



Development of the use of innovative drug therapy programmes in Poland 2012–2024

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Abstract

Introduction and Objective. The aim of this study was to evaluate the role of drug programs in the Polish: (1) assess whether the centralized financing model contributes to reducing regional disparities in access to modern drug technologies; (2) analyse trends in the number of programs, treated patients, and related public expenditures; and (3) examine associations between regional program utilization and selected socioeconomic indicators, including income, unemployment, and urbanization.

Materials and Method. A mixed-method approach was applied, combining a narrative review of the legal and institutional framework with a secondary analysis of National Health Fund (NFZ) data for 2012–2024. Indicators of program availability, patient numbers, and expenditures were analysed using dynamic measures of change.

Results. Between 2012 and 2024, the number of drug programs increased from 42 to 133, which was accompanied by a consistent annual growth of approximately 10–11% in both the number of patients and healthcare expenditures. Although regional variation in utilization and spending was observed, no statistically significant associations were found between drug program use and socioeconomic indicators. The average number of services per patient remained relatively stable over time, with a slight downward trend.

Conclusions. Drug programs represent a stable and effective component of the Polish healthcare system, supporting broader access to innovative therapies and potentially reducing socioeconomic inequalities. The lack of association with regional socioeconomic factors suggests that centralized financing and uniform eligibility criteria may mitigate disparities in access. Nevertheless, organizational and infrastructural factors, such as the distribution of specialized centres, likely continue to influence regional variation.

Key words

health care system, cost-effectiveness, health technology assessment, drug technologies, public financing, regional disparities

INTRODUCTION

The implementation of innovative drug technologies into the public financing system poses a significant challenge, requiring an assessment of clinical efficacy, safety, and impact on the public payer's budget. In Poland, this process is supported by independent expert teams within the Agency for Health Technology Assessment and Tariff System (AOTMiT), which evaluate the quality of scientific evidence and conduct economic analyses [1, 2]. During the analyzed period (2012–2024), drug programmes played a key role in financing high-cost therapies, serving as a specific reimbursement mechanism of the NFZ. These programmes include the modern therapies used, among

others, in oncology, rare diseases, and autoimmune disorders, while simultaneously ensuring cost control through precise eligibility criteria, monitoring of treatment outcomes, and negotiating financing terms [3, 4]. Unlike outpatient reimbursement pathways and chemotherapy financing, drug programmes are strictly regulated therapeutic frameworks that encompass both clinical indications and organizational requirements. Although they expand access to innovative therapies and reduce the patient's financial burden by eliminating co-payments, they also introduce limitations resulting from, for example, the need for certified centres and significant administrative workload [5–7]. The introduction of innovative therapies is also associated with clinical uncertainty. In Poland, this uncertainty is partly mitigated through the use of risk-sharing instruments and monitoring of treatment outcome, as provided for in the reimbursement legislation [4, 8]. At the same time, accessibility barriers persist, including the geographic distribution of centres

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authorized to implement drug programmes and regional differences in healthcare infrastructure [5–7].

OBJECTIVE

The aim of the study is to assess whether a stable model of financing therapies within drug programmes contributes to reducing regional disparities in access to modern drug technologies. An important component of access to drug programmes in Poland is the public patient information platform (<https://programylekowe.pl/>), which includes searchable lists of treatment centres, programme descriptions, and eligibility criteria. This system enhances transparency and supports patients and providers in navigating access pathways, thereby influencing the practical availability of therapies. This study uses a mixed approach, combining a narrative review of the evolution and legal foundations of drug programme implementation in Poland with a secondary analysis of administrative NFZ data. This design allows both contextualization of the institutional framework and empirical evaluation of trends and regional patterns.

MATERIALS AND METHOD

Data sources. Data from the National Health Fund (NFZ), the national public payer, was analyzed. Information on contracts implemented under drug programmes was obtained from the NFZ databases, broken down by territorial unit (province, county) with particular emphasis on the number of patients treated by gender, age group and costs incurred in connection with therapy between 2012–2024 (with the caveat that data for 2024 was incomplete at the time of generation). For this reason, all 2024 values should be interpreted as preliminary and potentially underestimated, and direct year-to-year comparisons involving 2024 may be biased. The dataset constitutes a secondary analysis of NFZ administrative records. The aggregated data were obtained upon request from the NFZ central database and are not publicly available in raw form; however, summary data on drug-programme contracts can be accessed through the NFZ statistical portal. Data for 2025, although available in partial form, were not included in the statistical analysis and serve only as supplementary contextual information. This data was supplemented with information contained in announcements of the Minister of Health and demographic information published by the Central Statistical Office (GUS). Demographic data was used to standardise actual values regarding patient numbers and expenditures. To assess whether socio-economic characteristics of provinces were associated with the use of drug programmes, correlation analyses were performed.

