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# IOWISZ (Evaluation Instrument of Investment Motions in Health Care) – as a tool to rationalise the spending of public funds in health care

#### **Abstract**

The article presents the most important issues related to the creation and functioning in the Polish health care system of the Evaluation Instrument of Investment Motions in Health Care (the so-called IOWISZ). The main objective of the publication is to provide a detailed characterisation and assessment of the operation of a relatively new tool for managing financial resources in health care, i.e. the IOWISZ. The specific structure of the IOWISZ system and the role assigned to this instrument by the regulator in the Polish health care system are presented. Furthermore, the origin and evolution of the IOWISZ system is presented as well as the experiences to date related to its functioning. The treatise also presents in detail the procedure for healthcare providers (investors) aimed at obtaining a positive opinion on the advisability of the investment under preparation, which is currently a prerequisite for the investment to be covered by public funding from the National Health Fund (NFZ). A review of the literature (including legal acts) made it possible to draw conclusions that the functioning of the IOWISZ system has contributed to the improvement of the effectiveness of public funds spending and rationalisation of capital expenditure in healthcare. The tool described is generally well evaluated by its users and still has a great potential for development when it comes to further improving the efficiency of the use of available (limited) resources in the Polish health care system. The arrival of the IOWISZ system meant that investments in health care became well-structured and correlated with the national health policy. To an increasing extent, investments are made in accordance with the maps of health needs and regional health and development policies, and consequently with the actual and diverse health needs of the inhabitants in each region of the country.

Keywords: IOWISZ, investment, investment efficiency, investment expediency.

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# INTRODUCTION

Recent years have seen a significant breakthrough in medicine related to the use of modern medical technologies, both diagnostic and therapeutic. Medical robotics, which allows even complex surgical operations to be carried out efficiently, is also increasingly used. At the same time, the existing infrastructure of medical entities is constantly being expanded and modernised to meet the ever-increasing expectations of patients, health care providers and payers, as well as the legislator, in this regard. A modern and safe infrastructure (including medical apparatus and equipment) at the disposal of health care entities unquestionably contributes to effective medical care. However, the widespread use of modern and expensive medical technologies has increased the demand for specialised medical staff and generates significant costs associated

therewith. The above challenges, combined with the chronic underfunding of the health care system in Poland and the uneven distribution of key resources in the system so that it does not meet the local needs of the population, still constitute an unresolved problem requiring effective intervention<sup>1</sup>. In this situation, the effectiveness of the use of the available (limited) financial resources for investments in health care becomes important<sup>2</sup>. A response to the challenges indicated above was the creation of the IOWISZ system, which is a modern tool for optimising the allocation of public funds in the Polish health care system.

#### **Definition and essence – the IOWISZ**

The Evaluation Instrument of Investment Motions in Health Care, abbreviated as IOWISZ, is an Information and Communication Technology (ICT) system which processes data necessary to issue an opinion on the reasonableness of capital

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<sup>&</sup>lt;sup>1</sup> The phenomenon of inequalities in health status and access to health resources was studied, among others, by the English physician Julian Tudor Hart (b. 1927) who was the first (1971) to notice and formulate the so-called inverse care law which states that 'availability of good medical care tends to vary inversely with the need for it in the population served' [2]. In other words, the availability of good quality health care is inversely proportional to the size of the population's real health needs [3].

<sup>&</sup>lt;sup>2</sup> This concept should be understood as such a use of investments that will ensure the greatest possible diagnostic/therapeutical benefit for patients (in particular, the greatest possible number of patients will receive health care services of the highest possible quality), taking into account the principles of cost-effective spending of public funds [4].

expenditure as referred to in art. 95d(1) of the Act of 27th August 2004 on health care services financed from public funds [1]. The Instrument for Evaluation of Applications for Investments in the Health Sector is thus a modern ICT tool, which, from the applicant's point of view, allows to complete and send an application (form) for issuing an opinion on the reasonableness of the investment to the competent public administration bodies. In essence, the IOWISZ is an ordinary electronic form, the filling in and sending of which results in obtaining a positive or negative opinion on the reasonableness with regard to the investment evaluated. The result of filling in and sending an application in the IOWISZ system is obtaining an opinion on the reasonableness of the investment which comes in the form of an electronic administrative document. The IOWISZ system was made available to applicants in September 2016 as a result of the entry into force of the amendment to the Act of 21st July 2016 amending the Act on health care services financed from public funds [5]. The IOWISZ system can only be accessed at the following internet address: http://iowisz. ezdrowie.gov.pl/. The administrator of the IOWISZ system is an entity subordinate to the Minister of Health, competent in the field of health care information systems, i.e. the Centre for E-Health (CeZ).

# Origin and development – the IOWISZ

The amendment to the Act of 21st July 2016 amending the Act on health care services financed from public funds included a delegation for the Minister of Health to issue a regulation that would indicate what the IOWISZ form should look like (art. 95h). The Minister of Health fulfilled the imposed (statutory) obligation by issuing the relevant regulation in September 2016 [6]. This was the beginning of the IOWISZ system in Poland. IOWISZ was created as a stand-alone tool to support the implementation of conclusions from Maps of Health Needs and education on proper investment in health care [7]. Initially (for almost 2 years), there was one form in use regardless of the type of investment (development or replacement/modernisation). On 13th July 2018, the Act of 12th April 2018 on amending the Act on health care services financed from public funds and certain other acts [8] entered into force as well as two implementing acts issued by the Minister of Health relating to the aforementioned Act. The new implementing acts significantly changed the shape of the application form in the IOWISZ system by distinguishing between the so-called 'replacement3/modernisation4 investments', which do not result in a change in the scope of the health care services provided, and other (so-called 'developmental'5) investments, the purpose of which is to change the scope of the health care services provided. Consequently, two slightly different forms were distinguished, designed to assess the reasonableness of the investment depending on the nature of the investment being evaluated. The templates of the above forms were defined by the Minister of Health in the following two executive acts, viz.:

- Regulation of the Minister of Health of 11th July 2018 on the application form of the Instrument for Evaluation of Applications for Investments in the Health Sector for investments resulting in a change in the scope of health care services provided (Journal of Laws 2018, item 1347) [9];
- Regulation of the Minister of Health of 11 July 2018 on the application form of the Instrument for Evaluation of Applications for Investments in the Health Sector for investments that do not affect the scope of health care services provided (Journal of Laws 2018, item 1348) [10].

