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INTERNATIONAL BANK FOR RECONSTRUCTION AND DEVELOPMENT

RESTRUCTURING PAPER

ON A

PROPOSED PROGRAM RESTRUCTURING
OF
ROMANIA HEALTH PROGRAM FOR RESULTS
APPROVED ON SEPTEMBER 17, 2019

TO

ROMANIA

Health, Nutrition & Population Global Practice
Europe And Central Asia Region

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ABBREVIATIONS AND ACRONYMS

DLI	Disbursement-Linked Indicator
DLR	Disbursement-Linked Result
PDO	Program Development Objective
PforR	Program-for-Results

DATA SHEET (Romania Health Program for Results - P169927)

Project ID	Financing Instrument	IPF Component
P169927	Program-for-Results Financing	No

Approval Date	Current Closing Date
17-Sep-2019	31-Dec-2023

Organizations

Borrower	Responsible Agency
Romania	Ministry of Health

Program Development Objective(s)

The Program Development Objective (PDO) is to increase the coverage of primary health care for underserved populations and improve the efficiency of health spending by addressing underlying institutional challenges.

Summary Status of Financing (US$, Millions)

Ln/Cr/TF	Approval Date	Signing Date	Effectiveness Date	Closing Date	Net Commitment	Disbursed	Undisbursed
IBRD-90050	17-Sep-2019	23-Sep-2019	12-Jan-2021	31-Dec-2023	557.20	87.16	473.62

Policy Waiver(s)

Does the Program require any waivers of Bank policies applicable to Program-for-Results operations?

No

I. PROGRAM STATUS AND RATIONALE FOR RESTRUCTURING

A. Program Status

1. The Romania Health Program-for-Results (PforR) was approved on September 17, 2019, the Loan Agreement was signed on September 23, 2019, and the Project became effective on January 12, 2021. Delays in the ratification and effectiveness were due to a change in Government in November 2019 and the COVID-19 outbreak, which led to changes in Government's approach to some health sector reforms and the need to prioritize actions to respond to the public health emergency. The project has been restructured once (July 2020) to ensure alignment between the PforR activities with the views and objectives of the new Government and to support non-pharmaceutical interventions and reforms to strengthen the health care system in response to the public health emergency caused by COVID-19.

2. The Program Development Objective (PDO) is to increase the coverage of primary health care for underserved populations and improve the efficiency of health spending by addressing underlying institutional challenges. Both progress towards achievement of PDO and overall implementation progress have been rated Moderately Satisfactory since June 2020.

3. As of September 30, 2021, there has been no disbursement under the operation. However, the World Bank confirmed on September 27, 2021 that disbursement-linked results (DLRs) 4.1 and 7.1 have been achieved and the achievement of said results has been verified in accordance with the provisions of the Project's verification protocol. As such, disbursements totaling EUR 75 million are expected in October 2021.

B. Rationale for Restructuring

4. This restructuring proposes to correct two points of oversight in the restructuring paper (RP) published on July 30, 2020, namely:
   - Revision of the amounts allocated for achievement of disbursement-linked indicators (DLIs) in the DLI Matrix to reflect USD equivalencies (as the default currency for this table). In the first restructuring, the values entered into the DLI Matrix under Annex 1 (page 15 of the RP published on July 30, 2020) were mistakenly made in EUR, despite USD being the default for this table. As the loan is denominated in EUR and includes DLR allocations in EUR, the proposed change is to ensure consistency between project documents and the Financing Agreement.
   - Revision of the Program Action Plan under Annex 2 (page 30 of the RP published on July 30, 2020), namely deletion of an action that is no longer relevant as it was associated with the original DLI 4 that was changed during the first restructuring, as cited in the RP published on July 30, 2020 (paragraph 10 (d)).

II. DESCRIPTION OF PROPOSED CHANGES

5. **Adjustments to the DLI Matrix.** The DLI Matrix has been revised to update the USD equivalencies for EUR allocations and is summarized below (Table 1) in both USD and EUR.

Table 1: Summary of Allocations by DLI, EUR and USD Equivalent

DLIs		Total Allocated Amount (EUR)	Total Allocated Amount (USD Equivalent)
1. Alignment of the minimum PHC package for the uninsured population with the basic PHC package for the insured population	**Sub-total**	**75,000,000**	**83,580,000**
	Year 1	-	-
	Year 2	*20,000,000*	*22,288,000*
	Year 3	*20,000,000*	*22,288,000*
	Year 4	*35,000,000*	*39,004,000*
2. Number of underserved communities receiving public community health care in collaboration with PHC providers	**Sub-total**	**90,000,000**	**100,296,000**
	Year 1	-	-
	Year 2	*15,000,000*	*16,716,000*
	Year 3	*25,000,000*	*27,860,000*
	Year 4	*50,000,000*	*55,720,000*
3. Share of the NHIH budget allocated to primary health care	**Sub-total**	**75,000,000**	**83,580,000**
	Year 1	-	-
	Year 2	*20,000,000*	*22,288,000*
	Year 3	*20,000,000*	*22,288,000*
	Year 4	*35,000,000*	*39,004,000*
4. Strengthening of PHC to respond to the COVID-19 outbreak	**Sub-total**	**50,000,000**	**55,720,000**
	Year 1	*50,000,000*	*55,720,000*
	Year 2	-	-
	Year 3	-	-
	Year 4	-	-
5. Scope and effectiveness of PHC traced through the share of diabetes medication initiated by PHC providers and proportion of adults (40+) receiving annual medical check up	**Sub-total**	**50,000,000**	**55,720,000**
	Year 1	-	-
	Year 2	-	-
	Year 3	*20,000,000*	*22,288,000*
	Year 4	*30,000,000*	*33,432,000*
6. Efficiency of NHIH expenditure improved through data-driven decision-making process	**Sub-total**	**50,000,000**	**55,720,000**
	Year 1	-	-
	Year 2	*25,000,000*	*27,860,000*
	Year 3	-	-
	Year 4	*25,000,000*	*27,860,000*
7. Efficiency of expenditure improved through implementation of centralized procurement	**Sub-total**	**60,000,000**	**66,864,000**
	Year 1	*25,000,000*	*27,860,000*
	Year 2	-	-
	Year 3	*35,000,000*	*39,004,000*
	Year 4	-	-
8. Pharmaceutical measures revised for better efficiency	**Sub-total**	**50,000,000**	**55,720,000**
	Year 1	-	-
	Year 2	*30,000,000*	*33,432,000*
	Year 3	-	-
	Year 4	*20,000,000*	*22,288,000*
	TOTAL	**500,000,000**	**557,200,000**

6. **Adjustments in the Program Action Plan**. The following action has been removed from the Program Action Plan given that (as of the first restructuring) it is no longer relevant to the Program: “strengthen the capacity to adapt, prevent and react to extreme weather events by developing/updating/revising internal procedures and guidelines at PHC.”