Study unit and variables. The unit of analysis was the province ($N = 16$). Because the distribution of variables, such as level of urbanization and rate of unemployment, deviated from the norm, the Spearman rank correlation coefficient (ρ) was used as the primary measure. For variables with approximately normal distributions, Pearson's r was calculated in parallel as a robustness check. Statistical significance was evaluated at the $\alpha = 0.05$ level. Given the limited number of correlations and the exploratory

nature of the analysis, no formal correction for multiple comparisons was applied; however, effect sizes (ρ/r values) and exact p -values are reported to allow readers to assess the magnitude and direction of the relationships.

Statistical analysis. To verify the stability of findings, an additional multivariate linear regression model was estimated, with the regional use of drug programmes (*per capita*) as the dependent variable and urbanization rate, income level, and unemployment rate included as potential covariates. The model was checked for multicollinearity using the variance inflation factor (VIF). According to the definition of Statistics Poland (GUS), household income comprises all revenues (monetary and non-monetary) of households, reduced by taxes and contributions, and intended for consumption expenditure and savings. The level of household income is published annually by Statistics Poland on its website, similarly to the unemployment rate and the urbanization rate.

Trend and dynamics analysis. The analyses primarily utilized dynamics tools, such as the relative rate of change and the medium-term rate of change. The relative growth rate (percentage growth rate) allowed for determining changes in the initial value relative to the final value, and expressing them as a percentage. This technique allows for the assessment of both the rate of growth (for positive values) and the rate of decline (for negative values) within a given period. Additionally, a variable-base chain approach was adopted, which allows for the comparison of the level of the analyzed phenomenon studied each year of the study (y_t) with the immediately preceding year (y_{t-1}), which was defined as:

$$\frac{d_t}{d_{t-1}} = \frac{y_t - y_{t-1}}{y_{t-1}}$$

To determine the trend of change throughout the study period, the average annual rate of change defined as the geometric mean was used. This formula is calculated as the $n-1$ root of the quotient of the absolute values of the phenomenon under study in the last year (y_n), divided by the value in the initial year (y_1), as follows:

$$\bar{I}_g = \sqrt[n-1]{\frac{y_n}{y_1}}$$

where: n – is the number of observations. The average rate of change, which allowed to indicate the average periodic percentage increase of the analyzed phenomenon over the total period under consideration, if these changes occurred unidirectionally.

Data processing and software. Data was generated from the NFZ databases by the public payer using database tools (SQL queries). The data were then aggregated and depersonalized. MS Excel and PQStat software were used for analysis.

RESULTS

Number of drug programmes. Since 2012, the number of drug programmes has increased from 42 to 133 in 2024 (Fig. 1). An increase to 139 programmes was observed in 2025; however, these data are presented only as supplementary context outside the formal analysis period. This demonstrates the dynamic development and expansion of access to modern

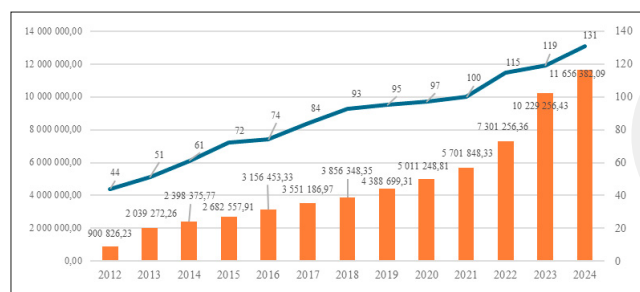


Figure 1. Number of programmes and their value (PLN-PLN) in 2012 – 2024. 2024* – preliminary data (risk of underestimation)

drug therapies in Poland. Particularly high growth rates were observed after 2018, which may be related to the introduction of new regulations and health policies.

