REPORT **INNOVATIONS**

medical fund

KRAKÓW 2021

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Kraków 2021

1 objectives

AND ASSUMPTIONS OF THE REPORT

Introduction

The aim of the report is to present systemic consequences related to the introduction of a new model of access to innovative drugs in Poland in the light of the Medical Fund Act.

For many years there has been a discussion in Poland on increasing the availability of new drug technologies, also known as innovative ones, especially in the treatment of rare and oncological diseases. The assumptions of systemic changes for drugs up to 2022 were presented in the National Drug Policy for 2018-2022 and in the announcements of the provisions of the National Rare Disease Plan 2021-2023.

Act on the Medical Fund

On November 26, 2020, the Act on the Medical Fund entered into force, on the initiative of the President of the Republic of Poland, which amended the provisions of the Reimbursement Act. It introduced new reimbursement paths for drug technologies with a high level of innovation and high clinical value, and changed the regulations on access to drugs under the RDTL (Emergency Access to Drug Tehnologies, pl. *Ratunkowy Dostęp do Technologii Lekowych)*.

Legal basis

Act of October 7, 2020 on the Medical Fund (Journal of Laws of 2020, item 1875).

Amended legal acts:

- Act of 12 May 2011 on the reimbursement of drugs, foodstuffs for particular nutritional uses and medical devices (hereinafter: the "Reimbursement Act") (Journal of Laws 2011 No. 122 item 696),
- Act of 27 August 2004 on healthcare services financed from public funds (Journal of Laws of 2004, No. 210, item 2135),
- Act of 28 April 2011 on the information system in health care (Journal of Laws of 2011, No. 113, item 657),
- Regulation of the Minister of Health of 8 January 2021 on minimum requirements to be met by the analyses included in the applications for reimbursement and setting the ex-factory price and for increasing the ex-factory price of a medicine, foodstuff for particular nutritional uses and medical device which have no reimbursed equivalent in an indication in question (Journal of Laws of 2021, item 74)

Medical Fund (MF) is a partial response to the goals set in the National Drug Policy

"The drug policy is being implemented in particular by ensuring real access to necessary pharmacotherapy for patients can actually benefit from the necessary pharmacotherapy. Public funding of drugs aims to ensure the greatest possible availability by reducing economic barriers.
A particular challenge is the availability of innovative drug technologies in line with clinical guidelines and European standards. In the case of therapies for rare and ultra-rare diseases, deviation from the generally accepted drug evaluation procedure should be considered (...)".

NATIONAL DRUG POLICY 2018-2022

„Effective, safe and rational pharmacotherapy is one of the foundations of an effective health care system".

NATIONAL DRUG POLICY 2018-2022

Rationality

=

promoting cost-effective (C / E) solutions for drug use by healthcare professionals and patients

NATIONAL DRUG POLICY 2018-2022

Medical Fund

One of the main goals of introducing the Medical Fund is to support access to the latest therapies, especially in rare and oncological diseases, as a response to the needs of patients in terms of health care and identified problems.

4 billion PLN per year of additional financial resources for health

- better health infrastructure,
- prevention, diagnosis and treatment of civilization diseases, including cancer and rare diseases
- easier access for patients with cancer and rare diseases to the latest drug therapies and treatments, also abroad
- Improved quality of life for patients and their families
- guarantee of unlimited hospital and specialist services for children

President's initiative

- 07.03.2020 — Draft of MF bill
- 23.06.2020
- 07.10.2020 — Adoption of the act
- 26.11.2020 — Entry of the act into force
- 26.02.2021 — list of highly innovative drugs
- 15.03.2021 — Detailed assessment published by AOTMiT
- 26.08.2021 — list of drugs of high clinical value
- 09.2021 — Potential reimbursement decisions

Reimbursement decisions

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MEDICAL FUND

financing

MF financing

ASSUMPTIONS

Medical Fund structure

- Strategic infrastructure subfund
- Subfund for the modernization of healthcare entities
- Prevention development subfund
- **Therapeutic and innovative subfund**

- Financing healthcare for children up to the age of 18,
- **Financing drugs for emergency access to drug technologies (RDTL),**
- Financing services provided to patients outside Poland,
- **Financing drug technologies with a high level of innovation,**
- **Financing technologies with high clinical value.**

MF financing assumptions:

38 billions in 9 years

annual budget up to 4 billion for all MF subfunds

The level of expenditure on new drugs at the level of PLN 700 million – as compared to PLN 12 billion for all indications from lists A, B, C – indicates limited budget capability.

