



External reference pricing for medicines in Ukraine: latest trends

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A – research concept and design; B – collection and/or assembly of data; C – data analysis and interpretation; D – writing the article; E – critical revision of the article; F – final approval of the article

Compared to the previous year, the share of healthcare expenditure in the state budget of Ukraine has decreased, which is associated with increased funding for the security and defense sector. In terms of gross domestic product, healthcare spending has reduced to 2.8 %, which corresponds to the figures for 2019. These circumstances indicate the importance of proper budget utilization, including effectively regulating medicine prices. One of the key elements of rational healthcare budget usage is the development and implementation of external reference pricing (ERP). A well-formulated and implemented ERP policy for pharmaceuticals contributes to improving patient access to essential medicines (EMs).

The aim of this study is to analyze the current status of ERP implementation in Ukraine and provide recommendations for improving this policy.

Materials and methods. During the research process, an analysis of the ERP's current regulatory framework was conducted, and ERP implementation in Ukraine was assessed according to adherence to the 14 best practice principles of ERP proposed by Sullivan, Kanavos & Kalo in 2015.

Results. In Ukraine, ERP has been introduced for medicines from the National Essential Medicine Lists (NEML) and the "Affordable Medicines" program. The Ministry of Health (MoH) of Ukraine has approved a Register of marginal wholesale prices for medicines purchased with state budget funds and subject to price regulation. Currently, the register includes 1239 medicinal products, of which 1233 are from NEML and 6 have undergone Health Technology Assessment (HTA). Approximately 58 % of medicines have a set price through ERP, 24 % are regulated by internal reference pricing (IRP), and nearly 18 % have declared prices. This indicates a lack of uniformity in approaches to price regulation for medicines and requires further improvements. According to the latest update of the Register of medicines for reimbursement under the state medical guarantees program, there are 486 medicines, including 72 insulins and 21 immunosuppressive medicines (184 medicines are provided with co-payment). Different approaches, including different reference countries and price calculation algorithms, are applied for the price regulation of medicines in NEML and the "Affordable Medicines" program. An assessment of the implementation of the ERP system in Ukraine based on the 14 best practice principles of ERP proposed by Sullivan, Kanavos & Kalo in 2015 showed that the current policy does not adhere to all principles.

Conclusions. The analysis revealed different approaches to pricing for medicines NEML and the "Affordable Medicines" program, indicating the need for harmonizing pricing policies for different lists. The adoption of a unified positive list can contribute to improving pricing policies and efficient resource utilization. Collecting, disseminating, and exchanging data on drug prices is crucial to support transparency in pricing and its control. Regular monitoring of prices in the market will help ensure compliance with pricing policies and take appropriate measures in case of violations. The implementation of a unified pricing regulation policy for medicines in Ukraine is an important step towards European integration and compliance with international standards.

Key words: pharmaceutical preparations, reference prices, external reference pricing, health technology assessment.

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Зовнішнє референтне ціноутворення на лікарські засоби в Україні: останні тенденції

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Порівняно з попереднім роком частка витрат на охорону здоров'я в державному бюджеті України зменшилася, що пов'язано зі збільшенням фінансування сектора безпеки й оборони. У відсотках до ВВП обсяг витрат на охорону здоров'я скорочується до 2,8 %, що відповідає показникам 2019 року. Ці факти свідчать про важливість належного використання бюджету, включаючи ефективне регулювання цін на лікарські засоби.

Один з основних елементів раціонального використання бюджету галузі охорони здоров'я – розроблення й впровадження зовнішнього референтного ціноутворення (РЦ). Належним чином сформульована та реалізована політика зовнішнього РЦ на фармацевтичні препарати сприяє покращенню доступу пацієнтів до основних лікарських засобів (ЛЗ).

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Мета роботи – аналіз сучасного стану впровадження зовнішнього РЦ на ЛЗ в Україні та надання рекомендацій для покращення цієї практики.

Матеріали та методи. У процесі дослідження проаналізували чинну нормативно-правову базу щодо зовнішнього РЦ, оцінили впровадження зовнішнього РЦ в Україні згідно з 14 принципами зовнішнього РЦ, що запропоновані Sullivan, Kanavos & Kalo в 2015 році.

