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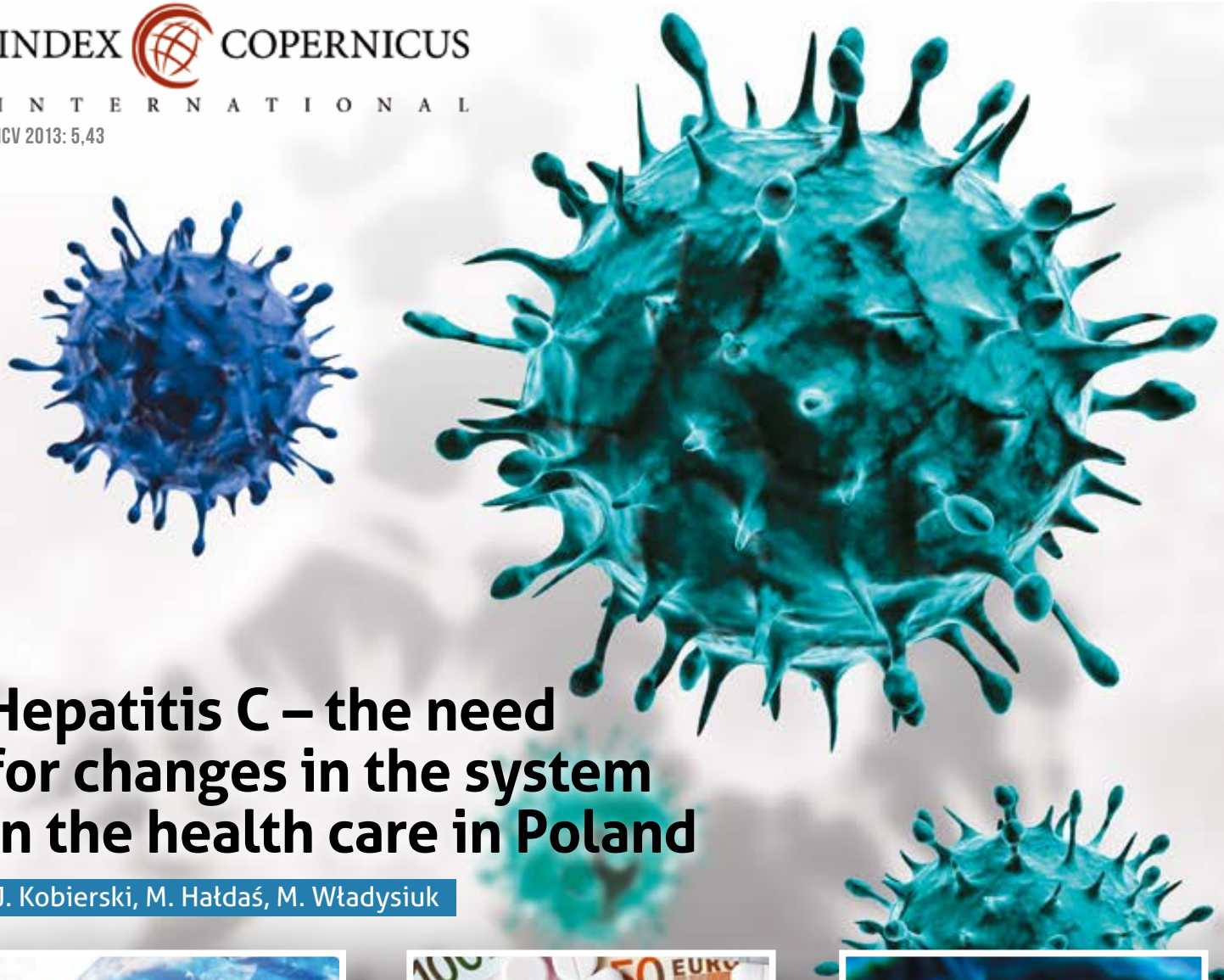