Maximum annual budget in 2021 under MF:

- with drugs with a high clinical value and drug technologies with a high level of innovation:

  707 million – 5% of CBR

- emergency access to drug technologies (RDTL):

  160 million – 3% on drugs used in chemotherapy and drug programs

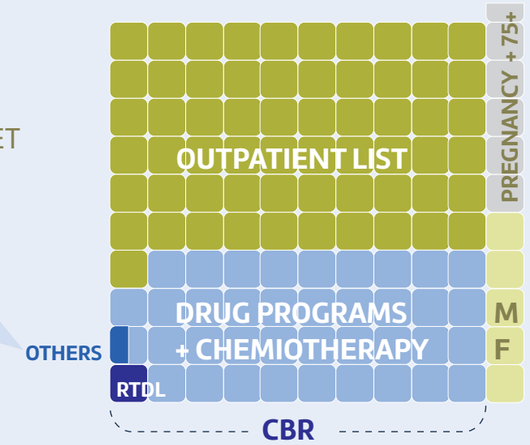
Financing of MF drugs

AND TOTAL REIMBURSEMENT BUDGET (CBR, *pl. Całkowity Budżet na Refundację*)

Public funding sources for drugs in Poland:

1 CBR – A TOTAL REIMBURSEMENT BUDGET

- outpatient list available at the pharmacy,
- drugs available under drug programs,
- chemotherapy drugs,
- drugs available as emergency access to drug technologies (RDTL),
- drugs available through direct import,
- foodstuffs for particular nutritional purposes imported from abroad.



2 Drugs financed from the state budget:

- 75+ list,
- drugs used in women during pregnancy,
- as part of the compulsory vaccination program,
- under the National Health Policy Programs (National Program for the Prevention of HIV Infections and AIDS; National Program for Treatment of Patients with Hemophilia and Related Hemorrhagic Diseases)

3 Drugs financed as part of the medical services

(hospitalization, ambulatory care) ie. DRG

4 Drugs financed by local governments

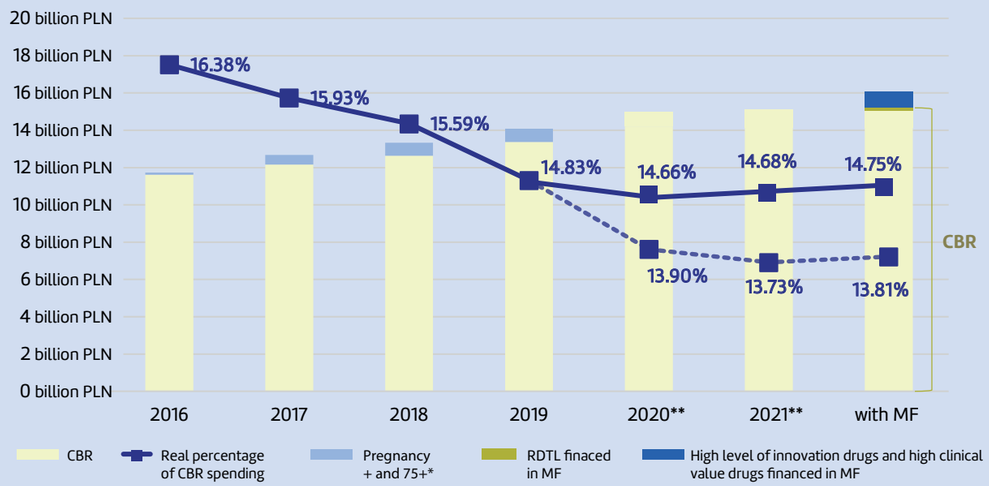
e.g. influenza vaccination

CBR AND MF INTRODUCTION

Estimation of the CBR share in the total expenditure on guaranteed services in the years 2012–2021 (including the Medical Fund)

Expenditure from the state budget on the CBR plus expenditure on highly innovative drug technologies and drugs with a high clinical value potentially will allow reaching 15.4% of the value of all expenses on guaranteed services. Adding 75+ and Pregnancy+ to CBR in 2020–2021 resulted in relative stabilization of drug spending. Without adding those categories relative drug spendings in 2020–2021 were much lower than in 2019.

Despite the increase in the absolute value of expenditure on drugs, a decrease in their share in the expenditure on guaranteed services is noticeable from year to year.



** In 2020 and 2021 expenditures on 75+ and Pregnancy+ were included in CBR.*
***Expenditure on reimbursed drugs includes estimated additional funds for drugs and RDTL within the Medical Fund + expenses for the Medical Fund were included in the expenditure on guaranteed services. Expenses in 2011-2019 based on NHF billing data. The data for 2020 was adopted from the NHF-financial plan for 2020 of December 29, 2020. The data for 2021 was adopted from the NHF financial plan for 2021 of September 30, 2020.*

