RSA in Drugs Reimbursement System in Poland and Abroad

Executive Summary

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Introduction

When compared with other EU Member States, also the „new ones", expenditure on healthcare in Poland is low. However, both patients and doctors expect quick and extensive access to new diagnostic and therapeutic methods. The number of new technologies increases every year and the media effectively inform the public about their presence and effects. The significant gap between the system's financial capacity and social expectations forces stakeholders to urgently search for new solutions which would enable them to provide modern technologies to those who need them. Control of spending given the obvious budget constraints an the need to simultaneously ensure value pricing is implemented in many countries through modern financial instruments, including risk-sharing instruments, which are being used more and more frequently to increase the availability of treatment, also in Poland.

The main objective of the „Risk-sharing instruments in Poland and abroad" project was conducting an analysis of risk-sharing agreements (RSA) used in Poland and providing practical recommendations on their further development based on other countries' experience. Risk-sharing instruments are presently one of the most important reimbursement tools which allow for providing Polish patients with access to modern, effective and at the same time expensive health technologies. Expanding the range of RSA types which are actually used will allow to further improve the quality and effectiveness of treatment of Polish patients and ensure rational use of available public funds, thus securing the financial stability of the public payer. During the project information on system of RSA notions, their classifications and types along with examples from other countries was gathered and presented, the mechanisms of their creation and implementation were discussed. The information has been collected for the purpose of increasing stakeholder awareness and expertise, which in turn is likely to improve implementation of the instruments to the healthcare system.

The final Report is the result of many months of work and commitment of several dozens of people representing public institutions (including the Ministry of Health, the National Health Fund and the Agency for Health Technology Assessment and Tariff System), pharmaceutical companies, clinicians, drug distributors as well as academic and market experts. This large group participated in regular meetings in order to discuss the current state of play and future development of risk-sharing instruments in Poland.

RSA in Poland – presently

A significant increase of expenditure on drugs financed from public funds has been recorded following the increase of outlays on healthcare since 2004[1]. Public administration bodies faced the need to find solutions which would ensure sustainability of the public payer's budget while increasing the patients' access to new therapies. Low spending on healthcare in Poland, including, in particular, very low public spending on prescription drugs (in 2011 it amounted to 0.6% of Poland's GDP)[2] does not offer too much leeway in terms of financing new health technologies, which are often much anticipated. As international cooperation developed following Poland's accession to the European Union and the need to adjust Polish provisions on financing pharmaceuticals from public funds to EU standards[3], the Ministry of Health started to carefully consider modern solutions which at that time were being developed in other Member States. These actions coincided with a significant increase of interest in expensive therapies, including treatment for rare diseases, a lot of which would obtain EU market authorisation in connection with the Regulation on orphan medicinal products and be very costly[4]. The European Commission's communication and the Council of the European Union's recommendations[5,6] resulted in the increased demand for action in this area.

Risk-sharing instruments have been introduced by the Act of 12 May 2011 on the reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices (hereinafter referred to as the Act on reimbursement)[7]. Introducing RSAs to reimbursement decisions issued by the Minister of Health was a natural consequence of the need to reconcile the patients' growing needs and the payers' limited financing capacity. At the same time, this solution corresponds with the direction of the changes adopted in the drug reimbursement system and made their formal implementation possible.

The Act on reimbursement allows for an open scope of solutions which may be introduced as a risk sharing instrument. These may consist in, among others:

- making the applicant's income dependant on the achieved health outcomes (outcome-based schemes);
- making the statutory ex-factory price dependant on ensuring by the applicant supplies at a reduced price of a drug, foodstuff for particular nutritional uses and medical device, which was agreed upon during negotiations (rebates);
- making the statutory ex-factory price dependant on the sales volume of a drug, foodstuff for particular nutritional uses and medical device (price-volume agreement),
- making the statutory ex-factory price dependant on refunding a part of the received reimbursement to the public payer (payback schemes) or
- determining other reimbursement conditions resulting in the increase of availability of guaranteed services or reduction of costs of these services[8].

