https://doi.org/10.31925/farmacia.2023.6.23 **ORIGINAL ARTICLE**

THE OUTCOMES OF MANAGED ENTRY AGREEMENTS IN ROMANIA FROM 2015 TO 2022

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Abstract

Managed Entry Agreements (MEA) are contracts between governments/payers and pharmaceutical companies done at a special discounted price, volumes and/or health outcomes to mitigate the uncertainty regarding a medicine's relative effectiveness, cost-effectiveness, or budget impact. A contribution to the knowledge in the field is provided by this article's analysis of eight years of implementation in Romania, which reveals data on the volumes, budgets and utilisation in various therapeutic areas. A descriptive analysis of the existing MEAs in Romania was performed, measuring the outcomes of MEA development in terms of the number of drugs reimbursed, the therapeutic areas covered, the treated patients and the resources allocated. In Romania, the MEAs are performed as Cost-Volume contracts (financial-based contracts) or Cost-Volume-Results contracts (outcome-based contracts). The number of drugs having MEA increased yearly in the period of 2015 and 2022, from 6 to 79 and from 2 to 12 therapeutic areas. The main drugs with Cost-Volume contracts, in 2022, were in the therapeutic areas of oncology, neurology and rare diseases. The Cost-Volume-Results contracts were used only in hepatitis C. The no. of patients treated with MEA drugs increased from 10 in 2015 to 250,726 patients in 2022. In Romania, the MEAs are, in 2022, a frequent pathway to the public reimbursement of new drugs, covering 16.82% of the total drug budget and representing 48.2% of the total innovative drugs entered to the market. MEAs proved to be a solid ground for the reimbursement of new drugs. The future steps for MEA are already envisaged in terms of new types of agreements that could bring additional benefits for the health care system and patients.

Rezumat

Acordurile de intrare gestionată pe piață (*Managed Entry Agreements* – MEA) sunt contracte între guverne/furnizori de sănătate și companii farmaceutice, încheiate la un preț redus special, volume și/sau rezultate de sănătate pentru a atenua incertitudinea cu privire la eficacitatea relativă, cost-eficacitate sau impactul bugetar al unui medicament. O contribuție la cunoștințele în domeniu este oferită de acest articol care analizează opt ani de implementare în România a acestor contracte și prezintă date privind numărul de medicamente, bugetele și utilizarea în diverse domenii terapeutice. A fost efectuată o analiză descriptivă a MEA existente în România utilizând surse publice de date din 2015 până în 2022, măsurând rezultatele dezvoltării MEA în ceea ce privește numărul de medicamente rambursate, domeniile terapeutice acoperite, pacienții tratați și resursele alocate. Numărul de medicamente cu MEA a crescut în perioada 2015 - 2022 de la 6 la 79, acoperind de la 2 la 12 arii terapeutice. Principalele medicamente cu contracte cost-volum au fost în oncologie, neurologie și boli rare. Contracte cost-volum-rezultat au fost utilizate doar în tratamentul hepatitei C. Numărul de pacienți tratați cu medicamente având MEA a crescut de la 10 în 2015 la 250,726 în 2022. În România, MEA reprezintă în 2022 o cale frecventă de rambursare a medicamentelor noi, acoperind 16,82% din bugetul total pentru medicamente și reprezentând 48,2% din totalul medicamentelor inovatoare nou incluse în listă. Pașii viitori pentru dezvoltarea MEA sunt deja previzionați în ceea ce privește noi tipuri de acorduri de intrare gestionată pe piață care ar putea aduce beneficii suplimentare sistemului de sănătate și pacienților.

Keywords: managed entry agreements, drug reimbursement, access to medication, health financing

Introduction

The Romanian healthcare system is mainly a public-financed system, spending EUR 15.63 billion in 2021, of which EUR 3.73 billion was for pharmaceuticals and other medical non-durable goods (23.88% of the total health expenditures). The overall public health spending (government schemes and compulsory contributory health care financing) accounted for 78.33% of the total health care spending in 2021, and the remaining 21.67% represents private financing (*via* out-of-pocket, private health insurance schemes and pre-paid services). The National Health Insurance House (NHIH) is the main public payer and administrator of the social health insurance scheme. NHIH expenditures in 2021 accounted for 76.73% of public spending on health care, while 23.27% represented other direct public expenditures

from the State Budget, Local Authorities and Ministry of Health [2].