Financing conditions

REGISTRY AND RSA

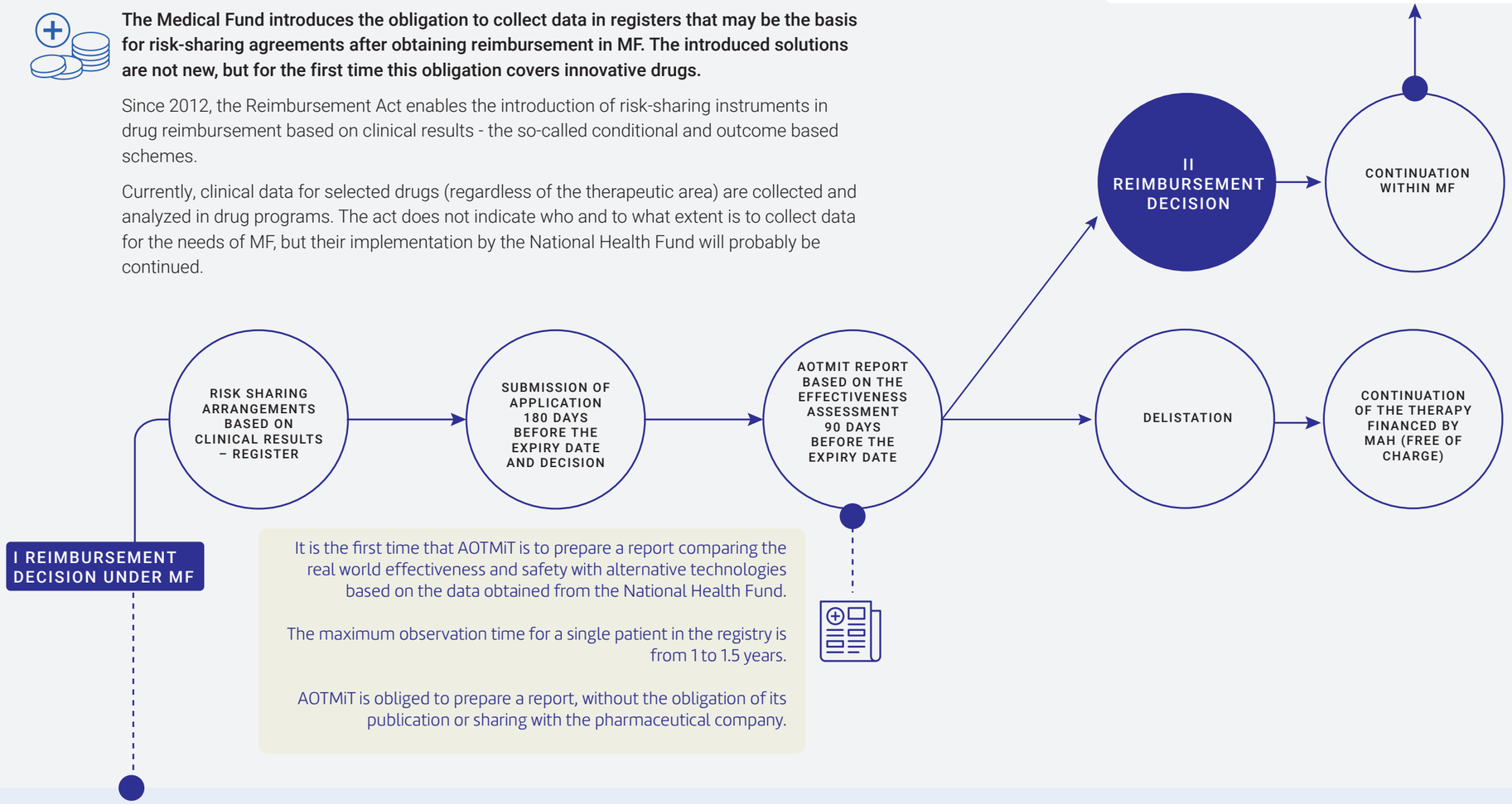
The Medical Fund introduces the obligation to collect data in registers that may be the basis for risk-sharing agreements after obtaining reimbursement in MF. The introduced solutions are not new, but for the first time this obligation covers innovative drugs.

Since 2012, the Reimbursement Act enables the introduction of risk-sharing instruments in drug reimbursement based on clinical results - the so-called conditional and outcome based schemes.

Currently, clinical data for selected drugs (regardless of the therapeutic area) are collected and analyzed in drug programs. The act does not indicate who and to what extent is to collect data for the needs of MF, but their implementation by the National Health Fund will probably be continued.

Pricing in case of continuation

In the case of both new categories of drug technologies, when the official selling price per one package or per patient is reduced as a result of including the risk-sharing instrument (*effective price*) in the subsequent decision to reimburse the product, the effective price can not be higher than the one decided for a different product which was on the reimbursement list on the day of the submission.



It is the first time that AOTMiT is to prepare a report comparing the real world effectiveness and safety with alternative technologies based on the data obtained from the National Health Fund.

The maximum observation time for a single patient in the registry is from 1 to 1.5 years.

AOTMiT is obliged to prepare a report, without the obligation of its publication or sharing with the pharmaceutical company.

Reasons for introducing the development of the AOTMiT report OER – Registry outcomes assessment:

1. Implementation of the standard for assessing risk sharing agreements for reimbursement purposes.
2. Lack of an HTA report when submitting a reimbursement application for continued reimbursement under MF.
3. The need to assess the health effects, compare them and determine the effective price (RWE data analysis).