Depending on the type of investment (resulting in a change in the scope of health care services provided or not affecting the scope of services provided), the applicant automatically receives the relevant form to be filled in after selecting one of the two op-

TABLE 1. Differences between the forms in the IOWISZ system depending on the type of investment ('developmental' vs. 'replacement/modernisation').

Type (nature) of the investment	Investment resulting in a change in the scope of health care services provided	Investments that do not affect the scope of health care services provided Replacement /Modernisation			
	Developmental				
Total number of questions (i.e. investment appraisal criteria)	34 (100%)	29 (100%)			
Number of close-ended (objective) questions	8 (23.5%)	10 (34.5%)			
Number of open-ended (subjective) questions	26 (76.5%)	19 (65.5%)			
Number of questions with maximum weight (i.e. 1.0)	9 (26.5%)	14 (48.3%)			
Number of questions with minimum weight (i.e. 0.2)	5 (14.7%)	2 (6.9%)			
Minimum number of points (total score) required for a favourable opinion	6 200 pts	950 pts			

Source: own work based on the Regulation of the Minister of Health of 28th December 2021, 2023

tions to specify the type of investment to be evaluated. The aforementioned forms differ slightly from each other (Table 1).

The 2018 forms, i.e. the most important component in the IOWISZ system, were applicable in an unchanged form for 2.5 years (i.e. until 1st Jan 2021). Another amendment to the Act of 10th December 2020 on amending the Act on health care services financed from public funds and certain other acts [12] made another modification to the IOWISZ system, introducing an improved version of the forms (i.e. Regulation of the Minister of Health of 1st February 2021 on the application form of the Instrument for Evaluation of Applications for Investments in the Health Sector for investments that do not affect the scope of health care services provided [13] and the Regulation of the Minister of Health of 1st February 2021 on the application

<sup>&</sup>lt;sup>3</sup> Replacement investments are undertaken in order to maintain an organisation's ability to function in its current operating formula. They therefore consist of replacing an existing but physically worn-out fixed asset with a new one. They only ensure the simple reproduction of fixed assets. Their overriding (main) objective is to maintain production (manufacturing) or sales (commercial) capacity at its current level. They are the least risky investments [11].

<sup>&</sup>lt;sup>4</sup>Modernisation investments are related to the replacement of assets that are still technically useful but economically obsolete in order to reduce the cost of labour, materials and other resources. Modernisation investments consist of replacing used fixed assets with new ones, but taking advantage of advances in technology. The implementation of modernisation investments is thus ultimately intended to reduce the operating costs of an organisation's operations [11].

<sup>&</sup>lt;sup>5</sup> Developmental investments are aimed at increasing additional free cash flow by generating additional revenue. This type of investment is most often associated with new market activities (sales of new services, products and goods) or expansion of existing activities into a new market [11].

form of the Instrument for Evaluation of Applications for Investments in the Health Sector for investments resulting in a change in the scope of health care services provided [14]). The most important changes at that time were:

- simplification of the application forms for an opinion on the reasonableness of an investment. The application and its evaluation were intended to concern the entire investment, and not its individual components as was the case until then;
- widening of the pool of health care entities for which a positive opinion on the reasonableness of an investment (OCI) is a precondition for being granted co-funding from public funds and being awarded a contract for providing healthcare services financed from public funds (or having the scope of the existing contract extended);
- waiving the requirement to apply for an opinion on the reasonableness of an investment in the case of small investments, i.e. not exceeding PLN 2m (the legislator acknowledged that such investments only slightly affect the development of the market of medical services);
- reserving the evaluation of investments with a value exceeding PLN 50m (e.g. construction of a hospital) as the exclusive competence of the Minister of Health.

The version of the forms developed in the IOWISZ system was valid for less than a year (10 months). From 1st January 2022 until now (January 2024), the current form of the main component within the IOWISZ system (i.e. the application forms) is regulated in the following two regulations issued by the Minister of Health:

- Regulation of 28th December 2021 on the application form of the Instrument for Evaluation of Applications for Investments in the Health Sector for investments resulting in a change in the scope of health care services provided (Journal of Laws of 2021, item 2487) [15], i.e. the so-called 'developmental' application form, and
- Regulation of 28th December 2021 on the application form of the Instrument for Evaluation of Applications for Investments in the Health Sector for investments that do not affect the scope of health care services provided (Journal of Laws of 2021, item 2488) [16], i.e. the so-called 'replacement' modernisation' application form.

However, the changes made to the forms were actually not of a fundamental importance as they were limited to clarifying and updating some of the questions (e.g. replacing the notion of 'priorities for regional health policy' denoted by the acronym PRPZ with the notion defining a strategic document in health care called 'Transformation Plan'). The changes also involved improvements in the interpretation and clarification of the meaning of certain questions (i.e. investment appraisal criteria).

The IOWISZ system is constantly evolving. Since its inception it has already been modified and improved three times. Therefore, this tool cannot be considered a finite being. In the following years, the instrument described herein will certainly continue to change in order to meet the expectations associated with it to the greatest extent possible.