III. SUMMARY OF CHANGES

	Changed	Not Changed
Change in Results Framework	✓	
Reallocation between and/or Change in DLI	✓	
Change in Implementing Agency		✓
Change in Program's Development Objectives		✓
Change in Program Scope		✓
Change in Loan Closing Date(s)		✓
Change in Cancellations Proposed		✓
Change in Disbursements Arrangements		✓
Change in Disbursement Estimates		✓
Change in Systematic Operations Risk-Rating Tool (SORT)		✓
Change in Safeguard Policies Triggered		✓
Change in Legal Covenants		✓
Change in Institutional Arrangements		✓
Change in Technical Method		✓
Change in Fiduciary		✓
Change in Environmental and Social Aspects		✓
Change in Implementation Schedule		✓
Other Change(s)		✓

IV. DETAILED CHANGE(S)

ANNEX 1: RESULTS FRAMEWORK

Results framework

Program Development Objectives(s)

The Program Development Objective (PDO) is to increase the coverage of primary health care for underserved populations and improve the efficiency of health spending by addressing underlying institutional challenges.

Program Development Objective Indicators by Objectives/ Outcomes

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
To increase the coverage of primary health care for underserved populations						
Number of the uninsured in Romania who are registered with family physicians and entitled to receive the minimum PHC package, which is aligned with the basic PHC package (Number)		0.00	0.00	0.00	500,000.00	2,000,000.00
Percentage of adults (40 years old and above) receiving annual medical check-ups from family physicians (disaggregated by gender) (Percentage)		1.00	1.00	1.00	10.00	20.00
To improve the efficiency of health spending						

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
Percentage of National Health Insurance House's annual budget allocated to PHC (Percentage, Custom) (Percentage)		6.50	6.50		8.00	10.00
Proportion of supplies and devices for emergency medical services (in value) procured under framework agreements (Percentage)		0.00			30.00	50.00

Intermediate Results Indicators by Result Areas

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
Improving coverage for underserved population						
Number of underserved communities covered by community health care in collaboration with PHC (Number)		0.00	0.00	0.00	100.00	300.00
Difference between the counties with the highest and lowest coverages of children who have received one dose of measles vaccination at 12 months old (Text)		48.6% Highest coverage: 100% Lowest coverage: 51.4%	0.47	0.45	0.43	0.41
Percentage of uninsured who are aware they are entitled to receive		Not applicable because they are not entitled yet			0.60	0.90

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
an improved PHC benefit package (aligned with the basic benefits package for the insured) (Text)						
Number of community health care workers (community health nurses and Roma health mediators) trained (Number)		0.00	0.00	1,500.00	2,000.00	2,000.00
Percentage of women living in communities covered by community health care receiving at least one annual visit from a community health care provider (Percentage)		0.00	0.00	0.00	40.00	70.00
Hospital-centric health system rebalanced towards effective primary care						
Percentage of metformin prescriptions initiated at the PHC level (Percentage)		0.00	0.00	10.00	20.00	30.00
Number of communication tools applied for universal access to PHC and framework contract modification (Number)		0.00	3.00	6.00	9.00	12.00
Number of public expenditure reviews conducted (Number)		0.00	1.00		1.00	3.00
Improving fiscal efficiency by addressing cristical cost drivers						
Percentage change in claims detected as unacceptable		0.00				0.00

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
(unnecessary care, non-optimized laboratory tests, intentional or unintentional errors, …) (Percentage)						
PHC claims (Percentage)		0.00	0.00	10.00	20.00	20.00
Hospital claims (Percentage)		0.00	0.00	5.00	10.00	20.00
Laboratory tests (Percentage)		0.00	0.00	10.00	20.00	30.00
Percentage of healthcare providers that automatically share data to the central EHR (Percentage)		0.00				0.00
PHC practices (Percentage)		0.00	0.00	0.00	30.00	90.00
Hospitals (Percentage)		0.00	0.00	0.00	10.00	60.00
Community health care information system upgraded to share data with the EHR (Yes/No)		No	No	No	Yes	Yes
Annual international price comparisons for all medicines with registered shortages in Romania (Yes/No)		No	No	Yes	Yes	Yes
Managed Entry Agreement signed for 50% of newly assessed patented drugs with conditional entry decision through HTA methodology (Percentage)		0.00	0.00	0.00	30.00	50.00

Indicator Name	DLI	Baseline	Intermediate Targets			End Target
			1	2	3	
Clawback tax regulation revised to improve access to cost-effective drugs (Text)		Clawback tax not revised			Clawback tax revised	Clawback tax revised
Revision of the list of drugs reimbursed by NHIH (Text)		List of drugs reimbursed by HNIH not revised using updated HTA methodology / HTA Methodology not updated	No	List of drugs reimbursed by NHIH revised		List of drugs reimbursed by NHIH revised

Disbursement Linked Indicators Matrix

DLI 1	Alignment of the minimum PHC package for the uninsured population with the basic PHC package for the insured population			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Outcome	Yes	Text	75,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	About 2 million uninsured do not have access to the basic PHC package			
Prior Results			0.00	
Year 1			0.00	

Year 2	Health Reform Law 95/2006 amended to provide at free to the uninsured population a minimun PHC package aligned with the the basic PHC package for the insured population	20,000,000.00	
Year 3	Annual Budget Law and Medium Expenditure Framework reflect the amended Health Reform Law 95/2006 to finance the minimum PHC package for the uninsured population as aligned with the basic PHC package for the insured population	20,000,000.00	
Year 4	At least 2 million uninsured persons registered with PHC providers (family physicians) to receive the minimum PHC package as aligned with the basic PHC package for the insured population	35,000,000.00	See Formula under Description of DLI

Action: This DLI has been Revised. See below.