Regarding the expenditures on medicines in 2021, out of EUR 3.73 billion, the NHIH spent EUR 2.51, representing 67.35% of the total medicines expenditures [14]. The remaining EUR 1.22 billion was spent for medicines out-of-pocket, with co-payments or *via* private health insurance or pre-paid financing mechanisms.

The expenditures of the NHIH are divided between 16 types of healthcare providers, and medicines (pharmaceuticals) are counted in two main different ways: outpatient medicines and medicines for the national health programs. The NHIH expenditures on medicines in the period 1999 - 2019 ranged from 18.6% to 41.6% of the total NHIH health expenditures and represent one of the main categories of expenditures of the NHIH, together with hospital expenditures [16].

The public financing of medicines is conducted through three main mechanisms: (1) unconditional inclusion of medicines in the Reimbursement List, (2) conditional inclusion of medicines in the Reimbursement List and (3) coverage of the medicine expenditure as part of a medical services reimbursement (DRG payment or cost *per* case for acute patients, day-hospitalization for chronic patients, episode of day-care or dialysis and emergency services).

The reimbursement of medicines from the Reimbursement List is done in different proportions, from 20% to 100% of the reference price, depending on the type of medicine and its inclusion on the sub-lists (A, B, C, D and E) of the Reimbursement List [19].

The inclusion of medicines in the Reimbursement List began in 2014 based on a scorecard Health Technology Assessment (HTA) mechanism, where points are granted for different criteria like: UK, France, or Germany HTA decision, number of EU countries with public reimbursement of the medicine, cost-comparison *etc.* There are two thresholds for a positive reimbursement status: more than 80 points for unconditional inclusion and between 60 - 79 points for conditional inclusion on the List [9].

Managed Entry Agreements (MEA) have several definitions with the same meaning, we selected the one by Klemp, Frønsdal and Facey [4], who consider "MEA as arrangement[s] between a manufacturer and payer/provider that enable access to (coverage or reimbursement of) a health technology subject to specified conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximise their effective use, or limit their budget impact".

Prior to 2015, there were no MEAs in Romania, and the only way to access the Reimbursement List was *via* unconditional reimbursement, meaning the reimbursement of the medicine at the reference price established by the NHIH, or Ministry of Health, followed by a government clawback taxation that was compulsory for all medicines [17].

Within the National Health Strategy 2014 - 2020, Romania assumed some strategic directions to follow in healthcare, and one of the most important referred to "the development and implementation of an evidence-based drug policy to ensure equitable and sustainable population access to medication". Part of this policy was the introduction of the new HTA legislation and the introduction of conditional inclusion on the List, through the utilisation of MEAs for better financial sustainability and cost predictability [3].

According to Carlson, MEAs, or Performance-Based Schemes, between payers and market authorization holders (MAHs), could be classified as: (1) non-health outcomes-based schemes or financial schemes and (2) health outcomes-based schemes [1].

In Romania, the 2014 HTA development was followed in 2015 by the introduction of the local MEAs, part of the conditional inclusion in the Reimbursement List [23]. The local MEAs performed in 2015 are classified as follows: (1) Cost-Volume (CV) Contracts: these are financial-based schemes (called Financial-Based Managed Entry Agreements-FBMEA) and (2) Cost-Volume-Result (CVR) Contracts: these are health-outcome schemes based on the achievement of the defined outcome (Outcome-Based Managed Entry Agreements-OBMEA).

As of December 2022, there were 73 medicines with CV contracts (FBMEA) for several therapeutic areas and only six medicines had CVR contracts (OBMEA) for specific interferon-free medicines used in hepatitis C treatment. Romanian FBMEAs rely on a negotiation of a confidential contract between the payer and the MAH with regard to the share of the contracted/treated number of patients *versus* the total eligible population for the respective treatment. The financial discount to be paid back by the MAH after obtaining the full reimbursement of the list price is calculated according to a specific table published in the local legislation (Table I). The applied discount is higher if there are several substitutable medicines on the market, due to the potential reduced market share to be obtained by each medicine [23].