# Role and objectives - IOWISZ

The main objective of the functioning of the IOWISZ system is to create a modern and practical tool for the rational and effective spending of public funds, both national and EU funds in the area of health care investments (e.g. construction or purchase, or modernisation of the infrastructure of health care entities). For years, the issue of investments in the Polish health care system remained unregulated. The above circumstances led, inter alia, to situations where neighbouring health care entities purchased the same expensive diagnostic or therapeutic equipment, but later on, they did not have appropriate contracts for its use, or the contract with the National Health Fund was for relatively small amounts, which meant that the equipment was only used to a small extent. This was pointed out by the European Commission (lack of rationality and transparency in investments), requiring improvements in this area. Wastage of public funds in terms of investments made was also mentioned in numerous reports by the Supreme Audit Office (NIK)<sup>6</sup>. The IOWISZ system was therefore intended to meet the expectations not only of the European Commission, but also of the Ministry of Health, the National Health Fund, service providers (investors) and patients and, as a consequence, contribute to improving the situation in the entire health care system by optimising the spending of public funds on investments. The main assumption adopted by the creators of the tool discussed was to ensure economical, adequate and anticipatory spending of public funds on sensible and legitimate investments (e.g. in the context of the potential for concluding contracts with the National Health Fund for the provision of healthcare services later on), to eliminate cases of duplication of similar investments within a small geographic area as well as to eliminate the so-called white spots on the map of healthcare services. The IOWISZ system is, therefore, an effective and relatively simple and fast tool to assess the reasonableness of investments that are planned in health care. From the point of view of service providers (applicants), the IOWISZ system enables them to obtain the desired 'product' in the form of an opinion on the reasonableness of the investment (an official administrative document) which is more and more often required when applying for all or part of the funds necessary to carry out the planned investment. What is more, the functionality of the IOWISZ system makes it possible for the applicants to use the instrument discussed themselves in order to conduct, completely free of charge, a preliminary selfassessment of the investment being planned, and thus obtain, for internal purposes, a positive or negative opinion on the

The findings of the NIK audit indicate that some healthcare providers undertook investment activities without recognising the actual health needs, e.g. purchased modern equipment, carried out construction works, or employed additional medical staff in a situation when there were already other healthcare entities providing the same services in the same region. This translated into low utilisation of available resources, including hospital beds. As indicated by the results of the NIK audit, there is also inadequate coordination of activities between individual district and provincial self-governments to ensure the comprehensiveness of the provision of health services, planning the participation of individual actors in the healthcare system, as well as the rational restoration and development of the material base [7]. In a similar context, conclusions have been formulated in such NIK reports as (1) *Purchase and use of medical apparatus co-financed within Regional Operational Programmes* (2013); (2) *Use of specialised medical apparatus in the process of providing publicly financed medical services in 2006-2008* (1st half) (2010); (3) *Use of subsidies of the Minister of National Defence by selected healthcare entities* (2015); (4) *Information on the results of the audit. Report: Health care system in Poland – current state and desirable directions of changes* (2019); (5) *Information on the results of the audit. Purchase and use of highly specialised medical equipment in healthcare entities* (2022).

investment in question<sup>7</sup>. In this way, the IOWISZ system contributes to improving the quality of the investment planning process in the area of health care by service providers (optimisation of the pre-investment stage) and makes the investments implemented more thoughtful (which means that they take into account the actual health needs of the population for whom the investment is ultimately targeted). The new legal regulations (beginning from 2021) have increased the role of the IOWISZ instrument in the healthcare system as they indicate that failure to obtain a positive opinion on the reasonableness of an investment has serious consequences for healthcare entities that decide to implement the investment, especially when applying for a contract with the NFZ. Under the current legislation, the implementation of an investment in the absence of a positive opinion from the IOWISZ system results in a 5-year exclusion from contracting with the NFZ as well as losing the option to increase the value of an existing contract in order to obtain public funding for the investment implemented8. Thus, if a service provider fails to obtain a positive opinion for its investment in the IOWISZ system, it will not be able to conclude a contract with the public payer (NFZ) that would include the completed investment during a period of five years counted from its completion. The above regulations force, as it were, healthcare providers (investors) to ensure that their investments in health care are not only compliant with the maps of health needs, but are also positively verified in the IOWISZ system. In other words, they should be sensible and legitimate in relation to the existing health needs in a given province. Obtaining a positive evaluation within the Instrument for Evaluation of Applications for Investments thus enables healthcare providers to develop in a long-term perspective in accordance with local health needs and to include the investment in the contract with the NFZ<sup>9</sup>.

On the other hand, from the point of view of those public entities that are involved in the shaping and financing of the healthcare system in Poland, the IOWISZ system is an instrument that supports and facilitates decision-making in the spending of public funds (national and EU) for investment in health care. Decisions made by public administration bodies

in the area mentioned above are objective and in line with the health needs of the nation. As a result, the IOWISZ system prevents chaotic and short-sighted development of the health services market in Poland. The IOWISZ increases the effectiveness of spending the available (limited) public funds and eliminates the occurrence of the phenomenon of 'medical arms race'10 among healthcare providers. For the Minister of Health and province governors, the form is a relatively new analytical tool in the management of the healthcare system, which allows making accurate decisions on allocating limited financial resources in the healthcare system based on a number of distinguished criteria. The IOWISZ system provides information ('prompts') whether it is worthwhile to open another hospital or outpatient clinic in a particular region, or whether it is worthwhile to buy a particular piece of medical apparatus and equipment, especially in the situation of a lack or shortage of specialised medical staff or where there is no demand or very low demand for health care services among the inhabitants in a particular area. The IOWISZ system contributes to the reduction or even elimination of the phenomenon of oversupply of health care (excessive investments) and also adjusts investments in the health sector to the actual needs of the residents of particular regions, which, in turn, leads to an increase in the effectiveness of spending public funds in the entire healthcare system. The IOWISZ system, therefore, puts investments in health care in order, reviews ('screens') them and contributes to their selection ('sifting out'), leaving only the sensible and justified ones to be implemented. Moreover, the IOWISZ system also increases transparency in the allocation of public funds for investments in the healthcare system.

# Design and structure - IOWISZ

The IOWISZ system is an application form consisting of 29 or 34 categorised questions depending on the type of investment to be assessed, divided into 4 main subcategories<sup>11</sup>. The following subcategories of questions can be distinguished:

1. People and human resources – this subcategory groups together questions that focus on the needs of the patient, the patient's family or carers and the medical staff involved

<sup>&</sup>lt;sup>7</sup> The applicant must have an account in the IOWISZ system. The applicant must have an account on the e-PLOZ platform before being authorised in the IOWISZ system [17].