DLI 1	*Alignment of the minimum PHC package for the uninsured population with the basic PHC package for the insured population*			
Type of DLI	***Scalability***	***Unit of Measure***	***Total Allocated Amount (USD)***	***As % of Total Financing Amount***
Outcome	*Yes*	*Text*	*83,580,000.00*	*0.00*
Period	***Value***		***Allocated Amount (USD)***	***Formula***
Baseline	*About 2 million uninsured do not have access to the basic PHC package*			
Prior Results			*0.00*	
Year 1			*0.00*	
Year 2	*Health Reform Law 95/2006 amended to provide at free to the uninsured population a minimun PHC*		*22,288,000.00*	

	package aligned with the the basic PHC package for the insured population		
Year 3	*Annual Budget Law and Medium Expenditure Framework reflect the amended Health Reform Law 95/2006 to finance the minimum PHC package for the uninsured population as aligned with the basic PHC package for the insured population*	*22,288,000.00*	
Year 4	*At least 2 million uninsured persons registered with PHC providers (family physicians) to receive the minimum PHC package as aligned with the basic PHC package for the insured population*	*39,004,000.00*	*See Formula under Description of DLI*

Rationale:
The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.

DLI 2	Number of underserved communities receiving public community health care in collaboration with PHC providers			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Outcome	Yes	Text	90,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	Community health services not in collaboration with PHC services			
Prior Results			0.00	
Year 1			0.00	
Year 2	Methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between		15,000,000.00	

	community health care and PHC developed and adopted by the MoH		
Year 3	Progress report on the first year of implementation of the new community healthcare tools in at least 100 underserved communities providing public community health care in collaboration with PHC	25,000,000.00	
Year 4	300 underserved communities providing public community health in collaboration with PHC providers	50,000,000.00	See Formula under Description of DLI
Action: This DLI has been Revised. See below.			

DLI 2	*Number of underserved communities receiving public community health care in collaboration with PHC providers*			
Type of DLI	***Scalability***	***Unit of Measure***	***Total Allocated Amount (USD)***	***As % of Total Financing Amount***
Outcome	*Yes*	*Text*	*100,296,000.00*	*0.00*
Period	***Value***		***Allocated Amount (USD)***	***Formula***
Baseline	*Community health services not in collaboration with PHC services*			
Prior Results			*0.00*	
Year 1			*0.00*	
Year 2	*Methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between community health care and PHC developed and adopted by the MoH*		*16,716,000.00*	
Year 3	*Progress report on the first year of implementation of the new community healthcare tools in at least*		*27,860,000.00*	

	100 underserved communities providing public community health care in collaboration with PHC		
Year 4	*300 underserved communities providing public community health in collaboration with PHC providers*	*55,720,000.00*	*See Formula under Description of DLI*

Rationale:
The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.

DLI 3	Share of the NHIH budget allocated to primary health care			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Output	Yes	Text	75,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	a) Share of the NHIH budget allocated to family medicine is 6.5%; b)Provider payment mechanisms for PHC providers limits effectiveness of PHC provision; c) Limited scope of PHC			
Prior Results			0.00	
Year 1			0.00	
Year 2	Framework contract is modified to increase the effectiveness of PHC through a) Revised provider payment mechanisms; and b) Expanded scope of services allowed at PHC		20,000,000.00	
Year 3	Share of the NHIH budget allocated to PHC is at least 8%		20,000,000.00	

Year 4	Share of the NHIF budget allocated to PHC is 10%	35,000,000.00	See Formula under Description of DLI
Action: This DLI has been Revised. See below.			

DLI 3	*Share of the NHIH budget allocated to primary health care*			
Type of DLI	***Scalability***	***Unit of Measure***	***Total Allocated Amount (USD)***	***As % of Total Financing Amount***
Output	*Yes*	*Text*	*83,580,000.00*	*0.00*
Period	***Value***		***Allocated Amount (USD)***	***Formula***
Baseline	*a) Share of the NHIH budget allocated to family medicine is 6.5%; b)Provider payment mechanisms for PHC providers limits effectiveness of PHC provision; c) Limited scope of PHC*			
Prior Results			*0.00*	
Year 1			*0.00*	
Year 2	*Framework contract is modified to increase the effectiveness of PHC through a) Revised provider payment mechanisms; and b) Expanded scope of services allowed at PHC*		*22,288,000.00*	
Year 3	*Share of the NHIH budget allocated to PHC is at least 8%*		*22,288,000.00*	
Year 4	*Share of the NHIF budget allocated to PHC is 10%*		*39,004,000.00*	*See Formula under Description of DLI*
Rationale: ***The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.***				

DLI 4	Strengthening of PHC to respond to the COVID-19 outbreak			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Process	Yes	Text	50,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	Limited scope of PHC services			
Prior Results			0.00	
Year 1	Regulations adopted to: (i) introduce in the benefits package for the uninsured population COVID-19-related services delivered at all levels of care including PHC; (ii) introduce remote consultations and prescriptions in the scope of services delivered by PHC providers; (iii) expand prescribing rights for PHC providers; and (iv) remove hourly caps on the number of consultations		50,000,000.00	
Year 2			0.00	
Year 3			0.00	
Year 4			0.00	
Action: This DLI has been Revised. See below.				

DLI 4	*Strengthening of PHC to respond to the COVID-19 outbreak*			
Type of DLI	***Scalability***	***Unit of Measure***	***Total Allocated Amount (USD)***	***As % of Total Financing Amount***
Process	*Yes*	*Text*	*55,720,000.00*	*0.00*
Period	***Value***		***Allocated Amount (USD)***	***Formula***
Baseline	*Limited scope of PHC services*			
Prior Results			*0.00*	
Year 1	*Regulations adopted to: (i) introduce in the benefits package for the uninsured population COVID-19-related services delivered at all levels of care including PHC; (ii) introduce remote consultations and prescriptions in the scope of services delivered by PHC providers; (iii) expand prescribing rights for PHC providers; and (iv) remove hourly caps on the number of consultations*		*55,720,000.00*	
Year 2			*0.00*	
Year 3			*0.00*	
Year 4			*0.00*	

Rationale:
The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.

