

***AROUND THE WORLD TABLE:  
ACCESS TO THERAPY **IN ROMANIA*****

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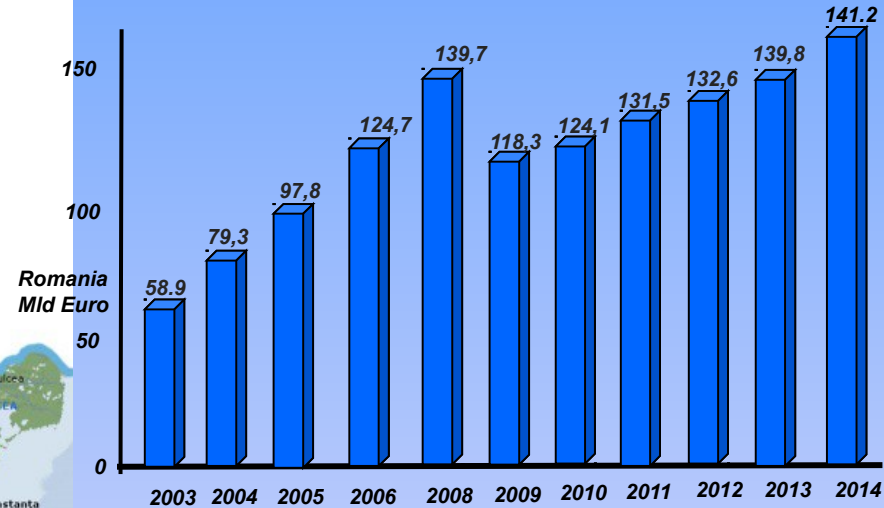
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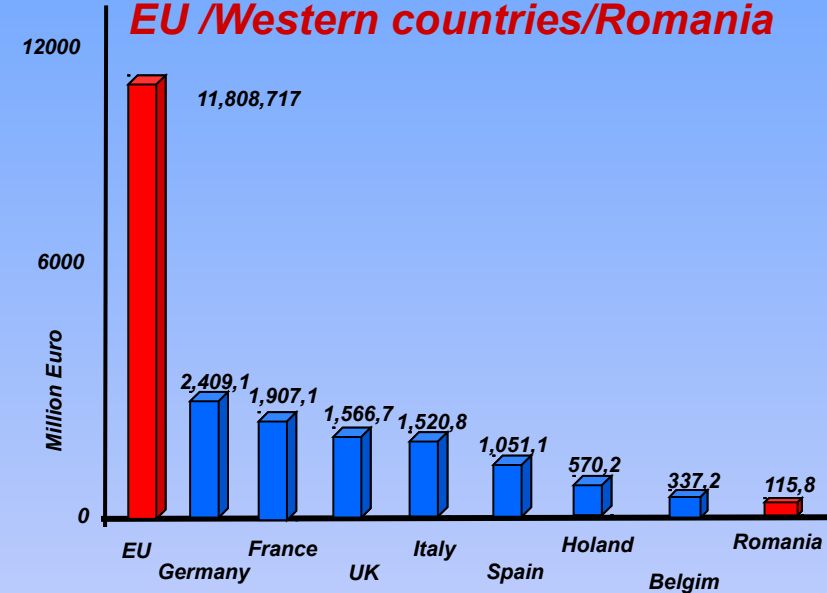
**20 mil. Inhabitants;  
5.6% HCV prevalence  
99.5% Genotype 1b**



**Internal Gross Revenue - Romania**

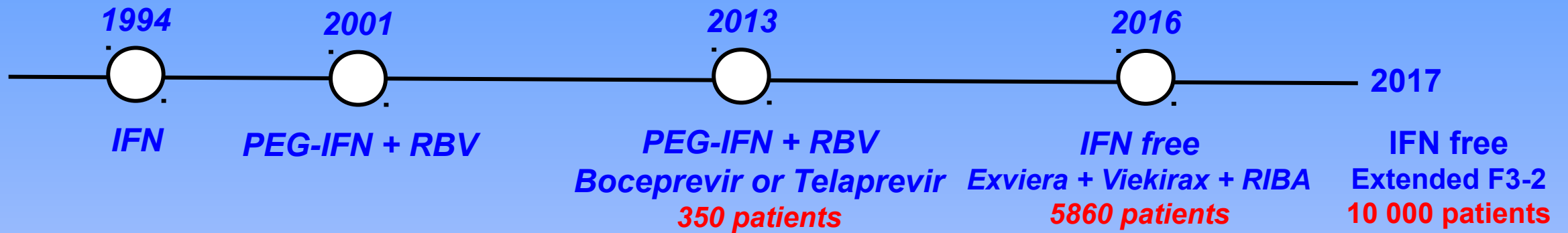


**Internal Gross Revenue – EU /Western countries/Romania**



**- 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%), a reflection of a reduced Internal Gross Revenue comparing to Western countries.**

**- Estimated number of patients with HCV is about 400 000, registered and screened ~16 000.**



*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 compassionated 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, all with advanced fibrosis –F4 – compensated cirrhosis and 250 with liver transplantation (from a total of 800). In preliminary data 99% of these patients have SVR.

**2017** -- We expect very soon the new contract cost-volume-efficacy for 2017 to extend the indication to F3 and F2 with co-morbidities on a total of 10 000 patients.

## ***Inclusion criteria for treatment***

***Viekirax (ombitasvir+paritaprevir+ritonavir), Exviera, Ribavirin***

- ***compensated cirrhosis HCV genotype 1b in naive and experienced patients (non or partial responders, breakthrough and relapses)***
  - ***F4 dg. on PBH or FIBROMAX***
- ***Child-Pugh A 5-6 points ( without ascites, icterus, SDH, encephalopathy)***
  - ***transplanted patients with VHC cirrhosis***

## ***Exclusion criteria for treatment***

- ***Child-Pugh A > 6 points ( ascites, icterus, SDH, encephalopathy)***
- ***AFP>8, dysplastic nodules, HCC; autoimmunity, alcohol abuse***
- ***chronic treatment that had to be continued with amiodarone, chinidine, claritromicine, carbamazepin, fenitoin, Phenobarbital, rifampicine, statines, mydazolam, cysaprid, ketoconazol, conivaptan, gemfibrozyl, ergotamine.***

## ***Actions planned to increase the patient's access to treatment***

- ***better funding from the government : resources provided by National Health Insurance House in 2017 as a credit line of 470 000 000 Euros***
- ***better defining the priorities and methodologies : more patients treated - 10 000 patients with hepatitis F3 and F2, than with cirrhosis -2000 with decompensate cirrhoses.***
- ***better negotiation of the cost-volume-efficacy contract with more companies: AbbVie, Gilead (Sofosbuvir+Ledipasvir), MSD.***
- ***better screening by improving the coordination between the 9 regional centers***
- ***keeping the political decedents constantly aware in order to***

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