Ideas & Solutions

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Outline and proposal

Pragmatic value assessment system for innovative medicines in Serbia

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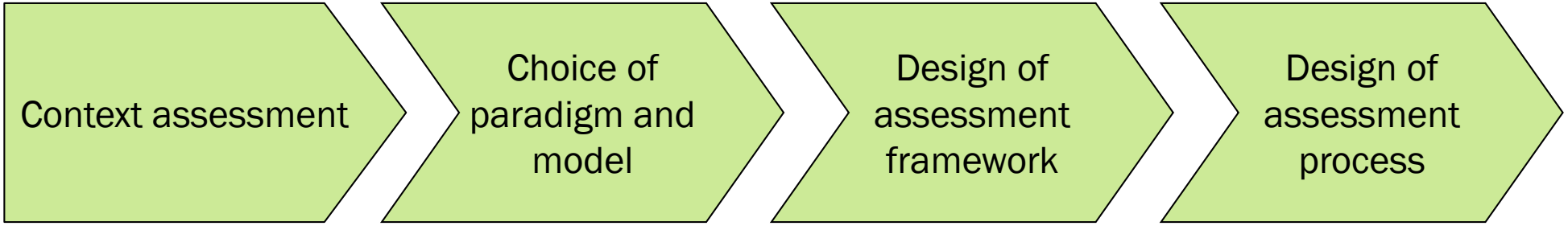
A 4-step rational approach to the design of drug assessment systems



- Goal to be reached
- Availability of sustained funding
- Availability of technical knowledge
- Availability of human resources
- Centralization of decision-making
- Weight of assessment in final decision
- …

- Economic evaluation or qualitative assessment or balanced assessment
- Heavy model or light model or ultra-light model
- Technology scope
- Payer perspective or societal perspective

- Metrics used
- Measurement methods applied
- Analytical tools
- Decision criteria

- Guidelines and protocols
- Legislative framework

- Assessment steps
- Deadlines and primary responsible persons
- Other participating stakeholders
- Process transparency
- IT implementation
- …

Background and rationale for a pragmatic value assessment system in Serbia

Serbian P&R decision system for innovative medicines

- Listing system based on pharma company* submissions
- No formal HTA but structured review of submissions (clinical and economic aspects)
- Limited availability of country-specific data
- Assessment and recommendation by National Health Insurance Fund (RFZO), with input from Republic Expert Committee (RSK)
- Formal decision by Central Committee for Drugs

Actual listing practice

- Limited or no patient access to most recent innovative therapies
- No positive listing decisions for innovative substances since 2011
- More than 80 new INN's awaiting any (pos or neg) listing decision in more indications
- Bottleneck: lack of recommendation by RFZO

Current challenge

How can RFZO arrive at a transparent and robust priority ranking of new INN's and indications, which can be the basis for listing decisions eventually supported by managed entry agreements?

Opportunity

Implement a fit-for-purpose, pragmatic value assessment system for the quick assessment of new INN's and indications

* Throughout this document, ‚pharma company' refers to the marketing authorization holder (MAH) or its representative in Serbia

Possible mission of a pragmatic value assessment system in Serbia

„Enable the clinical and economic value assessment of new therapeutic indications of innovative medicinal products

in a decision-oriented and resource-conscious way

to help competent authorities make consistent and transparent pricing & reimbursement decisions."

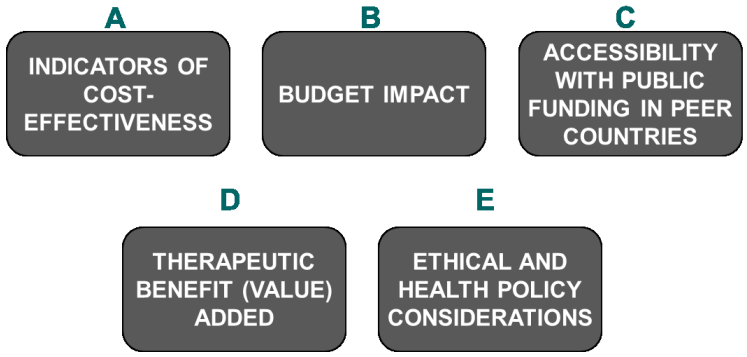
Benchmarking opportunities for the definition of assessment dimensions