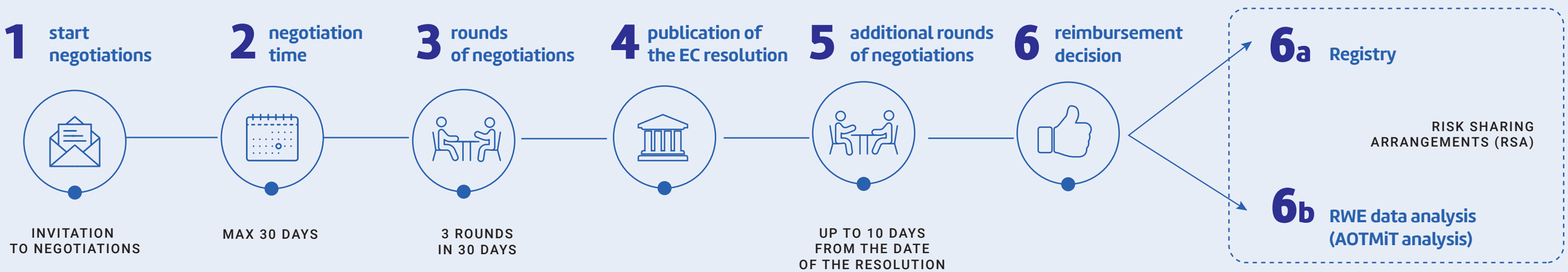
Price negotiations

Introduction of a time frame with the Economic Commission (EC) (up to 30 days) – so far the negotiation framework has not been established and is still not for drugs in the standard reimbursement path.

Uncertainties regarding the report on the real world effectiveness by AOTMiT, prepared before the expiry of the first reimbursement decision under MF.

Lack of clarity on the continuation of registers after the first reimbursement decision

Negotiations of the first reimbursement decision



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reimbursement path

Reimbursement and pricing processes

SUMMARY OF CHANGES

Highly innovative drugs

Shortening the duration of the reimbursement procedure for innovative drugs registered after 2020 to 60 days

No need to submit a full HTA report for highly innovative drugs – only the need to submit a payer budget impact analysis

Drugs of high clinical value

Introducing the list and keeping the reimbursement path identical to the standard one potentially extends the time to obtain a reimbursement

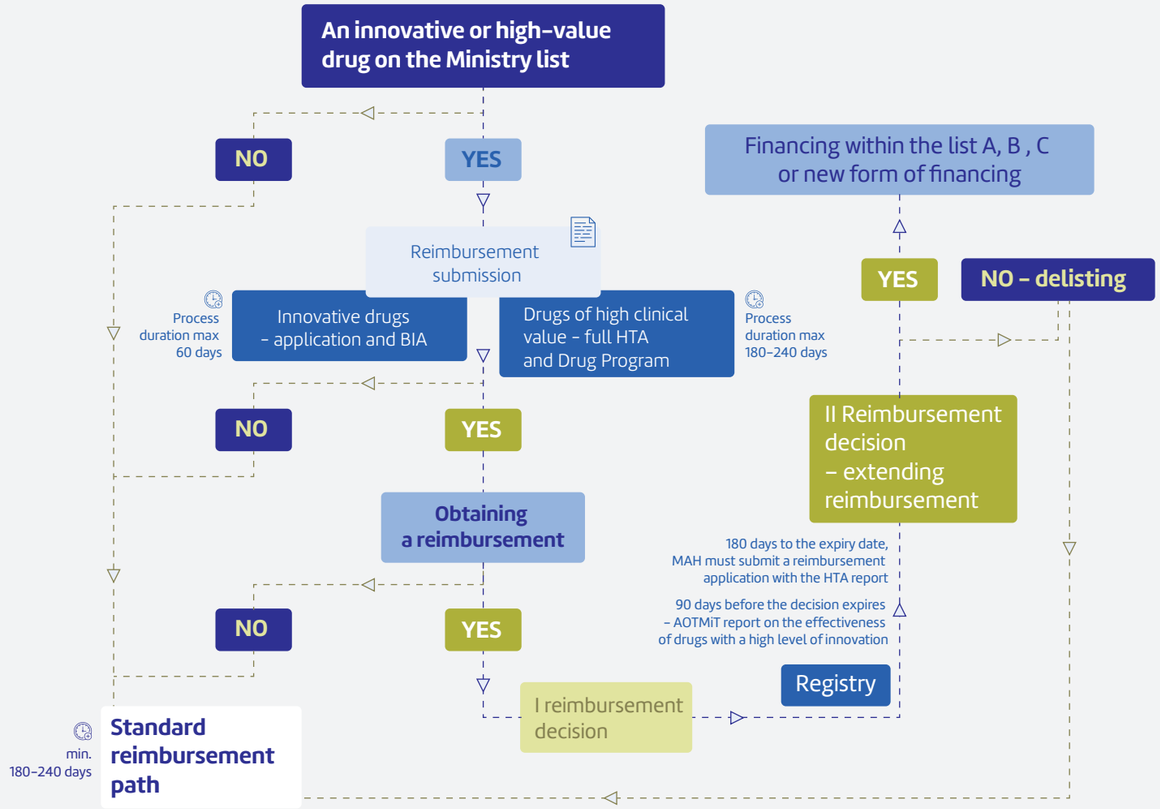
The need to submit a full HTA report for a drug technology of high clinical value