DLI 5	Scope and effectiveness of PHC traced through the share of diabetes medication initiated by PHC providers and proportion of adults (40+) receiving annual medical check up			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Outcome	Yes	Text	50,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	a) Initiation of diabetes medication at the PHC level is 0%; b) Number of adults (40+) receiving annual medical check-ups is 1%			
Prior Results			0.00	
Year 1			0.00	
Year 2			0.00	
Year 3	a) 10% of metformin prescription (a commonly used diabetes medication) initiated by PHC providers; b)10% of adults (40+) receiving annual medical check ups by PHC providers		20,000,000.00	EUR 10 million for a) and EUR 10 million for b)
Year 4	a) 20% of metformin prescription (a commonly used diabetes medication) initiated by PHC providers; b) 20% of adults (40+) receiving annual medical check ups by PHC providers		30,000,000.00	See Formula under Description of DLI
Action: This DLI has been Revised. See below.				

DLI 5	*Scope and effectiveness of PHC traced through the share of diabetes medication initiated by PHC providers and proportion of adults (40+) receiving annual medical check up*			
Type of DLI	***Scalability***	***Unit of Measure***	***Total Allocated Amount (USD)***	***As % of Total Financing Amount***
Outcome	*Yes*	*Text*	*55,720,000.00*	*0.00*
Period	***Value***		***Allocated Amount (USD)***	***Formula***
Baseline	*a) Initiation of diabetes medication at the PHC level is 0%; b) Number of adults (40+) receiving annual medical check-ups is 1%*			
Prior Results			*0.00*	
Year 1			*0.00*	
Year 2			*0.00*	
Year 3	*a) 10% of metformin prescription (a commonly used diabetes medication) initiated by PHC providers; b)10% of adults (40+) receiving annual medical check ups by PHC providers*		*22,288,000.00*	*EUR 10 million for a) and EUR 10 million for b)*
Year 4	*a) 20% of metformin prescription (a commonly used diabetes medication) initiated by PHC providers; b) 20% of adults (40+) receiving annual medical check ups by PHC providers*		*33,432,000.00*	*See Formula under Description of DLI*
Rationale: ***The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.***				

DLI 6	Efficiency of NHIH expenditure improved through data-driven decision making process			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Outcome	No	Text	50,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	0% (current level of avoiding unnecessary expenditures used as baseline)			
Prior Results			0.00	
Year 1			0.00	
Year 2	a) Health Data Management Strategy approved by MoH, and institutional arrangements implemented as defined in the said Strategy; b) Integrated management system in NHIH upgraded to allow improved detection of inefficient spending on claims management in PHC and hospital care, and laboratory tests.		25,000,000.00	
Year 3			0.00	
Year 4	a) An inter-operable system connects data between PHC providers, NHIH and MoH, to provide regular data cross-checks and inefficient spending data analytics; b).Efficiency of health spending increased by avoiding inefficient NHIH expenditures in an amount equivalent to 2.5% of total projected annual NHIH expenditures		25,000,000.00	
Action: This DLI has been Revised. See below.				

DLI 6	*Efficiency of NHIH expenditure improved through data-driven decision making process*			
Type of DLI	***Scalability***	***Unit of Measure***	***Total Allocated Amount (USD)***	***As % of Total Financing Amount***
Outcome	*No*	*Text*	*55,720,000.00*	*0.00*
Period	***Value***		***Allocated Amount (USD)***	***Formula***
Baseline	*0% (current level of avoiding unnecessary expenditures used as baseline)*			
Prior Results			*0.00*	
Year 1			*0.00*	
Year 2	*a) Health Data Management Strategy approved by MoH, and institutional arrangements implemented as defined in the said Strategy; b) Integrated management system in NHIH upgraded to allow improved detection of inefficient spending on claims management in PHC and hospital care, and laboratory tests.*		*27,860,000.00*	
Year 3			*0.00*	
Year 4	*a) An inter-operable system connects data between PHC providers, NHIH and MoH, to provide regular data cross-checks and inefficient spending data analytics; b).Efficiency of health spending increased by avoiding inefficient NHIH expenditures in an amount equivalent to 2.5% of total projected annual NHIH expenditures*		*27,860,000.00*	

Rationale:
The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.

DLI 7	Efficiency of expenditure improved through implementation of centralized procurement			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Outcome	No	Text	60,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	National Office for Centralized Procurement (ONAC) not operational and not mandated to work in health sector			
Prior Results			0.00	
Year 1	Framework agreements between ONAC and suppliers signed for 10 priority products to address the COVID-19 outbreak		25,000,000.00	
Year 2			0.00	
Year 3	Framework Agreements between the designated procurement agencies and suppliers signed for minimum of 60 medical supplies and devices for publicly owned hospitals and emergency medical services		35,000,000.00	
Year 4			0.00	
Action: This DLI has been Revised. See below.				

DLI 7	Efficiency of expenditure improved through implementation of centralized procurement			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Outcome	No	Text	66,864,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	National Office for Centralized Procurement (ONAC) not operational and not mandated to work in health sector			
Prior Results			0.00	
Year 1	Framework agreements between ONAC and suppliers signed for 10 priority products to address the COVID-19 outbreak		27,860,000.00	
Year 2			0.00	
Year 3	Framework Agreements between the designated procurement agencies and suppliers signed for minimum of 60 medical supplies and devices for publicly owned hospitals and emergency medical services		39,004,000.00	
Year 4			0.00	

Rationale:
The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.

