Access to antiviral drugs for treating HCV for HIV-positive patients in Russia: results and recommendations of the registration, policy and procurement analysis

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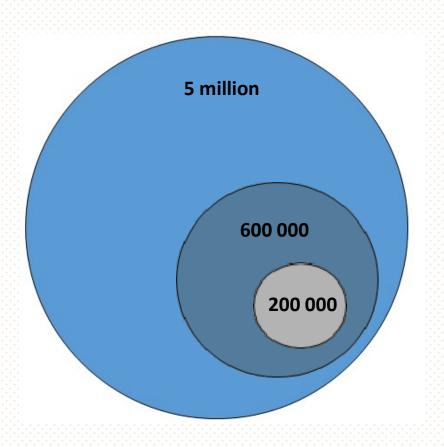
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- Monitoring of drug procurement since 2010, HCV procurement since 2012
- Coverage of the whole country (85 regions (entities) in Russian Federation)
- Around 5000 tenders annually
- Using specialized personnel for analysis the monitoring's results
- The results are presented at national-level conferences
- Annual reports

HCV. The purposes

- Understand how many people can receive HCV treatment;
- How much money is spent on purchasing HCV;
- Which drugs are procured and which quantities;
- Compare with the international recommendation;
- Develop recommendation for improving the HCV treatment landscape.

Prevalence of chronic hepatitis C in Russia, 2015



Expert estimates - at least 5 million people with HCV

Officially registered - 600 000 people

Co-infected with HIV and HCV - at least 200 000 people

Total number of patients who could receive a therapy for treating HCV is **5 000 – 10 000** people

Less than 1 % of the total estimated number of people with HCV

2.5 % co-infected patients

Registered drugs

• Data of the website grls.rosminzdrav.ru to HCV drugs registered in Russia in 2015:

INN	Note
Peg-inf 2a («Pegasys»)	Essential Medicines Lis Decree 1438
PegInf 2b («PegIntron», «PegAltevir»)	Essential Medicines List Decree 1438
CePegInf 2b («Algeron»)	Essential Medicines List
Simeprevir («Sovriad»/ «Olysio»)	Essential Medicines List (included in 2016)
Daclatasvir («Daklinza»)	registered in 2015
Asunaprevir («Sunvepra»)	registered in 2015
Ombitasvir/paritaprevir/ritonavir+Dasabuvir («Viekira Pak»)	registered in 2015
Sofosbuvir («Sovaldi»)	registered in 2016
Narlaprevir («Narlaprevir»)	registered in 2016
Telaprevir («Incivo»)	Lists of Essential Medicines in Russia (excluded in 2016)
Boceprevir («Victrelis»)	registered in 2013

Metodology

List of registered drugs www.zakupki.gov.ru

874 contracts concluded in 2015

- 3 INN for PegINF
- 6 INN for DAAs

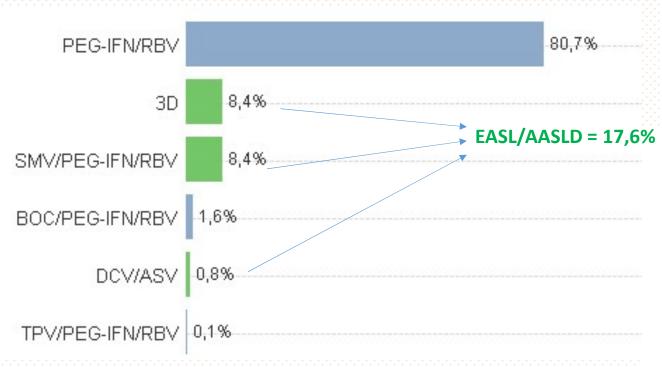
INN		Treatmo	ent duration		
Ce/PEG-IN	lF -	48 we	eks		
CNAVA TOVA	20				
SMV, TPV,	30		eks		
ВОС		→ 44 we	eks (according	to Russian r	ecommendation)
DCV ASV		→ 24 we	eks		

Monitoring and analysis results

• Total sum of the contracts = ~42 mln \$

Total number of patients: 5 100-9 300 **PEG-INF** patients ~4100 - 8200 **DAAs** patients ~1 000 Courses 18,5% 81,5% ■ PEG-INF ■ DAAs

Treatment regimens in Russia 2015

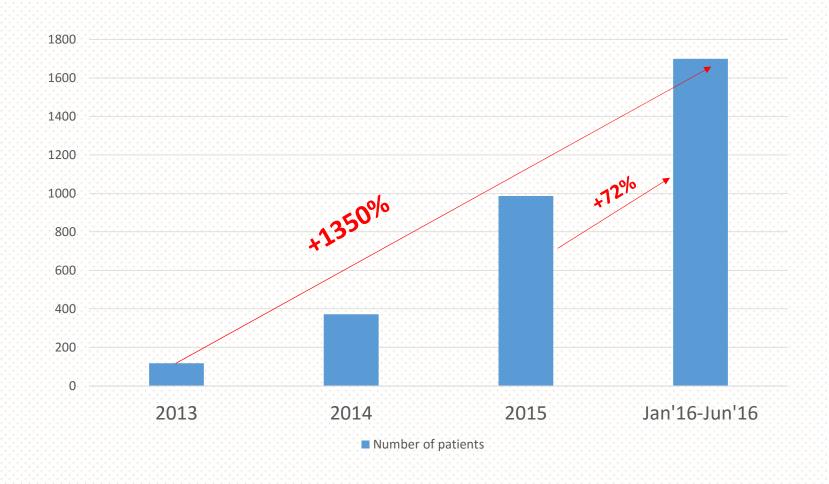




The price for the treatment course of DAAs 2016

INN	average weighted price per pack, \$	average weighted price per course, \$
Sofosbuvir	3 192	12 weeks – 9 576
3D	4 700	12 weeks – 14 100
Daclatasvir	1 860	12 weeks – 5 580 24 weeks - 11 160
Asunaprevir	190	24 weeks – 1 140
Simeprevir	3 400	12 weeks – 10 200
Boceprevir	1 190	44 weeks (Russian recommendation) – 13 090
Narlaprevir	-	-

Trend in procurement value of DAAs 2013-2016



Conclusions

- 1. The majority of HIV/HCV coinfected patients have still receive PEG-IFN-based therapy
- None of the DAAs are included in Decree No 1438
- 3. Sofosbuvir/ledipasvir is still not registered in Russia
- 4. High prices of DAAs range of 10,000 15,000 USD
- Clear trend towards DAAs
- 6. Sofosbuvir and several inf-free regimens were registered in Russia 2015-2016
- 7. Launching regional programmes for treating HCV

Recommendation

- 1. Update the regulatory framework in the field of HCV to include DAAs (SOF+DCV, SOF+SIM, 3D, SOF/LDV etc)
- 2. Include DAAs in the Essential Medicines List and Decree No 1438 for federally funded
- 3. Price reduction on DAAs, including opportunities provided by flexibilities of TRIPS