



Drug Reimbursement - Croatia

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Population: 4,292,095 (July 2017)

Area: 56,594 km²

Density: 75.8/km²

21 counties



Currency: Croatia Kuna

1 HRK = 0.13 €

GDP: 46.3 mEUR (2016)

GDP growth: 2.9%

88.3% government debt to GDP

Unemployment rate: 15.8%

Healthcare budget: 8% of GDP annually

HRK 23.5 billion (3.2 billion EUR)

761 EUR per capita



Age distribution: 0-14 yrs: 14.2%
 15-24 yrs: 11.4%
 25-54 yrs: 40.7%
 55-64 yrs: 14.8%
 ≥ 65 yrs: 18.8%

Life expectancy: Total population: 75.9 yrs
 Male: 72.7 yrs
 Female: 79.2 yrs

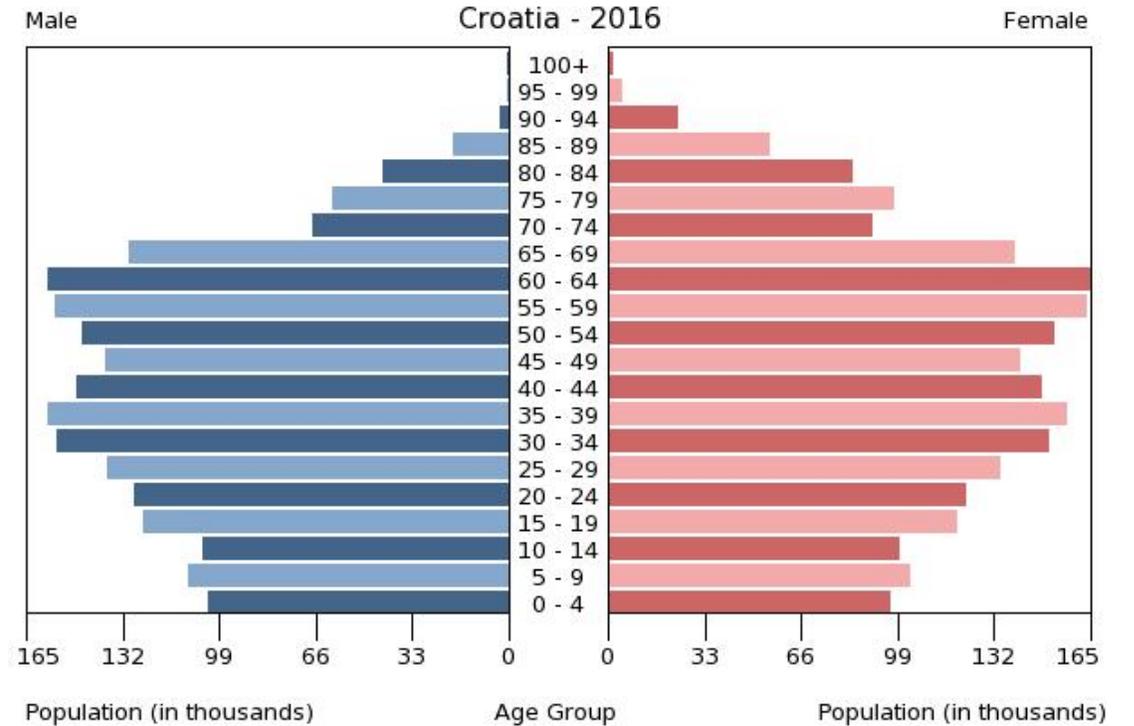
Demographic growth 2015-2020: -0.37%

Birth rate: 9 births/1000 population

Death rate: 12.1 death/1000 population

Employment rate: 56,8%

Retirement age limit: 65 years



Health System

Healthcare system (1)

The “social ownership” of health facilities has been replaced with state ownership, county ownership and private ownership.

The state owns large tertiary care hospitals, specialist institutes, health centers, and the majority of general and specialist hospitals.

Physicians increasingly provide primary care under contract with the insurance fund.

Healthcare system (2)

HRVATSKI ZAVOD ZA
ZDRAVSTVENO
OSIGURANJE



The financial organization of health care through a major third party payer - **the Croatian Health Insurance Fund (CHIF)** - plays a key role in the health system.

