PRIORITY SETTING - CRITERIA AND PROCESS OF RARE DISEASES MANAGEMENT IN CEE COUNTRIES
Bosnia and Herzegovina

Prof. Rasim Jusufović, PhD, MD
Tarik Čatić, PhD, Pharm
ISPOR *Bosnia and Herzegovina*

Barcelona, November 13, 2018
CEE Consortium Forum
ISPOR Europe 2018

Administrative organization of the country

- Health care system in Bosnia and Herzegovina is highly decentralised

STATE

Ministry of civil affairs – Department for Health
Agency for medicines and medical devices

2 Entities

Federation of Bosnia and Herzegovina

- Federal Ministry of Health
- Federal Health insurance fund
- 10 Cantonal ministries of health
- 10 Cantonal Health insurance funds

Republic of Srpska

- Ministry of health and social welfare
- Health inusurance funds

1 District

Brčko

- Department of health and other services
- Health insurance fund

- Financing and decision making on entities/cantonal level

Rare diseases in Bosnia and Herzegovina

- There are no precise epidemiology data but it is reported that:
  - In Republic of Srpska 427 people are suffering from rare diseases, of which 300 are children.
  - There are about 170 different illnesses, and most of them have rare hereditary diseases.
  - HIF of RS out of the available 500 million KM spent 8 million KM

  - Data for Federation of Bosnia and Herzegovina are not published but approximately it is expected that about 890 people are affected

https://www.cin.ba/usvojen-program-za-rijetke-bolesti-u-rs/
http://www.asocijacijaxy.org/doprinos-organizacija-civilnog-drustva-u-unapredjenju-polozaja-ljudi-koji-boluju-od-rijetkih-bolesti
http://www.etrafika.net/izdvojeno/60686/vise-od-400-oboljelih-od-rijetkih-bolesti-na-dijagnozu-cekaju-godinama/

Civil society initiative - NGOs

- Since officials did not place rare disease issue as a priority pioneers in activities on this field are NGOs and civil society organizations like patient associations
- In year 2013 NGO Asocijacija XY conducted project:
  "*Contribution of civil society organizations to improving the position of people suffering from rare diseases in Bosnia and Herzegovina*."
- The project was funded by the European Union.

https://europa.ba/wp-content/uploads/2015/05/delegacijaEU_20131023095702 48eng.pdf

Key project characteristics and findings

- The project addressed some of the major problems and challenges faced by people suffering from rare diseases in our society, namely:
  - lack of policies and strategies on rare diseases;
  - lack of data and register of people with rare diseases;
  - absence of rare diseases list;
  - stigma and discrimination;
  - lack of comprehensive health care;
  - lack of capacity of civil society organizations dealing with these issues.
- Project aims
  - Identify the number and types of rare diseases in BiH
  - Identify problems with rare diseases
  - Determine the level of knowledge and information of the patients, the parents of the children, the representatives of the user associations and health workers about rare diseases
  - Identify the availability of health care with rare diseases
  - **Make recommendations** for improving the position of people with rare diseases

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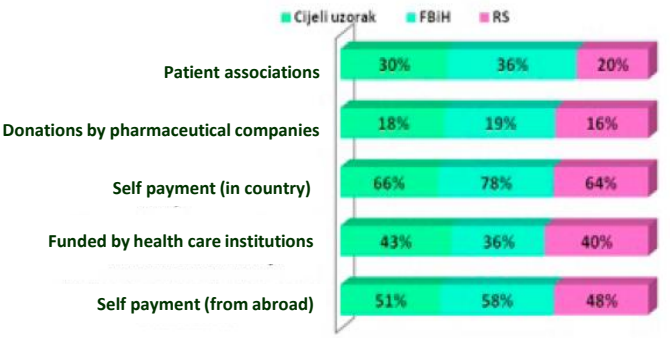
Key project characteristics and findings

- Patient responses on drug purchase
  - In the majority of cases, people themselves acquire drugs / therapy in BiH and abroad.



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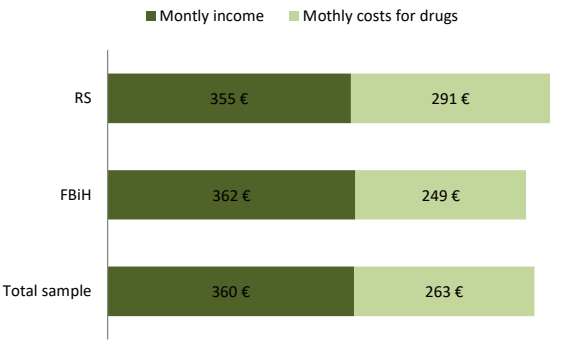
Key project characteristics and findings

- Parents (caregivers) information about average monthly costs for drugs comparing to monthly income



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Key project characteristics and findings

- Major issues identified by each keystakeholder

Issue	Teritorry	Patients	Parents (caregivers)	Patient associations	HCPs
Diagnosis	BiH	89%	94%	87%	79%
	FBiH	92%	93%	85%	82%
	RS	84%	100%	93%	75%
Difficult availability of new medicines	BiH	96%	93%	91%	84%
	FBiH	97%	97%	91%	97%
	RS	96%	94%	91%	94%
Lack of specifically educated medical staff	BiH	89%	96%	92%	76%
	FBiH	92%	97%	90%	97%
	RS	84%	94%	93%	94%
Lack of medical guides for treatment of rare	BiH	82%	71%	78%	54%
	FBiH	86%	70%	77%	77%
	RS	76%	77%	80%	25%

https://europa.ba/wp-content/uploads/2015/05/delegacijaEU_2013102309570248eng.pdf