<sup>&</sup>lt;sup>8</sup> Since the beginning of 2021, a statutory provision has been in force stating that in the absence of a positive opinion on the reasonableness of the investment, the healthcare provider may not participate in the proceedings on the conclusion of agreements on the provision of healthcare services financed from public funds if 5 years have not passed from the day on which the decision on the permission to use the investment was issued (art. 139a of the Act of 27th August 2004 on health care services financed from public funds). Moreover, the healthcare provider may not increase the value of an existing contract with the NFZ for providing healthcare services with the use of the investment in the absence of a positive opinion before the lapse of 5 years from the day on which the decision on the permission to use the investment was issued (art. 136(2)(3) of the Act of 27th August 2004 *on healthcare services financed from public funds*).

The evaluation of a particular investment in the IOWISZ system does not take place completely 'in isolation' from the financing of services by the National Health Fund (i.e. attention is paid not only to the existing health care needs in the province, but also to the payer's financial capacity in the context of possible contracts after the completion of the investment). Admittedly, the assessment of the reasonableness of the investment is generally issued irrespective of the possibility of subsequent financing of the services by the National Health Fund. Apart from one tangential point (the question in the form 'To what extent is the investment burdened with the risk of not obtaining public funding for the healthcare services provided?'). The assessment of the possibility to obtain the expected funding in connection with the investment therefore remains of little relevance for the assessment of the reasonableness of this investment. The interrelation between the assessments (reasonableness vs. possibility to obtain a contract) does not therefore determine the positive or negative assessment of the application/investment in the context of the multiplicity of other criteria and the additional points that can be obtained for their fulfillment [18].

This phenomenon involves an increase in the ownership and use of modern, specialised and usually expensive medical technologies by healthcare providers (mainly by hospitals) in order to attract both doctors and patients. The essence of this phenomenon is that these activities are not always medically justifiable given the actual needs of the population cared for by the provider. The phenomenon of 'medical arms race' manifests itself in the fact that providers do not compete on price (as the existence of a 'third party' in the system usually allows the patient to pay a 'zero' price for the medical services consumed), but above all on quality by acquiring the best and most modern (and usually the most expensive) medical technologies available (thus the competition shifts to the area of technology). The phenomenon described is based on two commonly held beliefs among both doctors and patients, i.e. 'new technology is better than old technology' and 'expensive technology is better than cheap technology' [19]. The above activities, referred to as 'medical arms race', can lead to the surplus and overconsumption of expensive medical technologies [20], an unbridled drive by healthcare providers to increase equipment capacity without regard to the existing real health needs of the populations being cared for [21,22].

<sup>&</sup>lt;sup>11</sup> The distinguished subcategories include questions/investment appraisal criteria that address similar issues.

in the patient's therapeutic process. These questions mainly explore the rights of the patient and their needs, as well as the ergonomics of the workplace with regard to the medical staff. The investment that scores the highest in this subcategory concerns the improvement of the patient's comfort during therapy and the preservation of their inalienable rights as well as the acceleration of their professional or social recovery as well as the improvement of the medical staff's working comfort.

- 2. Care this subcategory includes questions concerning the organisation of healthcare services provided in the context of the changing demographics of Polish society and with the participation of limited medical staff. The high scores that can be obtained in this group of questions relate to investments satisfying the need to reorganise the structure of services based on the maps of health needs in terms of improving the quality of health care in the aspect of population needs and appropriate allocation of medical staff.
- 3. Resources this subcategory concerns the existing and planned infrastructure, modernised equipment and financing of the investment after its completion by the public payer. The high scores obtained in this group of questions indicate investments responding to the needs defined in the maps of health needs and regional health policy programmes, as well as fulfilling the need to rationally reduce health care costs by investing in new equipment or its modernisation while ensuring its optimal use.
- 4. Thought within this subcategory, there are questions concerning the innovativeness and the scientific or educational value of the investment concerned, whether it addresses the need to develop medical care facilities and to offer patients new, effective medical technologies previously unavailable in the regional market including the potential improvement of teaching facilities. The highest scores in this category of questions are awarded to projects concerning innovative solutions taking into account the utilisation of Polish technical and scientific thought and that of the EU and EFTA countries [23].

Furthermore, two additional questions were distinguished, including compliance with the regional health policy programme (RPPZ) and the expected time of the planned investment. These two questions/investment appraisal criteria were not included in the above-mentioned four subcategories.

In the system being described, the questions specified constitute criteria for the evaluation of the investment. As the reasonableness of the investment can be assessed from various points of view, the legislator selected the questions in such a way that each of them explores a certain area of health care issues and reflects the health care priorities adopted. By means of the questions By means of the questions and the answers obtained, an evaluation of the investment is carried out. Each question (investment appraisal criterion) is assigned a weight from 0.2 to 1.0. Consequently, the IOWISZ system differentiates questions (investment appraisal criteria) by assigning different weights to them. In other words, not every question is equally important from the point of view of assessing the reasonableness of an investment. The legislator has indicated questions that are particularly important from the point of view of assessing the reasona-

bleness of the investment under preparation. These questions have been given the maximum weight (i.e. 1.0). These include the following questions/investment appraisal criteria:

- To what extent does the investment respond to demographic trends?
- To what extent will the investment improve health outcomes for the patient population in the area?
- To what extent will the investment improve the quality of health care?

The legislator also indicated criteria for the evaluation of investments that are relatively less important in its opinion, which were assigned the lowest weight (i.e. 0.2). These include the following questions/investment appraisal criteria:

- To what extent will the investment affect the ergonomics of the workplace with regard to the medical staff?
- To what extent will the investment improve the comfort of patients and their families?
- To what extent will the investment improve the skills of medical professionals?