Pharmaceutical spending

19% of the total health expenditures

Total pharmaceutical expenditure 198 EUR per capita

OTC expenditure 26 EUR per capita





Health insurance

Total population is covered by a basic health insurance plan provided by statute (15.5% of each employee's salary) and optional insurance

Administered by CHIF

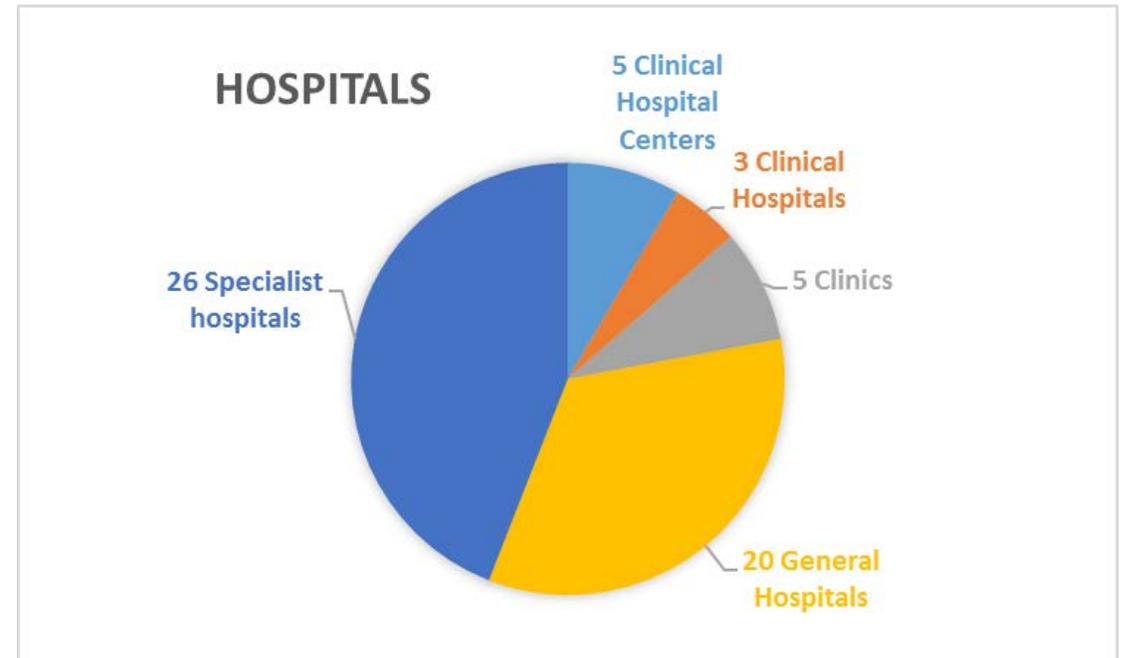
Health Professional Statistics

Number of **hospitals**: total 59

5 clinical hospital centres, 3 clinical hospitals, 5 clinics, 20 general hospitals, 26 specialist hospitals; 6 private specialist hospitals

Number of **doctors**: 17,102

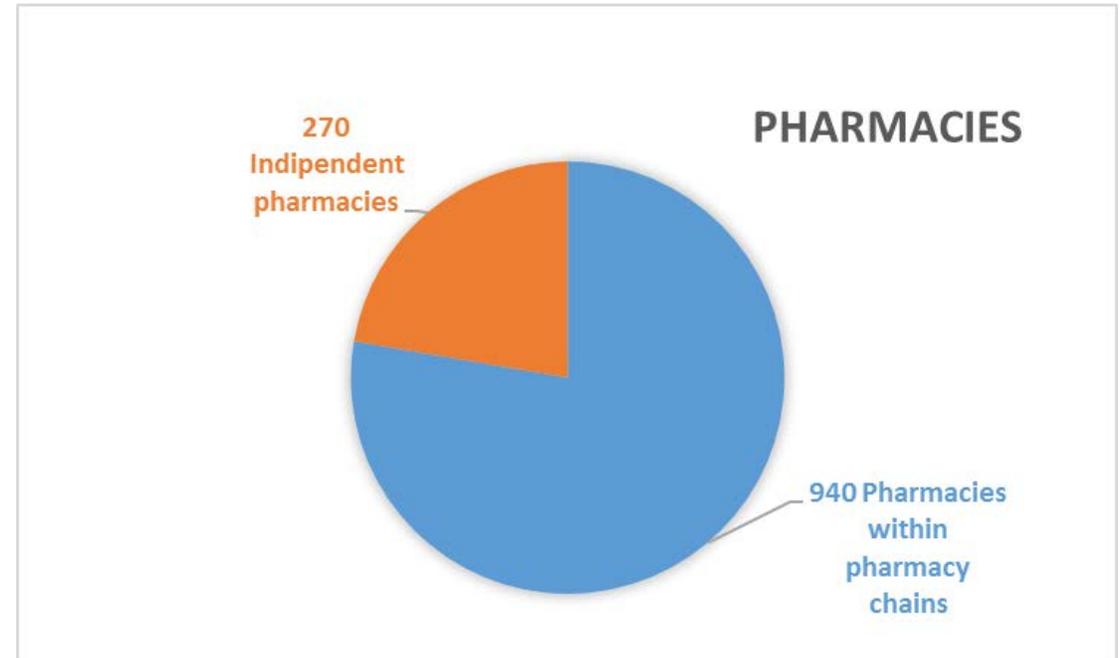
3.1 physicians/1,000



Health Professional Statistics

Number of **pharmacies**: 1,210 (940 pharmacies within 180 chains, with 80% of total MS)