International assessment systems

	Australia	France	Italy	Japan	Singapore	Spain (implicit)	Sweden	Taiwan
Better pharmacokinetics			X	X				
Budget impact	X				X	X		X
Clinical efficacy		X		X	X			X
Clinical trial								X
Cost-effectiveness	X				X	(X)	X	?
Currently untreated disease			X					X
Depth of action		X	X					
Industrial policy	X							
Logistics costs	X							X
Market size				X				
New mechanism				X				
Orphan disease				X				?
Patient equality							X	
Place in therapy landscape	X	X					X	X
Public health significance		X		X	X			
Relative price	X	X				X		X
Second-line therapy			X					
Severity of disease		X	X			X		
Side effect profile		X	X	X				X
Technological innovation			X		X			
Therapeutic value					X	X		X

Source: own compilation, Jasmine Pwu (Taiwan), Jeremy Lim (Singapore)

MCDA/PBA literature sources



Source: Dankó D. (2014):
Health technology assessment in middle-income countries: recommendations for a balanced assessment system.
Journal of Market Access and Health Policy, 2: 23181 -http://dx.doi.org/10.3402/jmahp.v2.23181

Proposed assessment dimensions for value assessment in Serbia

VALUE FOR PATIENTS AND SOCIETY

1. Added clinical benefit
2. International funding and assessment references
3. National health policy alignment
4. Social and ethical considerations

FINANCIAL IMPACT

5. Budget impact assessment

VALUE ASSESSMENT

The scoring logic is based on transparent principles

Principles

- Total scores between 0 and X are assigned to each new medicine seeking public funding in a new indication.
- Scoring is performed separately for each submitted indication.
- A minimum total score of Y is required for the new medicine to be considered for reimbursement in a new indication.
- Both *Value for patients and society* and *Financial impact* should independently enable a new medicine to reach the minimum score
- There is no minimum score requirement *within* assessment dimensions.
- Differentiated assessment logic for oncology and hematology

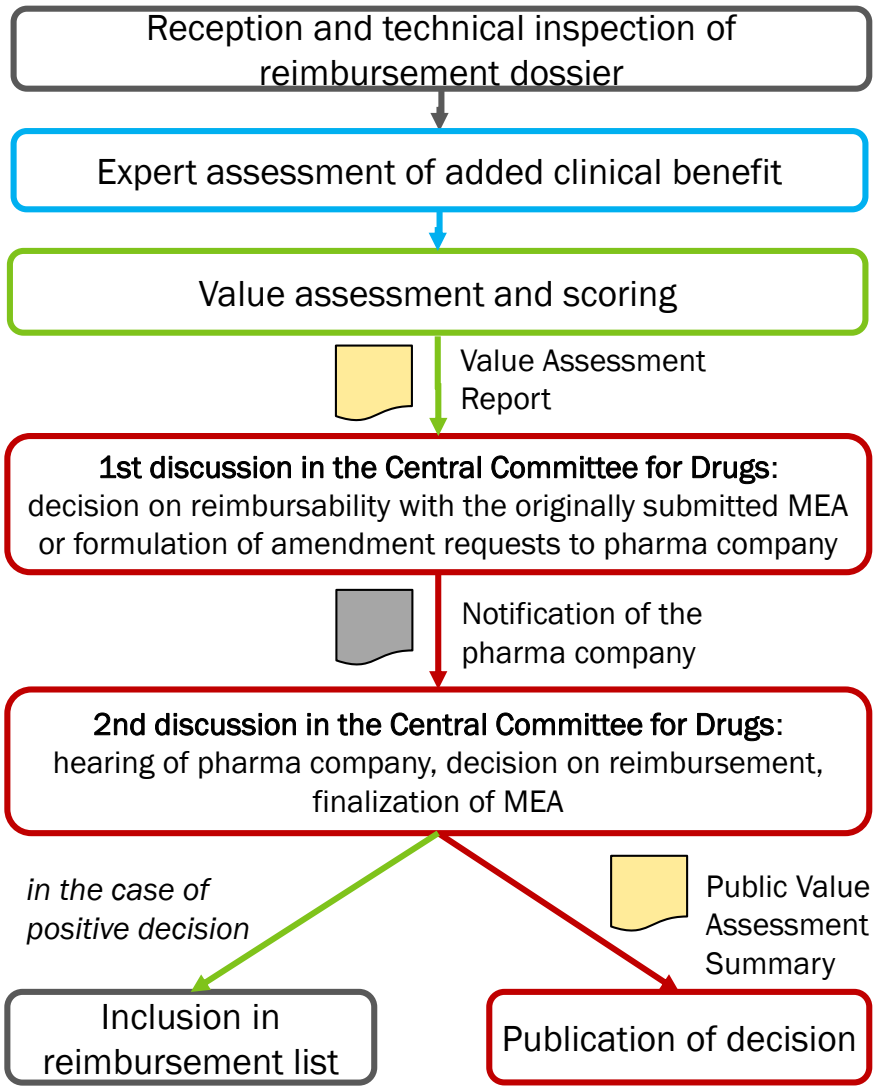
Scoring model (*work-in-process*)

