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RARE DISEASES MANAGEMENT IN SERBIA

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Rare diseases on the Drug List

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Indikacija	INN
multipli mijelom	lenalidomid, talidomid, bortezomib
limfom i multipli mijelom	pleriksafor
Hodgkin limfomi	brentuksimab vedotin
karcinom jetre	sorafenib
hronična imunološka trombocitopenijska purpura	romiplostim, eltrombopag
primarna apnea	kofein
Sickle cell sindrom	hidroksikarbamid
transplantacija matičnih ćelija hematopoeze	Thiotepa, busulfan
cistična fibroza	tobramicin
akutna limfoblastna leukemija	merkaptopurin
hemofilija A	oktokog alfa, moroktokog alfa, koagulacioni faktor VIII, humani, von Willebrand-ov faktor (vWF:Rcof)
juvenilni idiopatski artritis	adalimumab, etanercept, metotreksat, tocilizumab
pleuralni mezoteliom	pemetreksed
hemofilija B	nonakog alfa, koagulacioni faktor IX, humani
kongenitalna/idiopatska neutropenija	filgrastim, humani normalni imunoglobulin za intravensku upotrebu
ovarijalni karcinom FIGO stadijuma IIIc i FIGO stadijuma IV, karcinom jajovoda i primarni peritonealni karcinom	bevacizumab
sekundarni hipogonadizam	folitropin alfa, folitropin beta

Indikacija	INN
prolongirani akutni konvulzivni napadi kod dece	midazolam
invanzivna kandidijaza/aspergiloza	kaspofungin, vorikonazol
planocelularni karcinom glave i vrata	cetuksimab
beta talasemija major	deferasiroks
hronična mijeloidna leukemija	imatinib
gastrointestinalni stromalni tumori	imatinib
mijelofibroza	ruksolitinib
refraktorne epilepsije	levetiracetam
leukemija vlasastih ćelija	kladribin
karcinom nadbubrežne žlezde	mitotane
nehočkinski limfomi	rituksimab
plućna hipertenzija	sildenafil, bosentan
urođena hemofilija sa inhibitorima na faktor VIII	eptakog alfa-aktiviran
invazivne gljivične infekcije kod pacijenata primaoca matičnih ćelija hematopoeze	posakonazol
Tarnerov sindrom, nizak rast	somatropin
amiotrofična lateralna skleroza	riluzol
karcinom bubrega	sunitinib, pazopanib

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Fund for Rare Diseases

ИНН	Indication
imigluceraza	Gošeova bolest tip 1 i 3
taligluceraza	Gošeova bolest tip1
idursulfaza	MPS II (Hanterov sindrom)
alglukozidaza alfa	Pompeova bolest
laronidaza	MPS I
mercaptamin	Cistinoza
agalzidaza beta	Fabrijeva bolest
elosulfaza alfa	MPS IV (Morquio sindrom)
cerliponaza alfa	Batenova bolest
sebelipase alfa	LAL deficit
sapropterin dihydrochloride	BH4 deficit
nusinersen	SMA
everolimus	Neuroendokrini tumor pankreasa I pluća
pasireotid	Kušingova bolest
everolimus	SAGA tumor
everolimus	Tuberozna skleroza
vandetanib	Medularni karcinom tiroidne žlezde
pasireotid	Akromegalija
icatibant / conestat alfa	HAE
riociquat	PAH
selexipag	PAH