Number of **wholesalers**: 6



Pharmaceutical market

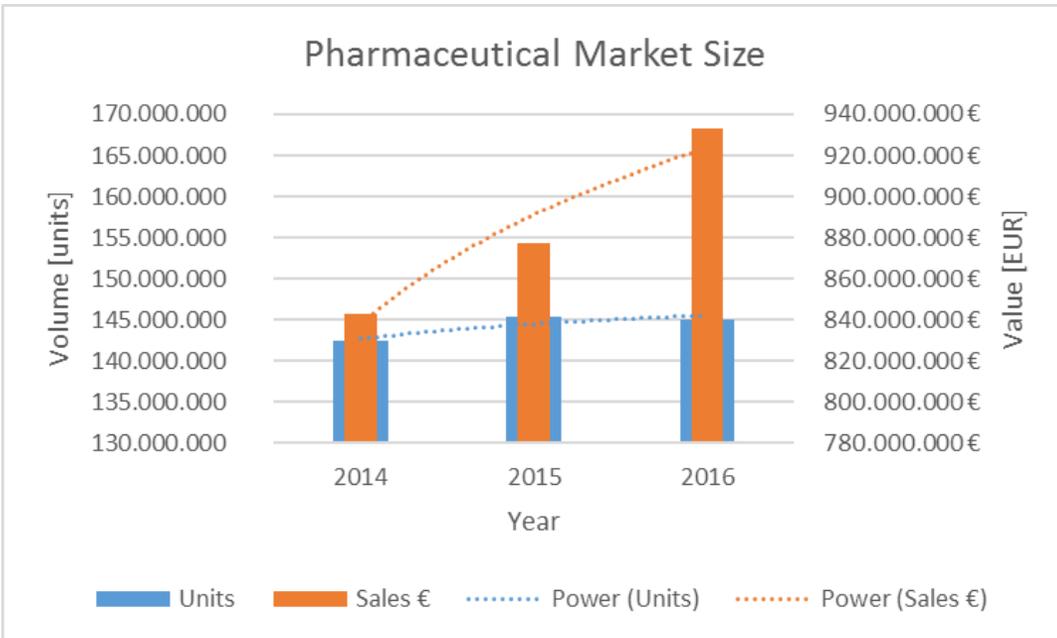
Pharmaceutical market

Total Pharma Market Size

Value size: 932,8 mEUR

Volume size: 145,1 mil. units

6,3% value growth; -0,2% volume decrease (2016/2015)

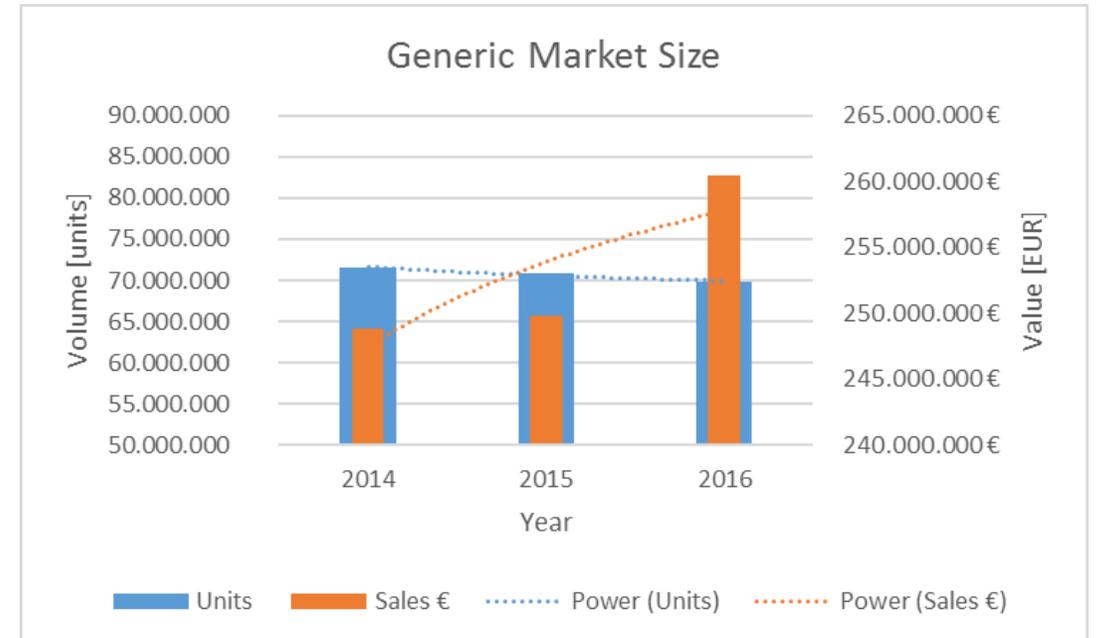


Generic Market Size*

Value size 260,4 mEUR (28% MS)