The largest increase in the number of new drug programmes, an increase of 14, was recorded in 2024. The stabilization in the number of programmes in 2020 – 2021 may indicate a period of adaptation and evaluation of the effectiveness of implemented solutions. Further growth was observed in subsequent years, reflecting the continuous development of the system and growing interest in new treatment options. By the end of 2024, 133 drug programmes were being publicly financed, of which 46 were in oncology and 62 were non-oncologic programmes. The sum of oncology and non-oncology programmes ($n = 108$) does not equal the total number of financed programmes ($n = 133$) because an additional group of 25 programmes belong to other clinical categories that are not included in this binary division. These include programmes dedicated to rare diseases, immunological disorders, metabolic conditions, haematologic diseases not classified as oncology, and other specialized therapeutic areas with separate classification in NFZ registries. Data for 2024 are incomplete and should be considered preliminary; the actual number of programmes and patients may be slightly underestimated.

Number of patients. The dynamics of health services in individual time periods, including the number of settled units, the value of services, the number of services provided, and the number of patients treated, is presented in Table 1.

Table 1. Dynamics of the value of settlement units, the value of settled settlement units, the number of services and the number of patients year/year

Pace of change	Value of realized settlement units	Value of settled units of account	No. of benefits	No. of patients
2013/2012	125%	126%	117%	36%
2014/2013	18%	18%	7%	14%
2015/2014	12%	12%	13%	17%
2016/2015	18%	18%	35%	23%
2017/2016	13%	13%	12%	18%
2018/2017	8%	9%	15%	12%
2019/2018	14%	14%	7%	12%
2020/2019	14%	14%	-3%	5%
2021/2020	14%	14%	5%	8%
2022/2021	28%	28%	17%	22%
2023/2022	40%	40%	19%	17%
2024/2023	-47%	-52%	-50%	-44%

2024* – preliminary data (risk of underestimation)

The year with the highest growth dynamics was 2013, when the provisions of the Reimbursement Act were first implemented in practice [16]. Subsequent years show a stabilization in the development of drug programmes, with slight increases observed in 2016/2015 and 2017/2016. The significant decline recorded in 2024/2023 is unreliable due to the incomplete data for 2024 at the time the analytical dataset was generated. The significant decline observed between 2023 and 2024 should be interpreted with caution, as 2024 data are preliminary and incomplete, which increases the risk of underestimation.

The increasing dynamics of the value of services indicates that more expensive drug technologies are being financed. The dynamics at the regional level (provinces) for the entire period of 2012–2024 under review are presented in Table 2. The values of reported health services financed from public funds in the ‘drug programmes’ model show a stable annual growth of 10 – 11%, both in terms of the number of health services performed and the number of patients treated.

Table 2. Average annual dynamics for the value of settlement units, value of settled settlement units, number of services and number of patients by province

Province	Value of realized settlement units	Value of settled units of account	No. of benefits	No. of patients
Poland	16%	15%	11%	10%
Dolnośląskie	16%	15%	11%	10%
Kujawsko-Pomorskie	14%	13%	8%	8%
Lubelskie	16%	15%	11%	9%
Lubuskie	15%	14%	11%	9%
Łódzkie	16%	15%	9%	9%
Małopolskie	17%	16%	13%	12%
Mazowieckie	17%	16%	10%	9%
Opolskie	14%	13%	9%	8%
Podkarpackie	16%	15%	13%	9%
Podlaskie	16%	14%	10%	8%
Pomorskie	18%	17%	11%	10%
Śląskie	16%	15%	11%	10%
Świętokrzyskie	15%	14%	11%	8%
Warmińsko-Mazurskie	15%	14%	11%	9%
Wielkopolskie	16%	15%	13%	9%
Zachodniopomorskie	16%	15%	11%	9%

2024* – preliminary data (risk of underestimation)

Source: National Health Fund (NFZ) data;

2024* – preliminary data (risk of underestimation)

Expenditures and costs. The exceptionally stable financing model helps bridge regional disparities in access to healthcare services. Contrary to the results of other analyses, no significant correlations were observed between the level of urbanization of, provinces, household income, or unemployment rates. Correlation analysis showed no statistically significant association between the use of drug programmes (*per capita*) and the analyzed socio-economic indicators. Spearman’s coefficients ranged from $\rho = -0.18$ to 0.22 , all with $p > 0.05$, indicating weak and non-significant relationships. Similar results were obtained using Pearson’s r (all $|r| < 0.25$, $p > 0.05$). The multivariate regression model likewise did not reveal statistically significant predictors of regional use of drug programs.