There are both open- and close-ended questions in the IO-WISZ system. The closed-ended questions can only be answered 'YES' or 'NO'. For a 'YES' answer, the applicant gets 10 points. A 'NO' answer scores 0 points. The score for closed questions is objective (zero-one). There is no room for subjectivity on the part of the evaluator. In contrast, the score awarded by the evaluator for the answers submitted to open questions is subjective (on a point scale). In the case of open-ended questions, the evaluating entity subjectively assigns points to the answers and the rationale for them on a 0-10 scale. The IOWISZ system does not specify in which cases the highest or lowest score on the 0-10 scale should be awarded to an investment. Therefore, in the case of open-ended questions, the body issuing the opinion has almost unlimited discretion in assessing the answers and, consequently, the applications submitted. Open questions contain a special space (box) for the applicant to justify the answer in writing. It is important to note that a maximum of 500 characters (approx. 1/3 of a page) can be entered in the space provided<sup>12</sup>. This means that the instrument developed and made available to applicants forces them, as it were, to answer the questions in a short and concise manner. Nonetheless, there is an option to add annexes (up to a maximum of 4 with a size of up to 10 MB), which allows for a more extensive and detailed presentation of the answers to the questions asked. It is considered good practice by the assessment bodies to include additional annexes in the form of documents that make it possible to support the information provided by the applicant (making it credible and putting it into context). In particular, these may be various types of reports, analyses, expert opinions and data specifying the needs and possibilities with regard to the planned investment. At this point, it is worth pointing out that one question that appears in both versions of the IOWISZ form is filled in automatically by the system. This question concerns the anticipated duration of the investment ('What is the anticipated duration of the investment?')<sup>13</sup>. After evaluating the answers within the framework of each question, the points scored are multiplied by the weights assigned to each question and then calculated according to an imposed

<sup>&</sup>lt;sup>12</sup> One standard page in Word is 1,800 characters or 2,500 characters of continuous text, and 1 typed page is 1,800 characters.

<sup>13</sup> In this question, the IOWISZ system uses the so-called investment lead time adjustment factor (6%) as a weight.

algorithm (different for each of the two types of investment distinguished, i.e. developmental and replacement/modernisation). In this way, the applicant gets the final score which translates into a positive or negative assessment of the planned investment. The point threshold for obtaining a positive opinion is 6,200 points or 950 points depending on the type of investment. In the case of the Applications for Investments in the Health Sector for investments resulting in a change in the scope of health care services provided, the minimum number of points to be scored for a positive opinion is 6,200 ('developmental'/modernisation' investment). In the case of the Instrument for Evaluation of Applications for Investments in the Health Sector for investments that do not affect the scope of health care services provided, the minimum number of points to be scored for a positive opinion 950 (a 'replacement' investment).

Taking into account the imposed restrictions on the comprehensiveness of answers and the introduction of uniform investment assessment criteria (questions) when applying for an opinion in the case of a planned investment, applicants (investors) should choose and describe the planned investment project in such a way as to obtain the highest possible number of points and, consequently, increase their chances of obtaining a positive opinion. It turns out that due to the specificity of the IOWISZ form, it is experience in the correct filling it in that plays a significant role in the final assessment as well as the ability to meet the expectations of the authorities assessing the application.

# Procedure – opinion on reasonableness of investment in the IOWISZ system

An application for an opinion on the reasonableness of an investment may be submitted by an entity (1) performing a medical activity or (2) one only intending to perform this type of activity, or (3) one intending to establish a medical entity. The application for an opinion is submitted to the body issuing the opinion via the IOWISZ system (only and exclusively in electronic form). The submission of an application for an opinion is subject to a non-refundable fee of PLN 4,000. This fee constitutes revenue of the Medical Fund referred to in the Act of 7th October 2020 on the Medical Fund and is paid to the Medical Fund's account. Confirmation of payment of the fee must be attached to the application. The authority issuing the opinion is a Provincial Governor competent with regard to the address of the investment (the system automatically selects the competent Provincial Office according to the previously indicated address). In addition to the provincial governor, the Minister of Health is another body issuing opinions on the reasonableness of investments. Depending on the authority, whether it is the Provincial Governor or the Minister of Health, the form

will be directed either to the competent Provincial Office or to the Ministry of Health. The application is submitted to the Provincial Governor in the case of an investment with an estimated value as of the date of submission of the application exceeding PLN 2m, but less than PLN 50m<sup>14</sup>. Applications for an opinion with an estimated value exceeding PLN 50m is obligatorily submitted to the Minister of Health<sup>15</sup>. There is a Commission for the Assessment of Investment Applications in the Health Sector under the Minister competent for health, which is an opinion and advisory body of that Minister<sup>16</sup>. Applications are considered in chronological order of receipt date. The body issuing the opinion checks the completeness of the application, and in the event of any formal deficiencies, it calls for rectification thereof within 7 days from the date of service of the call, failing which the application will not be processed. Within 7 days from the date of submitting a complete application for an opinion, the Provincial Governor transfers, via the IOWISZ system, the IOWISZ form filled in by the applicant the competent Director of a provincial branch of the National Health Fund for their opinion. Where the body issuing the opinion is the Minister of Health, the application is sent to the President of the NFZ for an opinion. Thus, prior to the issuing of the opinion by a Provincial Governor or the Minister of Health, the directors of provincial branches of the National Health Fund or the president of the NFZ, respectively, give their opinion on the investment. The Director of the Provincial Branch of the NFZ or the President of the NFZ, respectively, give their (internal) opinion within 14 days from the date of service of the application, by means of the IOWISZ system<sup>17</sup>, and then forwards the aforementioned opinion to the competent Provincial Governor or the Minister of Health, also by means of the IOWISZ system. On this basis, the body of first instance (Provincial Governor or Minister of Health) issues an opinion which is then delivered to the applicant. The assessment of applications in the IOWISZ system is therefore like a cascade. The procedure for obtaining an opinion (positive or negative) on the planned investment takes no longer than 45 days from the date of submitting a complete application<sup>18</sup>. A positive opinion on the reasonableness of the investment is valid for 3 years from the date of its issuance<sup>19</sup>. Importantly, the submission of applications for the issuance of an opinion is subject to criminal liability for making false statements. The applicant is obliged to submit a declaration with the following content, 'I am aware of the criminal liability for making a false statement'.