Результати. В Україні запроваджено зовнішнє РЦ для ЛЗ із Національного переліку основних лікарських засобів (Нацперелік) та програми «Доступні ліки». МОЗ України затверджено Реєстр граничних оптово-відпускних цін на деякі ЛЗ, які закуповуються за кошти державного бюджету та підлягають регулюванню цін. Нині реєстр включає 1239 лікарських засобів: 1233 ЛЗ – із Нацпереліку, 6 ЛЗ, – які пройшли оцінювання медичних технологій. Майже 58 % ЛЗ мають встановлену ціну через зовнішнє РЦ, 24 % ЛЗ регулюються внутрішнім РЦ, майже 18 % ЛЗ задекларували ціни. Це свідчить про неоднорідність підходів до регулювання цін на ЛЗ і потребує вдосконалення. Згідно з останнім оновленням Реєстру лікарських засобів, які підлягають відшкодуванню за програмою державних медичних гарантій, індексують 486 найменувань, включаючи 72 найменування інсулінів і 21 найменування імуносупресивних препаратів (184 найменування – із доплатою). Для регулювання цін на ЛЗ у Нацпереліку та програмі «Доступні ліки» застосовують різні підходи, включаючи різну кількість референтних країн і різні алгоритми розрахунку цін. Оцінювання впровадження системи зовнішнього РЦ в Україні на основі методології ефективного впровадження зовнішнього РЦ, яку запропонували Sullivan, Kanavos & Kalo у 2015 році, показало: чинна система не відповідає всім принципам ефективного зовнішнього РЦ.

Висновки. Аналіз показав різні підходи до ціноутворення для лікарських препаратів із Нацпереліку та програми «Доступні ліки»; це свідчить про потребу в узгодженні цінової політики для різних переліків. Ухвалення єдиного позитивного переліку ЛЗ може сприяти покращенню політики ціноутворення та ефективному використанню ресурсів. Збір, поширення й обмін даними про ціни на ЛЗ є ключовим для підтримки прозорості в ціноутворенні та контролю над ним. Регулярний моніторинг цін на ринку дасть змогу забезпечити дотримання цінової політики та вжити відповідних заходів у разі порушень. Запровадження єдиної політики регулювання цін на ЛЗ в Україні є важливим кроком на шляху до євроінтеграції та відповідності міжнародним стандартам.

Ключові слова: лікарські засоби, референтне ціноутворення, зовнішнє референтне ціноутворення, оцінка медичних технологій.

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The overall objectives of pricing policy should be clearly focused on achieving equitable access to high-quality medicines for patients, ensuring a price-quality ratio based on improving population health indicators [1].

Healthcare expenditures in Ukraine have shown positive dynamics year after year. From UAH 133.2 billion in 2020, healthcare expenditures increased to UAH 196.8 billion in 2022 [2,3]. Planned healthcare expenditures for 2023 are approximately UAH 176.9 billion. Compared to the previous year, the share of healthcare expenditures in the state budget has decreased, which is associated with increased funding for the security and defense sector. In terms of gross domestic product (GDP), healthcare spending is reduced to 2.8 %, which corresponds to the figures of 2019 [4]. These circumstances indicate the importance of proper budget utilization, including effectively regulating medicine prices.

One of the key elements of rational healthcare budget utilization is the development and implementation of external reference pricing (ERP). A properly formulated and implemented ERP policy for pharmaceuticals contributes to improving patient access to EMs [5].

Aim

The aim of this study is to analyze the current status of ERP implementation in Ukraine and provide recommendations for improving this policy.

Materials and methods

During the research process, an analysis of the ERP's current regulatory framework was conducted, and ERP implementation in Ukraine was assessed according to adherence to the 14 best practice principles of ERP proposed by Sullivan, Kanavos & Kalo in 2015 [6,7].

Results

We have considered ERP establishment for medicines from the National Essential Medicine Lists (NEML) [8] and the “Accessible Medicines” program [9,10].

Pricing policy for medicines from NEML. In 2019, Ukraine introduced a reference pricing model for medicines purchased by healthcare facilities using state or local budgets. As of January 2022, reference pricing was applied to 23 international non-proprietary names (INNs) from NEML. By the end of 2022, the implementation of new regulations led to the expansion of reference pricing to all medicines from NEML [11,12,13].