1 Explanatory memorandum to the draft Act on the reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices – Sejm paper No. 3491

2 Bogusławski S, Smaga A, Falkiewicz B, Kiełczewski T, Burliński P, Matczak M, Czarnuch M, Pieklak M, Łajszczak Sz. Wpływ ustawy o refundacji leków na dostęp pacjenta do farmakoterapii, budżet NFZ oraz branżę farmaceutyczną. Ocena skutków regulacji. (The impact of the Act on reimbursement on patient access to pharmacotherapy, the NHF budget and the pharmaceutical industry. Assessing the effects of the regulation.) Infarma. Warsaw 2014 .

3 Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ No L 40 of 11. 2. 1989 p. 8), hereinafter also referred to as the "transparency directive"

4 Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, 22.1.2000, p. 1)

5 Communication from the Commission to the European Parliament, The Council, The European Economic Committee and the Committee of the Regions on Rare Diseases: Europe's challenges [COM (2008) 679] – http://ec.europa.eu/health/ph_threats/non_com/docs/rare_com_en.pdf

6 Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02) – http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:151:0007:0010:EN:PDF

7 Journal of Laws of 2011, No. 122, item 696, as amended.

8 Article 11 (5) of the Act on reimbursement

By and large, the last listed type makes it possible to introduce complex tools used worldwide, which correspond to financed-based or performance-based risk-sharing agreements (outcome-based schemes or conditional reimbursement). However, the actual range of instruments used and the manner of their implementation depends also on the regulations described in separate legislation governing specific fields, e.g. public procurement or personal data processing. Their implementation is dependent also on practical aspects of management of the health services settlement system operated by the National Health Fund.

In different countries these instruments allow for reimbursement of new health technologies within complex RSA applied (in particular outcome-based schemes and conditional reimbursement) thanks to the fact that the payer pays for the health effect and saves money when the effect has not been proven or is insufficient. For this objective to be achievable, RSA require well-regulated and transparent cooperation between the payer, marketing-authorisation holders, healthcare providers (mostly hospitals), doctors and pharmaceutical distribution. RSA implementation and execution processes cannot be effectively carried out without proper planning and continuous monitoring of their course.

Introduction of risk-sharing instruments in Poland by way of the Act on reimbursement was intended to achieve several specific purposes (as indicated in the explanatory memorandum to the Act on reimbursement)[9]:

- providing access to new health technologies at a cost corresponding to the public payer's capacity;
- increasing the range of available tools aiming at reduction of public spending on healthcare within the framework of negotiations held by the Economic Commission with the applicants;
- limiting the negative effects of the reference pricing systems commonly used by UE Member States, which is based on comparisons of pharmaceutical prices between specific countries – the prices in Poland are among the lowest ones in Europe, which constitutes the applicants' significant argument against further decreases of statutory prices, as that would result in a domino effect – decreasing prices in other countries and deteriorating of the situation related to parallel export[10].

Due to the confidentiality of risk-sharing instruments, there are no publicly available statistics on their practical use in Poland. According to information published by the National Health Fund, as a result of payback the Fund received: at the end of 2013 about PLN 313 million, i.e. PLN 124.2 million in 2012 and PLN 188.7 million in 2013. However, these amounts do not fully reflect the effects of the concluded instruments and they should be considered as underestimated in comparison to the actual financial effect of the applied RSA, if only due to the failure to take into account rebates granted on their basis.