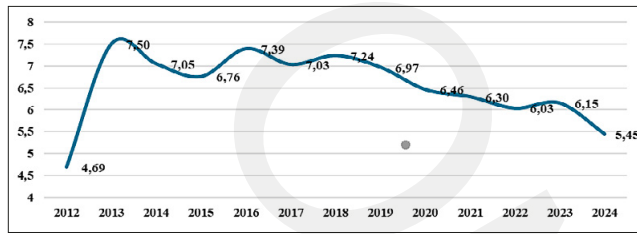


Figure 2. Average number of services per patient in drug programmes

Urbanization level ($\beta = 0.12$, $p = 0.41$), income ($\beta = 0.19$, $p = 0.27$), and unemployment rate ($\beta = -0.15$, $p = 0.33$) were not associated with the dependent variable. The time variable was not used for explanatory purposes in the models employed, and therefore did not require any specific explanations; it served simply as an identifier for a point or period in time, used to assess the dynamics of changes in phenomena, advancing year by year. The variance inflation factor ($VIF < 2$ for all predictors) indicated no problematic multicollinearity. The average number of health services provided per patient is presented in Figure 2. The coefficient of variation was calculated for the data. In the classical approach, the coefficient of variation is defined as

$$V_s = \frac{S_x}{\bar{x}_s}$$

where S_x denotes the standard deviation of the variable, and \bar{x}_s its arithmetic mean. A coefficient value below 25% suggests low variability of the phenomenon being studied. The number of health services provided per patient remains relatively stable in the analyzed period, as confirmed by the coefficient of variation at the level of $V_s = 11.96\%$. This is also confirmed by data on the number of services *per patient*, which shows a rather linear downward trend between 2012 and 2024 from approximately 7.5 to 5.45 services *per year*; 2024 values are preliminary and may be subject to underreporting. Figure 3 presents regional conditions at the provincial level, accounting for population size: (A) level of expenditure per patient, (B) percentage of the population participating in drug programmes, and (C) expenditure ratio.

Higher utilization rates are visible in the łódzkie, mazowieckie, and świętokrzyskie provinces, while lower values appear in the opolskie, lubuskie, and podlaskie provinces. Expenditure differences exhibit a partially overlapping pattern but also reflect regional treatment centre density, indicating that organizational and infrastructural factors likely contribute to variation. In the analyzed period of 2012 – 2024, the average expenditure under drug

programmes *per patient* across Poland amounted to PLN 32,642.9134. The percentage of the population using health programmes averaged 0.42% of the entire Polish population. The highest average expenditures per patient were recorded in the lubelskie (PLN 36,090), wielkopolskie (PLN 34,324), and opolskie (PLN 34,294) provinces. The lowest expenditures were recorded in the lubuskie and kujawsko-pomorskie (PLN 30,695 each) provinces, and the śląskie (PLN 31,038) province. In terms of the share of the regional population benefiting from drug programmes (ratio), the highest values were achieved in the following provinces: łódzkie (0.45%), mazowieckie (0.42%) and świętokrzyskie (0.41%).

DISCUSSION

The results of this study confirm a systematic and dynamic expansion of drug programmes in Poland over the past decade, reflected in the growing number of available therapeutic options and the increasing number of patients receiving treatment. Between 2006 – 2024, the number of drug programmes increased from approximately a dozen to more than 100, while the number of treated patients grew at a stable annual rate of around 10 – 11% [4]. This trend highlights the strengthening role of drug programmes as a key mechanism for improving access to innovative therapies, accompanied by rising public expenditure and the financing of increasingly costly drug technologies. The consistent year-to-year growth suggests that this financing model has become well established, predictable, and effectively integrated into the national healthcare system.

Importantly, despite substantial system expansion, no statistically significant correlations were identified between regional utilization of drug programmes and socio-economic indicators, such as income level, unemployment rate, or urbanization [5–7]. Although this might suggest the absence of territorial or social inequalities, the lack of correlation should not be interpreted as definitive evidence of equal access. Instead, it likely reflects the centralised structure of the Polish drug programme framework – characterised by national eligibility criteria, full reimbursement, and standardized reporting – which may buffer the influence of local socio-economic differences [5–7]. Nonetheless, previous research demonstrates that inequalities may persist through factors not captured in aggregated administrative datasets, including the uneven distribution of specialist centres, varying referral practices, and differences in providers' capacity [9, 10]. Patients living in rural or less urbanized