Table I

The FBMEA discounts are based on the market-share of the respective medicines

% of no. of treated patients from the no. of total eligible patients (market-share)	Discount (%) applied to drug consumption (single drug)	Discount (%) applied to drug consumption (multiple substitutable drugs)
< 5%	25%	30%
5 - 15%	30%	35%
15 - 25%	35%	40%

% of no. of treated patients from the no. of total eligible patients (market-share)	Discount (%) applied to drug consumption (single drug)	Discount (%) applied to drug consumption (multiple substitutable drugs)
25 - 35%	40%	45%
35 - 45%	45%	50%
45 - 55%	50%	55%
55 - 65%	55%	60%
65 - 75%	60%	65%
≥ 75%	70%	75%

The objective of this research is to present the process of development of Managed Entry Agreements in Romania, with the issues raised and the solutions adopted, and to analyse the outcomes for Managed Entry Agreements (MEAs) during eight the years of implementation (2015 - 2022).

Materials and Methods

Materials

We studied the evolution of the local legislation on MEAs (Laws, Government Ordinances, Government Decisions, Ministry of Health or National Health Insurance House Orders, *etc.*) and had discussions with stakeholders who operate the MEAs.

We identified the main issues and all the legislative updates introduced from 2015 to 2022 to overcome these issues or facilitate the implementation of the MEAs.

We performed an analysis of the existing drugs with MEAs in Romania, looking at public data sources from 2015 to 2022, measuring the outcomes of MEA development in terms of the number of drugs reimbursed, the therapeutic areas covered, the number of treated patients and the budgets allocated.

The public data sources used were the followings: the National Catalogues with Drugs List Prices in Romania (CANAMED), the monthly reimbursement List with commercial names published by the NHIH, the HTA reports of the drugs with MEAs published by the National Agency for Medicines and Medical Devices of Romania, the public information published by the NHIH about the eligible populations for the drugs with MEAs, the yearly State Law Budget, the quarterly reports of NHIH regarding the clawback payments, the yearly reports on NHIH activity, the Government Decision no. 720/2008 with the Reimbursement List, and the NHIH List with all active MEAs (Cost-Volume and Cost-Volume-Results contracts) published several times *per* year.

In Romania, access to a medicine on the Reimbursement List is not granted at some formal date but rather on a continuous basis (usually the List is updated 1 - 3 times *per* year), with new MEA medicines entering the list and other MEA medicines leaving the list or changing their status as unconditionally included medicines. In order to have data comparability for the yearly evolution of the MEA medicines, we decided to count and include in our analysis the data regarding the medicines with MEAs from the last month (December) of each year (2015 - 2022).

Results and Discussion

The main issues and the solutions implemented

The legislation that governs the MEAs in Romania is composed mainly of the Emergency Ordinance no. 77/2011 regarding the establishment of contributions for the financing of expenses in the field of health issued by the Government and the common Orders no. 3/1/2015 and no. 735/976/2018 regarding the methodology of cost-volume/cost-volume-results contracts issued by the Ministry of Health and National Health Insurance House [6, 7].

The Emergency Ordinance no. 77/2011 introduced regular clawback taxation for all medicines with unconditional reimbursement and, from 2014 a special clawback for medicines with conditional reimbursement through CV Contracts (FBMEA) and CVR Contracts (OBMEA) [23].

The FBMEA special clawback was a sum of the regular clawback tax (which at the end of 2014 exceeded 25%) and a supplementary discount between 5% and 30% (depending on the percentage of the number of patients contracted for each therapy compared to the number of eligible patients). Additionally, the volumes of medicines consumed, which exceed the volumes established by the CV/CVR contracts, were fully borne by the MAH. The sums collected by the Ministry of Finance from the CV/CVR contracts constitute revenues to the NHIH budget and are used for medicines included in the national health programs [22].

During 2015, the maximum threshold for the FBMEA discount increased in a first stage from 30% to 70%; later, the FBMEA discount was set between 10% and 50% [21].

In 2018, there was a new definition of the FBMEA: "Cost-volume contracts are mechanisms of a progressive patient-volume type to facilitate access to drugs that aim to manage the budgetary impact and do not pursue a predefined clinical result". Also, the notion of substitutable medicines and two discount grids were introduced, one for non-substitutable medicines (25 - 70% discount) and another for substitutable medicines (30 - 75% discount). The new FBMEA discount (clawback) was set up independently, without being summed up with the regular clawback tax [23].

The main issues and the implemented solutions regarding the evolution of the FBMEAs in Romania are summarised in Table II.

