (6 **groups**) **HU** • Has a **flexible system** with different levels and rates **PL, SV** • **Lump sum** co-payment(3.3zl) **PL** • **No for elderly (75+) PL**	• Politically unfavorable **CZ, HU, PL, SV** • Difficult to set up **CZ, HU, PL, SV**

Source: KSE analysis 2019

Funding solution instrument: Barriers and requirements to overcome

Funding solution instrument	Barriers		Requirements for implementation
Generic substitution	• Low adoption of **e-Rx** (applied only for Affordable Medicine reimbursement program), no instrument to **match dispensed drugs with prescription**, low capacity in **pharmacoeconomic calculations** (originator by generic, generic by generic in same group), • Lack of analytical and control possibilities **to control prescription, physicians against substitution, high administrative burden for enforcement** (need to control all pharma transactions), no **legal framework for substitution by dispenser, strong pharma** lobby(pressure)		• **Data:** Data on **patient, prescription and dispensing** • **Infrastructure:** Pharmacy **personnel** trained in appropriate substitution, Legislation to allow substitution by dispenser, **system to validate** substitution, QA of generics • **Methodology: Methodology to validate substitution**
Price cuts:	• **Strong pharma** lobby(pressure)		• **High political will** • **Infrastructure:** Legislation to **allow, regulate and enforce price cuts**
Clawback tax	• No legal framework for **operations with budget cap**		• **High political will** • **Infrastructure:** Legislation to **allow, regulate and enforce clawbacks**
Co-payment	• Low adoption of **e-Rx**(applied only for Affordable Medicine reimbursement program), no instrument to **match dispensed drugs with prescription**, low capacity in **pharmacoeconomic calculations, no defined body for pricing policy**, **Co-payment policy** needs to be aligned with Constitution and State law on financial guarantees for medical services.		• **Data:** Data on **patient, prescription and dispensing** • **Infrastructure: Capacity** in database management, data analysis, Legislation framework for use of Co-payment. **Procedures** on how to apply Co-payment, **System to validate** prescription and level of co-payment • **Methodology:** Selection or calculation of the **co-payment (levels, protected cohorts, reference drugs etc**.)

Source: KSE analysis 2019

Risk-sharing agreements: Financial-based agreements as dominant model of risk-sharing

Risk-sharing agreements	Strengths	Weaknesses
Financial Based Agreements	• **Indication limitation** capacity **CZ** • MAH offers discounts for other portfolio to increase cap threshold **CZ** • If drug **lost temporary reimbursement,** but doesn't achieve permanent – **MAH** have to **pay for patient to finish therapy CZ** • **All new** INNs are subject to risk-sharing **HU, PL** • Mainly **PVA, discounts, paybacks** due to relative simplicity and capacity restrictions **LV, SV** • **Complementary services** (within drug program) infrastructure requirements **PL** • **Possibility** to make undisclosed contracts with all Payers **SV**	• Restricted access – few special centers can offer new treatment **CZ** • Legal restrictions for **free-doses and complementary services CZ** • Mainly financial-based MEAs**, very (2-3) few outcome based HU, PL** • No **special body for negotiation LV** • No **framework for negotiation LV** • **Transparency** issues **LV**
Performance Based Agreements	• **Drug programs** give potential for outcome based elements **PL**	• **No infrastructural capabilities CZ, HU, LV, PL** • **No possibilities for manufacturer** to **build their data-collection systems** or collect data from state infrastructure **LV**
Coverage with Evidence Development (CED)	• MAH of **Highly Innovative drugs** that have temporary reimbursed obliged to **build infrastructure** for **RWE** collecting **CZ**	

Source: KSE analysis 2019

Risk-sharing agreements: Barriers and requirements to overcome

Risk-sharing agreements	Barriers		Requirements for implementation
Financial Based Agreements	• Lack of **data and tools** on **epidemiology, utilization patterns**, etc. • Low capacity in **pharmacoeconomic calculations** • Low **level of interaction between stakeholders(business and governmental body)** • Due to the nature of agreement excludes **transparency**		• **Data:** Data on **stock, waste, utilization**, etc. • **Infrastructure:** Legislation mandating use of RSS, Capacity in **Pharmacoeconomics, negotiation, evaluating clinical evidence,** system to **account stock, waste, utilization**. • **Methodology:** Selection and evaluation of **calculation, type of deal**
Performance Based Agreements	• Lack of **data and tools on epidemiology, utilization patterns, outcomes, patients** • Low capacity **in pharmacoeconomic evaluation, negotiation, evaluating clinical evidence** • Due to the nature of agreement excludes **transparency**		• **Data:** Data on **stock, waste, utilization, patients, clinical data**, etc • **Infrastructure:** Legislation mandating use of RSS, **Capacity in pharmacoeconomics, negotiation, evaluating clinical evidence, System to account for stock, waste, utilization, clinical and outcome data** • **Methodology:** Selection and evaluation of **calculation, type of deal**
Coverage with Evidence Development (CED)	• Lack of **data and tools** on **epidemiology, utilization patterns, outcomes, patients** • Low capacity in **pharmacoeconomic evaluation, negotiation, evaluating clinical evidence** • Due to the nature of agreement excludes **transparency**		

Source: KSE analysis 2019

Control mechanism instruments: as most dynamically developing and widespread

Control mechanism instruments	Strengths	Weaknesses
Internal price referencing	• Short interval **(6 months) CZ** • Referencing inside **therapeutic group CZ, HU, PL, SV, LV** • **API referencing HU** • Price linked to **tender system (cap) HU** • Create **price competition** inside groups **HU** • **therapeutic** groups by **ATC LV** • **Diagnosis-related** groups **LV** • Drug with **15% turnover** serve as reference **PL** • Price linked to co-**payments (cap) PL** • Short interval **(3 month) SV** • Referencing inside **therapeutic group** which are **often reassessed SV**	• Aggressive policy – lead to increase in **parallel export SV, CZ HU** • Internal pricing used inconsistently **LV** • No predefined rules and framework **LV** • **Not regularly** used (case-by-case, not dynamic market reaction) **PL** • **Low transparency PL**
International price referencing (external)	• One of the lowest prices **(3 min. of 18 countries)** due too short interval **(6 months) CZ** • **Market price may be higher** than referenced and include **co-payment CZ** • Requires reimbursement **in 3 member states HU** • **7 countries** in reference group(PL, HUN, CZ, SK, LIT, EST, DEN) **LV** • Price **can't be higher** than Lithuania and Estonia **LV** • **Revised** if price in reference countries were changed **LV** • Manufacturer submits prices from **all markets PL** • Manufacturers **have to declare** if they have **MEA** in any EU countries **PL** • Revised every **3-6 month SV** • **If product** marketed in less then 5 countries – **lowest price - 20%** set as maximum **SV**	• Manufacturers don't prioritize markets - **delayed introduction LV, PL, SV, CZ, HU**

Source: KSE analysis 2019

Control mechanism instruments: as most dynamically developing and widespread

Control mechanism instruments	Strengths	Weaknesses
Generic pricing rule	• after comparator - first generic on market **-30%,** second **-10%,** third **-5%(biosimilars -25%, -5%, -5%) SV** • First generic have to decrease price by **30%** comparing to originator, second **-10%,** third **-10%,** fourth **-5%. LV** • First generic: **75% of originator**; second and next generic drug on the list: price equal to the price of the **cheapest INN PL** • first generic product has to be at least **40% lower(biologics -30%) CZ**	
HTA	• **Simplified** HTA((100 cases / 30 FTEs/ 1 year vs. 10 cases)) **CZ, PL, SV** • **Manufacturer submits** cost-effectiveness and budget impact **CZ, PL** • Threshold **3xGDP per capita /QALY LV, HU, PL** • Strong **feedback and double check** from experts and professionals during HTA procedure **HU** • **3xGDP per capita/year gained LV** • **Threshold** of (**24xSalary/QALY** and **1.5 mil. Euro/year** for **orphans**) **SV** • **Threshold 1.2 mil CZ/QALY.**	• Is not a separate body **CZ, LV, HU** • **Limited capacity CZ** • **Soft recommendations** (final decision - minister) **PL** • **Several payers** - challenges for evaluation **SV** • **Threshold** (24 min. salaries/QALY) and conditional reimbursement **limit new players SV**
Prescription control	• Doctors are not obliged to prescribe by INN – **more freedom** for prescribers, retrospective control **CZ** • **Fines for doctors** whose medical recommendations exceeded the average – in terms of costs incurred **HU** • **Restricted access – higher probability** to reimburse **PL** • Prescription by INN, overly strict system led high level of control **(additional explanation) SV**	• Doctors are **not obliged to prescribe by INN CZ** • **Unfavorable** among prescribers **SV**

Source: KSE analysis 2019

Control mechanism instruments: Barriers and requirements in Ukraine

Control mechanism instruments	Barriers		Requirements for implementation
Internal price referencing	• Low capacity to **analyze generic pricing data within group** • Applied **only for Affordable Medicine reimbursement program** • Narrow **INN referencing (no ATC group referencing)**		• Real **negotiated prices** • **Procedures** on how to apply IRP • Procedures on how IRP feeds into **decision making process** possibly supported by legislation. • Selection or calculation of the reference price (e.g. **lowest price in the set, simple average of all products, weighted average**) • **Adjustments** to account for confidential discounts or rebates in list prices.
International price referencing (external)	• Low **capacity** • Applied **only for Affordable Medicine reimbursement program** • Low capabilities to manage **price system and revision, mark-ups** • Basket defined **on unknown criteria with no methodology** • Limited access **to negotiated prices in reference countries**.		• Real **negotiated prices** • Capacity in **database management, data analysis,** • **Legislation framework** for use of ERP. • Procedures on how to apply ERP, **including criteria** for choice of reference countries. • Procedures on how ERP feeds into the **decision-making process**. • A mechanism for **monitoring the magnitude of applied mark-ups and medicine prices.** • Selection or calculation of the reference price (e.g. **lowest price in the set, simple average of all products, weighted average**) • Date of the price in the reference countries (e.g. **current price versus price at launch**) • **Adjustments required** (i) to account for confidential discounts or rebates in list prices and (ii) for level of economic development.