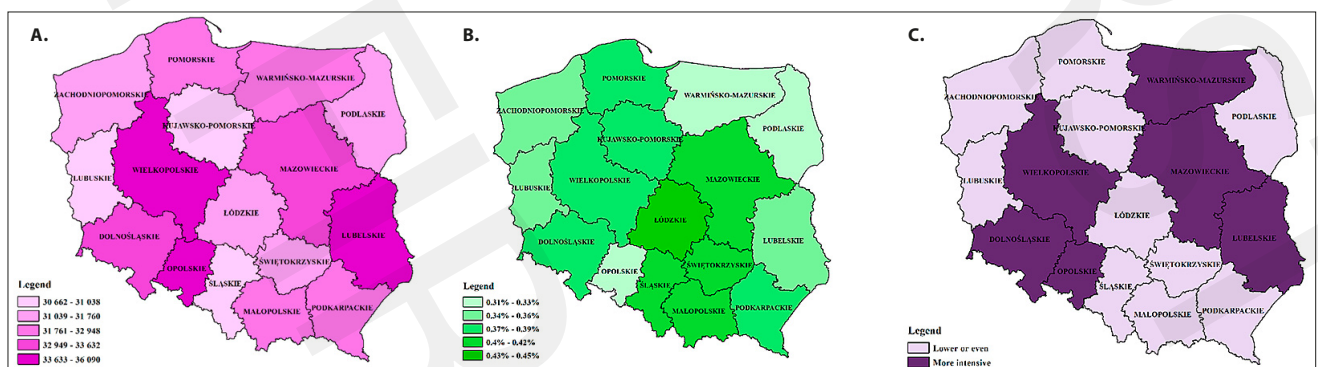


Figure 3. Regional conditions considering the provincial population.

A. Level of expenditure per patient. B. Percentage of population using programmes. C. Expenditure ratio

regions may face additional geographic or organizational barriers to specialist care, even when therapies are fully reimbursed [6, 7].

Furthermore, although drug programmes are publicly funded, patients may face ancillary costs, such as travel, accommodation, supportive medications, or specialized diets, which disproportionately burden individuals with lower socio-economic status [9]. Differences in health literacy and access to clear, standardized information can further exacerbate disparities, underscoring the need for effective communication between healthcare providers and patients and ensuring that all individuals are fully informed about available therapy options and programme pathways [11]. A decreasing average number of services per patient, combined with low regional variability, may reflect improvements in treatment standardization or evolving monitoring requirements. However, these trends should be interpreted cautiously due to the preliminary and potentially underestimated nature of the 2024 data.

Patients across Europe face substantial inequities in access to innovative anticancer medicines, with first patient access often occurring through early access programmes (EAPs) or off-label use rather than national reimbursement. A cross-sectional study of 19 hospitals in six European countries showed marked variation in time to patient access across and within countries, with earlier access frequently achieved before reimbursement – especially in specialized hospitals – highlighting the need for faster reimbursement processes and harmonized, data-generating EAPs to improve equitable access [12]. Early access to innovative therapies remains highly uneven across major global regions due to divergent regulatory frameworks, fragmented Health Technology Assessment (HTA) processes, and inconsistent early access mechanisms, highlighting the need for internationally coordinated, adaptive approval models that integrate early access planning and shared benefit–risk governance to ensure more equitable and timely patient access, particularly for rare and high-burden diseases [13]. Access to novel cancer medicines varies widely across Europe due to differences in reimbursement timelines, HTA processes, financial and organizational capacity, and health system infrastructure, indicating that while EU-level regulatory and HTA harmonization may reduce some disparities, achieving equitable access will require balancing innovation with affordability and health system sustainability [14].

Practical implications. The findings of the study have several practical implications for the operation of the Polish drug programme model. The steady expansion of the number of programmes and treated patients emphasizes the importance of maintaining a stable and predictable financing environment, which enables timely implementation of innovative therapies [4]. Drug programmes serve as a crucial policy instrument for improving access while controlling public expenditure through centralised price negotiations, standardised eligibility criteria, and uniform monitoring requirements. These structural features may reduce the influence of local administrative and financial disparities, supporting more equitable access across regions [5–7].

At the same time, modest regional differences observed in expenditures per patient and treatment prevalence highlight the role of organizational rather than socio-economic factors. These include the distribution of certified

treatment centres, local referral pathways, and administrative burdens associated with drug programme documentation [11, 15]. Policymakers should prioritise improving clinical infrastructure and optimising referral systems to ensure further reductions in avoidable regional variation.