Volume size: 69,8 mil. units

4,2% value growth; -1,6% volume decrease 2016/2015



*Generic Rx and OTC market

**The market segmentation branded vs. non-branded is not splitted, since all generic drugs are branded.

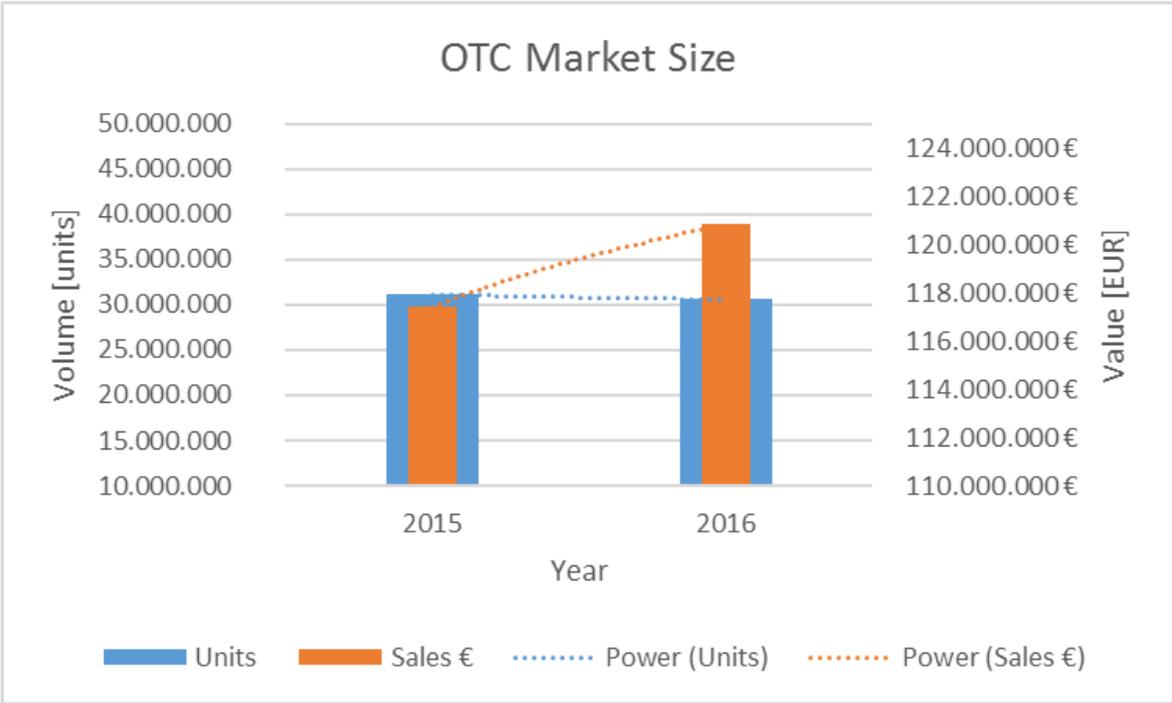
Pharmaceutical market

OTC Market Size

Value size: 120,8 mEUR

Volume size: 30,6 mil. units

2,9% value growth; -1,8% volume decrease 2016/2015