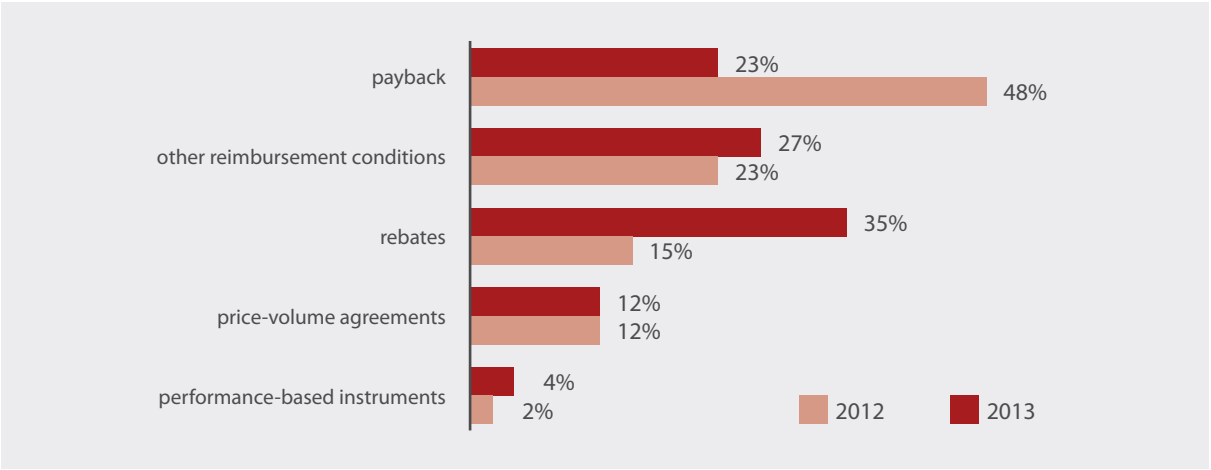
The current practice of the Minister of Health in use since the Act on reimbursement came into force suggests that the instruments are mainly used to reduce public expenditure with the greatest possible control over the NHF's budget allocated for financing new therapies. A result of such an approach is the extensive use of finance-based instruments, consisting in determining prices for healthcare providers at a lower level than those indicated in the announcement of the Minister of Health or payback (thereby lowering the actual cost to the National Health Fund), which in part led to achieving the third objective specified in the explanatory memorandum to the Act. At the same time, their potential for other purposes specified in the Act, in particular to ensure access to modern therapies, remains the subject of discussions and may be used in the future.

[9] Explanatory memorandum to the draft Act on the reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices – Sejm paper No. 3491

[10] Following negotiations, prices of many global brands were reduced to the European lowest level. This is a very strong incentive for the distribution sector to legally or illegally export certain drugs abroad. As a consequence, the availability of these drugs diminishes drastically, which is very difficult and burdensome for patients. Bogusławski S, Smaga A, Falkiewicz B, Kiełczewski T, Burliński P, Matczak M, Czarnuch M, Pieklak M, Łajszczak Sz. Wpływ ustawy o refundacji leków na dostęp pacjenta do farmakoterapii, budżet NFZ oraz branżę farmaceutyczną. Ocena skutków regulacji. (The impact of the Act on reimbursement on patient access to pharmacotherapy, the NHF budget and the pharmaceutical industry. Assessing the effects of the regulation.) Infarma. Warsaw 2014 .

The RSA mechanism most commonly proposed in reimbursement applications forwarded to AOTMIT in 2012 was the instrument consisting in making the ex-factory price dependent on the applicant ensuring supplies at a reduced amount determined in negotiations – this mechanism accounted for nearly 35% of all submitted proposals. In 2013 almost every second (48%) proposal put forward by applicants regarded an agreement making the statutory ex-factory price dependent on returning a part of obtained reimbursement to the public payer, i.e. a payback scheme. The above figures indicate that MAHs have adopted to the practice regarding instruments assumed by the Minister of Health, which is primarily the result of the first negotiations held with applicants, dating back to 2011, the time the first list of products reimbursed under the Act on reimbursement was being created.

Chart 1. RSA types proposed in the analyses assessed by AOTMiT



Particular elements of the process of developing and executing RSA are presented in the Report, including:

- preparation and submission of the application by the applicant;
- preparation of the verification analysis, the position of the Transparency Council and recommendation of the President of the Agency for Health Technology Assessment and Tariff System;
- negotiations with the Economic Commission;
- issuance of the reimbursement decision;
- implementation by the National Health Fund, including conclusion of agreements on provision of healthcare services;
- participation in the implementation by healthcare providers, including: acquisition of drugs and provision of benefits to beneficiaries;
- control of execution of risk-sharing instruments.

Development and execution of RSA in the Polish healthcare system involves the engagement of many stakeholders whose participation depends on the scope and type of the risk-sharing instrument. These stakeholders may include:

- the Minister of Health;
- the National Health Fund;
- healthcare providers, including the broadly understood medical personnel,
- entities in charge of pharmacies
- entrepreneurs in charge of pharmaceutical wholesalers;
- applicants who have obtained a decision on reimbursement and the statutory ex-factory price.