Hepatitis C – the need for changes in the system in the health care in Poland

J. Kobierski, M. Hałdaś, M. Władysiuk

Patients Registries - the role of the health system, new trends and hopes for Polish patients - 2nd JHPOR conference, Warsaw March 19th 2015

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Polish Experience in Financial Management of Medicines Market by Public Payer

T.Płusa

Ebola viral hemorrhagic fever

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Polish Experience in Financial Management of Medicines Market by Public Payer

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ABSTRACT

The most important features of medicines market in Poland are presented with the special reference to the terms and conditions of medicines reimbursement. A number of data on value and development of the pharmaceutical market, the value of reimbursement of medicines, changes in the numbers of open pharmacies, are presented also. The processes of decision making on reimbursing medicines in Poland before and after the Reimbursement Act are described in details. The implementation of the Act resulted in the increase of transparency of ways and methods for pricing of medicines, including them into the national health insurance system; the improved financial stability of public payer - gained by the precisely defined part of payer's budget, spent on medicines; patient-oriented approach in introducing new molecules into reimbursement system. The positive impact of the Reimbursement Act on the pharmaceutical market can be noted.

INTRODUCTION

The Medicines Reimbursement Act[1] was promulgated in 2011 to implement the Council Directive 89/105/EEC of Dec. 221th, 1988 ("Transparency Directive"), as well as to transform the reimbursement system in Poland in a way that provides the highest possible access to medicines, dietary foods for special medical purposes, and medical devices (hereinafter referred to as "refundable products") according to actual needs of public and financial capacities of public payer. Moreover, the relationships among the enterprises participating in market of refundable products should be clear and fully in accordance with the Transparency Directive. Special attention should be paid to transparency of ways and methods for pricing of products for human use and including them into the national health insurance system[1].

ORGANIZATION OF MEDICINES MARKET IN POLAND

Continuous progress of medicine and health sciences is the challenge for governments. New technologies and innovations offer new therapeutic possibilities which enable health recovery and in consequence, in longer perspective, the decrease of cost of health care, and decrease of lack of productivity. The costs related to above mentioned changes in medical technologies are a remarkable portion of the budget.

The methods of financing of medicines in Poland have been changed across the history. In 1919-1933 health insurance funds (Kasy Chorych – literally "Sick Cashes") organized the Social Insurance apothecaries and pharmacies[1] providing the access of society to medicines. The Minister of Social Care authorized such apothecaries[2]. After World War II, up to 1997, all medicines and therapies were financed by the State budget, via local authorities (voivodes). In 1997 the 16 independent, regional Sick Cashes (plus 1 for uniformed services) were implemented again. Each Sick Cash was limited to the area of a region (voievodship).

CONTINUOUS PROGRESS OF MEDICINE AND HEALTH SCIENCES IS THE CHALLENGE FOR GOVERNMENTS. NEW TECHNOLOGIES AND INNOVATIONS OFFER NEW THERAPEUTIC POSSIBILITIES WHICH ENABLE HEALTH RECOVERY AND IN CONSEQUENCE, IN LONGER PERSPECTIVE, THE DECREASE OF COST OF HEALTH CARE, AND DECREASE OF LACK OF PRODUCTIVITY.

In 2003 the united National Health Fund was created to finance the whole health care. The National Health Fund is the public payer covering the costs of health services, according to the Act[1] and regulations issued by the Minister of Health[2]. The organization, financing and accounting of costs of health services are defined in details by the regulations of the President of National Health Fund[1]. There are 17 main areas of contracts for services[1] plus contracts for medicines: a) open reimbursement, b) chemotherapy, c) therapeutic programs, d) as a part of the hospitals. The contract is signed up after the open competitions (tenders). The pharmacies and providers (primary health care, family doctors, outpatient specialist clinic et al.) are the main sources of information indispensable for information circulation and accounting system[1,2,3,4]. Electronic medical documentation is widely used in the hospitals, so much more complete data on medicines consumption come to the payer from the hospital reports than from other sources. On the distribution level named "hospital pharmacy" also the separate information is collected on oncological drugs (chemotherapy) consumption; and on the special therapeutic programs i.e. on the types of medicines which are financed separately. According to Polish law "reimbursement" is understood as the return of part or total value of medicines.