Source: IMS data

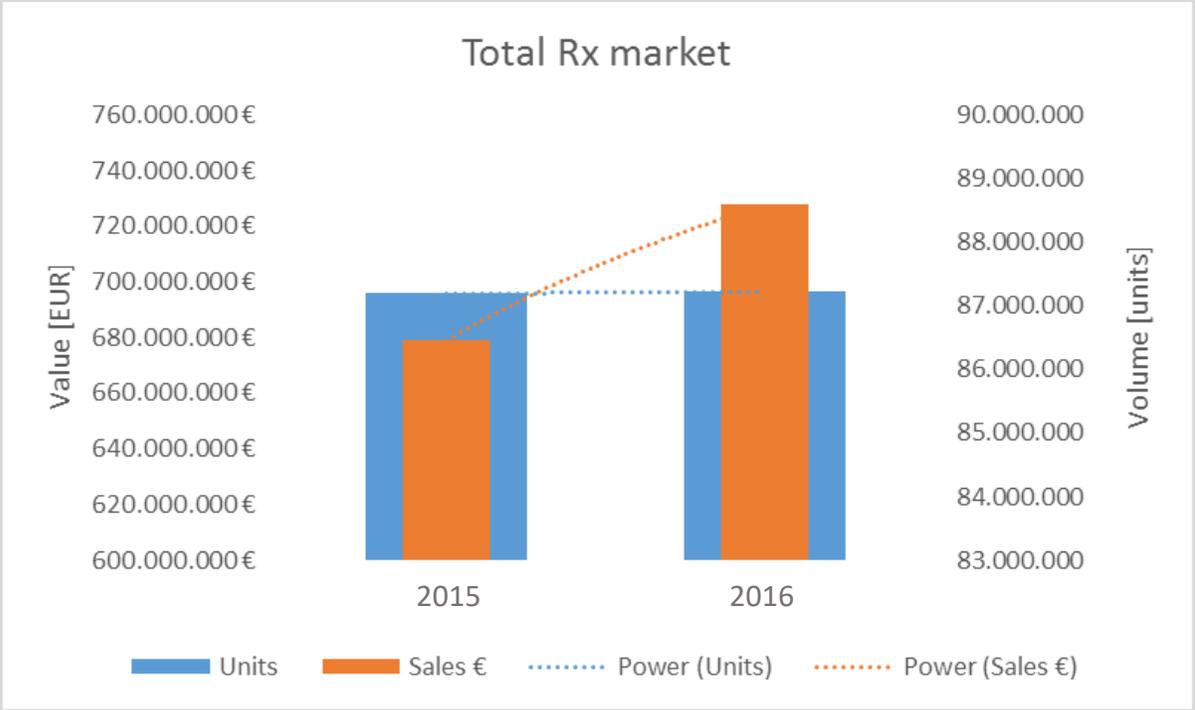
Pharmaceutical market

Total Rx market

Value size: 727,7 mEUR

Volume size: 87,2 mil. units

7,2% value growth; 0% volume trend (2016/2015)

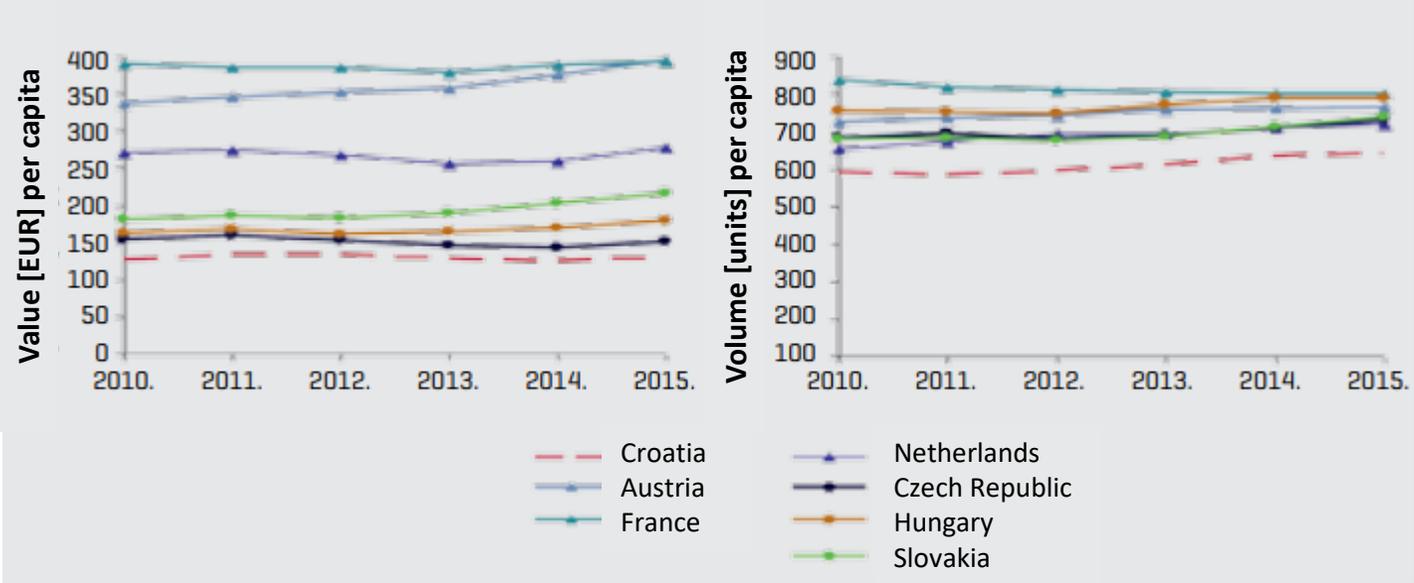


Source: IMS data

Pharmaceutical market

Trend of Rx medicines expenditure per capita

The expenditure for Rx medicines per capita is lower in comparison to other EU countries.