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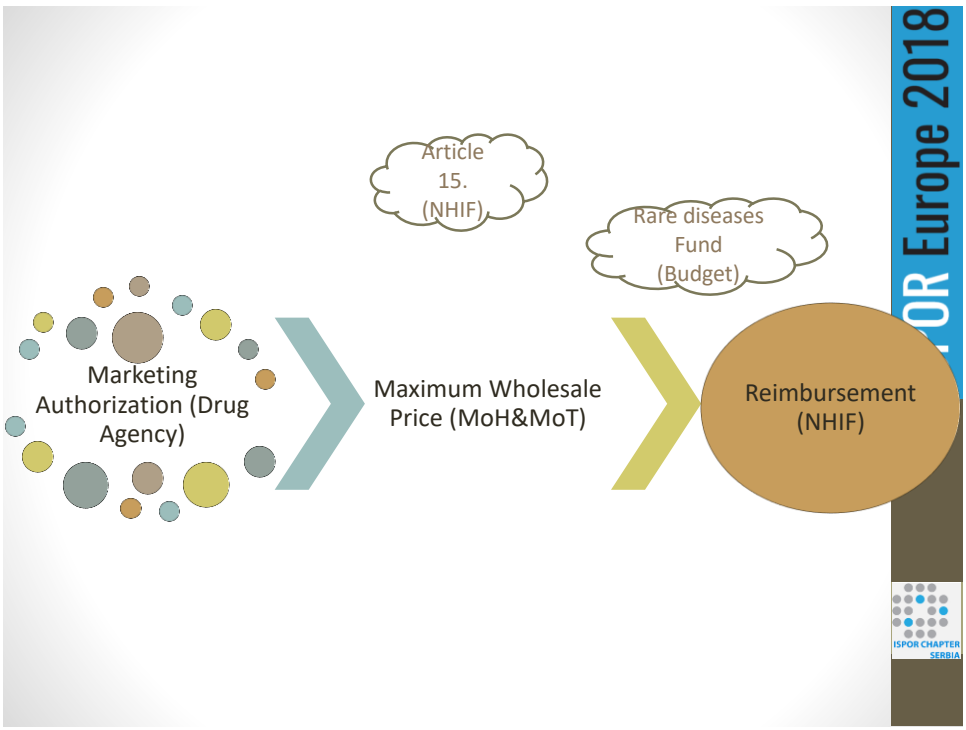

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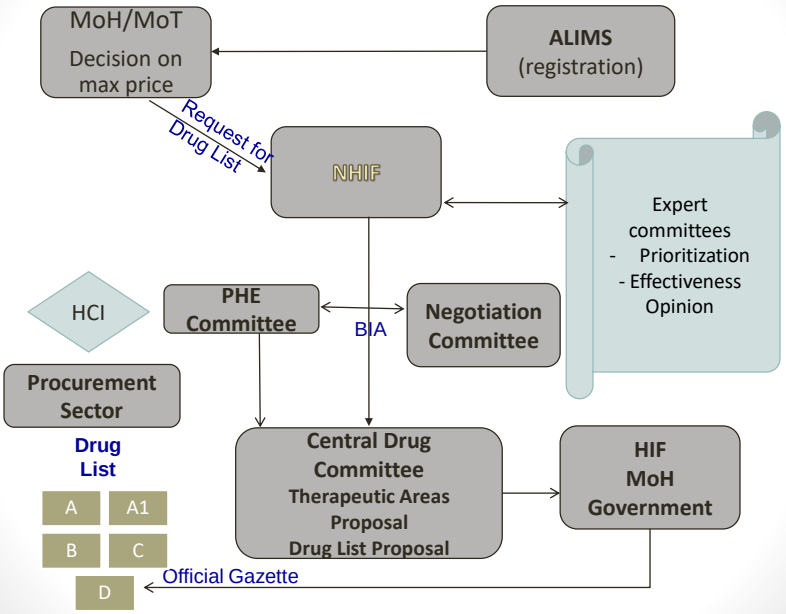
The Drug Flowchart



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The criteria for placing the drug on the Drug List

- General criteria:
  - pharmacotherapeutic justification
  - pharmacoeconomic justification
  - funding provided by the Financial Plan of the Republic Fund
- Specific criteria:
  - managed entry agreements
  - priority order