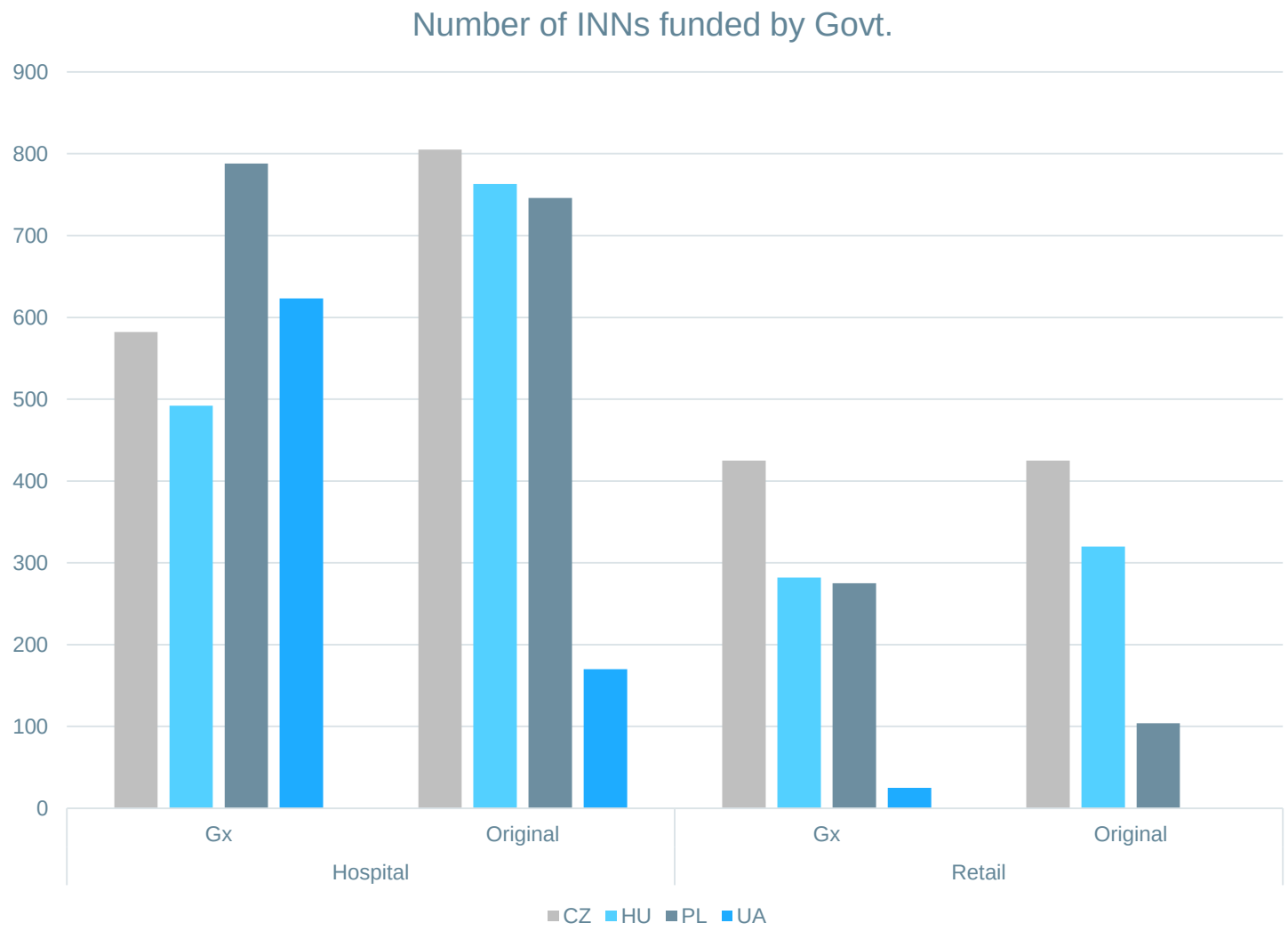
Source: KSE analysis 2019

Control mechanism instruments: Barriers and requirements in Ukraine

Control mechanism instruments	Barriers		Requirements for implementation
HTA	• Low capacity in **pharmacoeconomic evaluation** • Narrow scope of existing **HTA Department (no economic evaluation, only medical aspect)** • Is not a **separate body** • Legislation requires HTA evaluation **only for EML** • No **methodology** • **Funding sources** not defined		• Clinical data on **efficacy and safety of drugs.** • **Cost data**. • Data used in **economic modelling.** • Legislation mandating use **of HTA for reimbursement and price of pharmaceuticals**. • Capacity and system to consider **HTA evidence**. • **The decision-making criteria** to be used must be determined, as well as how analyses will be done or evaluated. • Determination of how results are to be communicated and whether **fees will be charged**. • High **political** will
Generic pricing rule	• No **legal procedure**		• **Legal** framework • **Methodological** approach and **control mechanism**
Prescription control	• Low adoption of **e-Rx(applied only for Affordable Medicine reimbursement program)** • Low infrastructural **capacity for analysis of prescription data** • Low capacity in **utilization analysis** • Physicians may **not comply with control measures** • High **administrative burden** • No **legal procedure**.		• Data on **patient, prescription and dispensing** • Legislation **framework for prescription control** • Capacity in **validating prescription**

Source: KSE analysis 2019

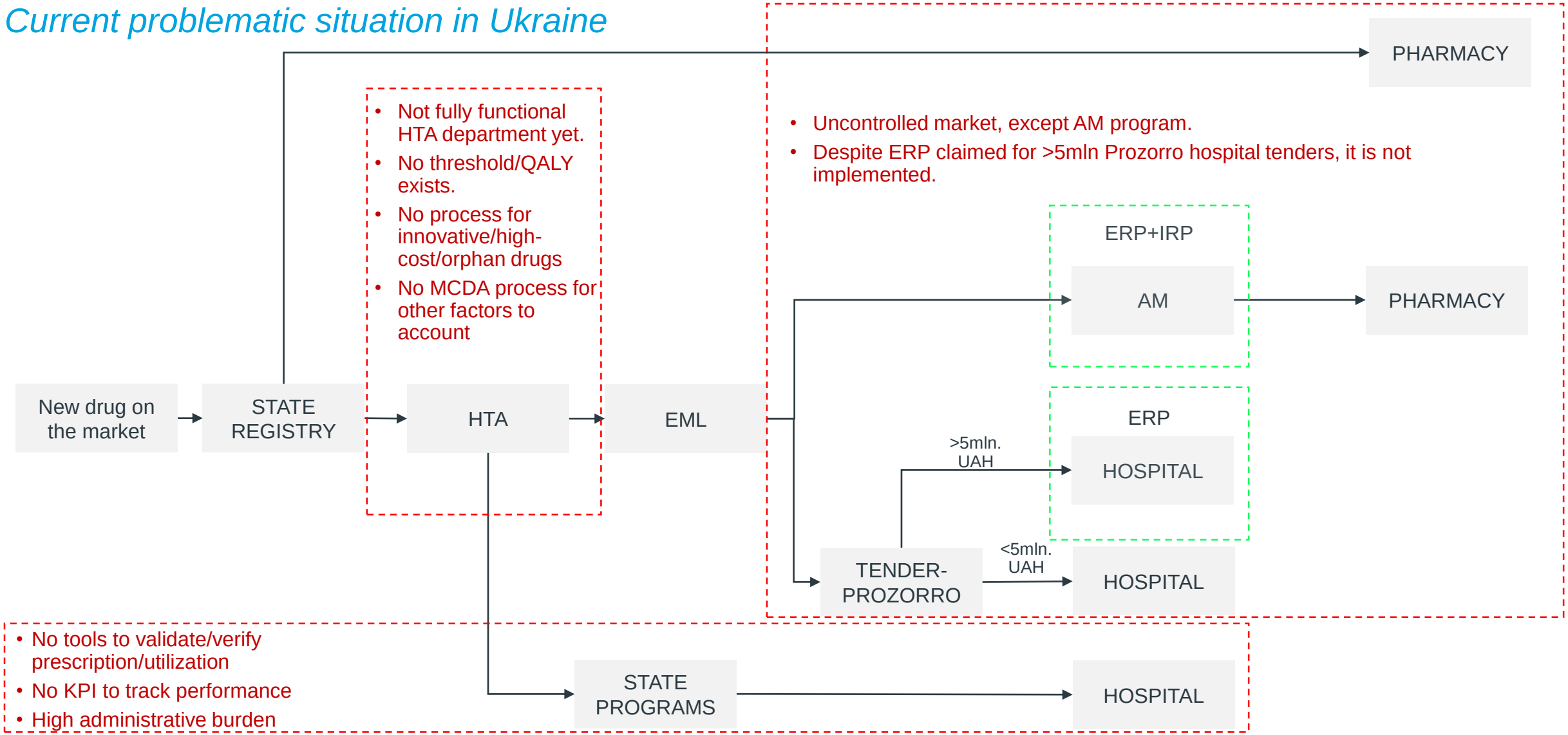
Ukraine is far behind by original drugs funded by State



Source: KSE analysis 2019

Inefficiencies exist on the each of drug flow in Ukraine

Current problematic situation in Ukraine



AM – Affordable Medicines Reimbursement program
EML – Essential Medical List
IRP – internal price referencing
ERP – external(international) price referencing