Currently, state regulation of prices for medicines included in the NEML is conducted through three scenarios:

- By setting marginal wholesale prices based on ERP, taking into account prices in five reference countries: Poland, Slovakia, Hungary, the Czech Republic, and Latvia [11,12,13].
- In the absence of prices for medicines in four of five reference countries, prices for medicines are set based on prices in Ukraine obtained from market research data (internal reference pricing, IRP) [11,12,13].
- In case there are no prices for the specified medicines in reference countries and in Ukraine, marginal wholesale prices are declared in accordance with the Resolution of the Cabinet of Ministers of Ukraine dated July 2, 2014, No. 240, “On declaring changes in wholesale prices for medicines” [13,14].

The calculation of marginal wholesale prices is based on referent prices (RPs) obtained from official sources of reference authorities. It is carried out by INN, dosage form, and dosage of medicines per unit of dosage form. RPs are formed taking into account identical pharmaceutical characteristics of medicines (INN, dosage form, dosage, quantity of dosage forms in packaging). If pharmaceutical characteristics of medicines (dosage, quantity of dosage forms in packaging)

are absent in reference countries, RP is determined based on the price per unit of active substance (1 ml for solution, 1 mg for solid form).

RPs for medicines are established in the national currency without accounting for delivery costs, retail mark-up, and value-added tax (VAT).

For ERP, the conversion of RPs from foreign currencies to the national currency is carried out at the official exchange rate set by the National Bank of Ukraine on the date of price determination.

The MoH of Ukraine has approved a Register of marginal wholesale prices for certain medicines purchased with state budget and subject to RP. Currently, the register of marginal wholesale prices includes 1239 medicines [15]: 1233 medicines from the NEML, 6 medicines that have undergone Health Technology Assessment (HTA).

For 58 % of medicines, prices are calculated through ERP, for 24 % through IRP, and almost 18 % through price declaration. This demonstrates a heterogeneous approach to price regulation for medicines and requires further improvement (Fig. 1).

Pricing policy for medicines in the “Accessible Medicines” program [8]. According to the latest update of the Register of Medicines eligible for reimbursement under the state medical guarantees program as of February 14, 2023, there are 486 items, including 72 insulins and 21 immunosuppressive medicines (184 items are provided with co-payment) [16].

There are various approaches to setting prices for medicines within the “Accessible Medicines” program:

1. Price regulation for medicines with a single active substance is conducted by comparing prices in 5 reference countries, including Poland, Slovakia, Hungary, the Czech Republic, and Latvia. The marginal wholesale price for medicines is calculated as the maximum cost of a daily dose of the corresponding dosage form, calculated through ERP, without considering supply and distribution mark-ups and VAT. The calculation uses the median of registered prices for each dosage form in terms of DDD.

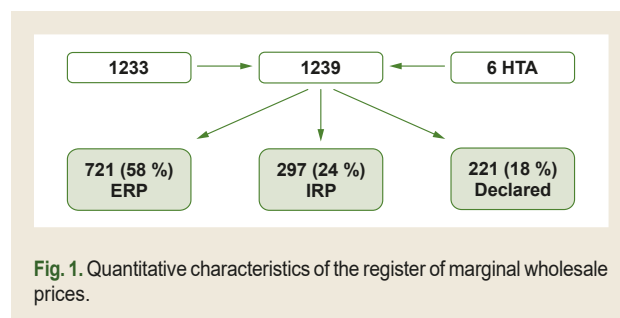


Fig. 1. Quantitative characteristics of the register of marginal wholesale prices.

2. Price regulation for insulins is conducted by comparing prices in 8 reference countries, including Poland, Slovakia, Hungary, the Czech Republic, Latvia, Bulgaria, Greece, and Romania. The marginal wholesale price for insulins is the maximum cost of the primary package of reimbursable insulin within the respective reference group, calculated based on ERP per international unit of insulin preparation and the quantity of international units in the primary package, without considering supply and distribution mark-ups and VAT.

3. The marginal wholesale price for combined medicines (containing two or more active substances) is determined as the maximum price for the respective dosage form for tablets, capsules, and modified-release tablets, or for the primary package of the medicine for granules, liquids, powders, inhalation powders, inhalers, nebulizers, calculated based on ERP without considering supply and distribution mark-ups and VAT.

The National Health Service of Ukraine (NHSU) recalculates the marginal wholesale prices for medicines purchased and/or reimbursed from the budget under the “Accessible Medicines” program twice a year (in January and July).

The analysis of determining the marginal wholesale prices for medicines purchased from the state budget has shown a diverse approach to price regulation for drugs in NEML and drugs purchased under the “Accessible Medicines” program.