Sensitivity analysis and robustness considerations. To enhance robustness, the analysis incorporated multiple statistical approaches, including Spearman and Pearson correlation coefficients, as well as multivariate regression models controlling for key socio-economic variables. Consistency across these methods suggests that the socio-economic factors available in the dataset are unlikely to be major determinants of regional drug programme utilization [5–7]. Nevertheless, the findings should be interpreted with caution. Data for 2024 were incomplete at the time of extraction and may underestimate both service volumes and expenditures. Reliance on aggregated administrative data limits adjustment for individual-level characteristics, such as disease severity, comorbidities, or socio-economic status. Sensitivity checks excluding 2024 data did not alter the direction of the observed trends, supporting the overall stability of results. However, additional robustness could be achieved in future studies by incorporating variables related to clinical infrastructure, provider capacity, and epidemiological burden, which were unavailable in the current dataset [8–10].

Future research directions. Future research should examine patient-level determinants of access to drug programmes, including comorbidities, disease stage, and socio-economic status, which cannot be captured in aggregated administrative data. Further studies should also incorporate indicators of clinical infrastructure, particularly the geographic distribution and capacity of specialized centres authorised to deliver drug programmes, as these factors may independently influence access [5–7, 11].

Extending analyses to include data beyond 2025 would help verify whether the observed patterns remain stable in the context of evolving reimbursement policies and the implementation of European HTA procedures. Investigating the impact of regional variations in referral practices, administrative burdens, and provider capacity, may further clarify the mechanisms driving observed differences.

Limitations of the study. This study has several limitations. First, 2024 data were incomplete and thus less comparable to previous years, introducing a risk of underestimation. Second, the NFZ dataset is aggregated and administrative in nature, preventing adjustment for individual-level characteristics, such as disease severity, comorbidities, or socio-economic status. Third, the analysis was conducted at the provincial level, which reduces the statistical power. Finally, the study did not include information on regional clinical infrastructure – such as the number and distribution of certified centres – which may significantly influence access to drug programmes [8, 9, 11, 15].

Furthermore, decisions regarding the inclusion of specific therapies in drug programmes are made by the Minister of Health, based on the assessment of the President of the AOTMiT and the recommendations of the Economic Commission, which negotiates financing terms and may propose risk-sharing mechanisms [8]. This institutional

process introduces additional complexity and may influence the availability of specific drug technologies across regions.

CONCLUSIONS

- 1) A public financing model based on drug programmes contributes to equalizing patient access to cost-effective and modern pharmacological therapies, regardless of place of residence, fulfilling the constitutional right to health care. These conclusions are supported by correlation and regression analyses, which demonstrated no statistically significant associations between regional socio-economic indicators and the use of drug programmes.
- 2) The analysis revealed no significant differences in the level of healthcare service provision related to the urbanization level of the provinces, household income, or unemployment rate. Changes between 2023 and 2024 were not interpreted due to the preliminary nature of 2024 data.
- 3) Drug programmes ensure continuity of therapy and protection of patients' interests also in crisis situations (e.g. during the COVID-19 pandemic), which is confirmed by the results of analyses conducted regarding the stability of service availability also during the pandemic.
- 4) The value of financial resources for health services financed from public funds under the 'drug programmes' model showed stable annual growth at the level of 10 – 11%. This increase concerned both the services provided and the number of patients treated.

RECOMMENDATIONS

Despite significant progress in the implementation and expansion of drug programmes, further improvements are possible to enhance equity, transparency, and responsiveness to regional needs.

The introduction of uniform principles will enable more efficient and cheaper verification of health technologies and will enhance the certainty of clinical evidence, which will result from greater cooperation, exchange of experiences and results between national institutions.

Strengthening the statutory role of the Ministry of Health in the process of negotiations with producers of new medical technologies, for example, by enabling the ministry to initiate reimbursement applications, will help streamline this process.

To increase the accessibility of drug programmes, their use should be as close to the patient as possible; implementation could be within the framework of Outpatient Specialist Care.

Cooperation among EU countries in the field of health technology assessment will allow marketing authorization

holders to reduce costs and streamline the assessment process, which will be conducted once across the entire EU. This mechanism will also strengthen the negotiating position of member states and the EU regarding the costs of acquiring new therapies.

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