Scope of vignette:
- authorised products (with marketing authorisation)
- decision process about routine use (and not individual requests for reimbursement)
- submissions for P&R made by manufacturers

Green = related to/any special considerations for rare disease and ultra-rare disease treatments

Romania	**Standard reimbursement and HTA process for pharmaceutical products**	**Special process for RDTs (points system)**
Overview of health system and P&R/HTA process	Social insurance based health system [1] MoH set the HTA guidelines, established the HTA unit within the National Agency for Medicines & Medical Devices (NAMMD), and is responsible for the final reimbursement decision (reimbursement List update via Gov Decision) HTA unit within NAMMD conducts HTA evaluations MoH and National Health Insurance House (NHIH, an autonomous public institution under the coordination of the MoH) make price decisions Positive list ('formulary') used [2]	
Differentiation of rare disease treatments in the P&R system	EMA orphan designation	
Eligible medicines	Any new medicines [2]	Any new medicines with OMP designation
Process	- MAH holder submits application to NAMMD - Within 10 days of the submission, NAMMD requests the approval of MoH specialty commissions on the choice of comparator in the submission - HTA unit within NAMMD evaluates the submission within 30 days by analysing the submitted documents, and calculating therapy costs - NAMMD sends the applicant an intermediary report, including critical analysis of the submitted documentation, proposals for amendments, requests for additional information	- Same, but OMPs get 70 points by default, enough for conditional reimbursement with a cost-volume agreement. - The 10 additional points, necessary for unconditional reimbursement (80p), may be obtained if: a. There is an ongoing RCT in Romania for the indication, or b. There is a EUnetHTA report on the indication, or c. There is an authorization for last instance treatment for the indication, or d. There is a donation for at least 50% of eligible patients, for at least 12 months, approved by NAMMDR

Romania	Standard reimbursement and HTA process for pharmaceutical products	Special process for RDTs (points system)
	- Recommendations for each submission are made based on a scorecard system (a submission can get max 100 points); the submission is scored according to a set criteria and a recommendation decision is made - Final evaluation decision is communicated to applicant within 90 calendar days of the submission date - The MAH may contest the decision within 7 days of its publication [2] - 60-79 points get conditional reimbursement (cost-volume agreements)- 80-100 points get unconditional reimbursement (no discounts, only treatment protocols)	**For non-orphan drugs with RD indications** there is another variation on the special assessment pathway: - Similar assessment criteria and number of points as for ordinary drugs, with: - Possibility of receiving 45 additional points from the following: a. Ongoing RCT in Romania for the indication, or b. EUnetHTA report on the indication, or c. Authorization for last instance treatment for the indication - Possibility of getting max. 30 points from the following: a. Treatment is the only option for patients aged between 0-12 months, with an average overall survival of under 24 months b. It is the only treatment for a disease in a stage where: - It increases overall survival by at least 3 months, or - Results in a progression free period > 3 months c. It is a treatment for a RD which does not affect more than 5 /10 000 persons in EU, that is life threatening or chronically debilitating, according to OrphaNet or EU country statistics
Disease specific expert input (e.g. clinicians or patients in any stage of the process)	- NAMMD requests opinions and information from MoH specialty commissions, NHIH and any institution sub-ordinated to or co-ordinated by the MoH	
Key domains in assessment	- Cost effectiveness - Clinical effectiveness - Budget impact [3]	

Romania	Standard reimbursement and HTA process for pharmaceutical products	Special process for RDTs (points system)
Evidentiary requirements		Not necessarily more leniency for RDTs. For initial HTA purposes, assessment is mainly based on HTA reports produced by HAS France, NICE, SMC, IQWIG, G-BA, which do not accept poor quality evidence.
PROMs	None	
Appraisal framework		Same, also consider if there is no other treatment option or, if there is, if the new drug brings a significant benefit. [3]
Reimbursement decision	Ministerial Order 861/2014, which sets out the evaluation criteria and methods for the evaluation of medicines for inclusion of medicines in the reimbursement formulary. [2] Possible recommendations include: a) inclusion on the formulary with unconditional reimbursement (min 80 points); b) inclusion with conditional reimbursement (60-79 points); c) non-inclusion; d) exclusion - Within 30 working days of any NAMMD decision regarding conditional inclusion, MAH submits a request to the NHIH declaring its readiness to begin contract negotiations - Unconditional reimbursement is processed through the MoH and Romanian government - If prioritisation criteria are met, conditional reimbursement is processed through the NHIH negotiation committee, and Romanian government [2, 3] - Prioritisation criteria: - drugs for diseases in evolution, without therapeutic alternative; - drugs approved by EMA through accelerated procedure; - medicines corresponding to INNs for specific treatment of diseases with major impact on public health (Hep B, C, MDR-TB, HIV/AIDS), according to the Law 95/2006 for Reform in healthcare updated and to National Strategy for Health 2014-2020 (rare diseases, cardiovascular diseases, diabetes mellitus, onco-haematology)	

Pricing process	- External reference pricing [3] - International reference is valid for the maximum price - which is approved by MoH, and generic price referencing is used if the drug lost its patent; - For reimbursement purposes, generic referencing and TRP are also used as additional mechanisms. For rare disease drugs, which are on the National Programs sub-list (C2), TRP is not utilised but generic reference is possible, if the drug lost its patent.	
Managed entry agreements	- Confidential discount - Budget cap – limited number of patients	Only cost - volume agreements used, not cost-volume-results agreements.
Main challenges in appraising medicines for rare diseases	□ Lack of good quality clinical data X Lack of real world data - For assessing health outcomes in the real world, collecting and analysing data have to be improved. □ Introducing value for money □ Monitoring treatment efficacy □ Managing budget impact □ Lack of criteria/transparency of OMP P&R processes □ Making arrangements to work for all stakeholders □ Lack of long-term meaningful outcomes	
Impact of special processes	OMPs and medicines for rare diseases are privileged in the HTA and reimbursement process, comparing with other drugs.	
Proposed policy change	Health Technology Assessment legislation was updated on the 31st of July 2020[4]	
SOURCES		
1	https://ec.europa.eu/health/sites/health/files/state/docs/chp_romania_english.pdf	
2	HTA Romania WB Project - Report I EN.pdf	
3	Brief - Drugs HTA. P&R rules in Romania.ppt	
4.	http://legislatie.just.ro/Public/DetaliiDocumentAfis/228188	

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This vignette was compiled based on information provided by country experts and desk research. The information provided may be incomplete or contain inaccuracies. If you have any comments or updates, please email us at the following email addresses:

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