Source: Rulebook on Criteria for Listing of Reimbursement Medicines

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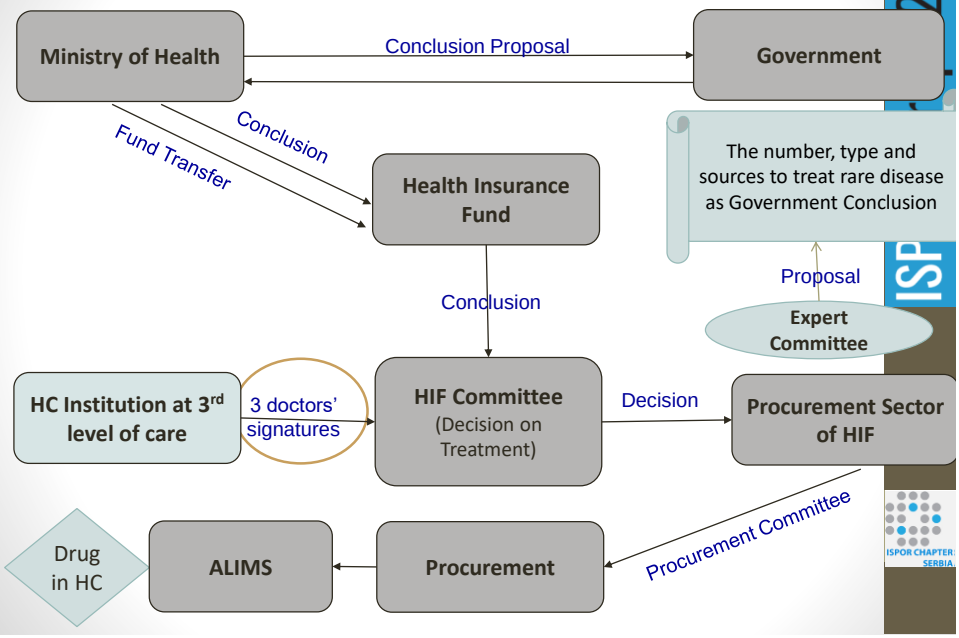
Additional parts of the POU

- According to the Healthcare Law and Health Insurance Law, if is not possible to realize the right to the healthcare due to financial constraints of NHIF, Republic of Serbia will ensure, through its own budget, that realization for the population groups listed in mentioned laws.
- In that purpose, few years ago has been established by Ministry of Health (MOH) a special fund for rare metabolic diseases and rare tumors, each year approved by Government.
- **Current regulation does not specify specific criteria that will direct which drug belongs to which fund (NHIF that covers drugs on the Drug list or Special fund for rare diseases and tumors).**
- **The management of resources coming from this Special fund is limited just on the clinical decision of choosing the most appropriate patient that will benefit the most from given medicine.**

Orphan Drugs & Rare Diseases



Current Status

- Situation Analysis
- Action Plan to introduce HTA as tool
- Strategy of Public Health
- New Health Care Law
- New Heal Insurance Law

- NGO's activities – introducing of MCDA

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Criteria

NEEDS

- Disease severity
- Size of affected population
- Availability of other therapeutic options
- Burden of disease on everyday life of patent, family and community

EFFECTIVENESS

- Impact of the therapy on quality of life and life extension
- Impact on health status and outcomes recorded by patients
- Safety and adverse events
- Evidence of clinical effectiveness

BUDGET IMPACT

- Cost of therapy
- Cost of healthcare except the drug

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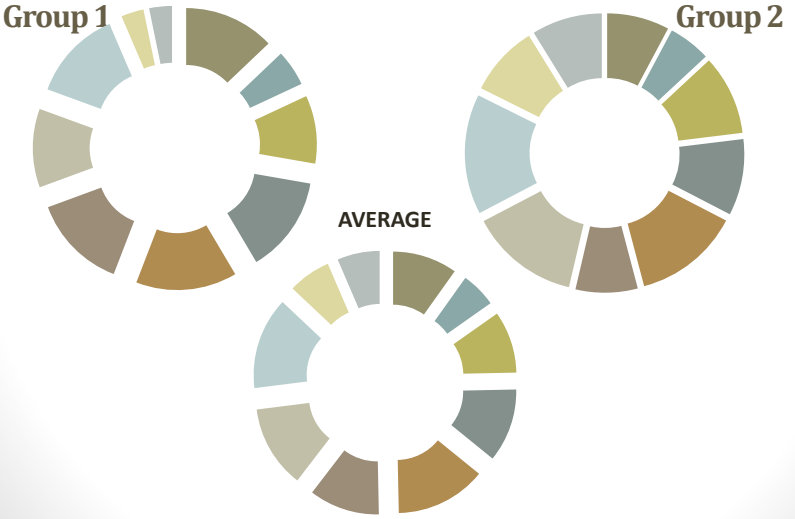
Different wages among different groups of stakeholders



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