Source: KSE analysis 2019

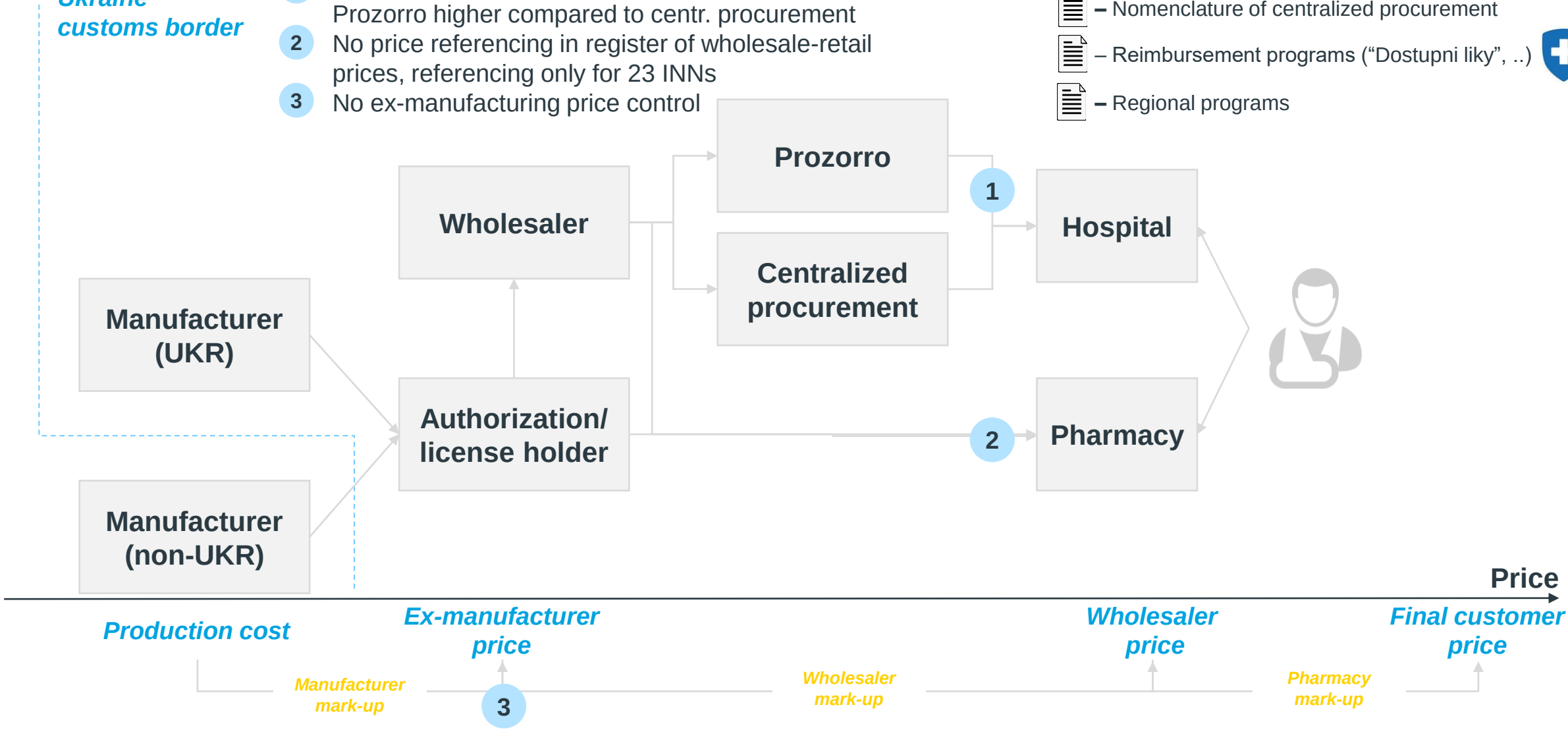
3 problems in current pricing regulation

Nomenclature and price governing documents:

- National register of wholesale-retail prices
- EML
- Nomenclature of centralized procurement
- Reimbursement programs (“Dostupni liky”, ..)
- Regional programs

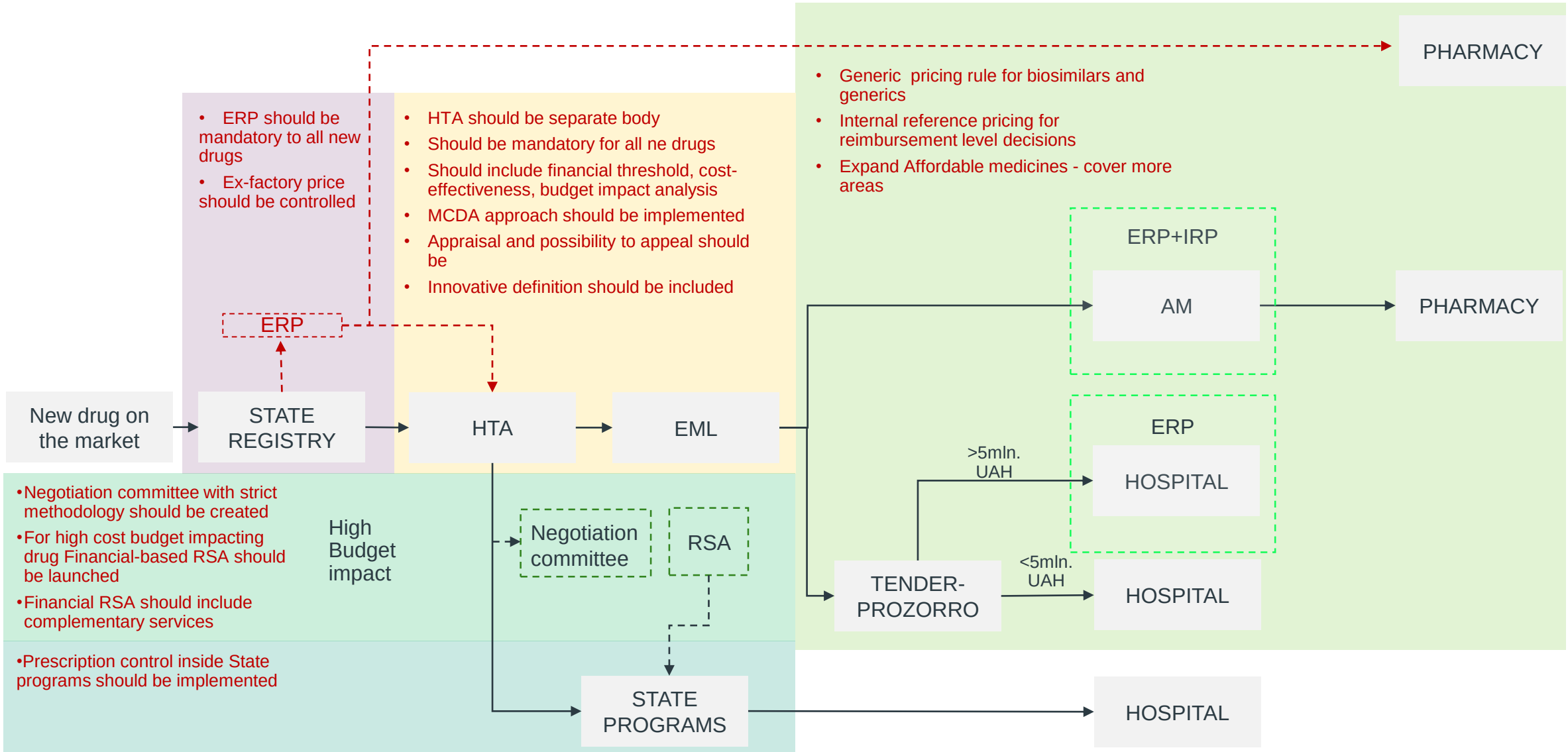
Problems:

1. Prices in register of wholesale-retail prices and Prozorro higher compared to centr. procurement
2. No price referencing in register of wholesale-retail prices, referencing only for 23 INNs
3. No ex-manufacturing price control



Source: KSE analysis 2019

Recommendations map



AM – Affordable Medicines Reimbursement program
EML – Essential Medical List
IRP – internal price referencing
ERP – external(international) price referencing