The need to prepare a full HTA report when submitting a reimbursement application for a reimbursement extension
(art.25c of the Reimbursement Act)

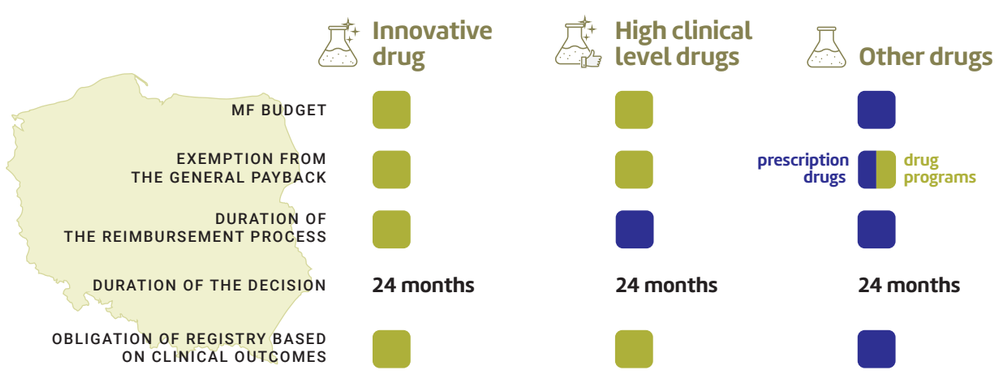
Introduction of the obligation to publish the results of negotiations with the Economic Commission as a response to the requirement to increase transparency.

Reimbursement options

FOR INNOVATIVE DRUGS AND WITH HIGH CLINICAL VALUE



Benefits of reimbursement pathway in Poland



Proof of availability

Proof of availability on the market, information on prices obtained: in the light of the new provisions of the Reimbursement Act, the applicant, together with the reimbursement application, shall submit a proof of the product's availability on the market at the time of submitting the application, or in the case of an advanced therapy medicinal product – commitment to ensure technological readiness for its production.

It is a simplification of the previous rule, according to which the applicant, together with the reimbursement application, submitted a proof of availability in trade at the time of submitting the application. Currently, in the case of an advanced therapy medicinal product, it is sufficient to oblige the applicant to ensure technological readiness for its production.

The change should be considered positive, as in some cases it may in some cases be difficult to provide proof of availability for new drug technologies. However, it is uncertain whether the applied exemption – only for advanced therapy medicinal products, will cover all potential cases in which the submission of a proof of availability will be problematic.

Detailed path

REIMBURSEMENT AND PRICE FOR
AND A HIGH CLINICAL VALUE DRUGS

Scope of the list:

1. Drug
2. Indication
3. Date of marketing authorization
4. The level of innovation
5. Scope of data collected in the register, including indicators for assessing the effectiveness of the therapy and expected health effects.

The reimbursement and pricing process for innovative drugs has been shortened to AOTMiT's assessment (made a priori, before the application submission) and price negotiations, but without specifying a time frame for all stages of the process, except for the price negotiation stage conducted for the first time.

The implementation of changes in the field of highly innovative drugs is unclear, as it does not imply significant modifications to the path, but only imposes the obligation to introduce a register, which was already possible in Poland in the drug monitoring system.

ACT ON MEDICAL FUND 26/11/2020 → THE FIRST LIST OF HIGHLY INNOVATIVE DRUGS 02.26.2021 → THE FIRST LIST OF DRUG TECHNOLOGIES WITH A HIGH CLINICAL VALUE 26.08.2021

Responsibilities of individual stakeholders

	Standard path	Highly innovative drugs	High clinical value drugs
AOTMiT		Innovation assessment and AOTMiT list	Innovation assessment and AOTMiT list
MoH		Opinion on the list Publishing the list of MoH	Opinion on the list Publishing the list of MoH
MoH	Reimbursement application	Reimbursement application	Reimbursement application
Aplicant (MAH)	HTA analysis	BIA	HTA analysis + Drug program
MoH	Order to AOTMiT		Order to AOTMiT
MoH	Determining the content of the drug program		Determining the content of the drug program
AOTMiT	Check minimum requirements		Check minimum requirements
Aplicant (MAH)	Complementing the analyzes		Complementing the analyzes
AOTMiT	AOTMiT verification analysis The opinion of the Transparency Council Recommendation of the President of AOTMiT		AOTMiT verification analysis The opinion of the Transparency Council Recommendation of the President of AOTMiT
MoH	Negotiations with EC	Negotiations with EC (max 30 days)	Negotiations with EC
Reimbursement decision	Based on criteria in reimbursement act (article 12)	Based on criteria in reimbursement act (article 12)	Based on criteria in reimbursement act (article 12)
RSA	Possible financial or based on clinical outcomes	Registry, possible financial or based on clinical outcomes	Registry, possible financial or based on clinical outcomes
Statutory duration of the proces	180 days + 60 days drug program	60 days	180 days + 60 days drug program