Table II

The main issues and solutions regarding MEA development in Romania, 2015 - 2022

Issue	Solution	Year of solution implementation
Price within FBMEA adjusted with a yearly price correction for the one-year contract of FBMEA	Fixed price for one year of the FBMEA contract; yearly price correction applies; a clear methodology for price correction for these medicines at the beginning of a new year of FBMEA	2019; 2021
A clear definition of the methodology for the eligible population	Transparency of the arguments used in the definition of the eligible population	2019; 2020
Only one medicine wins (the one with the lowest price) if there were several substitutable medicines	All substitutable medicines accepted, but with a higher discount for all of them	2018
Very high discounts are required for FBMEA (25 - 100%)	Lower discounts, but differentiated for single medicines FBMEA (25 - 70%) or substitutable medicines FBMEA (25 - 75%)	2018
FBMEA discount tops up of the regular clawback tax	FBMEA discount independent of the regular clawback tax	2018
Long negotiation timeline and clear deadlines for the negotiation process (up to three months)	Shortened negotiation process (up to one month), clear terms and a new "rapid re-negotiation" for medicines already with FBMEA	2020
The # of eligible patients not related to the already-treated patients (which induced the exclusion of FBMEAs for medicines dedicated to chronic diseases)	Introduction of the "adjusted number of effectively treated patients", which considers some of the already treated patients in the previous year's FBMEAs	2020
Several FBMEAs for the same INN if the drugs cover several indications	Conclusion of one single FBMEA for all indications of the same INN	2020

The number of medicines reimbursed

The number of medicines having a conditional reimbursement MEA increased yearly from four with FBMEAs and two with OBMEAs in 2015 to seventy-three with FBMEAs and six with OBMEAs in 2022. This increase was smaller in the first 3 - 4 years of FBMEA implementation and higher in the last three years (Table III).

Table III

Evolution of the # of medicines with MEAs in Romania, 2015 - 2022

	2015	2016	2017	2018	2019	2020	2021	2022
Total # of medicines with FBMEA	4	8	16	22	21	38	54	73
Total # of medicines with OBMEA	2	2	3	4	4	4	4	6

The therapeutic areas covered

The number of medicines with conditional reimbursement *via* FBMEA increased yearly from four in 2015, which covered only one therapeutic area in 2015 (oncology), to 73 medicines, covering 11 therapeutic areas in 2022. The therapeutic areas covered with FBMEAs (Table IV) showed an extension towards chronic diseases and reflected the improvement in the operational aspects of FBMEA contracting. For OBMEAs during these eight years of implementation, there was only one therapeutic area covered (hepatitis C).

Table IV

The evolution of # of medicines with FBMEA in different therapeutic areas in Romania, 2015 - 2022

	2015	2016	2017	2018	2019	2020	2021	2022
All therapeutical areas	4	8	16	22	21	38	55 *	74 *
Oncology	4	7	12	18	18	22	24	27
Rheumatology	0	1	1	0	0	0	1	2
Cardiology	0	0	1	1	1	4	6	6
Haematology	0	0	2	2	1	1	1	2
Dermatology	0	0	0	1	0	0	2	4
Neurology	0	0	0	0	1	5	8	10
Endocrinology	0	0	0	0	0	2	3	8
Ophthalmology	0	0	0	0	0	2	2	3
Rare diseases	0	0	0	0	0	2	7	9

	2015	2016	2017	2018	2019	2020	2021	2022
Gastroenterology	0	0	0	0	0	0	1	2
Nephrology	0	0	0	0	0	0	0	1

*As presented in the Methods section, we analysed the distribution of medicines with FBMEAs in each therapeutic area, considering the situation of contracting the FBMEA in December of each of the years of analysis. For the years 2021 and 2022, there was one medicine (INN tofacitinib) that had an FBMEA in two different areas (rheumatology and gastroenterology), and consequently, our analysis of the distribution of the number of medicines with FBMEAs counted 55 medicines in 2021 and 74 medicines in 2022.

Also, our analysis showed that while some medicines started as FBMEAs, others left the FBMEA to become medicines with unconditional reimbursement, either due to the improvement in their HTA status or due to the appearance of biosimilars/generics on the market.

The distribution of the medicines with FBMEAs in regard to therapeutic areas in 2022 shows that most of the medicines were in oncology (36.5%), neurology (13.5%), rare diseases (12.2%) and endocrinology (10.8%) (Figure 1).