The medicines market can be divided into two segments: OTC (over the counter) medicines and Rx medicines; and into three levels of distribution: manufacturer; wholesaler; and retail customer (community pharmacy, hospital pharmacy, or out-of-pharmacy customers). The

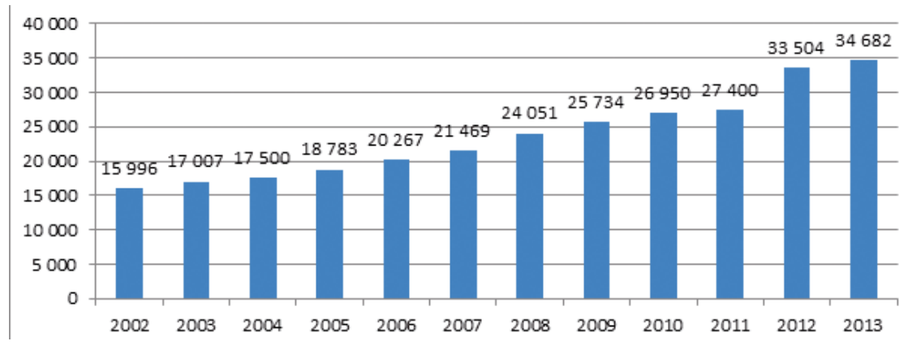

Figure 1. The value of the pharmaceutical market in the period 2002-2013 (in thousands PLN)
Source: Own data based on Pharma Expert annual reports

continuous increase of value of pharmaceutical market was observed in Poland in 2002 – 2013 (Fig. 1).

The mean annual increase of the pharmaceutical market as a whole (reimbursed medicines, full price medicines and OTC) was approx. 6.2%. The highest increase was observed in 2006 (12%) the lowest one – in 2011 (1.7%). Parallel to the increase of the market the number of community pharmacies was also increased; i.e. the places selling medicines which the public payer was obliged to reimburse full price of medicine or its part. (Fig. 2).

The sharp rise (+62%) of the number of pharmacies in 2006 was related to the end of the pro-

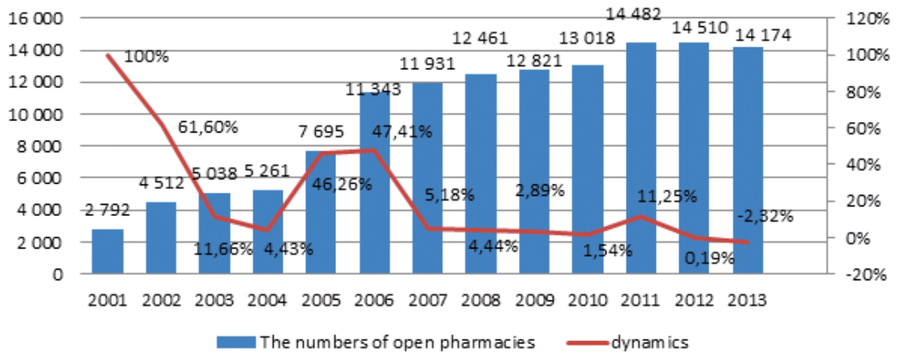

Figure 2. The number of open pharmacies in 2001-2013

cess of privatization of pharmacies formerly belonging to state enterprise CEFARM. That forced pharmacists to open new, own, private pharmacies.

The increased number of pharmacies (places selling medicines) was reflected in the increasing share of the cost of drugs in the payer's budget (Tab. 1) and in the positive dynamics of growth of costs in relation to the total budget of the payer.

Between 2004 and 2011 the reimbursement for chemotherapy drugs and therapeutic programs was not set out separately in the National Health Fund's financial plan but fully integrated into the hospital treatment founding.The dynamic changes in pharmaceutical market compared to financial resources in 2004 – 2013 disclosed that the increase of reimbursement of medicines was significantly greater than inflation rate (Tab.2).