Source: IMS data

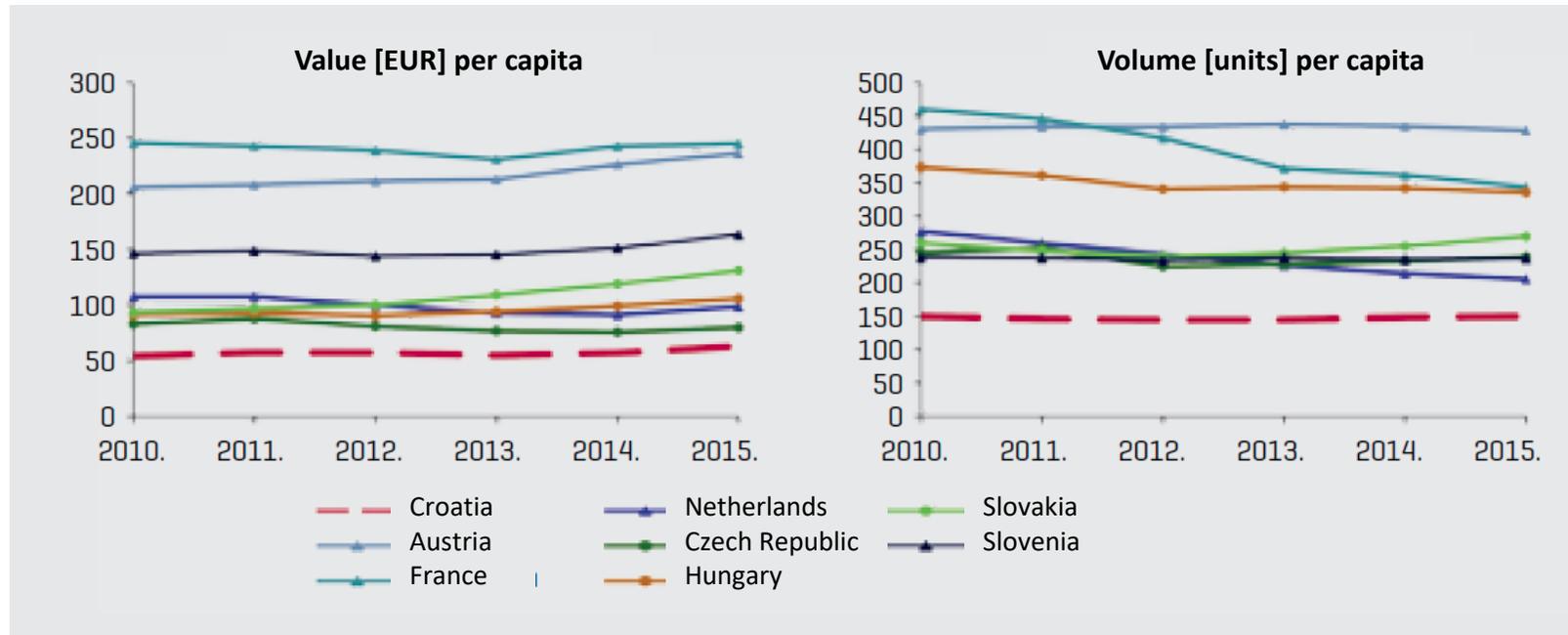
Pharmaceutical market

Innovative medicines expenditure per capita

Value: 62,5 EUR

Volume: 155 units

The expenditure for innovative medicines per capita is lower in comparison to other EU countries.



Pharmaceutical market

Four leading ATC categories = 478,9 mEUR (65,8% of total)