The legislator has provided for an appeal procedure (protest) in event that the applicant does not agree with the opinion obtained in the first instance (the opinion is negative). In the protest, the applicant indicates, inter alia, the criteria with the assessment of fulfilment of which the applicant disagrees.

<sup>&</sup>lt;sup>14</sup> The legislator set a lower limit of PLN 2m that obliges the healthcare provider to undergo an evaluation of the investment being prepared within the IOWISZ system. This is supposed to be a facilitation for healthcare providers, who often carry out replacement and modernisation investments of small financial amounts and who would also have to go through the procedure in the IOWISZ system if the aforementioned limit did not exist. This seems to be a rational solution. Thus, the IOWISZ system focuses on significant (strategic) investments in health care.

<sup>&</sup>lt;sup>15</sup> Initially, the thresholds requiring investment assessment were set at PLN 3m for inpatient investment and PLN 2m for outpatient care. These amounts referred to the total capital expenditure over two consecutive years.

<sup>&</sup>lt;sup>16</sup> Members of the Commission are not entitled to remuneration.

<sup>&</sup>lt;sup>17</sup> The opinion is based, inter alia, on the national plan (Minister of Health), the provincial plan (Provincial Governor), maps of health needs, and data from the Register of Healthcare Providers.

<sup>&</sup>lt;sup>18</sup> Where an entity is requested to rectify formal deficiencies, the 45-day period runs from the beginning. The system assigns a new application number, which is a correction of the previous one.

<sup>&</sup>lt;sup>19</sup> A positive opinion on the reasonableness of an investment issued as of 1st January 2021 is valid for three years from the date of issue. In contrast, opinions issued before 1st January 2021 are valid indefinitely.

The protest must be submitted to the Minister of Health through a Provincial Governor within 14 days from the date of service of the opinion. The protest is not subject to a fee. The Provincial Governor then forwards the protest to the Minister of Health within 14 days from the date of its receipt. The Minister of Health considers the protest within 30 days from the date of service. It should be noted that within 14 days from the date of receipt of the protest, the Provincial Governor may change their opinion to a positive one. If this is the case, they do not forward the protest to the Minister of Health. After the protest has been considered, the applicant receives a positive opinion of the second instance on the reasonableness of the investment, or the negative opinion on the matter is maintained.

After the appeal procedure before the Minister of Health has been exhausted, where the negative opinion on the protest is maintained, the entity that received the opinion may file a complaint to the Provincial Administrative Court within 14 days from the date of service of the opinion on the protest directly to the competent Provincial Administrative Court together with complete documentation in the case (a complaint filed after this deadline will not be considered). The Provincial Administrative Court decides the case within 30 days from the date of lodging the complaint. The entity that filed the complaint with the Provincial Administrative Court or the Minister of Health may file a cassation complaint with the Supreme Administrative Court within 14 days from the date of service of the decision of the Provincial Administrative Court together with complete documentation in the case. A complaint lodged after this deadline will not be considered. The Supreme Administrative Court will decide the case within 30 days from the date of filing the complaint.

### Statistics – IOWISZ

The largest number of positive decisions (opinions) on the reasonableness of investments (OCI) in the period under consideration, i.e. 2016 – Nov 2023, were issued by the Ministry of Health (487), which is almost 4 times more than the average number of positive decisions issued by Provincial Offices (125). The largest number of positive decisions on the reasonableness of investments (above the average) in the period under consideration was issued by six Provincial Offices (Mazowieckie, 273; Wielkopolskie, 195; Warmińsko-Mazurskie, 172; Śląskie, 161; Małopolskie, 158; and Dolnośląskie, 127). On the other hand, the fewest positive opinions were issued by the Offices in the Podkarpackie (62) and Lubuskie (38) Provinces. Thus, one should emphasise the significant geographical variation in the number of positive decisions issued in the IO-WISZ system depending on the province. Of all the seventeen entities authorised to issue decisions on the reasonableness of investments in the IOWISZ system, the largest number of positive opinions were issued by the Ministry of Health (i.e. 487); nevertheless, it was 16 Provincial Offices that granted the vast majority of positive evaluations in the IOWISZ system in the period analysed, i.e. over 80% (1999 decisions) (Figs. 1 and 2).

The number of positive assessments issued by the Ministry of Health ranged from 11.8% (2017) to 27.3% (2022) relative to all the positive decisions issued in the IOWISZ system by all the eligible entities. The remainder of the positive assessments in the IOWISZ system were issued by Provincial Offices, from 72.7% (2022) to 88.2% (2017). In the period under consideration (i.e. 2016 – Nov 2023), a relatively increased number of positive applications issued by Provincial Offices

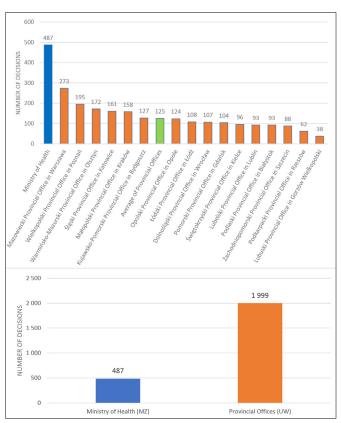


FIGURE 1. Aggregate number of positive decisions (opinions) on the reasonableness of investments (OCI) issued in the IOWISZ system by the Ministry of Health (MZ) and Provincial Offices (UW) in Poland in 2016 – Nov 2023.

Source: own work based on data from the Ministry of Health (Department of Analyses and Strategies), Dec 2023

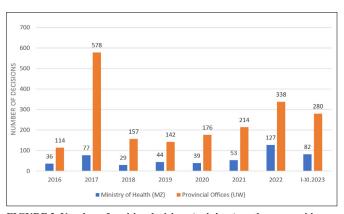


FIGURE 2. Number of positive decisions (opinions) on the reasonableness of investments (OCI) issued in the IOWISZ system in Poland in 2016 – Nov 2023 broken down between the Ministry of Health (MZ) and the Provincial Offices (UW).