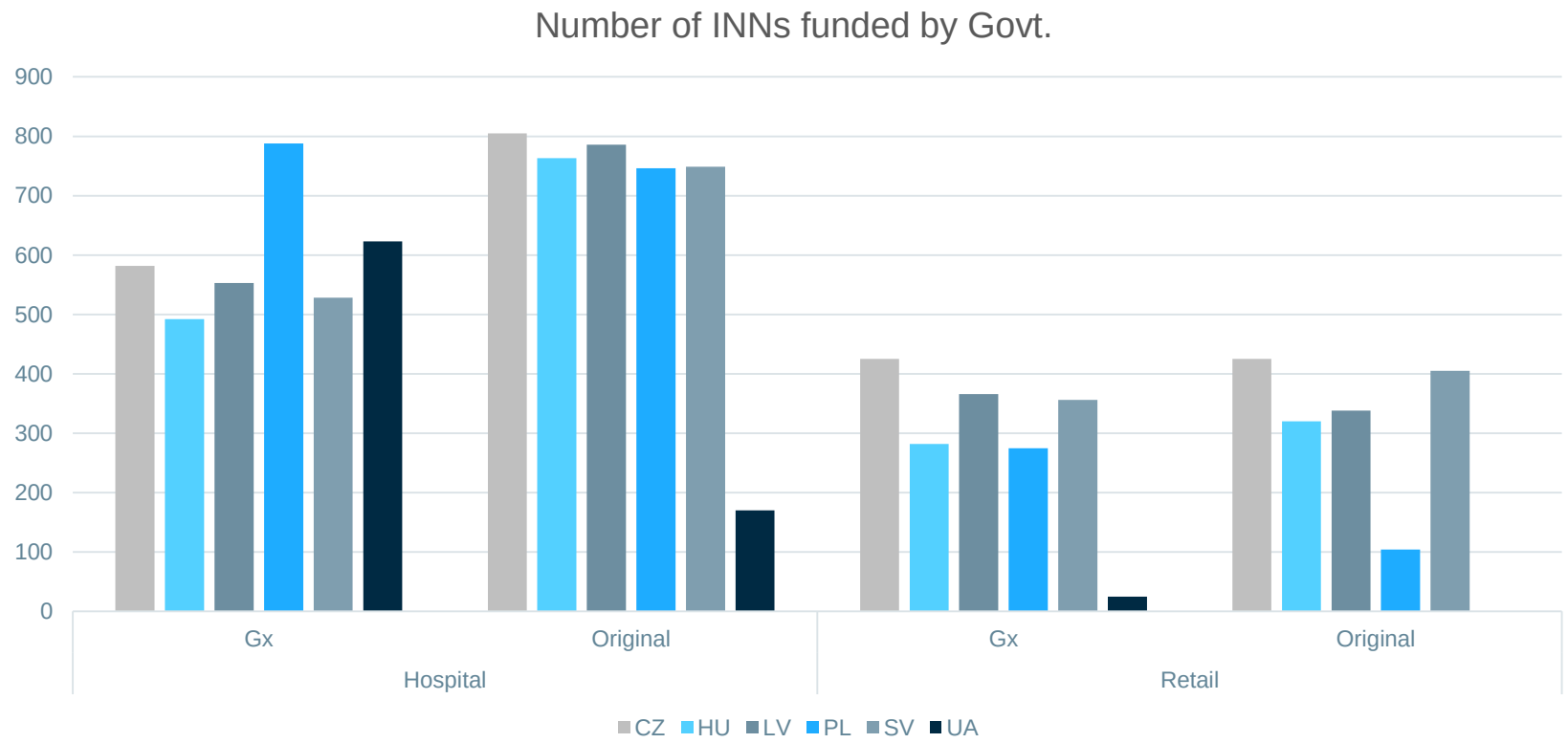
Source: KSE analysis 2019

Timeline of instruments implementation – detailed regulatory changes

Instrument		Measure		Legislation changes
	Co-payments	• Implement protection caps for threatened population - create dynamic calculations		• Changes to the Constitution, State law on financial guaranties, MOH and MinFin orders, NHSU legal acts.
	Generic pricing rule	• Define percentage for 1st, 2nd, 3rd generics/biosimilars entering market after originator		• Changes to NHSU, SEC and MPU legal acts
Reference pricing	Internal (therapeutic)	• Define groups selection and grouping criteria for reimbursation level definition • Implement ERP during authorization procedure for all drugs entering the market		• Changes to the State law on financial guaranties, Necessary NHSU, SEC and MPU legal acts
Reference pricing	External	• Control ex-factory prices • Implement ERP caps in Prozorro		
	HTA	• Separate body • Beyond EML • Mandatory for all new drugs funded by state • Public appraisal (public methodology and guidelines)	• Appeal • Cost-effect, BIA, threshold • Innovation definition • MCDA approach	• Changes to the State law on financial guaranties, KMU decree, MOH and MinFin orders, NHSU legal acts.
	Prescription control	• System for demand and prescription calculation for State programs • Penalties/incentives system		• MOH order and NHSU legal acts
Risk-sharing agreements	Financial	• Medium for business govt. interaction	• Financial RSA for high-cost, budget impct drugs – • Complementary services in State programs	• Changes to the State law on financial garanties, public procurement, development of KMU decree, MOH, MDETA (ministry of economy), MSP (Ministry of social policy) orders, AMC, NHSU and MPU legal acts.
Risk-sharing agreements	Performance		• Pilot outcome-based for high-cost drug with known effectiveness in State programs	

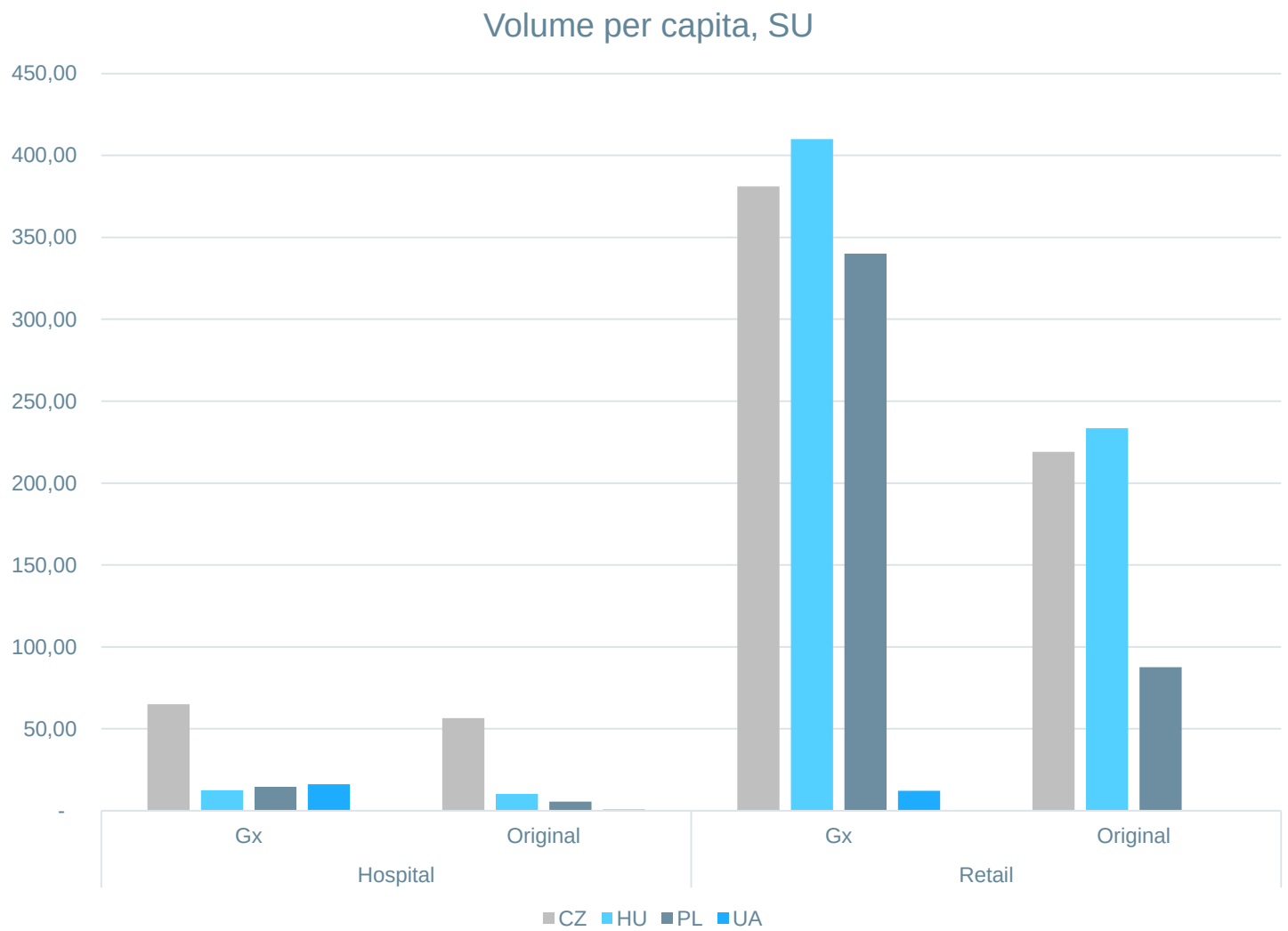
Source: KSE analysis 2019

Ukraine is far behind by original drugs funded by State



Source: KSE analysis 2019

Ukraine is far behind by original drugs funded by State



Source: KSE analysis 2019

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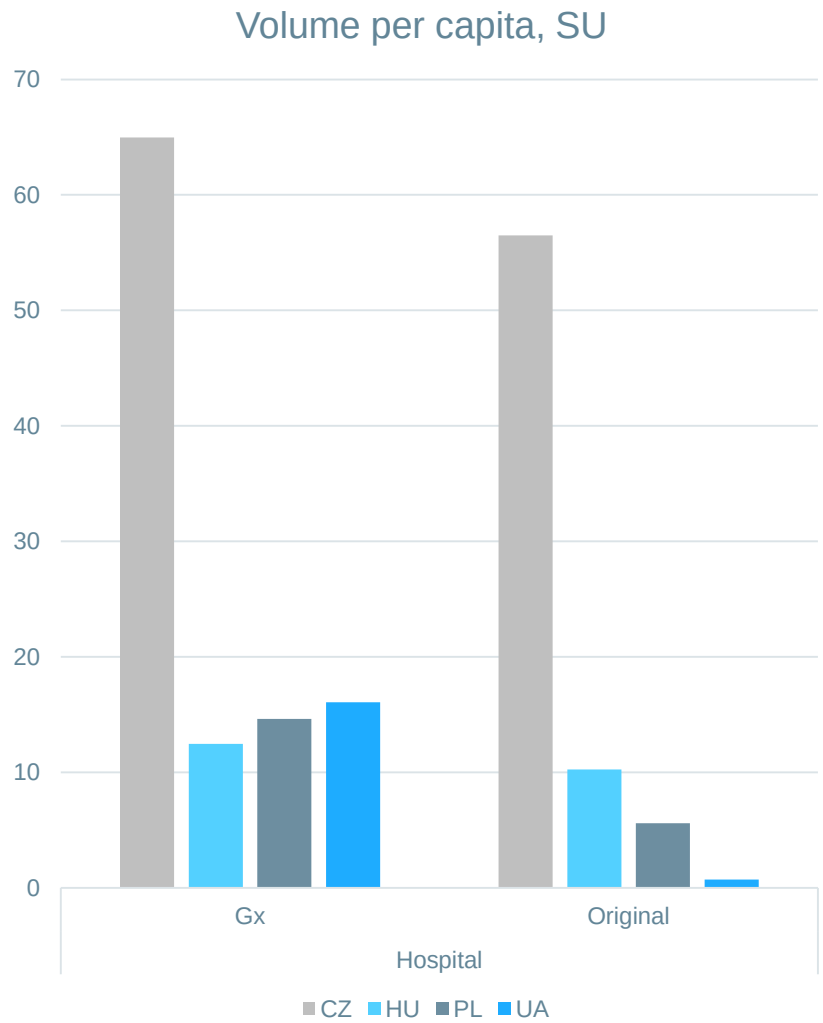