Dimension	Max. score
1. Added clinical benefit	A
2. International funding and assessment references	B (< A)
3. National health policy alignment	C (< B)
4. Social and ethical considerations	D (= C)
5. Budget impact assessment	E (= A + B)

Selected assessment criteria (illustration)

Assessment criterion	Score
11.1. Based on the clinical evidence summarized in the product SmPC approved by EMA, the medicine is expected to provide important improvement in the primary clinical endpoint against the comparator.	P
11.2. Based on the clinical evidence summarized in the product SmPC approved by EMA, the medicine is expected to provide moderate improvement in the primary clinical endpoint against the comparator.	Q < P
22.1. The medicine has received an unrestricted positive recommendation from the Scottish Medicines Consortium (SMC) for use in its requested indication.	P
22.2. The medicine has received a restricted positive recommendation from SMC for use in its requested indication.	Q < P
31. The medicine in the requested indication helps the implementation of national health policy priorities which have been officially declared by the government of Serbia and/or priorities set for the national health insurance system in the Plan for Health Care Protection from Compulsory Health Insurance.	Q < P
44. The medicine is submitted for reimbursement in an indication group in which no previously not reimbursed INN's have been granted public funding since DD/MM/YYYY.	Q < P
51.1. The net budget impact of the medicine in the requested indication, taking into consideration the financial mitigation effect of the pending managed entry agreement for the product, would be negative or zero (neutral).	R
51.2. The net budget impact of the medicine in the requested indication, taking into consideration the financial mitigation effect of the pending managed entry agreement for the product, would be positive but it would not exceed X% of the total net value of RFZO pharma expenditures.	S << R

Process blueprint for value assessment and listing decisions in Serbia*



* Proposal in compliance with *Law on health insurance*; *Rulebook on criteria, methods and procedures for placing the medicines on the List*

On the basis of value assessment, medicines will be assigned to three categories

Total score granted in the Value Assessment Report

based on the originally submitted managed entry agreement (MEA)