Rare disease drugs availability

Federation of BH

- Of 158 branded medicines for the rare diseases treatment but **without orphan designation** from ORPHANET list, in 67 (42%) medicines are reimbursed
- When it comes to medicines **with orphan designation** of 98 medicines on ORPHANET list only 7 (7%) medicines are reimbursed
- There are no special criteria or recognition of orphan designation when it comes to reimbursement process criteria.
- Orphan medicines are reimbursed with the same reimbursement process as any other medicine

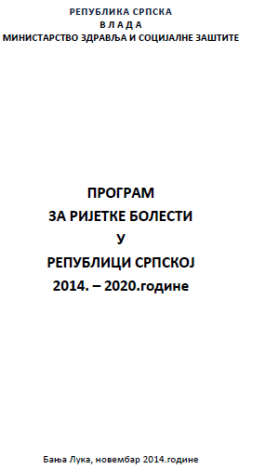
Republic of Srpska

- Only 26 medicines intended for rare disease treatment but **without orphan designation** in EU are reimbursed in Federation of BH, of which 3 are not reimbursed for orphan disease indication
- No special process for reimbursement of orphan drugs in Federation of Bosnia and Herzegovina since this therapeutic class is not recognized, so the same reimbursement approval process apply like for all other drugs

T.Catic, V.Guzvic et al. RARE DISEASES IN BOSNIA AND HERZEGOVINA: OVERVIEW ON PRESENT SITUATION (in publicatrion)

Program for rare diseases in Republic of Srpska 2014-2020

- **Objectives**
  - prevention, early diagnosis and diagnosis of rare diseases; improvement of recording; improving the awareness of health professionals and the general public on rare diseases, coordination with reference medical and research institutions and associations of patients with rare diseases.
- **Activities to be taken**
  - Appointing a coordinator for rare diseases in Republic of Srpskas
  - Forming the Commission and establishing a Center for Rare Diseases in the Republic of Srpska
  - Establishment of records for rare diseases in the Republic of Srpska
  - Improving the prevention and diagnosis of rare diseases, congenital anomalies and genetic predispositions / tendencies
  - Improve control and control over the overall treatment of genomic and congenital diseases


РЕПУБЛИКА СРПСКА
В Л А Д А
МИНИСТАРСТВО ЗДРАВЉА И СОЦИЈАЛНЕ ЗАШТИТЕ

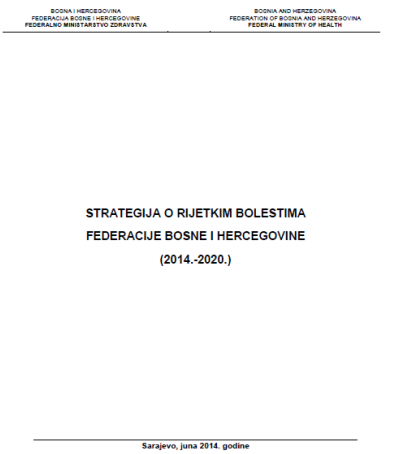
ПРОГРАМ
ЗА РИЈЕТКЕ БОЛЕСТИ
У
РЕПУБЛИЦИ СРПСКОЈ
2014. – 2020.године

Бања Лука, новембар 2014.године

Strategy on rare diseases in Federation of Bosnia and Herzegovina 2014-2020

- **General objective**
  - Ensure an appropriate institutional framework and mechanisms for accessible, comprehensive and quality health care as well as the provision of persons with rare diseases

- **Specific objectives**
  - Establishing mechanisms for monitoring rare diseases
    - Establishing a registry for rare diseases
  - Improvement of early diagnosis and access to medical treatment (screening, access to health care etc)
  - Improving the mechanisms for a comprehensive approach to rare diseases


BOSNA I HERCEGOVINA
FEDERACIJA BOSNE I HERCEGOVINE
FEDERALNO MINISTARSTVO ZDRAVSTVA

BOSNIA AND HERZEGOVINA
FEDERATION OF BOSNIA AND HERZEGOVINA
FEDERAL MINISTRY OF HEALTH

STRATEGIJA O RIJETKIM BOLESTIMA
FEDERACIJE BOSNE I HERCEGOVINE
(2014.-2020.)

Sarajevo, juna 2014. godine

Key post-project policy implications

- Entity governments adopted key documents in 2014
  - **Program for rare diseases in Republic of Srpska 2014-2020**
    - Establishing Center for rare diseases in 2015
    - All insured persons who have been diagnosed with a rare illness HIF fully bear the costs of health care, regardless of age and diagnosis as of 2018
  - **Strategy on rare diseases in Federation of Bosnia and Herzegovina 2014-2020**
    - Initiative for establishing a fund for the treatment of rare diseases adopted by Federal parliament in 2017

https://www.cin.ba/usvojen-program-za-rijetke-bolesti-u-rs/
https://www.kc-bl.com/Lat/?p=6393
https://www.nezavisne.com/novosti/drustvo/Oboljeli-od-rijetkih-bolesti-oslobodjeni-placanja-participacije/483641
http://www.fmoh.gov.ba/index.php/zakoni-i-strategije/strategije-i-politike/336-strategija-o-rijetkim-bolestima-fbih-2014-2020
https://www.vecernji.ba/vijesti/podrzana-inicijativa-o-fondu-za-lijecenje-od-rijetkih-bolesti-1165535

Conclusions

- Analysis performed by NGO Asocijacija XY significantly improved awareness and activities in the field of rare diseases
- Both entities have adopted strategies regarding policy approach to rare diseases
- Strategy in RS is more precise with specified activities of which some are already implemented
- In FBiH no significant actions put in place – except initiative for Rare disease Fund (still only initiative)
- Low access to rare disease medication
- No specific funding and RB process approach in place