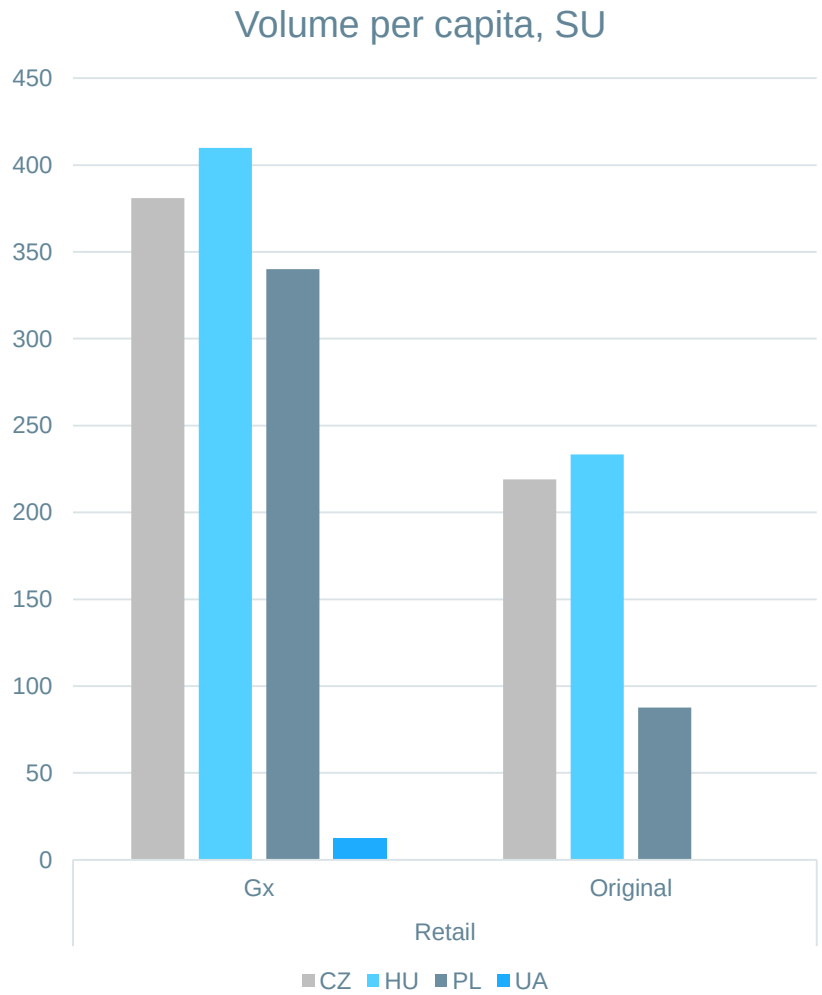

Source: KSE analysis 2019

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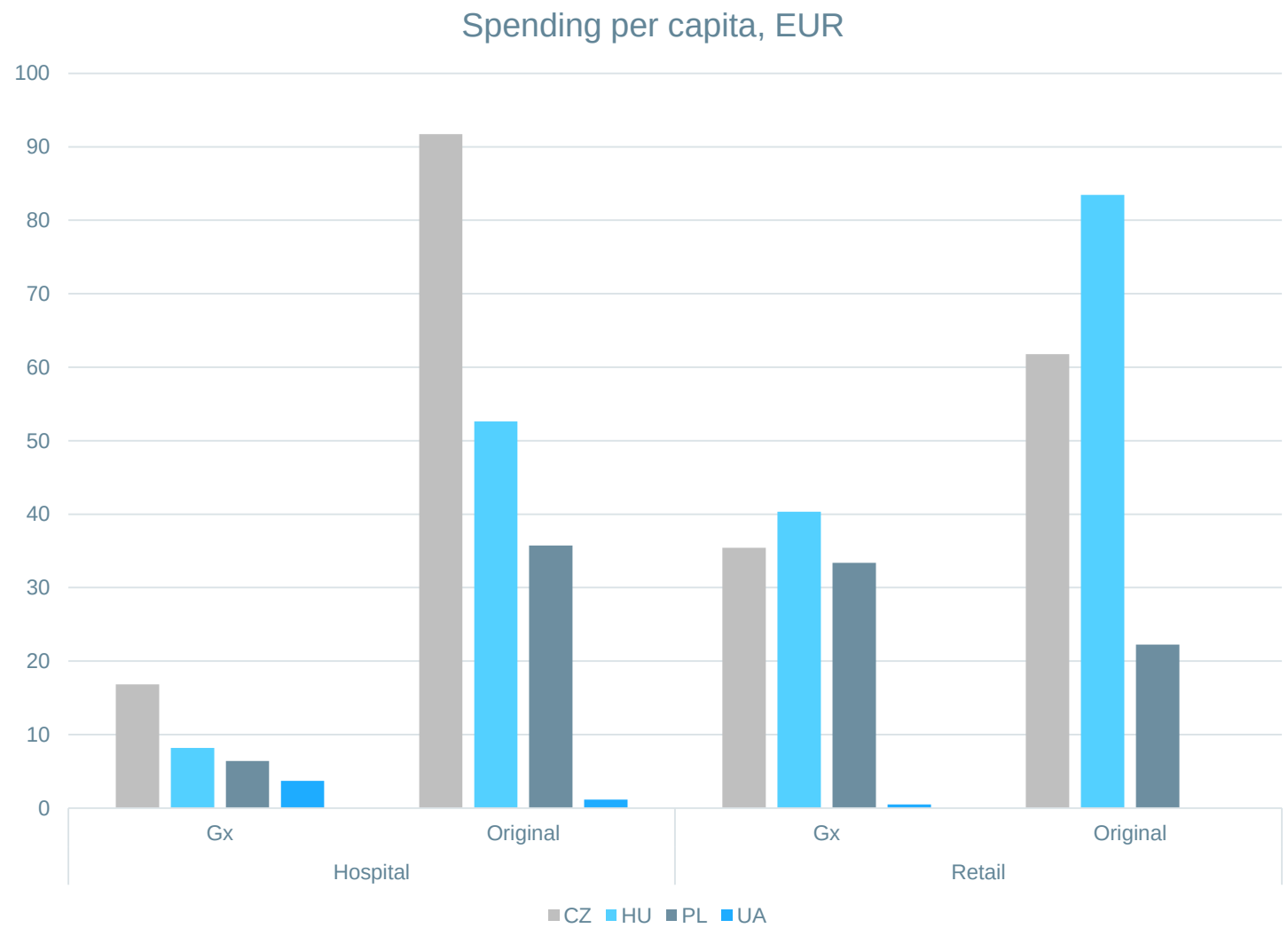