L category - ANTINEOPLASTIC & IMMUNOMODULATING AGENTS

Volume 2016: 0,95 mil. units

Value 2016: 172,8 mEUR

Growth 2011-2016: 33% volume, 67% value

C category - CARDIOVASCULAR SYSTEM

Volume 2016: 26,1 mil. units

Value 2016: 102,4 mEUR

Growth 2011-2016: 7% volume, -29% value

N category - NERVOUS SYSTEM

Volume 2016: 19,1 mil. units

Value 2016: 102,3 mEUR

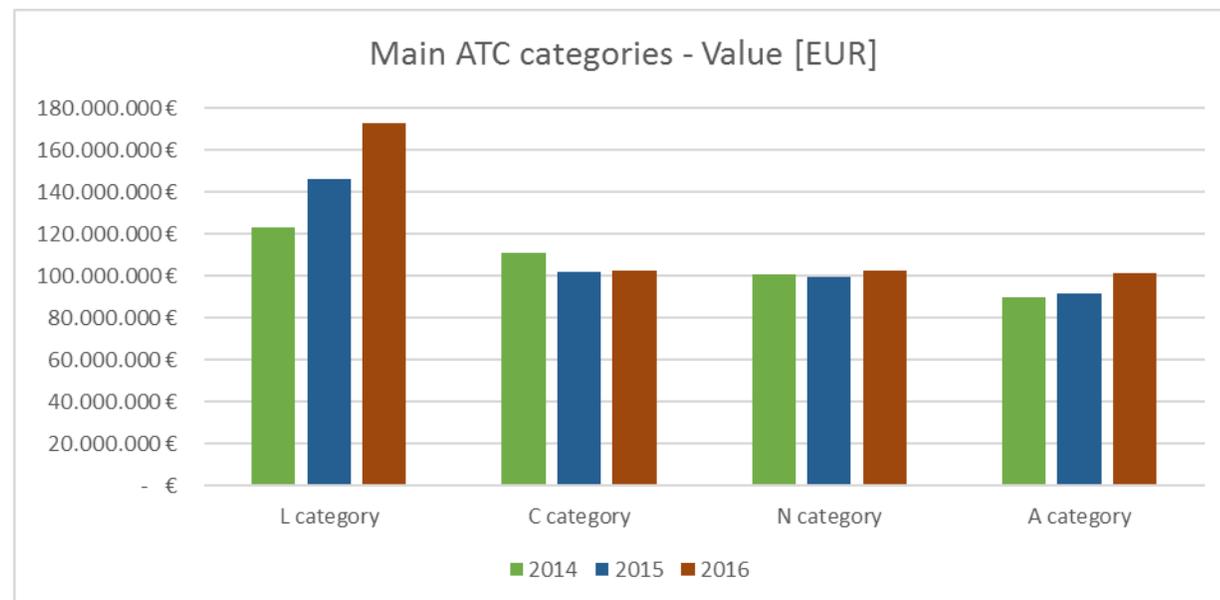
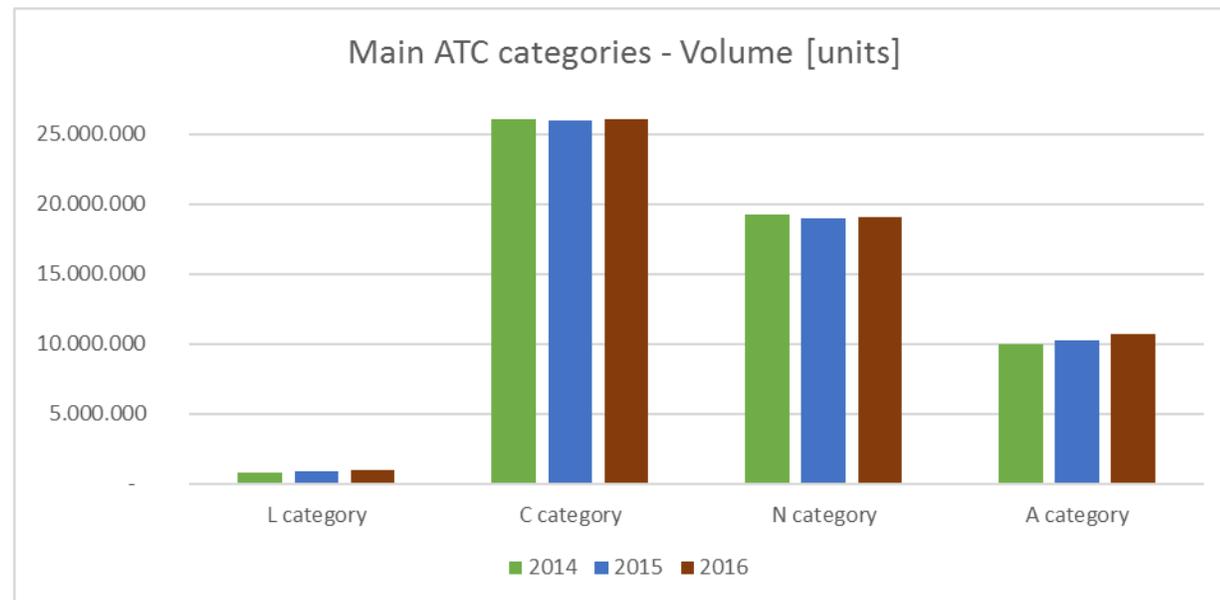
Growth 2011-2016: 3% volume, -1% value

A category - ALIMENTARY TRACT & METABOLISM

Volume 2016: 10,7 mil. units

Value 2016: 101,4 mEUR

Growth 2011-2016: 16% volume, 12% value



Substitution and reimbursement

Reimbursement system (1)

The competent authority for reimbursement is **CHIF**, which acts as major third party payer for medicines.

Having been granted a marketing authorization, a pharmaceutical company may apply for reimbursement for its product at CHIF.



Reimbursement system (2)

In the reimbursement decision, the Reimbursement Committee acts as an advisory body that, following an evaluation of the application, recommends based on specified criteria if the medicine is eligible for reimbursement and on which of the two Croatian reimbursement lists it should be placed.