Source: own work based on data from the Ministry of Health (Department of Analyses and Strategies), Dec 2023

in 2017 (+336.7% YoY) and 2022 (+74.2% YoY) could be observed, which was due to some regulatory changes affecting the functioning of the IOWISZ system (the first full calendar year of the operation of the system (2017) and the enforcement of the 5-year exclusion from contracting with the NFZ where an investment was carried out without obtaining a positive opinion). A similar trend was observed for the number of applications positively assessed by the Ministry of Health, also in 2017 (+113.9% YoY) and 2022 (+139.6% YoY). In the remaining years, the number of positively assessed applications in the IOWISZ system was relatively stable in the case of both Provincial Offices (about 181 per year) and the Ministry of Health (about 47 per year) (Figure 3).

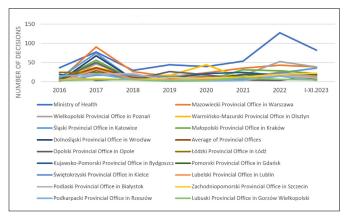


FIGURE 3. Number of positive decisions (opinions) on the reasonableness of investments (OCI) issued in the IOWISZ system by the Ministry of Health (MZ) and Provincial Offices (UW) in Poland in 2016 – Nov 2023. Source: own work based on data from the Ministry of Health (Department of Analyses and Strategies), Dec 2023

The vast majority of applications submitted for issuing an opinion on the reasonableness of investments in 2016 – Nov 2023 were considered positively, both by the Ministry of Health (75%) and the Provincial Offices (80%), which demonstrates a very high level of preparation of the planned investments that applicants decided to have evaluated in the IOWISZ system. The highest share of positive decisions in the period analysed was in the Opolskie (ca. 95%) and the Warmińsko-Mazurskie (ca. 94%) Provinces, while the least positive evaluations were received by applications submitted in the Podkarpackie (ca. 65%) and the Łódzkie (ca. 67%) Provinces. As far as the individual Province Offices are concerned, there were years in which even 100% of applications submitted received a positive assessment in the IOWISZ system. On the other hand, there were also years in which the percentage of positively assessed applications in the NEISZ system in the individual Provinces reached a value of less than 35% so the situation in this respect varied significantly (Table 2).

# **CONCLUSION**

After several years of operation of the IOWISZ system (since September 2016), it should be concluded that it has contributed to a significant improvement in the efficiency of public funds spending and rationalisation of capital expenditure in the Polish healthcare system.

Investing in health care has been regulated (organised) and correlated with the state health policy. Investments in health care are more and more often implemented in accordance with the maps of health needs (regional and national) and regional health and development policies (priorities for regional health policy), and consequently with the actual, diverse and changing health needs of the population in each region of the country.

The functioning of the IOWISZ system has contributed to an improvement in the quality of the investment planning process and thus to a more economical, reliable and targeted spending of public funds (including EU funds) on investments in the healthcare sector. More and more often, investments are made following a sound analysis of the actual health needs of local communities rather than the ambitions of local decision-makers. Moreover, more and more frequently the chance of signing a contract with the National Health Fund is considered in the investment decision-making process so that once the investment is made, its full potential can be utilised. Investment decisions are increasingly rarely made on an ad hoc basis, without a sound review of the health needs of patients and despite the lack of interest on the part of the NFZ to provide funding for the resulting extended range of health services.

A key motivating factor for undergoing assessment in the IOWISZ system is the possibility of obtaining a contract with the NFZ for the provision of healthcare services and thereby obtaining public funding for investment. Otherwise, the healthcare entity is not eligible to apply for a contract with the NFZ or have the existing one extended in order to obtain

TABLE 2. Share of applications for issuing a decision/opinion on the reasonableness of investments (OCI) positively assessed in the IOWISZ system by the Ministry of Health (MZ) and Province Offices (UW) in Poland in 2016 – Nov 2023.

Entity issuing a decision/opinion on the reasonableness of an investment (OCI)	2016	2017	2018	2019	2020	2021	2022	I-XI.2023	TOTAL
Ministry of Health (MZ)	82%	80%	76%	80%	68%	82%	80%	61%	75%
Provincial Offices (UW)	78%	82%	83%	60%	85%	84%	85%	75%	80%
Dolnośląski Provincial Office in Wrocław	90%	100%	88%	64%	95%	80%	77%	29%	74%
2. Kujawsko-Pomorski Provincial Office in Bydgoszcz	33%	83%	88%	50%	75%	78%	89%	74%	77%
3. Lubelski Provincial Office in Lublin	33%	76%	78%	31%	100%	100%	88%	74%	74%
4. Lubuski Provincial Office in Gorzów Wielkopolski	100%	83%	100%	100%	60%	83%	100%	80%	86%
5. Łódzki Provincial Office in Łódź	73%	49%	62%	29%	86%	100%	86%	94%	67%
6. Małopolski Provincial Office in Kraków	60%	80%	67%	100%	75%	100%	97%	91%	86%
7. Mazowiecki Provincial Office in Warszawa	83%	89%	81%	48%	82%	83%	86%	81%	82%
8. Opolski Provincial Office in Opole	86%	93%	80%	100%	100%	100%	100%	100%	95%
9. Podkarpacki Provincial Office in Rzeszów	78%	91%	50%	8%	100%	100%	82%	30%	65%
10. Podlaski Provincial Office in Białystok	67%	69%	91%	50%	71%	80%	74%	56%	73%
11. Pomorski Provincial Office in Gdańsk	80%	91%	88%	33%	100%	79%	94%	95%	84%
12. Śląski Provincial Office in Katowice	83%	87%	86%	100%	100%	75%	79%	67%	81%
13. Świętokrzyski Provincial Office in Kielce	40%	100%	94%	72%	80%	70%	96%	100%	87%
14. Warmińsko-Mazurski Provincial Office in Olsztyn	93%	97%	100%	100%	96%	90%	83%	92%	94%
15. Wielkopolski Provincial Office in Poznań	-	71%	80%	47%	61%	59%	79%	69%	68%
16. Zachodniopomorski Provincial Office in Szczecin	100%	80%	100%	91%	75%	100%	86%	96%	90%

public funds for the completed investment (exclusion for 5 years). Moreover, more and more often obtaining a positive opinion on the reasonableness of an investment is a prerequisite for obtaining public or foreign funding for the implementation of an investment.