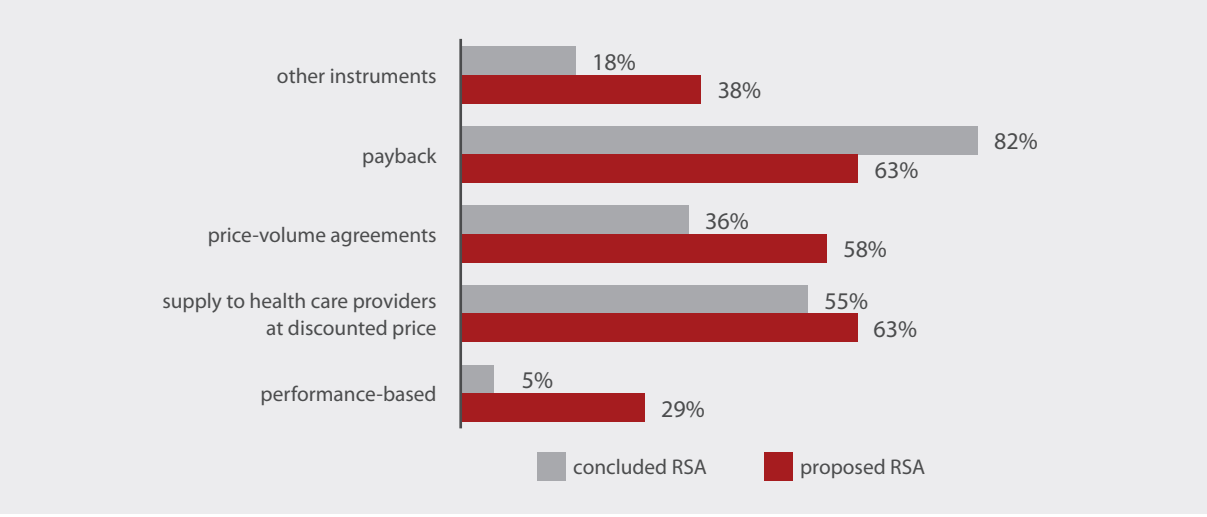
In practice, negotiations with the Economic Commission are the most important step of reimbursement proceedings from the perspective of introducing risk-sharing instruments. These negotiations regard detailed reimbursement conditions, including the content of the RSA, their impact on the payer's budget and feasibility. Only after the negotiations have taken place does the Minister of Health de facto decide on the reimbursement and also decides whether to accept any instrument.

The National Health Fund – both the Central Office and the Regional Branches – play a key role in the implementation and execution of risk-sharing instruments. This is due to the fact that, in accordance with the Act of 27 August 2004 on healthcare services financed from public funds, the President of NHF is responsible for monitoring, supervising and controlling the execution of the concluded instruments and reporting to the Minister of Health on their execution by the applicants.

The Act on reimbursement provides significant leeway for development of cooperation between the applicants and public administration authorities for the purpose of increasing patients' access to the latest treatments. However, in practice the implementation of instruments is dependent on the involved entities' actual organisational and technical capacities and the applicable provisions of law regulating particular specific fields (e.g. public procurement), and thus the configuration and flexibility of the system.

According to results of surveys conducted in May 2014 among General Managers of 36 pharmaceutical companies whose products account for 69% of the total reimbursement expenditure (2013), in the opinion of 69% of respondents, the introduction of risk-sharing instruments is favourable for the Polish pharmaceutical market. 82% of companies obtained a reimbursement decision determining the refund of a part of the received reimbursement and 55% a guarantee of supplies at a discounted price. Only 5% of respondents said that performance-based solutions had been introduced. Results of that study are presented in the graph below[11].

Chart 2. Types of RSA proposed by applicants and agreed upon in the decision of the Minister of Health



The first three years of the Act on reimbursement being in force have shown that simple financial-based risk-sharing instruments are a very effective tool for managing access to new therapies, with essentially the payer's full control over the expenditure. That is why they are so commonly used today. It seems that complex instruments should be an important complement to the currently existing solutions. Other countries' experience indicates that simple finance-based schemes are the ones introduced most often, however there are situations in which performance-based schemes constitute an optimal solution, or even the only one. Their implementation goes beyond the purely financial aspects and the settlement system, which are the current focus for both AOTMiT and the Economic

[11] Results of that survey were presented at the Project-opening conference in June 2014.