DLI 8	Pharmaceutical measures revised for better efficiency			
Type of DLI	**Scalability**	**Unit of Measure**	**Total Allocated Amount (USD)**	**As % of Total Financing Amount**
Outcome	No	Text	50,000,000.00	0.00
Period	**Value**		**Allocated Amount (USD)**	**Formula**
Baseline	Shortcoming of existing pharmaceutical policy: a) External reference pricing for pharmaceutical carried out sporadically b) List of drugs reimbursed based on outdated health technology assessment (HTA) methodology c) Great potential to expand use of Management Entry Agreements (MEA)			
Prior Results			0.00	
Year 1			0.00	
Year 2	(a) New HTA methodology for inclusion of new drugs to the list of drugs approved; (b) Annual recalculated prices for medication published on the MoH website and annual list of reference prices published on the NHIH website.		30,000,000.00	
Year 3			0.00	
Year 4	MEA signed by NHIH and market authorization holders for 50% of newly assessed patented drugs with the conditional entry decision using the new HTA methodology		20,000,000.00	
Action: This DLI has been Revised. See below.				

DLI 8	*Pharmaceutical measures revised for better efficiency*			
Type of DLI	***Scalability***	***Unit of Measure***	***Total Allocated Amount (USD)***	***As % of Total Financing Amount***
Outcome	*No*	*Text*	*55,720,000.00*	*0.00*
Period	***Value***		***Allocated Amount (USD)***	***Formula***
Baseline	*Shortcoming of existing pharmaceutical policy: a) External reference pricing for pharmaceutical carried out sporadically b) List of drugs reimbursed based on outdated health technology assessment (HTA) methodology c) Great potential to expand use of Management Entry Agreements (MEA)*			
Prior Results			*0.00*	
Year 1			*0.00*	
Year 2	*(a) New HTA methodology for inclusion of new drugs to the list of drugs approved; (b) Annual recalculated prices for medication published on the MoH website and annual list of reference prices published on the NHIH website.*		*33,432,000.00*	
Year 3			*0.00*	
Year 4	*MEA signed by NHIH and market authorization holders for 50% of newly assessed patented drugs with the conditional entry decision using the new HTA methodology*		*22,288,000.00*	

Rationale:
The value of the total financing allocated to the DLI has been revised to correct an error - the original figures were in EUR (not USD). Revised allocations reflect estimated USD equivalencies of EUR allocations.

ANNEX 2: PROGRAM ACTION PLAN

Action Description	Source	DLI#	Responsibility	Timing		Completion Measurement	Action
Sufficient allocation of Program funding in the budget and timely remittance of financing to implementing entities	Fiduciary Systems		MoPF	Recurrent	Continuous	Program funding consistent with annual workplans.	No Change
Strengthen the enforcement of the existing regulations for medical waste management to handle, collect, record, store, decontaminate, transport and disposal of waste by developing/updating/revising internal procedures and guidelines at PHC	Environmental and Social Systems		MoH	Other	First 2 years of Program implementation	Analysis of MoH internal regulations norms for implementing the procedures for reactive and preventive identified priorities for medical waste management confirmed	No Change
Strengthen the capacity to adapt, prevent and react to extreme weather events by developing/updating/revising internal procedures and guidelines at PHC	Environmental and Social Systems		MoH	Other	First 2 years of Program implementation	Analysis of MoH internal regulations/norms for implementing the procedures for reactive and preventive identified priorities for adaptation to climate change effects confirmed	Marked for Deletion
Develop and implement existing communication tools, as may be relevant, to increase public	Environmental and Social Systems		MoH, NIPH, CSO, other	Other	Second and third years of Program implementation	Findings on the level of public awareness regarding access to basic services package for uninsured	No Change

awareness of Program initiatives in consultation with the World Bank							
Strengthening a unit of the MoH to ensure integration at the institutional level of strategic planning for primary and community health care services	Technical		MoH	Due Date	31-Dec-2020	A ministerial order will be issued to specify the unit staffing, job descriptions and qualifications, overall institutional mandate, and operational budget.	No Change
Determining the benefit package for PHC, including the currently uninsured	Technical		MoH, NHIH, MoPF	Due Date	30-Jun-2021	Benefit package for PHC determined and incorporated in the Health Care Law 95/2006.	No Change
Conducting public expenditure review based on defined scope of work	Technical		MoPF	Other	At least 2 times during Program period	PER conducted and results analyzed and used for decision making	No Change
Maintain records of and track the number of patients, on a sample basis, whom community health workers have referred to acquire IDs for their registration with family physicians	Environmental and Social Systems		NHIH, MoH, MoSPJ	Recurrent	Yearly	Reporting by community health workers on the number of patients who have been referred by community health workers to acquire an ID for their registration with family physicians	No Change
Adequate arrangements and technical capacity to prepare Program financial statements and have them timely audited	Fiduciary Systems		MoH	Recurrent	Continuous	Timely preparation and audit of Program financial statements.	No Change
Technical	Fiduciary Systems		MoH/MoPF/ON	Other	First year of	Report on	No Change

assistance for the establishment of centralized procurement of medical supplies – including systems and staffing			AC		Program implementation	completed review and implementation of report's recommendations – included in annual progress report	
Technical assistance for the establishment and maintenance of electronic platforms for collation of procurement needs of implementing entities to support timely centralized procurement	Fiduciary Systems		MoH/MoPF/ONAC	Due Date	30-Dec-2022	Report on system functionalities and roll-out data, including information on capacity building of actual and potential users – included in annual progress report.	No Change
Conducting training of community nurses and Roma mediators on public community health care in collaboration with PHC providers	Technical		MoH	Other	Year 2 of Program implementation	Training conducted and evaluation report from training participants available.	No Change