- **Applicant (MAH):** BIA
- **Public institutions:** AOTMiT list / MoH / (No HTA report, no details about AOTMiT analysis)
- Negotiations with the EC with a time limit of up to 30 days

60 days
A HIGHLY INNOVATIVE DRUGS: BIA

THE MINISTER OF HEALTH REQUESTS THE OPINION OF THE TRANSPARENCY COUNCIL, THE NATIONAL CONSULTANT AND THE PATIENT OMBUDSMAN → PUBLICATION OF THE LIST OF DRUG TECHNOLOGIES SELECTED BY MOH → SUBMISSION OF REIMBURSEMENT APPLICATIONS BY MAH

DRUGS WITH A HIGH CLINICAL VALUE:
HTA Analysis
240 days

- **Applicant:** HTA Report + Drug Program
- **Public institutions:** AOTMiT list / MoH / AOTMiT verification analysis;
- The opinion of the Transparency Council / Recommendation of the President of AOTMiT
- Price negtiations with EC with no time limit

The reimbursement and pricing process

FOR HIGHLY INNOVATIVE DRUGS

I stage

- Drug technologies registered by EMA after January 1, 2020
- AOTMiT's selection of drug technologies used in rare and oncological diseases
- Assessment of the degree of innovation of selected drug technologies
- Publication of the list by AOTMiT in BIP (Public Information Bulletin, pl. *Biuletyn Informacji Publicznej*)

3 months

- Consultation of the list by the Ministry of Health with the Transparency Council, the National Consultant and the Patient Rights Ombudsman
- Publication by the Ministry of Health of the list of selected drug technologies on the website and in the BIP along with informing the manufactures

no deadline

II stage

- Submission of the reimbursement application
- Reimbursement Application Assessment
- Negotiations with the Economic Committee
- Reimbursement decision

60 days

The reimbursement and pricing process

FOR DRUGS OF HIGH CLINICAL VALUE

I stage

- Drug technologies registered by EMA after January 1, 2017
- AOTMiT's selection of drug technologies with high clinical value
- Assessment of the degree of innovation of selected drug technologies
- Publication of the list on the website and sending it to the Ministry of Health

9 months

- Consultation of the list by the Ministry of Health with the Transparency Council, the National Consultant and the Patient Rights Ombudsman
- Publication by the Ministry of Health of the list of selected drug technologies on the website

no deadline

II stage

- Submission of the reimbursement application
- Reimbursement Application Assessment by AOTMiT as in thestandard procedure
- Negotiations with the Economic Committee
- Reimbursement decision

240 days

New tasks of public institutions in the light of MF

AOTMiT

- Development of a methodology for the evaluation of innovative drugs
- Development of documents (arguments and calculations) for the needs of negotiations
- Preparation of a list of drugs with evaluation indicators
- Publication by AOTMiT, 90 days before the end of the reimbursement decision, of a report on the effectiveness of drug technologies covered of reimbursed highly innovative drugs and quality of the treatment based on data from medical registers

Economic Commission

- Negotiating the terms of risk-sharing agreements based on clinical outcomes
- Publication of the results of price negotiations

National Health Fund

- Development of a data model based on documentation from the course of the process after the reimbursement decision is issued
- Transfer of data from registry to AOTMiT for analysis after 1.5 years of drug reimbursement

4/

criteria

Criteria listed in the MF Act	Criteria included in the AOTMiT documents
Unmet needs	significance of the disease (or specific indication), which include the severity of the consequences and the prevalence in Poland;
Health priorities	satisfying the unmet medical needs, availability in Poland, and effectiveness of the treatment in a given disease;
Expected health outcomes	Strenghts of the proposed intervention including the efficacy and safety (side effects) in in the considered indication; relevance of the most important endpoint;
Strenght of the intervention	innovation distance – the difference between the current state and possible improvement following the introduction of the innovative technology;
Quality of the scientific evidence	quality of the scientific evidence;
Population size	budget impact including the size of the target population;
	process innovation of technology – whether the operation is innovative in terms of the grip point and the mechanism of action;
	therapy costs; health effect costs (preferably LYG).