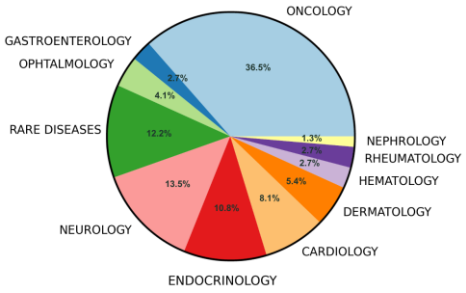

Figure 1.
Distribution of FBMEA medicines in 2022 based on the therapeutic area

We also performed an analysis of the intensity of FBMEA medicines *versus* the unconditional medicines included in the List for the main therapeutical area (onco-haematology) and from 2015 to 2022, out of the 89 new medicines included in the List from this therapeutical area, 41 medicines were FBMEA (46%).

The number of treated patients

Regarding the number of patients treated with medicines with an MEA, we analysed the public sources available for the years 2016 - 2022: State Law Budget, NHIH activity reports for the respective years and public presentations at the ISPOR local Conference [12].

In 2015, FBMEAs officially started in the month of November, and considering the novelty of contracting, prescribing and delivery, only a few patients obtained the medicines in that year (around 10 patients following the authors' discussions with officials and company representatives). OBMEAs also started at the end of 2015, but the results (outcome) of the treatment were measured in 2016, so no patients were counted in 2015.

The number of patients treated *via* MEAs increased dramatically from 10 in 2015 to over 4000 in 2016 and to reach 250,726 in 2022 (Table V).

Table V

Evolution of the # of patients who received medicines with MEAs, Romania, 2015 - 2022

Year	No. patients receiving medicines with OBMEA	No. patients receiving medicines with FBMEA	No. patients receiving medicines with MEA
2015	0	10	10
2016	3,176	932	4,108
2017	5,825	2,819	8,644
2018	11,175	15,718	26,893
2019	13,000	26,618	39,618
2020	6,520	86,269	92,789
2021	2,690	147,482	150,172
2022	3,308	247,418	250,726

Budgets allocated

In terms of the budgets allocated for these MEAs, we analysed the data published in the yearly NHIH activity reports [13]. The public data provided in these reports includes two types of budgets available: (1) the budget for the FBMEA of the medicines used in the National Health Programmes (NHP) and (2) the budget for the remaining medicines with FBMEAs alongside the medicines with outcome-based MEAs (OBMEAs).

The yearly evolution of budgets dedicated for the FBMEA medicines as part of the NHP (in the areas of oncology, haematology, neurology, cardiology and rare diseases) shows a continuous increase from EUR 5.3 mil. in 2015 to EUR 342.1 mil. Euro in 2022 (Table VI). This budget of EUR 342.1 mil. in 2022 for the medicines from the NHP with FBMEAs represents 80% of the total budget for all MEAs (FBMEAs and OBMEAs) in Romania (EUR 538.4 mil.) and is correlated with the increased number of medicines with FBMEAs in the respective therapeutic areas.

During these eight years of implementation of the MEAs, not only the absolute budgets increased almost twice, but the share of the budget used for the reimbursement of medicines with MEAs also increased from 0.29% in 2015 to 16.8% in 2022 (Table VII).

Table VI

Evolution of the budget for medicines, including the drugs with FBMEAs and with OBMEAs (EUR mil), 2015 - 2022

	2015	2016	2017	2018	2019	2020	2021	2022
Total budget for medicines (including MEAs)	1,845.7	1,860.2	2,046.2	2,222.6	2,535.1	2,616.0	2,843.1	3,201.7
Budget for medicines without MEAs	1,840.4	1,757.2	1,816.0	1,884.9	2,004.0	2,093.8	2,353.6	2,663.2
Budget for medicines with MEAs, from which	5.3	103.0	230.2	337.7	531.1	522.2	489.5	538.4
Budget for medicines from the NHP with FBMEAs	5.3	15.7	40.3	119.9	168.2	254.8	343.7	342.1
Budget for other medicines with FBMEAs and OBMEAs	0.0	87.3	189.9	217.8	362.9	267.4	145.8	196.3

Table VII

Evolution of the % of the budget for medicines with FBMEAs and with OBMEAs of the total medicines budget, 2015 - 2022

