AROUND THE WORLD TABLE: ACCESS TO THERAPY IN ROMANIA

ADRIANA POPESCU

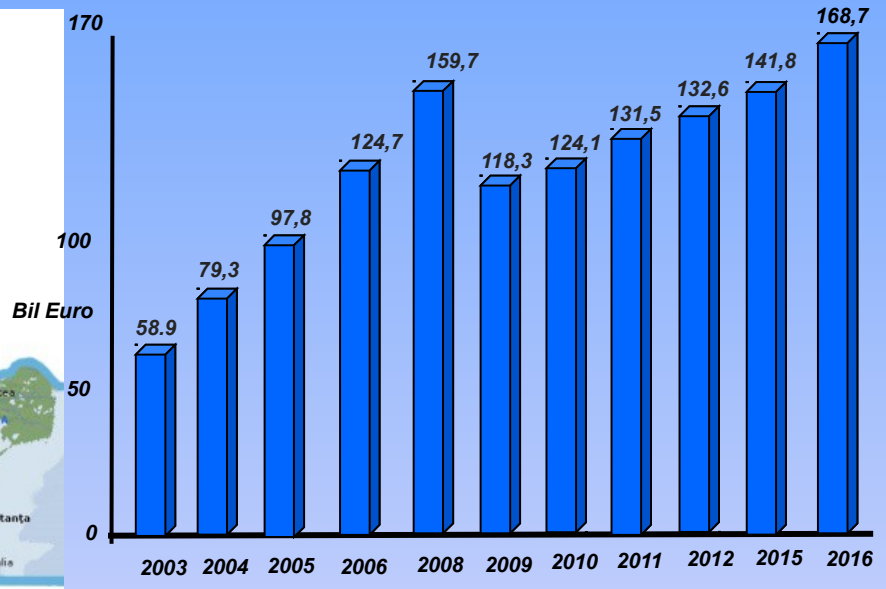
Clinical Institute Fundeni Bucharest

Department of Internal Medicine

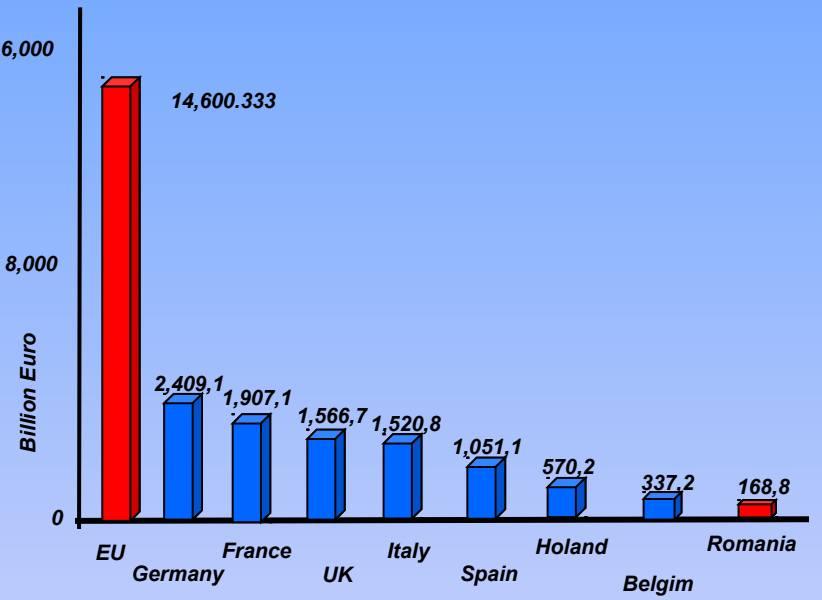
RASL trustee

20 mil. Inhabitants;
3.23-5% HCV prevalence
99.5% Genotype 1b

Internal Gross Revenue - Romania



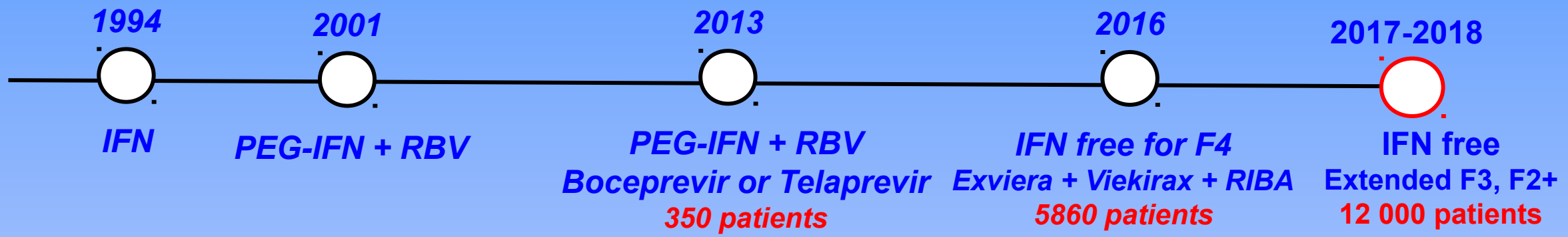
Internal Gross Revenue – EU /Western countries/Romania