Commission. All stakeholders in the pharmaceutical reimbursement system agree that there is a strong need for further development of RSA schemes, both in terms of simple instruments (improving the functioning and management of simple finance-based schemes) and complex instruments (both finance-based and performance-based). The main areas of RSA development should be as follows:

- expanding the scope of RSA types for specific treatments, which would help increase the number of eligible patients,
- expanding the use of RSA not only for control of expenditure but also for verification of the legitimacy of using new technologies in terms of their effectiveness and safety,
- modifying and expanding the functionality and interoperability of tools used for accounting and reporting data to the payer, including designing a structurally coherent system for collecting not only data on usage but also an actual assessment of efficacy of specific therapies in the Polish population,
- creating a platform for dialogue between public institutions and private entities, with the purpose of an on-going exchange of views on developing, implementing and controlling the execution of RSA in Poland. This dialogue should also involve doctors, in order to enable them to comprehend the difficulties which assessing the reasonableness of expenditure on medical treatment in the context of assessing health effects entails.

Recommendations

The work carried out within the project framework, in particular the dialogue between stakeholders conducted during the project meetings allowed for developing two types of recommendations:

- general recommendations, related to the development of risk-sharing instruments in Poland and communication between stakeholders;
- specific recommendations, related to selected aspects of risk-sharing instruments. The recommendations in question include both issues related to currently applied solutions, as well as those related to schemes which are being successfully used abroad and which have not yet been implemented on a larger scale in Poland, despite the interest of all parties:
  - templates and guidelines regarding risk-sharing instruments;
  - implementing risk-sharing schemes – in particular with regard to cooperation with stakeholders;
  - confidentiality of risk-sharing instruments;
  - using in-kind rebates;
  - implementing instruments based on conditional reimbursement;
  - implementing outcome-based instruments;

General recommendations – development of risk-sharing instruments

For the sake of the future of risk-sharing instruments in Poland, it is vital to maintain continuous dialogue between all parties involved in their implementation. The development of risk-sharing instruments is dependent not only on the existence of a legal basis describing their functioning, but also on making practical and sometimes very complex management actions in terms of implementation. Until now, a broader discussion about risk-sharing instruments in Poland was only sporadic and was largely conducted only as part of ongoing reimbursement proceedings with regard to specific products. As a result, the currently functioning instruments are duplicates of the few initially introduced schemes. A dialogue regarding practical, concrete implementation issues will help address difficulties in the preparation and execution of RSA, both for the public and private entities. Such actions may also help increase trust between the parties, which would significantly facilitate the implementation of complex risk-sharing schemes.

Recommendations:

1. It is necessary to continue work on RSAs by way of creating a working group on development of complex risk-sharing instruments in Poland, which would include representatives of the MoH, NHF, AOTMiT, the pharmaceutical industry, clinicians, healthcare providers, distributors and experts; in the future the group could be affiliated with the Minister of Health.
2. Further discussions should include different RSA models which will correspond to the needs of all stakeholders – the discussion should consider not only on the concept in general, but above all detailed solutions related to their implementation and execution.
3. New legal solutions which would keep up with the development of RSA models in Poland and which would enable their effective implementation and settlement should be searched for and introduced.
4. It is necessary to maintain a proper and detailed analysis of the number, types and impact of the RSA types on the National Health Fund's budget, as well as periodically publish such information.
5. It is recommended to conduct training courses and workshops in the scope of procedures and practical aspects of implementing RSA intended for AOTMiT, the Transparency Council and the Economic Commission as well as the applicants.

General recommendations – organisation of the process

Searching for prospective solutions is necessary also for purely practical reasons. Currently, the administrative burden of RSA rests in practice mainly with the National Health Fund, which is responsible both for settling the instruments, as well as their monitoring and control. There are areas which require increased effort in order to ensure effective functioning of instruments – particularly in terms of exchange of information. NHF's special role consists also in acting as liaison between different stakeholders. The Fund's position, competencies and capabilities will need to evolve along with the development of instruments.

Recommendations:

1. Creation of an RSA coordinator function within NHF structures (as an independent position or acting with the support of a relevant team, depending on the needs resulting from the number and type of implemented risk-sharing instruments).

   The coordinator would be chiefly responsible for cooperation with the MoH and Regional Branches of the NHF with regard to implementation of the RSA as well as collection and exchange of information on current issues related to the implementation of already approved risk-sharing instruments. The coordinator would also ensure harmonisation of ongoing activities carried out by the various NHF Regional Branches and tasks transferred to other entities for implementation, including the possible settlement of the problems in dealing with healthcare providers. The RSA coordinator function should be completely separated from the reimbursement decision-making process, including planning and negotiating of individual instruments.
2. "Institutionalisation" of communication on the development and implementation of RSAs between the MoH and NHF by way of appointing persons responsible for RSA who would be actively involved in that topic in each of those institutions. In NHF this function would be served by the RSA coordinator.
3. Strengthening NHF's structures and resources in order to provide reasonable verifiability of proper management, implementation and settlement of RSAs (both finance-based and performance-based instruments).