Table 1. The value of reimbursement of medicines in proportion to public payer's budget (in thousands PLN)

	2004 r.	2005 r.	2006 r.	2007 r.	2008 r.	2009 r.	2010 r.	2011 r.	2012 r.	2013 r.	Plan 2014 r.
Therapeutic programs									1730897	2001718	2321826
Chemotherapy									468478	406491	516111
Reimbursement (pharmacies)	6118389	6323264	6695761	6727324	7367045	8238157	8546258	8831868	6863071	7183774	8063146
Total reimbursement of medicines	6118389	6323264	6695761	6727324	7367045	8238157	8546258	8831868	9062446	9591983	10901083
Costs of health services	30487361	33003941	35965840	40122980	49348746	55038582	56643910	58224321	59875547	62077983	63643735
Total costs of NHF	31089631	33534053	36709475	42257315	51657798	57632663	59325751	60923073	62672399	64775011	67318117
Costs of reimbursement as % of health services costs	20,07%	19,16%	18,62%	16,77%	14,93%	14,97%	15,09%	15,17%	15,14%	15,45%	17,13%

Source: NHF data

Table 2. The development of pharmaceutical market in Poland in 2004 - 2013

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	Plan 2014
Dynamics of budget	7,86%	9,47%	15,11%	22,25%	11,57%	2,94%	2,69%	2,87%	3,35%	3,93%
Dynamics of reimbursement	3,35%	5,89%	0,47%	9,51%	11,82%	3,74%	3,34%	2,61%	5,84%	13,65%
Dynamics of pharmacies' reimbursement	3,35%	5,89%	0,47%	9,51%	11,82%	3,74%	3,34%	-22,29%	4,67%	12,24%
Inflation rate	2,10%	1,00%	2,50%	4,20%	3,50%	2,60%	4,30%	3,70%	0,90%	

Source: Central Statistical Office and NHF data

Financing of all health services fulfill the principle of social solidarity, i.e. all citizens pay the compulsory contribution for health insurance[1]. According to Social Insurance Office (ZUS) the levels of contribution stay as high as 9% of 2227.80 PLN (basic).

MEDICINES FINANCING BY THE PUBLIC PAYER UP TO 2011

BETWEEN 2004 AND 2011 THE REIMBURSEMENT FOR CHEMOTHERAPY DRUGS AND THERAPEUTIC PROGRAMS WAS NOT SET OUT SEPARATELY IN THE NATIONAL HEALTH FUND'S FINANCIAL PLAN BUT FULLY INTEGRATED INTO THE HOSPITAL TREATMENT FOUNDING.

The medicines financing was based on the Minister of Health regulations on two lists of medicines: basic medicines and supplementary medicines. Basic medicines were reimbursed as the lump sum irrespectively from the price of a package , but up to the price limit established by the regulation. The supplementary medicines were reimbursed either up to 30% or 50% but only up to the price limit (reimbursement limit) established by the Ministry of Health. The limits should be updated 4 times a year (every quarter). In practice the limits were updated 1 – 2 times a year. The patient paid the difference between the cost of a medicine and reimbursement sum paid by the public payer. See the following example.

In case when the value of medicine gross price was equal to financing limit, the patient did not pay the difference between them. Financing limit was established on the basis of the lowest price of the medicine (or its equivalent – usually a ge-

Price of a medicine (100 PLN)	100 PLN
Financing limit	80 PLN
Patient's fee (lump sum)	100 PLN – 80 PLN +3,20 PLN = 23,20 PLN
Patient's fee 30%	100 PLN-80 PLN + (80PLN *30%) =20 PLN +24 PLN =44 PLN
Patient's fee 50%	100 PLN-80 PLN + (80PLN *50%) =20 PLN +40 PLN =60 PLN

neric medicine). Reimbursement limit was bound to the financing limit so it was possible for Minister and public payer to finance new compounds without paying attention to their current market prices. Separation of amounts paid by the budget (payer) from the market development was essential for correct (right) economic development. Reimbursement decisions were made by the Minister of Health with assistance of Medicines Economy Team (see figure below).