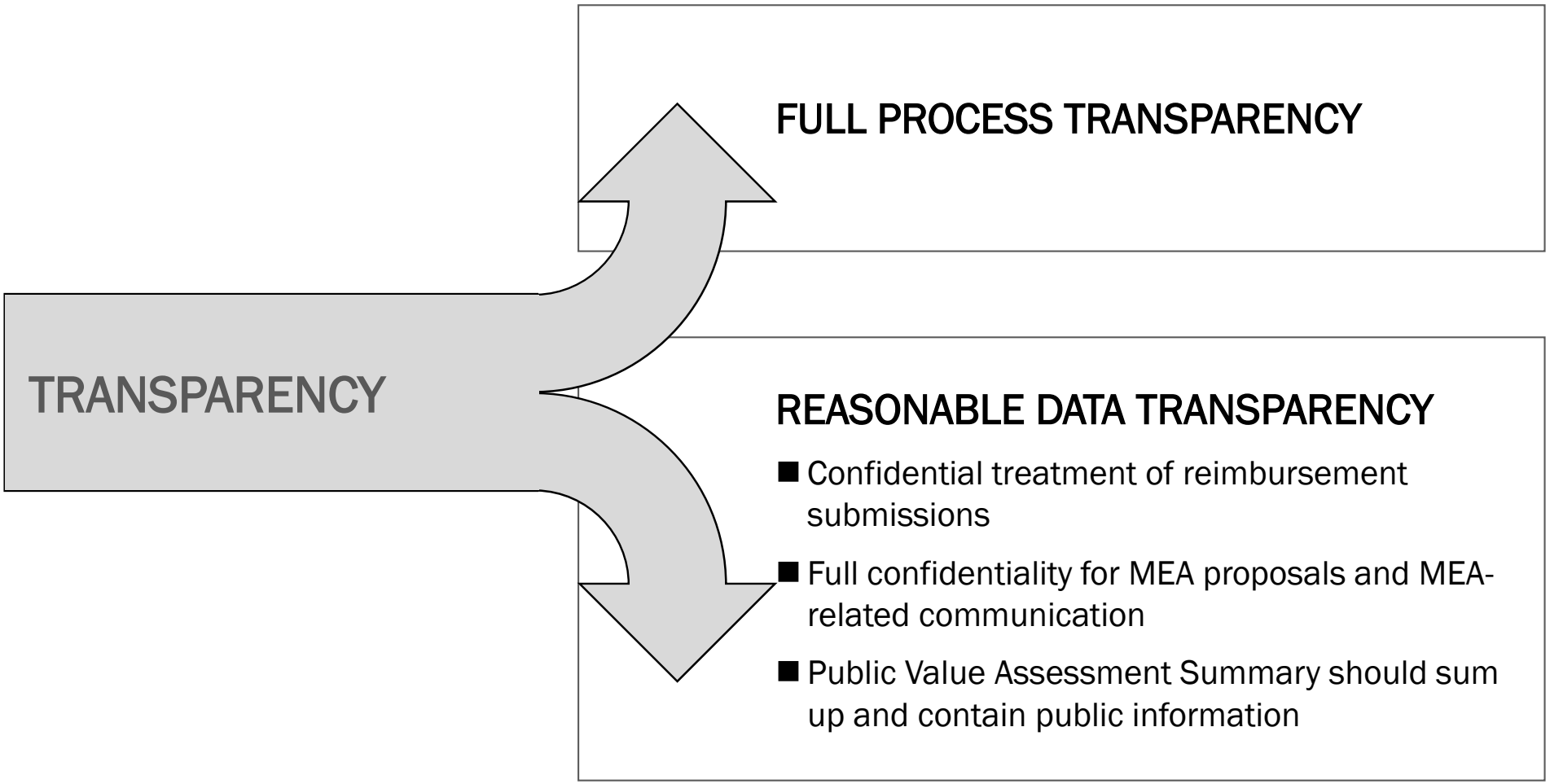
Total amended score after pharma company hearing