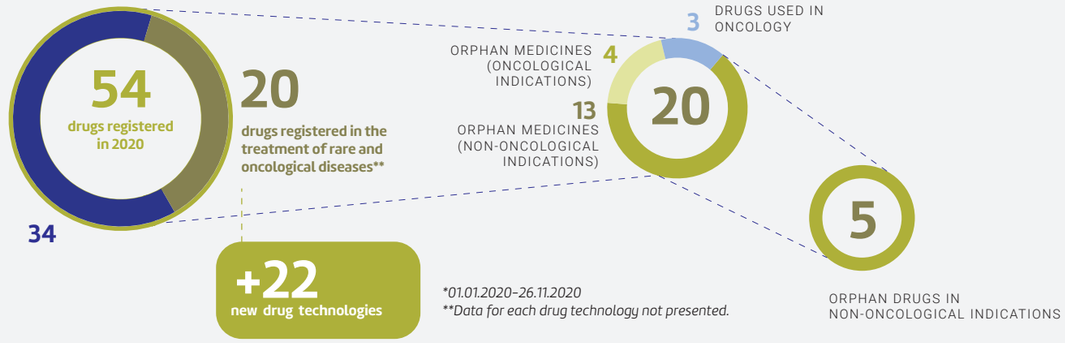
Assessment of drug technologies from the Highly innovative drug (HID) list by the Transparency Board and the Patient Ombudsman

	Brand name	Substance	Registration	Indication	Orphan status	Pediatric	Oncology	Priority assessment – Transparency Board	Patients Ombudsman opinion	HID List by MoH
1	Ayvakyt	avapritinib	24.09.2020	Gastrointestinal Stromal Tumors	Yes		Yes	Negative	Conditional	
2	Dovprela	pretomanid	31.07.2020	Multidrug-Resistant Tuberculosis	Yes			Yes	Conditional	Yes
3	Givlaari	givosiran	2.03.2020	Hepatic Porphyrais	Yes	>12 years		Yes	Yes	Yes
4	Idefirix	imlifidase	25.08.2020	Kidney Transplantation	Yes			Yes	Yes	Yes
5	Isturisa	osilodrostat	9.01.2020	Cushing Syndrome	Yes			Negative	Conditional	Yes
6	Oxlumo	lumasiran	19.11.2020	Primary Hiperoxaluria	Yes	Yes		Negative	Yes	Yes
7	Piqray	alpelisib	27.07.2020	Breast cancer			Yes	Negative	Negative	
8	Polivy	polatuzumab vedotin	16.01.2020	B-Cell Lymphoma	Yes		Yes	Negative	Yes	
9	Reblozyl	luspatercept	25.06.2020	Myelodysplastic Syndromes, beta-Thalassemia	Yes			Negative	Conditional	
10	Rozlytrek	entrektynib	31.07.2021	Cancer medicine used for treating patients from 12 years of age with solid tumors that have a genetic abnormality called NTRK gene Fusion	Yes	>12 years	Yes	Negative	Negative	
11	Zolgensma	onasemnogene abeparvovec	18.05.2020	Apinal Muscular Atrophy	Yes	Yes		Yes	Yes	Yes

5/ high level of innovation

DRUGS LIST

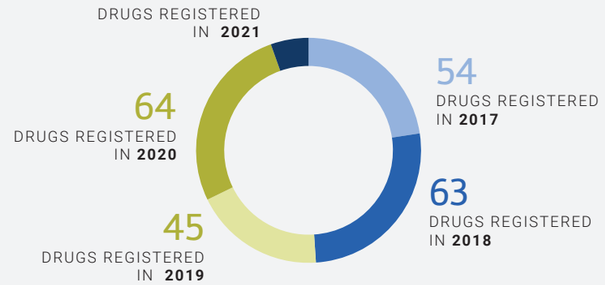
Number of potential drugs assessed by the HTA Agency in order to create a list of highly innovative drugs which is the basis for the list of MoH



*01.01.2020–26.11.2020
**Data for each drug technology not presented.

Drugs of high clinical value
EMA – 237 drugs registered between 2017–2021
Number of reimbursed drugs – 27
Number of drugs assessed by AOTMiT – 210 registered in all indications (February 18, 2021)

Drugs that are assessed under the list of drugs of high clinical value



Summary of parameters of individual drug technologies	RDTL	High level of innovation	high clinical value
Form of access	Individual	Group	Group
Who can apply	Physician	Manufacturers of drugs placed on the Ministry of Health's list after the publication of the list by Ministry of Health	
		Medicines for which no reimbursement application has been submitted	Medicines not reimbursed
Publication frequency of the lists	Lack	Once a year	Once, only in 2021
Medicines	Medicines not reimbursed in a given indication	Medicines registered after 01/01/2020	Medicines registered after 01/01/2017
Therapeutic area	All indications	Orphan medicines or oncology	All indications
Assessment procedure	National or regional consultant	Simplified, only BIA	Full HTA assessment
Registry	Not applicable	Obligatory	Not obligatory
Payment level	3% of the spending chemotherapy and drug programs	5% of the total budget for reimbursement (CBR)	
Delistation	Not applicable	Pharmaceutical companies cover the cost of the continuation	

6

EMERGENCY ACCESS
TO DRUG TECHNOLOGIES

RDTL

RDTL – emergency access to drug technologies

ACCESS FOR INDIVIDUAL PATIENTS

Emergency access to drug technologies (RDTL) is a system of issuing individual consents for the treatment of patients for whom all available therapeutic options financed from public funds have been exhausted. Drugs financed under the RDTL are available free of charge to patients, and their cost is covered by the National Health Fund.