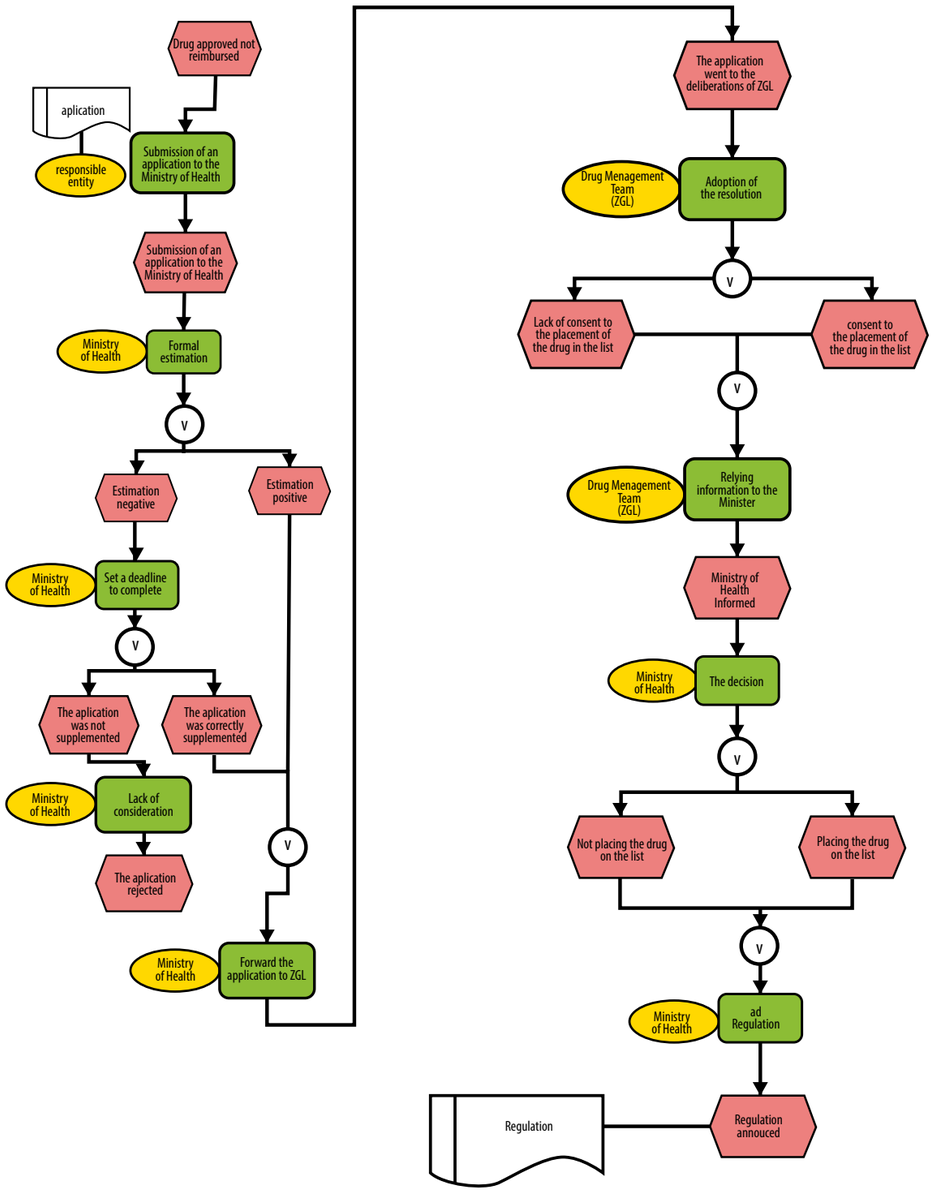

Figure 3. EPC diagram of information flows in the process of pricing and establishing limits of reimbursement before 01.2012[1]

On the basis of applications for reimbursement submitted by manufacturers the Team has prepared the opinion/recommendation to the Minister of Health. There was no time limitation for decision making by the Ministry. The decisions on reimbursement were made by the Minister, and published in relevant lists.