based modified MEA following amendment requests from CCD

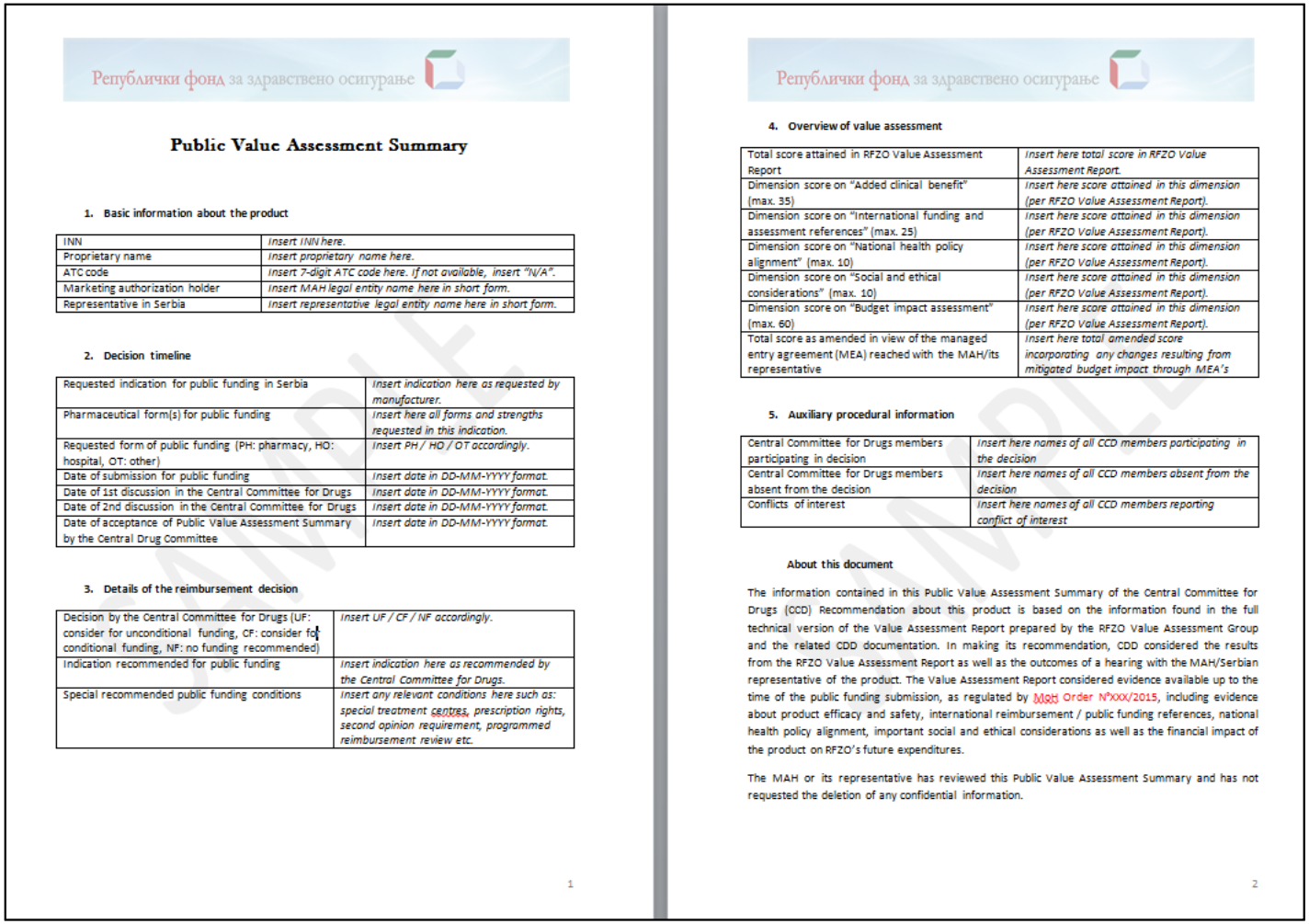
< F	The medicine is not eligible for reimbursement in the requested indication
F – G	The medicine is eligible for **conditional reimbursement** in the requested indication
≥ G	The medicine is eligible for **unconditional reimbursement** in the requested indication

- Programmed re-assessment of the product at 24 months after the listing decision, based on accumulated new evidence
- Reimbursement may be restricted in clinically justified cases or the managed entry agreement can be re-negotiated