RDTL allows the needs of individual patients to be met. Under the Medical Fund Act, decision-making was transferred from the level of the Ministry of Health (and AOTMiT) to the level of hospitals treating patients and national and provincial consultants.

Legal basis

The Act on the Medical Fund modified the provisions of the Act on healthcare services of 2004, Article 47d, f, and the scope of procedures and principles of financing RDTL

Financing

RDTL can only be applied for in network hospitals:

- 3rd degree;
- oncological or pulmonary;
- pediatric;
- nationwide.

Hospitals can settle RDTL up to the nationwide cup (3% of the sum of amounts allocated to financing drugs covered by drug programs and drugs used in chemotherapy, which hospitals have specified in contracts for the provision of healthcare services).

Expenditure on RDTL is included in the CBR (Total Reimbursement Budget).

Changes in RDTL

	Previous state	Current state
Decision maker	The hospital applied to the Ministry of Health for approval to finance the drug. The application was assessed by AOTMiT.	The hospital independently decides on the use of a given drug technology after obtaining a positive opinion from a national or provincial consultant.
Therapeutic area	all	all
RDTL budget	Until February 2020 financed up to the limit set up by NHF. From February 2020, RDTL has been excluded from the budget limit.	3% of drug expenditure under drug and chemotherapy programs
Refusal of funding	• Opinion of AOTMiT • Failure to submit the application by the company in a timely manner • Reimbursement of a given drug in a given indication was decided not to be justified • Negative reimbursement decision was issued	• The company did not submit the application within 90 days from the publication of the information by the Ministry of Health in the Public Information Bulletin • A decision was issued to discontinue the reimbursement procedure • Reimbursement of a given drug in a given indication was decided not to be justified • Negative reimbursement decision was issued • The drug was included on the list of drugs which can not be financed under RDTL
Reimbursement aplication	The Ministry of Health invited the company to submit a reimbursement application when: • in the opinion of AOTMiT, it was justified to reimburse this drug • it was essential for saving patients' lives or health	If the cost of treatment with a given drug as part of RDTL on an annual basis, in a given indication, financed by all service providers, exceeds 5% of the budget for RDTL under MF, the company is required to submit an application within 90 days since the publication of this information in the BIP.

Financing

Under the RDTL, it is possible to have treatment with a non-reimbursed drug or the one reimbursed in a different indication financed by the National Health Fund.

1 As part of the RDTL process, the hospital, at the doctor's request, applies to the National Health Fund after obtaining a positive opinion from a national or provincial consultant in a given field of medicine. For this purpose, the hospital approaches the consultant by submitting the form (Annex 2 to the order of the President of the National Health Fund No. 20/2021 / DSOZ).

2 The consultant presents his opinion on the use of the drug in the patient on the appropriate form (Annex 3 to the order of the President of the National Health Fund No. 20/2021/DSOZ).

3 The hospital settles with the provincial branch of the NHF based on the invoice documenting the purchase of the drug (with the consultant's opinion or information on the continuation attached) (Annex 4 to the order of the President of the National Health Fund No. 20/2021/DSOZ).

4 Template of the application – Order of the President of the National Health Fund No. 20/2021/DSOZ

RDTL – emergency access to drug technologies

ACCESS FOR INDIVIDUAL PATIENTS

The maximum budget is **3%** of expenditure on drugs under drug and chemotherapy programs nationwide – i.e. for 2021 it is PLN

160.1 million
(as of 02.2021).

Eligibility criteria for RDTL:

- The drug is authorized
  The drug is available on the market
- All available treatment options have been exhausted
- It is not on the list of drugs ineligible for funding under the RDTL
- **The RDTL application have been completed**

The drug cannot be financed under the RDTL:

- Failure to submit a reimbursement application in the event of exceeding 5% of the RDTL budget (up to 90 days)
- Discontinued reimbursement procedure
- Negative recommendation of AOTMiT in the reimbursement procedure
- Negative MoH decision

Communication on the list of drugs not eligible for funding under the RDTL procedure

Did the drug spending across the country exceed 5% of the RDTL budget?

yes

Publication of information in BIP by the NHF and informing the Ministry of Health

up to 90 days

The MAH submits a standard reimbursement application

no

Possibility of further financing under RDTL

If a given drug is reimbursed in other indications, the price of this drug in RDTL cannot be higher than the effective price of this drug in the reimbursement.

Positive opinion

3 months
or 3 treatment cycles

next 3 months
or 3 treatment cycles

repeating the cycle
doctor's opinion
– continuation of treatment

Negative opinion

the patient cannot appeal against this decision

Positive opinion of a specialist doctor regarding the effectiveness of therapy

Treating physician

National or provincial consultant

Doctor treating the patient

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