SUMMING UP - FINANCING OF DRUGS BY THE PUBLIC PAYER FROM 01.2012 R TO 12.2013

After promulgation of Reimbursement Act the majority of organizational concepts was not changed. The decree of Minister of Health was the base for three areas of reimbursement: pharmacy reimbursement (community pharmacies); chemotherapy; and therapeutic programs. The changed legislation caused the more dynamic activities of pharmaceutical enterprises by making the administrative procedure more open; systematic updating of Minister Decrees on lists of reimbursed medicines, chemotherapy and therapeutic programs took place every 2 months. It should be mentioned here that during previous six years (since 01.2005 to 12.2011) Minister of Health issued 13 decrees containing above mentioned lists. That is the same number of decrees as issued in two years – 01.2012 to 12.2013. To the end of 2013 the number of reimbursed medicines increased from 2922 medicines (first list) to 3818 (list No XIII). 39 new molecules were introduced into the reimbursement system, including 14 molecules used in chemotherapy. 11 therapeutic programs were modified. The most important changes were as follows:

1. **Diabetology – reimbursement of long-acting insulin analogues (detemir, glargin).**
2. **Cardiology – 5 new medicines (ivabradine, rosuvastatin, ambrisentan, tadalafil rivaroxaban).**
3. **Hepatitis type C – 2 new medicines (boceprevir, telaprevir).**
4. **Sclerosis multiplex - 2 new medicines (fingolimod, natalizumab).**
5. **Epilepsy – new medicine of 3rd generation (retygabine) and for first line – levamicetam, lamotrygin).**
6. **Psoriasis – two therapies with biological medicines (ustekinumab, adalimumab).**
7. **Rheumatic diseases – 3 new biological compounds (certolizumab, toclizumab, denosumab).**
8. **Bronchial asthma – biological medicine omalizumab.**
9. **Food allergy – seven preparations for elimination diet (nutramigen AA, neocate advance, neocate LCP, bebilon pepti 1 DHA, bebilon pepti 2 DHA, nutramigen 1 LGG, nutramigen 2 LGG).**
10. **Nocturnal enuresis in children – 1 medicine (desmopressin).**
11. **Orphan diseases: Pompe's disease – therapy of adult patients; phenylketonuria (21 dietary preparations), Huntington's disease – one medicine (tetrabenazine).**
12. **New molecules reimbursed in oncological diseases:**

1. Prostate cancer – three medicines (abiraterone acetate, degarelix, zoledronic acid),
2. Breast cancer - one medicine of the second line (exemestane),
3. Ovarian cancer - one medicine (bevacizumab),
4. Malignant melanoma – one medicine (vemurafenib),
5. Pancreatic cancer – two medicines (everolimus, sunitynib),
6. Leukemia – four medicines (bendamustin, clofarabine, arsenic trioxide, azacitidine),
7. Lymphoma – one medicine (bendamustine),
8. Multiple myeloma – one medicine (lenalidomid),
9. Renal cell carcinoma – one medicine (pazopanib),
10. Head and neck carcinoma – one medicine (cetuximab),
11. Treatment of pain in cancer patients – one medicine (pregabaline).
12. Treatment of side effects in chemotherapy – antiemetic medicine (aprepitant)

900 new medicines were enlisted in the decrees of Minister of Health since Jan. 2012 to Dec. 2013. The total sum of patients' fees was also tending to decrease at this time. Additional changes in legislation were: the determination of time for making decision by Minister; and the establishment of Economic Commission consisting of experts, which evaluate the rationale for funding (reimbursing) the given technology by the public payer. The decrees are assessed by the public (social) consulting and regularly published on website of Ministry of Health. The information flows in the process of decision making on including medicines into reimbursement were also changed (Fig. 4).