Aspects of transparency along the decision process



Proposed template of the Public Value Assessment Summary



Републички фонд за здравствено осигурање

Public Value Assessment Summary

1. **Basic information about the product**

INN	*Insert INN here.*
Proprietary name	*Insert proprietary name here.*
ATC code	*Insert 7-digit ATC code here. If not available, insert "N/A".*
Marketing authorization holder	*Insert MAH legal entity name here in short form.*
Representative in Serbia	*Insert representative legal entity name here in short form.*

2. **Decision timeline**

Requested indication for public funding in Serbia	*Insert indication here as requested by manufacturer.*
Pharmaceutical form(s) for public funding	*Insert here all forms and strengths requested in this indication.*
Requested form of public funding (PH: pharmacy, HO: hospital, OT: other)	*Insert PH / HO / OT accordingly.*
Date of submission for public funding	*Insert date in DD-MM-YYYY format.*
Date of 1st discussion in the Central Committee for Drugs	*Insert date in DD-MM-YYYY format.*
Date of 2nd discussion in the Central Committee for Drugs	*Insert date in DD-MM-YYYY format.*
Date of acceptance of Public Value Assessment Summary by the Central Drug Committee	*Insert date in DD-MM-YYYY format.*

3. **Details of the reimbursement decision**

Decision by the Central Committee for Drugs (UF: consider for unconditional funding, CF: consider for conditional funding, NF: no funding recommended)	*Insert UF / CF / NF accordingly.*
Indication recommended for public funding	*Insert indication here as recommended by the Central Committee for Drugs.*
Special recommended public funding conditions	*Insert any relevant conditions here such as: special treatment centres, prescription rights, second opinion requirement, programmed reimbursement review etc.*

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Републички фонд за здравствено осигурање

4. **Overview of value assessment**

Total score attained in RFZO Value Assessment Report	*Insert here total score in RFZO Value Assessment Report.*
Dimension score on "Added clinical benefit" (max. 35)	*Insert here score attained in this dimension (per RFZO Value Assessment Report).*
Dimension score on "International funding and assessment references" (max. 25)	*Insert here score attained in this dimension (per RFZO Value Assessment Report).*
Dimension score on "National health policy alignment" (max. 10)	*Insert here score attained in this dimension (per RFZO Value Assessment Report).*
Dimension score on "Social and ethical considerations" (max. 10)	*Insert here score attained in this dimension (per RFZO Value Assessment Report).*
Dimension score on "Budget impact assessment" (max. 60)	*Insert here score attained in this dimension (per RFZO Value Assessment Report).*
Total score as amended in view of the managed entry agreement (MEA) reached with the MAH/its representative	*Insert here total amended score incorporating any changes resulting from mitigated budget impact through MEA's*

5. **Auxiliary procedural information**

Central Committee for Drugs members participating in decision	*Insert here names of all CCD members participating in the decision*
Central Committee for Drugs members absent from the decision	*Insert here names of all CCD members absent from the decision*
Conflicts of interest	*Insert here names of all CCD members reporting conflict of interest*

About this document

The information contained in this Public Value Assessment Summary of the Central Committee for Drugs (CCD) Recommendation about this product is based on the information found in the full technical version of the Value Assessment Report prepared by the RFZO Value Assessment Group and the related CDD documentation. In making its recommendation, CDD considered the results from the RFZO Value Assessment Report as well as the outcomes of a hearing with the MAH/Serbian representative of the product. The Value Assessment Report considered evidence available up to the time of the public funding submission, as regulated by MoH Order N°XXX/2015, including evidence about product efficacy and safety, international reimbursement / public funding references, national health policy alignment, important social and ethical considerations as well as the financial impact of the product on RFZO's future expenditures.

The MAH or its representative has reviewed this Public Value Assessment Summary and has not requested the deletion of any confidential information.

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- Easy-to-understand structure
- Plain language
- No trade secret disclosed
- Published only in electronic format on RFZO website