The IOWISZ system is viewed positively by the majority of entities operating in the healthcare system due to its methodical attempt to make the assessment of the reasonableness of the planned investments more objective. However, it is still not an ideal tool. Some shortcomings can be pointed out with regard to the assumptions, such as basing the assessment on a subjective assessment of experts that may be susceptible to influence, or the relatively high dependence on expert assessments and too little on hard indicators. Nevertheless, it should be pointed out at this point that the legislator made an attempt to make the process of forming an opinion within the framework of the established system more objective by establishing multiple (cascade) evaluations of investments according to multiple criteria.

In summary of the above, the IOWISZ system should be considered as an extremely useful and necessary tool supporting decision-making processes and allowing for effective and efficient management of the supply of resources in the health care system. The IOWISZ system should continue to be improved and should remain, as far as possible, linked to and coherent with the maps of health needs and the priorities set for the state's health policy.

### REFERENCES

- 1. Ustawa z dnia 27 sierpnia 2004 r. o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. 2022, poz. 2561).
- 2. Hart JT. The Inverse Care Law. The Lancet. 1971;7696(297):405-12.
- Włodarczyk C. Wprowadzenie do polityki zdrowotnej. Warszawa: Wolters Kluwer Polska; 2010. p. 1-228.
- Najwyższa Izba Kontroli (NIK). Informacja o wynikach kontroli. Zakup i wykorzystanie wysokospecjalistycznej aparatury medycznej w podmiotach leczniczych. Warszawa: NIK; 2022. p. 1-179.
- Ustawa z dnia 21 lipca 2016 r. o zmianie ustawy o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych (Dz. U. 2016; poz. 1355).
- Regulation of the Ministry of Health of 15th September 2016 on the application form of the Instrument for Evaluation of Applications for Investments in the Health Sector, Journal of Laws 2016, item 1539.
- Najwyższa Izba Kontroli (NIK). Informacja o wynikach kontroli. Raport: System ochrony zdrowia w Polsce – stan obecny i pożądane kierunki zmian. Warszawa: NIK; 2019. p. 1-182.
- Ustawa z dnia 12 kwietnia 2018 r. o zmianie ustawy o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych oraz niektórych innych ustaw (dz. U. 2018, poz. 1128).
- Rozporządzenie Ministra Zdrowia z dnia 11 lipca 2018 r. w sprawie formularza Instrumentu Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia dla inwestycji skutkujących zmianą zakresu udzielanych świadczeń opieki zdrowotnej (Dz. U. 2018, poz. 1347).
- 10. Rozporządzenie Ministra Zdrowia z dnia 11 lipca 2018 r. w sprawie formularza Instrumentu Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia dla inwestycji pozostających bez wpływu na zakres udzielanych świadczeń opieki zdrowotnej (Dz. U. 2018, poz. 1348).
- Rogowski W. Rachunek efektywności inwestycji. Wyzwania teorii i potrzeby praktyki. Kraków: Wydawnictwo Nieoczywiste; 2016. p. 1-672.
- Ustawa z dnia 10 grudnia 2020 r. o zmianie ustawy o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych oraz niektórych innych ustaw (Dz.U. 2020, poz. 2345).
- 13. Rozporządzenie Ministra Zdrowia z dnia 1 lutego 2021 r. w sprawie formularza Instrumentu Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia dla inwestycji pozostających bez wpływu na zakres udzielanych świadczeń opieki zdrowotnej (Dz.U. 2021, poz. 249).

- 14. Rozporządzenie Ministra Zdrowia z dnia 1 lutego 2021 r. w sprawie formularza Instrumentu Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia dla inwestycji skutkujących zmianą zakresu udzielanych świadczeń opieki zdrowotnej (Dz.U. 2021, poz. 252).
- 15. Rozporządzenie Ministra Zdrowia z dnia 28 grudnia 2021 r. w sprawie formularza Instrumentu Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia dla inwestycji skutkujących zmianą zakresu udzielanych świadczeń opieki zdrowotnej (Dz. U. 2021, poz. 2487).
- 16. Rozporządzenie Ministra Zdrowia z dnia 28 grudnia 2021 r. w sprawie formularza Instrumentu Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia dla inwestycji pozostających bez wpływu na zakres udzielanych świadczeń opieki zdrowotnej (Dz. U. 2021, poz. 2488).
- Centrum e-Zdrowia. Podręcznik użytkownika Systemu Instrument Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia (IOWISZ). Warszawa: Centrum e-Zdrowia; 2022. p. 1-36.
- Małopolski Urząd Wojewódzki w Krakowie (MUW). [https://www.malopolska.uw.gov.pl/doc/INFORMACJE\_DEPARTAMENTU.pdf] (access: 15.06.2023).
- Garber S, Gates SM, Keeler EB, et al. Redirecting Innovation in U.S. Health Care: Options to decrease spending and increase value. Santa Monica: RAND Corporation; 2014. p. 1-130.
- 20. Bhattacharya J, Hyde T, Tu P. Health Economics, Bloomsbury Publishing, London: Red Globe Press; 2013. p. 1-624.
- Rudawska I. Opieka zdrowotna. Aspekty rynkowe i marketingowe. Warszawa: Wydawnictwo Naukowe PWN; 2007. p. 1-212.
- 22. Iłowiecka K. Analiza i ocena narzędzi regulacji podaży świadczeń opieki zdrowotnej określonych w ustawie o świadczeniach opieki zdrowotnej finansowanych ze środków publicznych. Ubezpieczenia Społeczna. Teoria i praktyka. 2016;120(3):67-85.
- Ministerstwo Zdrowia (MZ). Projekt Rozporządzenia Ministra Zdrowia z dnia 27.07.2016 r. w sprawie formularza Instrumentu Oceny Wniosków Inwestycyjnych w Sektorze Zdrowia. Warszawa: Rządowe Centrum Legislacji; 2016.

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