Recommendations relating to narrower, but very significant issues were presented below. These regard mainly tasks related to activities and responsibilities of the Ministry of Health and other bodies responsible for the process of introducing new medicinal products to the reimbursement system, at all operating stages of instruments – starting with the evaluation of proposals, through their implementation and their execution.

Specific recommendations – templates and applications

Representatives of pharmaceutical companies who participated in the Project indicated that meeting the MoH's expectations regarding applicants which include RSA propositions are often very troublesome for the applicants. This is associated i.a. with the fact that the Act on reimbursement does not provide for any templates of a document which would cover the content of the proposed RSA. As a result, solutions are developed on an individual basis and are non-standardised, and information gaps on the part of both the applicants and the public institutions lead to the fact that negotiations are conducted in a non-optimal way which hinders the achievement of an agreement.

Recommendations:

1. The MoH, AOTMiT and NHF should determine the scope of information necessary to properly evaluate risk-sharing instruments. This information can take the form of official guidelines for applicants and templates of applications regarding risk-sharing instruments.
2. Guidelines and templates of applications can be of a purely informative nature which would not be binding directly for the authorities and the applicants. In the future, along with the development of good practices, they may be subject to relevant legislative changes.
3. Applications involving complex risk-sharing instruments should include a comprehensive and detailed description of the proposed solutions in the scope of their implementation and the justification for the choice of the instrument.
4. The MoH should publish principles as well as verification and evaluation criteria of the proposed risk-sharing schemes in order to ensure transparency of the actions taken and the repeatability of results of the procedures held.

Specific recommendations – RSA in the reimbursement procedure

There is a lack of analysis and evaluation of the implementation methods at the stage of discussing the application in terms of RSA (e.g. during negotiations with the Economic Commission), which makes it extremely difficult to put complex instruments into use. Lack of support which would be provided by experts working in different areas of the healthcare system (clinicians, representatives of healthcare providers and pharmaceutical wholesalers) results in the preference of the simplest financial instruments caused by the will to avoid the potential pitfalls associated with new solutions, both at the management level, as well as the level of specific solutions in terms of reporting and controlling risk-sharing instruments

Recommendations:

1. Appointment of a multidisciplinary expert team which would assess the capacity to implement specific, complex risk-sharing instruments by way of consulting their proposal, which would support the Ministry of Health in examining of the application (in parallel to the work performed by AOTMiT). Such a team should consist of representatives of the NHF, healthcare providers, Coordinating Teams, and in the future probably also the Centre for Healthcare Information Systems (CSIOZ) and possibly other stakeholders. The applicant should be able to provide further clarification at this team's meetings.
2. Creating procedures and implementing processes for consultations between the applicant and the MoH and NHF representatives conducted before the formal submission of the RSA proposal. The purpose of such consultations would be to discuss practical solutions in the implementation of the proposed RSA, corresponding to the execution capacities of the NHF and healthcare providers.

Specific recommendations – RSA implementation

As a result of restrictions on the method of evaluating the proposed instruments and a lack of practice in cooperation with applicants during the implementation phase, the actual commencement of the provision of services (drug programmes) in hospitals is often significantly delayed in time, which delays patients' access to treatment. This is due to the fact that implementation works are commenced only after the Minister of Health had published announcements containing information about reimbursement coverage of a product with an agreed upon the RSA scheme. At the same time, the NHF's access to data submitted by the applicant at the stage of applying for reimbursement is limited, which may be important during the implementation of instruments based on health effects.