- ***Romania was financially exhausted and affected by poverty after the collapse of the communist regime. The budget allocated to Healthcare system was constantly low (4.5-5.5%), a reflection of a reduced Internal Gross Revenue comparing to Western countries.***

- ***Estimated number of patients with HCV is more than 600 000 (80% with CHC) and with HBV is 800 000; 350 000 deaths/year by CHC (IV-th place in Europe at mortality of liver cause).***

-***Romania is one among other European countries where detection, prevention and treatment policies on viral hepatitis were implemented with a delay.***



1994 ⟶ *starts INF therapy: 4.000 patients*

2001 ⟶ *starts PEG INF + RIBA: 26.000 patients / 10 years*

2013 – 350 patients treated on compassioned bases with I generation PI

2016 – Start the IFN free therapy with Exviera and Viekirax on a cost-volume-efficacy based contract of The National Health Insurance House with AbbVie company for initially 5860 patients/year 2016, all with advanced fibrosis –F4 – compensated cirrhosis and 250 with liver transplantation (from a total of 800). 99.32% of these patients obtained SVR.

2017 -- A new contract cost-volume-efficacy with AbbVie for 10 000 patients with F4, F3 and F2 with co-morbidities : 250 dialyzed , lymphoma, haemophylia, cryoglobulinemia, aso.

--A second contract for 2000 patients with decompensate cirrhosis with Gilead company for Sofosbuvir+Ledipasvir in liver transplanted patients.

Viekirax (ombitasvir+paritaprevir+ritonavir), Exviera (dasabuvir), +/- Ribavirin

Inclusion criteria for treatment

- VCH patients with genotype 1b (99% of Romanians), fibrosis F4, F3 and F2 with co-morbidities, established on liver biopsy or FIBROMAX

- *naive and experienced patients (non or partial responders, breakthrough and relapses)*
- *compensated cirrhosis Child-Pugh A (5-6 points), including transplanted patients.*

Exclusion criteria for treatment

- *Child-Pugh A > 6 points (ascites, icterus, HRS, encephalopathy)*
- *AFP>50 UI/l, dysplastic nodules, HCC; alcohol abuse*
- *chronic treatment that had to be continued with amiodarone, chinidine, claritromicine, carbamazepin, fenitoin, fenobarbital, rifampicine, statines, mydazolam, cysaprid, ketoconazol, conivaptan, ergotamine and so.*

Targets reached to increase the patient's access to treatment

1. *better funding from the government : the budget provided by the National Health Insurance House in 2017 increased at about 3,09 billion RON (about 500 000 000 Euro) for treatment starting from May 2017 to May 2018.*
2. *better defining the priorities and methodologies : more patients treated - 10 000 patients with hepatitis F3 and F2, and with advanced cirrhosis -2000 .*
3. *better negotiation of the cost-volume-efficacy contract with more companies: AbbVie and also Gilead :Sofosbuvir+Ledipasvir.*
4. *better screening by improving the coordination between the 9 regional centers*
5. *better implication of the patients' organizations to force the political decedents to continue funding the treatment constantly, especially under the circumstances of the extended immigration.*

2018

- *Free access to treatment for all patients with HCV, F2, F1 and F0 inclusive .*
- *A new contract of The National Health Insurance House with all companies : AbbVie, Gilead and Merk, of an enlarged value and cheaper price, starting at the end of the actual program from May 2018.*
- *Romanian Ministry of Health will finance with European funds of 191 million euro a national campaign of screening for 5 programs: viral hepatitis, TB, breast and uterine cancer, prenatal screening. The target is screening of 30% of population until 2020 and all until 2030, when more than 80% will have access to treatment.*
- *The management of this program should be based on family doctors network on a consensus bases for indications to send the positive screened patients for treatment to gastroenterologists, hepatologists, internists, infectious diseases.*
- *Creation of a National Registry of viral hepatitis*


Join us at www.arsf.eu or www.balkanhep.eu