Source: KSE analysis 2019

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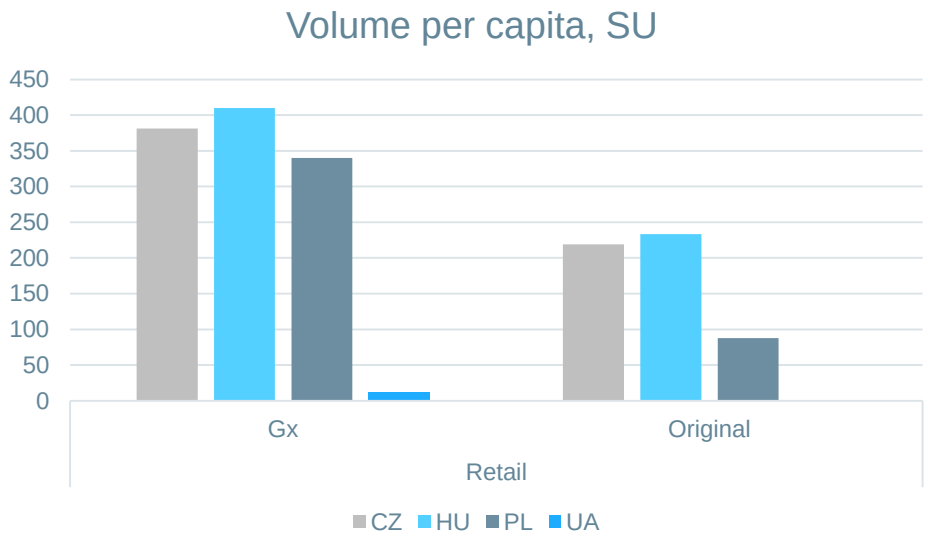
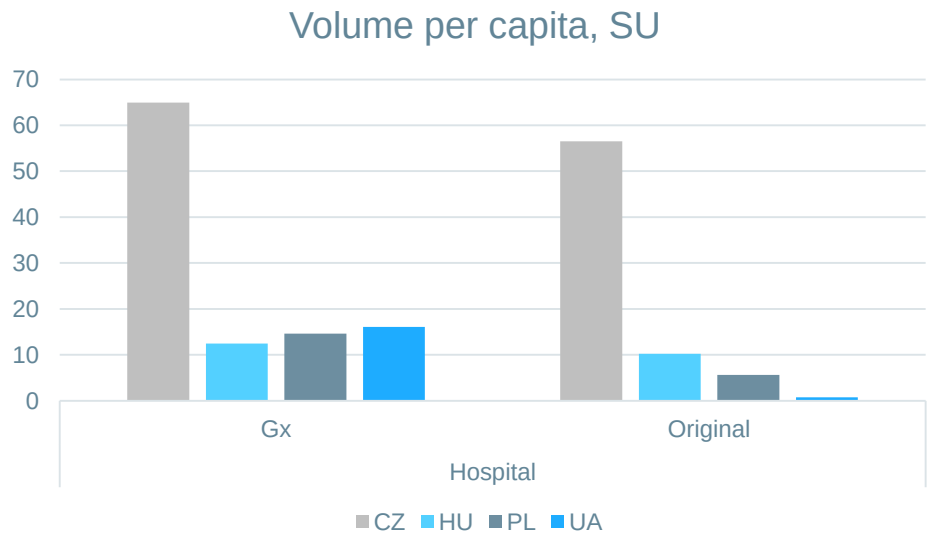
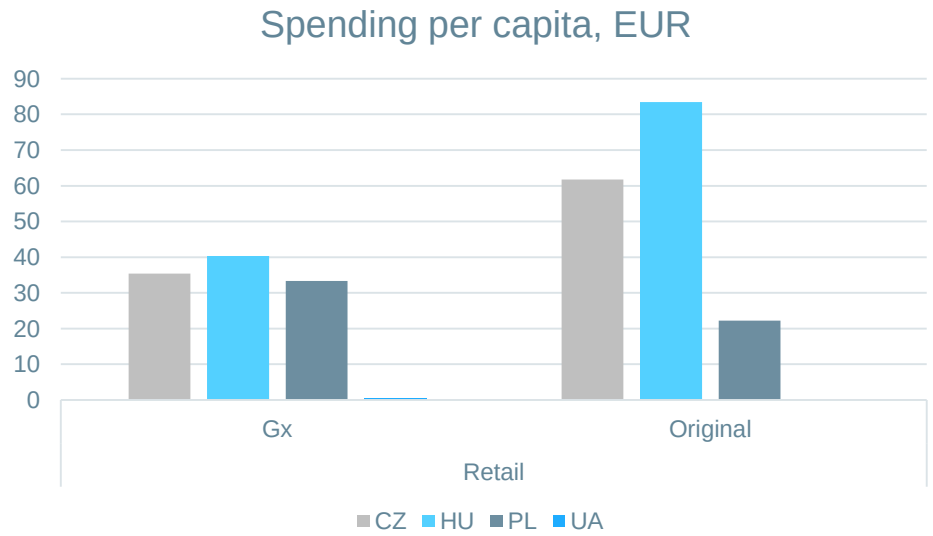
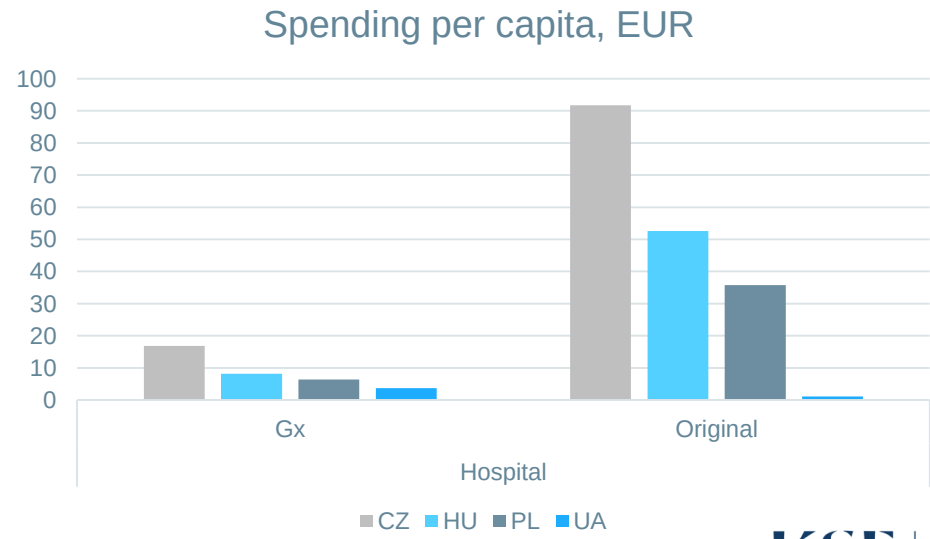


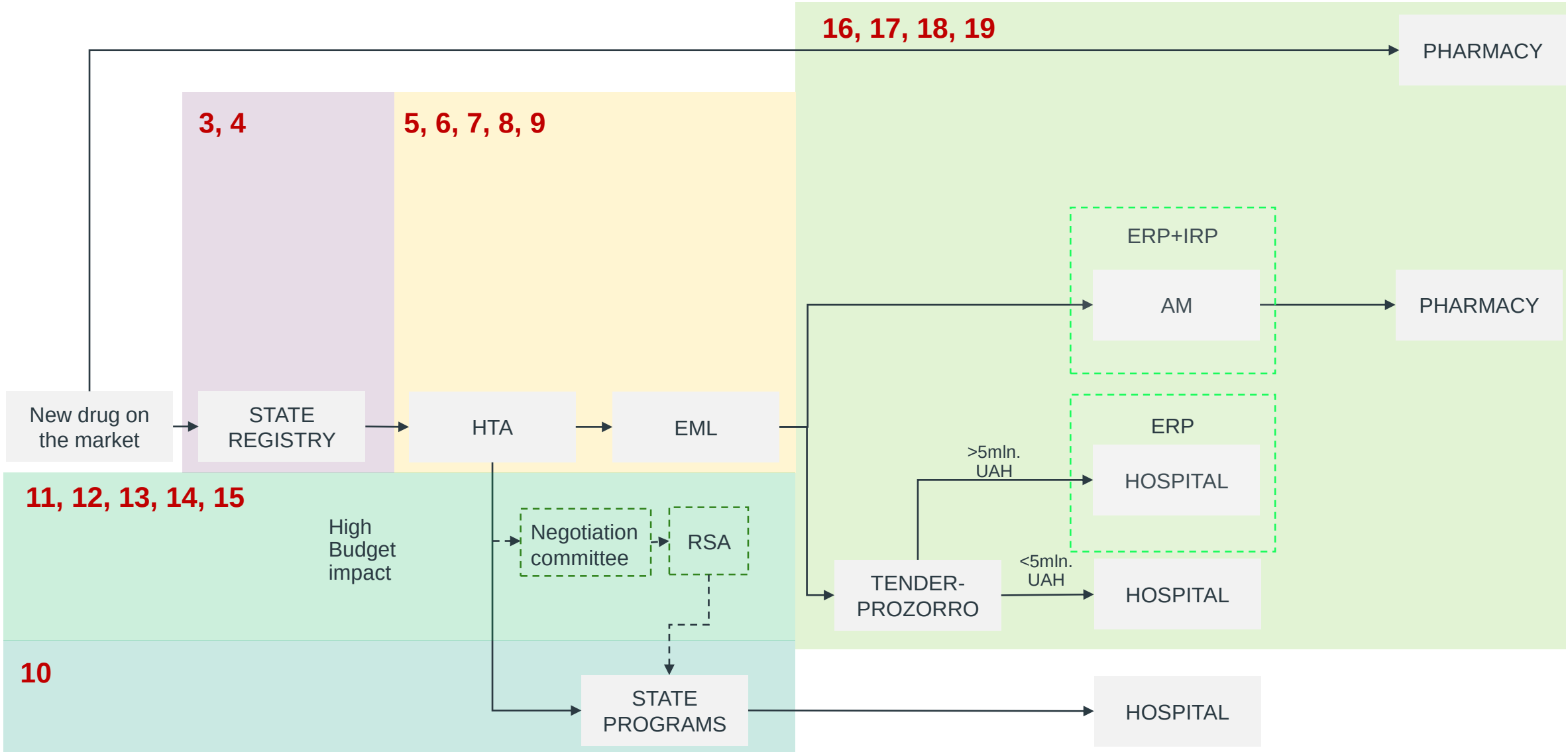






Source: KSE analysis 2019

Drug Pricing and regulation



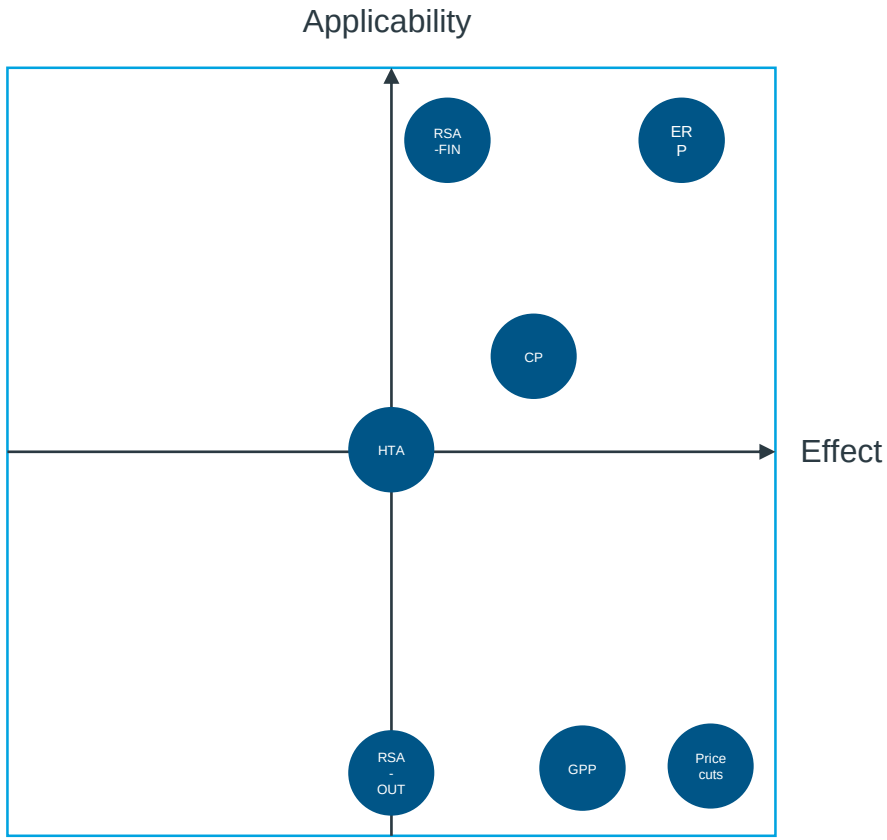
AM – Affordable Medicines Reimbursement program
EML – Essential Medical List
IRP – internal price referencing
ERP – external(international) price referencing