Recommendations:

1. Administrative decisions and all documents (including those submitted to AOTMiT) regarding risk-sharing instruments should be forwarded to the NHF immediately after the decision becomes final. The NHF must have as much time as possible for planning and implementing the instrument before its entry into force on the date specified in the reimbursement decision. This pertains particularly to calculation models, detailed descriptions of applications with practical aspects, analyses and statements from AOTMiT and the Transparency Council, which are submitted to the Minister of Health and the Economic Commission by the applicants at the stage at which conditions of the instruments are being determined.
2. One should consider issuing decisions with a deferred date of entrance into force in the case of complex RSA schemes (finance-based, outcome-based and conditional ones), which would allow the NHF to develop the necessary documentation, developing contractual provisions and RSA documents before a tender for healthcare providers is announced, and modifying necessary reporting instruments (including IT tools).
3. Healthcare providers, including physicians-clinicians, should be involved in the process of determining details of the RSA implementation at the stage of works performed by the National Health Fund. This can be done e.g. by involving Coordination Teams in the communication process, in particular by ensuring the possibility of feedback from healthcare providers and medical personnel to the RSA coordinator in the NHF Central Office and Regional Branches.
4. Systems for settling risk-sharing instruments should be planned at the early stages of their implementation and the systems should be adjusted to particular RSA types (including the control system), in order to reduce administrative costs and possibly controls, respecting the principle of minimal burden for particular entities.

Specific recommendations – cooperation with stakeholders

The current organisation of implementing risk-sharing instruments and the current practice of their implementation are far from optimal with regard to ease of obtaining results provided for by the instruments in question. Healthcare providers who sign contracts on provision of healthcare services in the scope of concluded instruments are often not aware of the obligations they would be burdened with. This lack of knowledge hinders the healthcare providers' ability to optimally manage their resources. The current organisation model negatively impacts the effectiveness of the executed finance-based instruments due to the extended time needed for settlement and the numerous misunderstandings between the institutions executing the RSA and the increase of the administrative burden for all participants of the process.

Recommendations:

1. Detailed terms and conditions of the instruments to which the healthcare provider will be required to comply should be reflected in the contract for the provision of benefits. Should it be required for the purpose of the instrument's effective execution, the health-care provider should be informed about its detailed provisions, e.g. in the case of an instrument entailing the sale of a drug to the healthcare provider for a price lower than that listed in the Minister of Health's announcement or the scope of collecting data in outcome-base instruments, which significantly impact that healthcare provider.
2. Contracts concluded with healthcare providers should clearly define the scope of their costs related to the execution of risk-sharing instruments and clearly indicate the source of their funding, including the method of their settlement with the NHF.
3. Healthcare providers should be informed about the existence of risk-sharing instruments, the execution of which will involve their provision of a service, which would enable them to contact the applicant, should it be necessary for the proper execution of the instrument;
4. The MoH should be informed by the NHF about the violation of the decision only if that violation has been confirmed as part of internal NHF procedures which should include obtaining explanations directly from the applicants.

Specific recommendations – confidentiality of RSA

Although restrictions in access to confidential information with regard to risk-sharing instruments are necessary – this results both from the goal with which the instruments are concluded as well as protection of the rights of companies, the need for procedures and practices regarding exchange of information will increase along with the increasing complexity of the adopted risk-sharing instruments. At present, access to information on the content of instruments is restricted to the Ministry of Health and the Central Office of the National Health Fund. However, at the same time all participants of the system could benefit from limited disclosure of the concluded instruments, as is the case in other countries.

Recommendations:

1. Limited disclosure of risk-sharing instruments should be introduced in the form of information published by public institutions about the fact that an RSA was included in the reimbursement decision, about the type of the instrument and its general conditions (without disclosing, either directly or indirectly, the pricing conditions). A detailed scope of information regarding particular types of instruments should be determined in consultation with representatives of applicants.
2. The MoH and representatives of the applicants should establish rules which would determine the scope of information provided to particular participants of the system during the implementation of the instrument and the timetable for the disclosure of such information. The MoH and the applicant should each time establish the scope of data which would be disclosed, so that all entities participating in the execution of instruments (including healthcare providers and Regional Branches of NHF) have access to information which is necessary for effective implementation of their obligations.

3. Within the framework or new rules on confidentiality, the MoH and the NHF should prepare and implement procedures which would ensure confidentiality of information sensitive to applicants, which constitutes a company secret. Such procedures should also include cooperation with healthcare providers participating in the implementation of particular instruments.

Specific recommendations – in-kind rebates

The challenges faced by the Minister of Health, other public institutions and the applicants encourage searching for new solutions. That is why the Project covered not only an analysis of the current situation, but also a look at the possible future steps – implementation of instruments based on more complex mechanisms, which have already been implemented in other countries.