ANNEX 3: VERIFICATION PROTOCOL TABLE—DISBURSEMENT LINKED INDICATORS	
DLI 1	**Alignment of the minimum PHC package for the uninsured population with the basic PHC package for the insured population**
Description	This DLI aims to support the shift from input-based to results-based financing, facilitating improvements in the efficiency and predictability of expenditures in the Romanian health system, while addressing demand-side financial barriers to health care access. Year 2: The Health Reform Law 95/2006 will be amended to provide the minimum PHC package for free to the uninsured with the same services as the basic PHC package for the insured population. With regard to prescriptions and referrals, the minimum PHC package for the uninsured population will include simple prescriptions and referrals; reimbursement of drugs and outpatient specialist consultations, laboratory services and imaging services will not be included. Year 3: Annual budget law and medium expenditure framework will reflect the amended Health Reform Law 95/2006 to finance the coverage of the minimum PHC package for the uninsured with the same services as the basic PHC package for the insured population. Year 4: Two million uninsured people will be registered with family physician to receive the minimum PHC package with the same services as the basic PHC package for the insured population. Formula: EUR 35 million divided by 2 million multiplied by actual number of uninsured registered with PHC providers (family physicians) to receive the aligned minimum PHC package, up to a maximum amount of EUR 35 million.
Data source/ Agency	Year 2: Official Gazette from MoH and MoPF Year 3: Official Gazette from MoH and NHIH Year 4: NHIH reports on the number of people registered with family physicians for the aligned minimum PHC package
Verification Entity	Independent Verification Entity (IVA)
Procedure	Year 2: the IVA will confirm that the amendment of the law grants free access to the minimum PHC package to the uninsured with the same services as the basic PHC package for the insured population as described above. Year 3: the IVA will confirm that budget allocation for projected expenditure for the minimum PHC package for the uninsured with the same services as the basic PHC package for the insured population to be transferred to NHIH is approved by the budget Law and reflected in the medium expenditure framework. Year 4: the IVA will confirm that the NHIH reports include 2 million uninsured people that are registered and there is claim of PHC services among this group.
DLI 2	**Number of underserved communities receiving public community health care in collaboration with PHC providers**
Description	This DLI aims to improve the effectiveness of community health services and leverage partnerships between public provision of community health care and largely private family physicians to address supply-side barriers to PHC in underserved communities. Year 2: The MoH will develop and adopt methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between community health care and PHC providers. The methodological guidelines and template agreements will specify the scope of work of community health nurses, Roma health mediators,

	and family physicians in the continuum of care between community healthcare and PHC, the technical standards for each procedure, and mechanisms for collaboration (between community healthcare and PHC) and supervision by the DPHAs. The household monitoring instrument will also include standardized evaluation of health risks for each household in the geographical area of each community nurse. Year 3: The MoH will issue a Progress report on the first year of implementation of the new community healthcare tools in at least 100 underserved communities providing public community health care in collaboration with PHC. The agreements for collaboration between community healthcare and PHC providers will be signed. Community health nurses will be hired, trained, and supported by the MoH to provide health promotion services based on the standards defined by the MoH, to provide services according to the guidelines to at least 100 local authorities that meet the criteria of underserved communities defined in the PAD, and facilitate linkages to PHC per the collaboration agreement signed. In communities with up to 700 self-identifying Roma, a Roma health mediator will also be hired (at the request of the community), trained, and supported by the MoH and local authority to ensure registration of vulnerable groups to receive PHC services. Year 4: Formula: EUR 50 million divided by 200 multiplied by the number of additional communities (above the initial 100) providing public community healthcare in collaboration with PHC, up to a maximum amount of EUR 50 million.
Data source/ Agency	Year 2: Ministerial order/MoH, Year 3: MoH's report based on the existing electronic system for community health care (AMCMSR), Year 4: Existing electronic system for community health care (AMCMSR) from MoH
Verification Entity	IVA
Procedure	Year 2 (Development of standards): Methodological guidelines and household monitoring instruments for community health care, and template agreements for collaboration between community health care and PHC providers developed and adopted by the MoH. The IVA will confirm the issuance of Ministerial order. Year 3: (100 communities) The IVA will confirm, using the existing electronic system for community health care (AMCMSR), the number of localities that have community services in place and reporting, including for each locality: a) the number of community health nurses and Roma health mediators working in the area; b) the number of agreements for collaboration signed; c) summary reports on the number of services delivered (household visits, communication with PHC providers and referrals to PHC providers) per month; and d) supervision reports prepared by the DPHA. The verification protocol will include spot checks/surveys to be conducted with technical support to confirm the results achieved to complement and validate system generated data. Year 4 (300 communities): The IVA will confirm, using the existing electronic system for community health care (AMCMSR), the number of localities that have community services in place and reporting, including for each locality: a) the number of community health nurses and Roma health mediators working in the area; b) the number of agreements for collaboration signed; c) summary reports on the number of services delivered (household visits, communication with PHC providers and referrals to PHC providers) per month; and d) supervision reports prepared by the DPHA. The verification protocol will include spot checks/surveys to be conducted with technical support to confirm the results achieved to complement and validate system generated data.

DLI 3	Share of the NHIH budget allocated to primary health care
Description	This DLI aims to support efforts by the Ministry of Health to reorient the health system towards primary health care, by adjusting the incentives for service provision through revision of clinical guidelines and provider payment mechanisms and increasing overall funding for primary health care. Negotiations between the NHIH and the family physician's association will continue as currently is the case, and the framework contract will then be approved by the NHIH Board and MoH. Year 2: Milestone a): Provider payment mechanisms for family physicians will be modified to incentivize an increase in the scope and supply of primary health care services. Specifically, capitation methods will also be adjusted for gender, the threshold on the volume of services reimbursed through fee-for-services will be increased, performance-based payment mechanisms for attaining service coverage targets and quality will be introduced, and family physicians will be reimbursed for services introduced through the revision of clinical guidelines (e.g., initiation and coordination for chronic diseases care). Milestone b): Relevant regulations will be modified by the Ministry of Health in consultation with physician associations to expand the scope of services in primary health care to include initiation and coordination of care for diabetes mellitus and cervical cancer and other such as chronic obstructive pulmonary diseases, psychiatric conditions, and chronic pain, including prescription of related medication and the required diagnostic tests. These normative changes will be translated to regulation through the framework contract. Year 3: The share of the NHIH budget allocated to family medicine is at least 8%. Numerator: annual NHIH budget for service delivery allocated to family medicine. Denominator: total NHIH budget for service delivery allocated to goods and services and transfers in the same year as for the numerator. Year 4: The share of the NHIH budget allocated to family medicine is 10% by Year 4. Numerator: annual NHIH budget for service delivery allocated to family medicine. Denominator: total NHIH budget for service delivery allocated to goods and services and transfers in the same year as the numerator. Formula: EUR 17.5 million multiplied by percentage points of the share of NHIH budget above 8% allocated to family medicine, up to a maximum amount of EUR 35 million (percentage points of the share of NHIH budget should be rounded to the first decimal digit (e.g., 9.7%)).
Data source/ Agency	Year 2: Official Gazette from MoH and NHIH, Year 3: Official Gazette/NHIH, Year 4: Official Gazette/NHIH
Verification Entity	IVA
Procedure	Year 2: The IVA will confirm that the revised framework contract reflects changes in provider payment mechanisms and reimbursement for expanded scope of PHC as described in the PAD. Year 3: The IVA will assess the official gazette documenting legislation on the budget for NHIH to confirm that the allocated amount for family medicine is at least 8% of the total NHIH budget. Year 4: The IVA will assess the official gazette documenting legislation on the budget for NHIH to confirm that the allocated amount for family medicine is 10% of the total NHIH budget.