	2015	2016	2017	2018	2019	2020	2021	2022
Total budget for medicines (including MEAs)	100%	100%	100%	100%	100%	100%	100%	100%
Budget for medicines without MEAs	99.71%	94.46%	88.75%	84.81%	79.05%	80.04%	82.78%	83.18%
Budget for medicines with MEAs, from which	0.29%	5.54%	11.25%	15.19%	20.95%	19.96%	17.22%	16.82%
Budget for medicines from the NHP with FBMEAs	0.29%	0.84%	1.97%	5.40%	6.63%	9.74%	12.09%	10.69%
Budget for other medicines with FBMEAs and OBMEAs	0.00%	4.69%	9.28%	9.80%	14.32%	10.22%	5.13%	6.13%

One of the future steps for the development of local MEAs is to create the requisites for a paying-for-performance agreements for medicines. In this regard, the collection of patient clinical data to assess the performance of a medicine should be matched with the data on medicine consumption at the patient level. Even if the Diagnosis Related Groups (DRG) payment of hospitals requires the collection of patient-level clinical data from 2003, this hospital data collection doesn't integrate the medicine consumption either in hospitals or in community pharmacies for the medicine prescriptions [15]. The available published data on medicine costs in Romania comes from different researcher analyses and has different degrees of estimation [5]. The future in this regard could be promising due to an already announced project of the Ministry of Health and NHIH to update the Integrated Platform of Health Insurance and to develop an eHealth system in Romania to allow such a possibility [8].

One particular aspect of the local MEAs is related to the flow of funds and NHIH budget development. The discounts offered by the MAH as part of these MEAs follow this financial mechanism: the payer (NHIH) reimburses the list price for the respective medicines and following each quarter, the NHIH submits a notification to the MAH with the actual payments for the respective quarter, the effective number of patients treated and the number of therapeutic units reimbursed for the respective MEA medicine. In the same notification, the MAH also receives the sum to be paid as a claw-back taxation (the discount presented earlier) towards the Romanian Fiscal Agency of the Ministry of Finance (MoF) by the 25th of the next month [7]. The MoF collects these funds and will allocate them towards NHIH at the State Budget rectifications throughout the year if there are more funds collected than initially forecasted.

The local reform of the health sector supported by the International Bank for Reconstruction and Development through a loan from 2019, extended in 2020 and 2023, includes provisions regarding the development of MEAs in Romania *via* one outcome indicator: by the end of 2024, at least 50% of innovative medicines will get a positive HTA decision using conditional reimbursement, meaning using a MEA [20].

Analysing the public data available for the year 2022, we saw that from 56 innovative medicines with positive HTA reports, 27 medicines (48.2%) obtained a conditional reimbursement decision *via* a MEA (25 medicines with FBMEA and two medicines with OBMEAs), which means that the 2024 policy outcome (50% medicines with MEAs) could be achieved. For 2023, the total set of data was not available when the analysis was performed.

The future of MEAs in Romania will be related to the planned reforms of the healthcare sector, especially in the areas of pricing, reimbursement and HTA. The draft of the Romanian National Health Care Strategy 2023 - 2030 has provisions covering the development of the HTA and the future contracting mechanisms [18], and there are two consultancy projects in this area contracted by the Ministry of Health, which started in early 2023, where one expected outcome is a draft of a Policy Proposal that will explicitly also include the area of the future MEAs [10, 11]. For the moment, there is no formal announcement as to how the future EU HTA legislation, applied in February 2025, will interrelate with the actual and future HTA and MEA frameworks in Romania.

Conclusions

In Romania, in the period from 2015 to 2022, MEAs increased continuously, reaching in 2022 the following levels: 16.82% of the total medicine budget, 48.2% of the total innovative medicines and a total of 250,726 patients. The distribution of the medicines with FBMEA in regard to therapeutic areas in 2022 shows that most of the medicines were in oncology (36.5%), neurology (13.5%), rare diseases (12.2%) and endocrinology (10.8%), while OBMEAs are used only for hepatitis C.

MEAs are now part of health care reform and policy and continue to develop, similar to other countries in the European Union. The future steps for MEAs are already envisaged in terms of Paying for Performance mechanisms, which could bring additional benefits for the healthcare system.

Conflict of interest

The authors declare no conflict of interest.

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