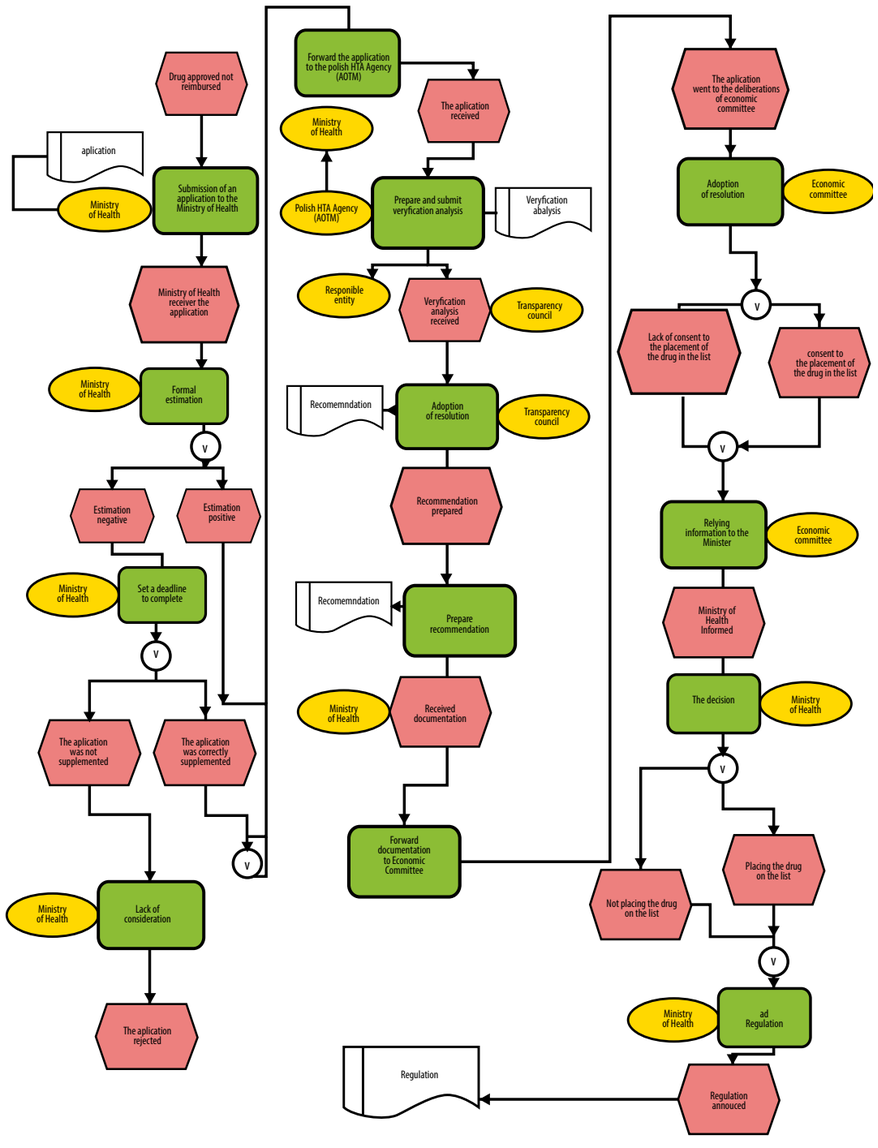

Figure 4. EPC diagram of information flows in the process of pricing and establishing limits of reimbursement after 01.2012

CONCLUSIONS

The expected main objectives of Medicines Reimbursement Act were fully achieved. The main result was the increase of transparency in decision making during reimbursement process, also the increased flexibility and mobility of changes were noted. Additional effect of the Act was the improved financial stability of public payer - gained by the precisely defined part of payer's budget, spent on medicines. Another effect of the Act was the patient-friendly (patient-oriented) approach in introducing new molecules into reimbursement system. The changes in medicines market forced by the Act suggested the positive trend in diminishing the prices of medical technologies, especially those well-established and older ones. Currently the manufacturers are fully informed about terms and timing of considering their applications, and the administrative decision will be made.

In spite of relatively short time (2 years since Jan. 1st 2012) the positive impact of the Reimbursement Act on medicines market can be observed. ■

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