Second Priority recommendations for Ukraine

Instrument		Recommendations
Co-payments		17) **Affordable Medicine reimbursement program** already use elements of co-payment and reference pricing but it **have to cover more therapeutic areas** and include far more INN of different groups 18) It is recommended to make system for **co-payment calculation and risk assessment system** to facilitate sustainable growth of Affordable medicine reimbursement program 19) In case of reimbursement list growth **Internal (therapeutic) reference pricing** for Affordable Medicines program can go beyond INN(ATC 4) referencing to stimulate intra-/intergroup competition **20) Generic pricing policies and instruments** are efficient funding solution and have to be implemented to start sustaining drug cycle 21) It is recommended to create **medium** for and start **systematic** and **transparent business-government interactions** **22) Outcome-based RSA** can be launched in **pilot** for centrally procured **high-cost drugs** with feasible outcome and registry in place. 23) All legislation changes may be implemented as **complex and single Law** that have to include(co-payment framework and set-up, mandatory and systematic International reference pricing for whole market)
Generic substitution		
Generic Pricing rule		
Price Cuts		
Reference pricing	**Internal (therapeutic)**	
	International (external)	
HTA		
Prescription control		
Risk-sharing agreements	Financial-based	
	Performance-based	
	Coverage with Evidence Development (CED)	
Claw-back tax		

Source: KSE analysis 2019

Matrix of Effect/Applicability



GPP – include generic/biosimilars policies(internal reference pricing, generic substitution, generic pricing rule, prescription control)
CP – co-payment

Source: KSE analysis 2019

Big discrepancies in consumption of regional hospitals

5 oblast hospitals (Odesa, Lviv, Dnipro, Zaporizhya, Kharkiv)

Region		Standart units					Spend 2018, mln. UAH			
		Dni	Zap	Lvi	Ode		Dni	Zap	Lvi	Ode
Number of beds		1 175	800	1 110	970		1 175	800	1 110	970
Drug analgetics	Fentanyl	42 000	20 000	60 000	26 900		2.5	1.0	3.0	1.4
	Trimeperidine	2 000	300	18 000	5 820		0.3	0.03	1.9	0.7
Carbapenems	Meropenem	2 200	6 500	3 200	1 500		0.7	1.6	0.8	0.4
Injection anestethics	ПРОПОФОЛ + ТИОПЕНТАЛ + НАТРИЯ ОКСИБУТИРАТ + КЕТАМИН	27 700	10 500	15 800	30 450		0.6	0.4	0.7	1.6

Source: KSE analysis 2019

Strengths (1/2) – Generic promotion tools as an effective funding solution

Instrument type	Instrument	Czech republic	Hungary	Latvia	Poland	Slovakia
Co-payments		• **Fixed co-payments** led to quick fin. result • In every therapeutic group there is **fully reimbursed** drug • **Protective limits** for elderly	• Flexible (reviewed **yearly**), different levels/rates (6 **groups**)		• Has a flexible system with different levels and rates • Lump sum co-payment(3.3zl) • **No for elderly (75+)**	• Has a **flexible system** with different levels and rates • Protective caps for patients of different ages and social status • **Quarterly** revised
Generic substitution		• Highly effective cost cutting measure **(up to 40%)** • Positive list for prescription • Doctors tools with price information	• Highly effective cost cutting measure • Pharmacist/doctor tools to incentivize generic prescription	• 2020 law include pharmacist obligation to substitute drug with cheap generic	• Highly effective cost cutting measure • High willingness to uptake **biosimilars** • **Brand prescription** have to be justified by physician	• Highly effective cost cutting measure • Payers control prescription in centralized manner by IT system
Price Cuts (Cap)		• Effect with extern. on the whole market **(2008 and 2011, ~30% reimb. list)**		• **Stepwise cost-cut** for generics, biosimilar		
Reference pricing	Internal	• Short interval **(6 months)** • Referencing inside **therapeutic group**	• **Therapeutic group** referencing • **API referencing** • Price linked to **tender system (cap)** • Create **price competition** inside groups	• **therapeutic** groups by **ATC** • **Diagnosis-related** groups	• **Therapeutic group** referencing • Drug with **15% turnover** serve as reference • Price linked to co-**payments (cap)**	• Short interval **(3 month)** • Referencing inside **therapeutic group** which are **often reassessed**
	International	• One of the lowest prices **(3 min. of 18 countries)** due too short interval **(6 months)** • **Market price may be higher** than referenced and include **co-payment**	• Requires reimbursement **in 3 member states**	• **7 countries** in reference group(PL, HUN, CZ, SK, LIT, EST, DEN) • Price **can't be higher** than Lithuania and Estonia • **Revised** if price in reference countries were changed	• Manufacturer submits prices from **all markets** • Manufacturers **have to declare** if they have **MEA** in any EU countries	• Revised every **3-6 month** • **If product** marketed in less then 5 countries – **lowest price-20%** set as maximum

Source: KSE analysis 2019

Strengths (2/2) – Financial RSA

Instrument type	Instrument	Czech republic	Hungary	Latvia	Poland	Slovakia
HTA		• **Simplified** HTA • **Manufacturer submits** cost-effectiveness and budget impact	• Threshold 3xGDP per capita /QALY • Strong **feedback and double check** from experts and professionals during HTA procedure	• Threshold of 3xGDP per capita /QALY, 3xGDP/year gained	• **Simplified** HTA (100 cases / 30 FTEs/ 1 year vs. 10 cases) • **Manufacturer submits** cost-effectiveness and budget impact	• **Simplified** HTA • **Manufacturer submits** cost-effectiveness and budget impact • **Threshold** of (**24xSalary/QALY** and **1.5 mil. Euro/year** for **orphans**)
Prescription control		• Doctors are not obliged to prescribe by INN – **more freedom** for prescribers, retrospective control	• **Fines for doctors** whose medical recommendations exceeded the average – in terms of costs incurred		• **Restricted access – higher probability** to reimburse	• Prescription by INN, overly strict system led high level of control **(additional explanation)**
Risk-sharing agreements	Financial-based	• Indication limitation • MAH offers discounts for other portfolio to increase cap threshold • If drug **lost temporary reimbursement,** but doesn't achieve permanent – **MAH** have to **pay for patient to finish therapy**	• **All new** INNs are subject to risk-sharing	• Mainly **PVA, discounts, paybacks** due to relative simplicity and capacity restrictions	• **All new** INNs are subject to risk-sharing • **Complementary services** (within drug program) infrastructure requirements	• Mainly **PVA** due to relative simplicity and capacity restrictions • **Possibility** to make undisclosed contracts with all Payers
	Performance -based				• **Drug programs** give potential for outcome based elements	
	Coverage with Evidence Development (CED)	• MAH of **Highly Innovative drugs** that have temporary reimbursed obliged to **build infrastructure** for **RWE** collecting				
Claw-back tax			• **Clawbacks** and **paybacks as a function of volume**		• Not used with risk sharing thus **doesn't affect innovative therapies**	

Source: KSE analysis 2019

Weaknesses(1/2)

Instrument type	Instrument	Czech republic	Hungary	Latvia	Poland	Slovakia
Co-payments		• Politically unfavorable • Difficult to set up	• Politically unfavorable • Difficult to set up		• Politically unfavorable • Difficult to set up	• Politically unfavorable • Difficult to set up
Generic substitution		• Poor compliance • **Additional monitoring tools** required	• Poor compliance, • **Additional incentive system for doctors**		• No clear regulation for biosimilars	• Poor compliance, • **Price monitoring system for patients**
Price Cuts (Cap)		• Used as **crisis tool** during certain period(2009)				
Reference pricing	Internal (therapeutic)	• Aggressive policy – lead to increase in **parallel export**	• Aggressive policy – lead to increase in **parallel export**	• Internal pricing used inconsistently • No predefined rules and framework	• **Not regularly** used (case-by-case, not dynamic market reaction) • **Low transparency**	• Aggressive policy – lead to increase in **parallel export**
	International					
HTA / Pharmaco-economics		• Is not a separate body • **Limited capacity**		• Is not a separate body • Limited capacity	• **Soft recommendations** (final decision - minister)	• **Several payers** - challenges for evaluation • **Threshold** (24 min. salaries/QALY) and conditional reimbursement **limit new players**
Prescription control		• Doctors are **not obliged to prescribe by INN**				• **Unfavorable** among prescribers

Source: KSE analysis 2019

Weaknesses(2/2)

Instrument type	Instrument	Czech republic	Hungary	Latvia	Poland	Slovakia
Risk-sharing agreements	Financial-based	• Restricted access – few special centers can offer new treatment • Legal restrictions for **free-doses and complementary services**	• Mainly financial-based MEAs**, very (2-3) few outcome based**	• No **special body for negotiation** • No **framework for negotiation** • **Transparency** issues	• Mainly financial-based MEAs**, very few (2-3) outcome based**	
	Performance-based	• **No infrastructural capabilities**	• **No infrastructural capabilities**	• No **infrastructural capabilities** • **No possibilities for manufacturer** to **build their data-collection systems** or collect data from state infrastructure	• No **infrastructural capabilities**	
	Coverage with Evidence Development (CED)					
Claw-back tax			• Due to **high tax** limits the access to innovative therapies			