One of the major solutions of that type is the use of in-kind rebates for the purpose of settlements within the RSA (and thus the applicants providing healthcare providers with free-of-charge packages of pharmaceuticals). Given the current legal situation, the use of in-kind rebates requires a prior in-depth analysis of how concrete solutions can be implemented in terms of law and accounting. Such actions are justified by the rational benefits which in-kind rebates offer to all participants of the system (i.a. they offer a solution to the problem of disposal of partially used doses of the drug, i.e. the so-called wastage and other problems encountered by healthcare providers).

Recommendations:

1. Introduction of broader implementation of RSA settled by way of rebates in the form of free-of-charge supplies of drugs – both in the case of finance-based and performance-based instruments.
2. Commencing an expert discussion on the future use of legal solutions for the purpose of introducing free-of-charge supplies of drugs (i.e. in-kind rebates as part of public procurement or donations), in particular considering financial consequences of their use for all participants in the system, or taking possible legislative steps.
3. The need to provide the NHF with tools for monitoring the implementation of instruments in terms of in-kind rebates and the introduction of a possibility to monitor free-of-charge drugs.

Specific recommendations – performance-based RSA

Performance-based instruments which have been successfully introduced in other countries should be implemented based on public systems for collecting medical data due to the fact that financing of the therapy is dependent on particular patients' clinical response to the drug. Currently, provisions of law do not provide for a possibility of collecting and processing data on the patient's health condition for the purpose of RSAs in the public system as well as in the scope of the Therapeutic Programme Monitoring System. Along with the development of the Medical Information System, within a few years introduction of such instruments from the technical point of view should become relatively easy thanks to the central collection of unit medical data of patients collected as mart of their medical records.

Recommendations:

1. The Therapeutic Programme Monitoring System may constitute a basis for introducing sets of unit medical data on the patients' health condition to public use. At the same time, for their effective use, it is crucial to determine issues related to ownership of the collected personal data, the admissibility and correctness of their processing, and the consistency with the entire IT system in healthcare.
2. Regardless of the selected method of public data collection, it is necessary to ensure interoperability of information systems in the form of collecting and joint processing of information from various sources, in particular medical data together with financial data. One should take into consideration actions which would aim at integrating those systems with future solutions in terms of computerisation of healthcare, such as e-prescription. In the future, medical data collection should be carried out within the framework of the Medical Information System, where data will be entered on the basis of patients' medical records.

3. It is necessary to indicate an entity responsible for substantive matters i.e. decision-making and settling clinical issues arising from actions taken by doctors in the course of treatment with products covered by a performance-based RSA – this role could be played by Coordinating Teams.
4. Information collected through public and private medical data sets should be published or made available for scientific purposes, in accordance with applicable regulations.

Specific recommendations – conditional reimbursement RSA

Currently there are no legal obstacles which would make it impossible to introduce any risk-sharing instruments based on conditional reimbursement in cases when studies are conducted and financed by the applicants and the settlement system is controlled by the NHF. However, in this respect, the greatest doubts among representatives of the public institutions is making reimbursement decisions and settlement dependent on the aggregated data (results of experimental or observational studies at the population level) presented by the applicants.

Recommendations:

1. One should consider the introduction of conditional reimbursement instruments based on financial data collected with the NHF's current settlement system and medical data collected separately by the applicant as part of its clinical trials (experimental or observational).
2. Non-public medical data (in particular in the context of collected data sets financed by the applicants) can be used to create and settle conditional reimbursement RSAs. It will be necessary for the MoH and representatives of the applicants to agree upon guidelines regarding the scope and mode of disclosing aggregated data necessary for the creation of performance-based instruments.
3. Prior to the full implementation of conditional reimbursement instruments, implementation in the form of a pilot project should be carried out in order to develop a uniform system and possibly develop legislative changes.

The „Risk-sharing instruments in Poland and abroad" constituted an unusual and very valuable case of an open and constructive exchange of views between all stakeholders in the pharmaceutical reimbursement system. It helped identify areas which require improvements of existing processes, as well as directions for further development – especially in terms of outcome-based and conditional reimbursement instruments. All parties were greatly committed to the dialogue, which naturally produced good results, i.a. in the form of practical recommendations which are the beginning of what might be further work on specific solutions.