DLI 4	Strengthening of PHC to respond to the COVID-19 outbreak
Description	This Disbursement-Linked Indicator aims to strengthen PHC to respond to the COVID-19 outbreak, including the capacity of PHC providers to deliver COVID-19 services to uninsured populations and to deliver regular PHC services efficiently during the outbreak. Year 1: The Government will adopt regulations to: (i) introduce in the benefits package for the

	uninsured population COVID-19-related services delivered at all levels of care including PHC; (ii) introduce remote consultations and prescriptions in the scope of services delivered by PHC providers; (iii) expand prescribing rights for PHC providers; and (iv) remove hourly caps on the number of consultations. All these measures will be valid during the state of alert declared during the epidemic.
Data source/ Agency	Year 1: Official Gazette
Verification Entity	IVA
Procedure	Year 1 (regulations passed/scheme established): The IVA will confirm that government regulations (i) introducing in the benefits package for the uninsured population COVID-19-related services delivered at all levels of care including PHC; (ii) introducing remote consultations and prescriptions in the scope of services delivered by PHC providers; (iii) expanding prescribing rights for PHC providers; and (iv) removing hourly caps on the number of consultations have been issued.
DLI 5	**Scope and effectiveness of PHC traced through the share of diabetes medication initiated by PHC providers and proportion of adults (40+) receiving annual medical check up**
Description	Year 4: Formula: EUR 15 million divided by 10 and multiplied by (percentage of metformin prescription initiated by PHC providers minus 10 percentage points) up to EUR 15 million for (a) and EUR 15 million divided by 10 and multiplied by (percentage adults (40+) receiving annual medical check-ups minus 10 percentage points) up to EUR 15 million for (b). This DLI serves as a tracer indicator for increased scope and improved effectiveness of PHC services. Years 3 and 4: the total allocation of EUR 50 M is divided equally between result related to metformin (EUR 25 M) and annual check up (EUR 25 M); Year 3: a) Due to the expansion of the scope of primary health care, the percentage of metformin prescriptions for Diabetes Mellitus Type 2 initiated by family physicians will increase to 10%. Numerator: number of metformin regimen initiation by family medicine physicians in a given 12 months period. Denominator: total number of metformin regimen initiations in the same 12 months as for the numerator. b) The NHIH will revisit the scope of preventive check-ups for asymptomatic adults, ensuring its focus on most cost-effective preventive interventions and revise the framework contract accordingly. The result will be estimated based on the following: Numerator: number of adults (40+) receiving annual medical check-ups as defined in the PAD during a given year (if a person receives both preventive check-up and case management during the same year, it will only be counted once). Denominator: number of adults (40+) registered with family physicians to receive basic package during the same year as for the numerator. Year 4: a) same as for Year 3, but the target is 20%; b) same as for Year 3, but the target is 20%.
Data source/ Agency	Year 3: Existing e-prescription system/NHIH system reports Year 4: Existing e-prescription system/NHIH system reports
Verification Entity	IVA
Procedure	Years 3 and year 4: The IVA will confirm that the existing system reports include the numerator, the denominator and the share as defined. The IVA will also confirm that mechanisms for reviewing and checking reported data in the system are in place (such as outliers, unexplained changes in patterns, mismatching) and actions are taken to address the identified inconsistencies based on related evidence.

DLI 6	Efficiency of NHIH expenditure improved through data-driven decision making process
Description	This DLI will support efforts to build IT systems that will enable improved legal, financial, organizational and data analytics capacity to improve policy decisions for identifying and reducing inefficient health expenditure and promoting performance management in service provision. “Inefficient health expenditures" means spending that is detectable by data analytics as non-optimal. For instance, unnecessary care (referrals, visits, laboratory tests, etc.), non-adherence to best practices, duplication of services, non-optimized laboratory tests, non-optimal use of infrastructure and medical equipment, low workforce productivity, detectable high cost centers such as high readmissions, over-prescribing centers, etc., and errors, including coding, claimed services not connectable to medical conditions, and frauds. Year 2: a) A Health Data Management Strategy is developed and aims at increasing the stewardship role of the Ministry of Health in overseeing the efficient, reliable, complete, and timely collection and reporting of data for decision-making via centralized systems. A stakeholders' agreement in the form of a policy paper will define as a minimum: (i) a single vision of IT domain in health, including consolidation and coordination of current systems and projects already underway at NHIH and MoH, (ii) overall future architecture of health data management and eHealth systems and their interaction, (iii) institutional arrangements on improved data governance and responsibilities for the implementation of the Strategy, and (iv) action plan, including sources of investments and sustainable systems' development and maintenance. b) System reports from integrated NHIH management system showing the detected cases of inefficient spending in healthcare claims (PHC claims, hospitals claims, and separately laboratory tests). Year 4: a) The advanced methodology and algorithms for identifying inefficient spending are expanded by using data analytics and cross-check on the connected data among NHIH, MoH and providers. An inter-operable system that connects data among NHIH, MoH, and providers (based on Government Cloud support) is established to allow: - integration of key central systems (expanded national EHR, key registries such as HR registry, NHIH core systems, ePrescription, eReferrals), providers' systems (PHC, hospitals, pharmacies, laboratories) and community care information system; - interaction between the systems based on interoperability standards, and data and registers models according to the EU recommendations; - Integrated Health Management Information System (HMIS) as a Business Intelligence (BI) and data analytics tool that allows consolidation of administrative and financial data, implements data cross-checks and smart analytics aimed at reducing losses caused by inefficient spending and provides analytical reporting on healthcare system resources (human resources, facilities, etc.) and key performance indicators (KPIs). - The National Health Data Observatory as a data warehouse and data reporting/analytics tool that identifies health data consumers, data sets and data sources, consolidates public health data sets and registries, provides key national healthcare system indicators, including key national reporting indicators to EU, WHO... (NOTE: The HMIS and Observatory can be implemented as one technical system, but with distinctive features). b) The MoH, NHIH and IPH will use improved methodology and algorithms to utilize new tools and information available, including blended methods of monitoring and evaluation (automatic with the combination of manual/classic audit), improvements of the definition of data sets to be provided by providers, legal consolidation of data on healthcare systems resources, etc. To improve legal, financial, organizational and data analytics capacity to make better policies and decisions, thus increasing the efficiency of the