Additionally, we conducted an evaluation of the implementation of ERP policy in Ukraine based on the 14 ERP best practices proposed by Sullivan, Kanavos & Kalo in 2015 (Table 1).

Table 1. Adherence to the 14 best practice principles by Ukraine ERP system

Best practice principles of ERP	ERP in Ukraine: Directions of discussions
The objectives of ERP systems should be clear and align with health system objectives	It is necessary to develop a clear strategy for aligning ERP with the overall goals of the healthcare system, including the usage of appropriate regulatory frameworks and involving a wider range of stakeholders
ERP systems should focus on in-patent products considered for the purposes of coverage, pricing, and reimbursement decisions	The existing pricing policy requires further refinement, particularly in terms of clearly distinguishing between approaches to pricing for patented and generic medicines
Prices developed via ERP do not override HTA conclusions or value-based price approaches	Currently, only 19 medicines are included in the NEML based on HTA recommendations [8]. There is a need to set up a transparent mechanism for establishing a connection between ERP and HTA
The ERP system should have administrative simplicity and transparency	Updating the list of reference countries, transparency of price sources, currency regulation clarity, improvement of appeal procedures, as well as the introduction of a unified positive list will contribute to the optimization of administrative processes and increase accountability in the healthcare system
Stakeholders should participate in the design and review of the ERP system	Ukraine currently has no clear mechanism for involving stakeholders in the pricing processes. Exploring the possibility of expanding the participation of different stakeholders in the development and updating of ERP will help improve decision-making processes and policy implementation in this area

Cont. of table 1.

Best practice principles of ERP	ERP in Ukraine: Directions of discussions
Stakeholders are able to appeal regulator decisions	In the regulatory documents of Ukraine, clear criteria for stakeholders to challenge the regulator's decisions regarding pricing are not defined
Reference countries should be selected based on similarities in economic status and health system objectives	The establishment of clear criteria for the inclusion and exclusion of reference countries is necessary to create a transparent approach. Furthermore, considering the difference in GDP between Ukraine and other reference countries, it is crucial to make calculation adjustments to ERP
International implications of ERP implementation should be considered	There is no information regarding the potential impact of implementing ERP in Ukraine on international consequences
Publicly available ex-factory prices should form the basis of the ERP system	There is an issue of availability transparent information regarding ex-factory prices. To improve the ERP, it is important to develop clear criteria for selecting official sources from reference countries and determine the frequency of their updates. The creation of a corresponding IT infrastructure will help enhance market monitoring and data collection. Ukraine should explore the possibility of gaining access to international official databases, such as EURIPID, which are widely used in Europe [17]
The mean of prices in reference countries should be used	We consider it acceptable to use different approaches to ERP (such as the lowest, median, or average of the three lowest prices) in the context of Ukraine
ERP system respects the patent status of products it covers based on the provision of IP that prevails in the reference country	Ukraine complies with the legislation on pharmaceutical patents [18]
ERP formula should avoid the impact of exchange rate volatility	It is necessary to establish a unified approach for price revision to address the challenges posed by exchange rate fluctuations
Price revisions should be kept to a minimum and should be carried out consistently to avoid the perception of opportunistic behaviour	Additional clarifications are needed within the pricing policy regarding the frequency of price revision and the relevant processes aimed at achieving this goal
ERP-based prices should be aligned with other tools used when negotiating reimbursement	Further analysis and discussion are needed on how ERP is used in conjunction with other recommended pricing policies by the WHO [5]

Discussion

During the analysis, we noticed varying ERP approaches for different access programs that procure medicines using the state budget. This issue has been previously emphasized by some Ukrainian researchers in their studies. Nevertheless, the legislative framework in Ukraine has not been yet aligned with these findings, which can result in confusion and reduced transparency.

Conclusions

1. The analysis revealed different approaches to pricing for medicines NEML and the “Affordable Medicines” program, indicating the need for harmonizing pricing policies for different lists. The adoption of a unified positive list can contribute to improving pricing policies and efficient resource utilization.

2. Collecting, disseminating, and exchanging data on drug prices is crucial to support transparency in pricing and its control. Regular monitoring of prices in the market will help ensure compliance with pricing policies and take appropriate measures in case of violations.

3. The implementation of a unified pricing regulation policy for medicines in Ukraine is an important step towards European integration and compliance with international standards.

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