Source: KSE analysis 2019

Requirements (1/2)

Instruments		Data required	Infrastructure	Methodological consideration	Other req
Co-payments		• Data on **prescriptions, dispenses, prices**	• **Capacity** in database management, data analysis • Legislation framework for use of Co-payment. • **Procedures** on how to apply Co-payment • **System to validate** prescription and level of co-payment.	• Selection or calculation of the **co-payment (levels, protected cohorts, reference drugs etc**.).	• High **political** will
Generic substitution		• Data on **patient, prescription and dispensing**	• Pharmacy **personnel** trained in appropriate substitution • Legislation to allow substitution by dispenser • **System to validate** substitution	• When and how substitution will be made, i.e. allowed, encouraged, or mandated • Methodology to **validate substitution**	
Price Cuts					• High **political** will
Price referencing	Internal (therapeutic)	• Real **negotiated prices**	• **Procedures** on how to apply IRP • Procedures on how IRP feeds into **decision making process** possibly supported by legislation.	• Selection or calculation of the reference price (e.g. **lowest price in the set, simple average of all products, weighted average**) • **Adjustments** to account for confidential discounts or rebates in list prices.	
	International	• Real **negotiated prices**	• Capacity in **database management, data analysis,** • **Legislation framework** for use of ERP. • Procedures on how to apply ERP, **including criteria** for choice of reference countries. • Procedures on how ERP feeds into the **decision-making process**. • A mechanism for **monitoring the magnitude of applied mark-ups and medicine prices.**	• Selection or calculation of the reference price (e.g. **lowest price in the set, simple average of all products, weighted average**) • Date of the price in the reference countries (e.g. **current price versus price at launch**) • **Adjustments required** (i) to account for confidential discounts or rebates in list prices and (ii) for level of economic development.	

Source: KSE analysis 2019

Requirements(2/2)

Instruments		Data required	Infrastructure	Methodological consideration	Other req
HTA / Pharmaco-economics		• Clinical data on **efficacy and safety of drugs.** • **Cost data**. • Data used in **economic modelling.**	• Legislation mandating use **of HTA for reimbursement and price of pharmaceuticals**. • Capacity and system to consider **HTA evidence**.	• **The decision-making criteria** to be used must be determined, as well as how analyses will be done or evaluated. • Determination of how results are to be communicated and whether **fees will be charged**.	• High **political** will
Prescription control		• Data on **patient, prescription and despensing**	• Legislation **framework for prescription control,** • Capacity in **validating prescription**		
Special process for innovative drugs			• Legislation framework for **highly innovative drugs**	• Definition of **innovative drug, criteria for reimbursement, methodological framework**	
Special budget for innovative drugs					• High **political** will
Risk-sharing agreements	Financial-based	• Data on **stock, waste, utilization**, etc.	• Legislation mandating use of RSS • Capacity in **Pharmacoeconomics, negotiation, evaluating clinical evidence** • System to **account stock, waste, utilization**.	• Selection and evaluation of **calculation, type of deal.**	• High **political** will
	Performance-based	• Data on **stock, waste, utilization, patients, clinical data**, etc.	• Legislation mandating use of RSS • Capacity in **pharmacoeconomics, negotiation, evaluating clinical evidence** • System to **account for stock, waste, utilization, clinical and outcome data**.	• Selection and evaluation of **calculation, type of deal.**	• High **political** will
	Coverage with Evidence Development (CED)	• Data on **stock, waste, utilization, patients, clinical data**, etc.	• Legislation mandating use of RSS • Capacity in **pharmacoeconomics, negotiation, evaluating clinical evidence** • System to **account for stock, waste, utilization, clinical and outcome data**.	• Selection and evaluation of **calculation, type of deal.**	• High **political** will
Claw-back tax					

Source: KSE analysis 2019

Barriers applicable for Ukraine 1/2

Instruments		Barrriers
Co-payments		• Low adoption of e-Rx(applied only for Affordable Medicine reimbursement program) • No instrument to match dispensed drugs with prescription • Low capacity in pharmacoeconomic calculations, no defined body for pricing policy • Co-payment policy needs to be aligned with Constitution and State law on financial guarantees for medical services.
Generic substitution		• Low adoption of e-Rx(applied only for Affordable Medicine reimbursement program) • No instrument to match dispensed drugs with prescription • Low capacity in pharmacoeconomic calculations (originator by generic, generic by generic in same group) • Lack of analytical and control possibilities in e-Rx system to control prescription • Physicians against substitution • High administrative burden for enforcement (need to control all pharma transactions) • No legal framework for substitution by dispenser • Strong pharma lobby(pressure)
Price Cuts		• Strong pharma lobby(pressure)
Price Referencing	Internal(therapeutic)	• Low capacity to analyze generic pricing data within group • Applied only for Affordable Medicine reimbursement program • Narrow INN referencing (no ATC group referencing)
	International	• Low capacity • Applied only for Affordable Medicine reimbursement program • Low capabilities to manage price system and revision, mark-ups • Basket defined on unknown criteria with no methodology • Limited access to negotiated prices in reference countries.

Source: KSE analysis 2019

Barriers applicable for Ukraine 2/2

Instruments		Barrriers
HTA / Pharmaco-economics		• Low capacity in pharmacoeconomic evaluation • Narrow scope of existing HTA Department (no economic evaluation, only medical aspect) • Is not a separate body • Legislation requires HTA evaluation only for EML • No methodology? • Funding sources not defined
Prescription control		• Low adoption of e-Rx(applied only for Affordable Medicine reimbursement program) • Low infrastructural capacity for analysis of prescription data • Low capacity in utilization analysis • Physicians may not comply with control measures • High administrative burden • No legal procedure.
Special process for innovative drugs		• No definition of innovative drug • Low capacity in MOH
Special budget for innovative drugs		
Risk-sharing agreements	Financial-based	• Lack of data and tools on epidemiology, utilization patterns, etc. • Low capacity in pharmacoeconomic calculations • Low level of interaction between stakeholders(business and governmental body) • Due to the nature of agreement excludes transparency
	Performance-based	• Lack of data and tools on epidemiology, utilization patterns, outcomes, patients • Low capacity in pharmacoeconomic evaluation, negotiation, evaluating clinical evidence • Due to the nature of agreement excludes transparency
	Coverage with Evidence Development (CED)	• Lack of data and tools on epidemiology, utilization patterns, outcomes, patients • Low capacity in pharmacoeconomic evaluation, negotiation, evaluating clinical evidence • Due to the nature of agreement excludes transparency
Claw-back tax		• No legal framework for operations with budget caps.

Source: KSE analysis 2019

Scope of work and project status

Project status

Stage / Activities	Responsible	Current status
Stage 1: Healthcare systems overview	IQVIA	Final results
1.1 Countries benchmarking economic (GDP, per capita, populations, etc) and healthcare (expenditures, dynamics, etc): Ukraine vs CHLPS-countries **(Czech Republic, Hungary, Latvia, Poland, Slovakia)**		
1.2 Organization and financing of healthcare systems (public finances, employer insurance, private insurance, out of pocket, co-payment, transitioning)		
1.3 Structure of healthcare system spending's (expenditure on drug and medical device procurement, medical staff salaries, healthcare facilities, prevention, urgent care services, high cost treatments, etc.);		
1.4 Coverage of healthcare (patient population / diseases, health indicators (DALY, QALY, etc), level of care covered (% in primary, secondary), level of reimbursement;		
1.5 Government priorities and key healthcare challenges		
Stage 2: Analysis of instruments for access to innovative therapies	IQVIA / KSE	
2.1 Identification and prioritization of criteria for target therapeutic groups selection	KSE	Final results
2.2 Target KPIs of CHLPS- countries and Ukraine (e.g. mortality, morbidity, health outcomes, budget impact, etc.) and their dynamics to track instruments efficiency;	IQVIA	Final results
2.3 Overall use of innovative treatments in CHLPS-countries and Ukraine (share of innovations, access to innovative therapies, share of government purchases on innovative treatments);		
2.4 Detailed overview of instruments for access to innovative therapies in CHLPS-countries and Ukraine for therapeutic areas which are covered by innovative therapies. Cases of instruments with achieved results (on healthcare indicators);		
2.5 Analysis on how instruments were chosen and implemented and underling reasoning in CHPL- counties	KSE	Final results
2.6 Barriers / prerequisites in Ukraine for improvements of healthcare system performance (including access to innovative therapies)	KSE	Final results

Project Governance: we have a core project team with relevant experience ready to start immediately and deliver the project

IQVIA | KSE Project team

Role	Team member	Responsibility
Steering Committee	 **Alexey Savin | IQVIA** Regional Principal, East Europe  **Andriy Kovalyov | KSE** Head of consultancy center  **Yaroslav Kudlatskyi | KSE** Head of Healthcare research centre	• Responsible for successful project delivery, strategic direction for the overall project, steering committee • Executive senior team support
Project Management	 **Olga Makarova | IQVIA** Senior Consultant, Russia, Ukraine & CIS  **Artem Shtepa | KSE** Senior medical analyst	• Responsible for day-to-day project management and deliverable development • Team leadership and tasks setting • Focal point of contact for project team
Project delivery team	 **Evgeny Skoryna | IQVIA** Senior Consultant, Ukraine & CIS **Regina Sitdikova | IQVIA** Associate Consultant  **Vasyl Nagibin | KSE** Senior medical analyst **Timea Fejes| IQVIA** Senior Consultant, Hungary **Tamas Bobal | IQVIA** Consultant, Hungary	• Day-to-day project support, responsible for research and analysis • Mix of local market and broader strategic experience • Running interviews with local experts • Preparation of pieces of analysis, models, other deliverables