	healthcare system by avoiding unnecessary NHIH expenditures.
Data source/ Agency	Year 2: a) Official Gazette and collaboration protocols/MoH documenting: (i) the adoption of Health Data Management Strategy, (ii) implementation of the institutional arrangements in accordance with the Strategy (establishment of a Strategy implementation unit, and agreed institutional responsibilities of the MoH, NHIH, IPH and other stakeholders), (iii) establishment of standardization and software certification mechanisms. b) System reports from integrated NHIH management system showing the detected cases of inefficient spending in healthcare claims (PHC claims, hospitals claims, and separately laboratory tests). Year 4: a) System reports from central registries, National EHR, NHIH core systems, ePrescription, eReferrals, community health care information system, HMIS and Health Data Observatory that show system utilization and data exchange between systems/MoH, NHIH and IPH. b) The report on calculated NHIH expenditure reduction due to improved data management in the last 12 months. Projected NHIH expenditure (based on trend from the period 2014-2020) will be compared with actual NHIH expenditure to estimate expenditures avoided by reducing losses (MoH and NHIH).
Verification Entity	IVA
Procedure	Year 2: a) The IVA will confirm the Official Gazette and collaboration protocols include i) the adoption of Health Data Management Strategy, (ii) implementation of the institutional arrangements in accordance with the Strategy (establishment of a Strategy implementation unit, and agreed institutional responsibilities of the MoH, NHIH, PHI and other stakeholders), (iii) establishment of standardization and software certification mechanisms. b) The IVA will confirm that system reports from the integrated NHIH management system show detection of cases of inefficient spending in health care claims and laboratory tests. Year 4: a) The MoH, NHIH and IPH will provide system reports from central registries, National EHR, NHIH core systems, ePrescription, eReferrals, community health care information system, HMIS and Health Data Observatory. The IVA will confirm the reports include: (i) level of systems implementation, (ii) level of systems usage, (iii) mapping of data exchange between the systems, and (iv) effectiveness of systems' support to business processes. b) The IVA will confirm that the methodology for projecting expenditures and calculating expenditure reduction as an outcome of improved data management is used by NHIH.
DLI 7	**Efficiency of expenditure improved through implementation of centralized procurement**
Description	This Disbursement-Linked Indicator aims to facilitate coordination between relevant agencies to address barriers to centralized procurement in the health sector. Year 1: The National Office for Centralized Procurement will conclude framework agreements with suppliers for 10 priority products to address the COVID-19 outbreak, using technical specifications provided by the Ministry of Interior. Year 3: The designated centralized procurement agencies will conclude framework agreements for at least 60 medical supplies and devices for publicly owned hospitals contracted with the NHIH and emergency medical services, using technical specifications provided by the Ministry of Health and the Ministry of Interior as needed.
Data source/ Agency	Year 1: E-procurement system/ONAC Year 3: E-procurement system/designated centralized procurement agencies

Verification Entity	IVA
Procedure	Year 1: The IVA will confirm that the snapshots provided by ONAC include signed framework agreements for 10 priority products to address the COVID-19 outbreak. Year 3: The IVA will confirm that the snapshots provided by the designated centralized procurement agencies include signed framework agreements for 60 medical supplies and devices for publicly owned hospitals and for emergency medical services.
DLI 8	**Pharmaceutical measures revised for better efficiency**
Description	This DLI aims to support changes in pharmaceutical policy to ensure regular implementation of price referencing, improvement of the health technology assessment methodology, and the increase in implementation of managed entry agreements facilitating access to medicines while ensuring efficiency gains. Year 2: (a) The National Agency for Medicines and Medical Devices will revise the health technology assessment methodology for inclusion of new drugs on the positive list to incorporate cost-effectiveness of medication in Romania; (b) To improve transparency and accountability, the pricing process for medicines will be completed annually and published on the Ministry of Health website, while the list of reference prices calculated based on the prices set by the Ministry of Health will be published on the National Health Insurance House web page. The total allocation of EUR 30 M is divided equally between results related to HTA (EUR 15 M) and drug pricing (EUR 15 M). Year 4: The Ministry of Health will increase the number of MEA signed for drugs with conditioned entry into the list of medicines reimbursed from the National Health Insurance House. Cumulative of 50% of newly listed patented drugs with conditional entry decision will be introduced in the positive list through the revised health technology assessment methodology and reimbursed by the National Health Insurance House subject to concluded MEAs. Numerator: newly-listed patented drugs with conditional entry decision, introduced in the positive list through the revised health technology assessment methodology and reimbursed by the National Health Insurance House, for which MEA have been concluded between the NHIH and market authorization holders; Denominator: all newly-listed patented drugs with conditional entry decision introduced in the positive list through the revised health technology assessment methodology and reimbursed by the National Health Insurance House; Time period: Cumulative as of the year 2.
Data source/ Agency	Year 2: (a) Official Gazette/MoH/NHIH (HTA); (b) websites of MoH and NHIH (drug pricing) Year 4: Contracts, NHIH
Verification Entity	IVA
Procedure	Year 2: (a) The IVA will confirm that the official gazette reflects legislation documenting the adoption of the new HTA methodology; (b) the IVA will confirm that the MoH website includes the description of pricing process for medication and NHIH website includes the list of reference prices endorsed by independent experts in this field. Year 4: The IVA will confirm the registration numbers of contracts for newly listed patented drugs subject to MEA, the list of newly assessed patented drugs with the conditional entry, and the share as defined above.