The final decision is taken by the board of CHIF.



Drugs are divided into 2 reimbursement lists:



Drug Lists

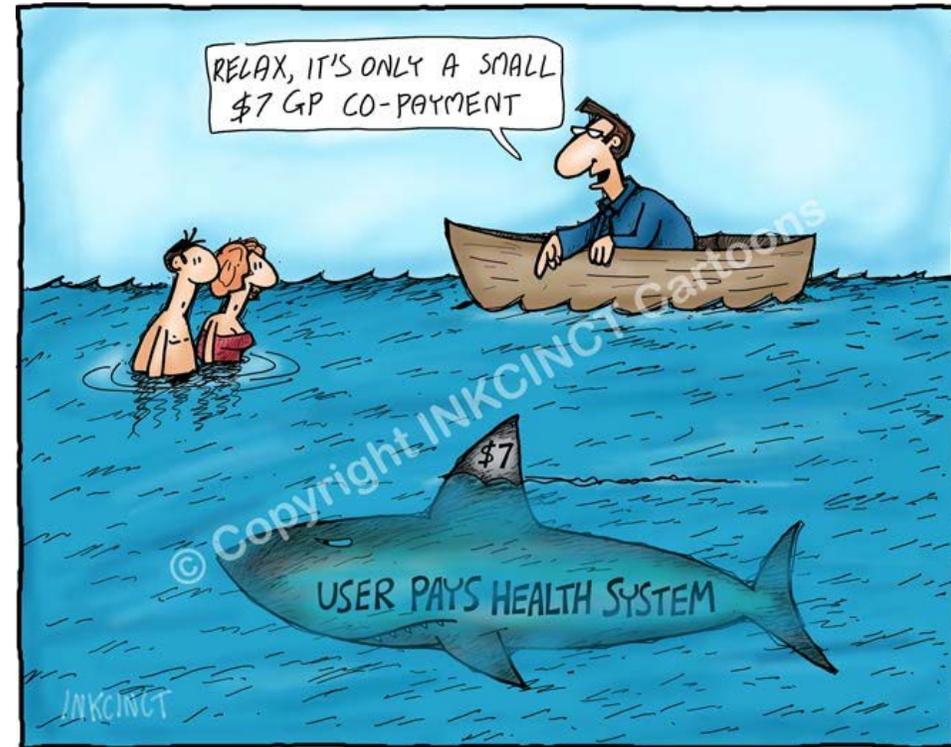
The costs of the **Baseline list** are fully covered by CHIF. All medicines from the Baseline list can be used for hospital treatments, while part can be prescribed.

The costs of the **Supplementary list** are partly covered by CHIF. The difference between the covered amount and the full price is paid by the insured person or its supplementary insurance. All medicines from the Supplementary List can be prescribed.

Level of co-payment

Depends on the drug, but maximum is 74%.

CHIF has its own rules for the determination of co-payment level.



Reimbursement process (1)

CHIF decides on the reimbursement of prescription pharmaceuticals.

The official timeline for CHIF to issue a decision on reimbursement is 180 days (the real length of the procedure ~ 1 year).

CHIF sets reimbursement limits for most prescription medicines through therapeutic price referencing.

Reimbursement process (2)

38 therapeutic groups are established at the 3rd, 4th or 5th ATC classification levels.

The therapeutic reference price for each product is subsequently determined based on the price of the cheapest product within the therapeutic group having at least 5% of the market share over a 12-month period (measured in terms of defined daily dose), with the aim of avoiding market shortages.

Reimbursement process (3)

In 2006, the government introduced internal reference pricing, setting limits to the reimbursement level for all drugs for which lower-priced generic drugs were available on the market. The reference price for all generically equivalent drugs was fixed at a level that the authorities regarded as acceptable.

If the price of any product was higher than the reference price, payment or reimbursement would only be granted up to the level set by the government, and the difference would have to be paid by the patient.

Reimbursement process (4)

For new products applying for reimbursement, there are 3 maximum reimbursement price levels:

- 100% of the average reference price for innovative drugs with a significant impact on recovery and without a pharmacologically similar (at 3rd ATC level) product registered in Croatia
- 90% of the average reference price for innovative drugs with a pharmacologically similar (at 3rd ATC level) product already reimbursed by CHIF
- 65% of the average reference price for generics (every newly reimbursed generic 10% below the cheapest reimbursed generic)

Reimbursement requirements (1)

The Regulation on Reimbursement introduced in 2009 has significantly increased the reimbursement requirements.

The new requirements include:

- budget impact analysis;
- cost–effectiveness analysis (voluntarily);
- a report of scientific evidence, particularly demonstrating the advantages of the medicinal product for the suggested indication over comparator treatments;
- comparison of the reimbursement status and financing of the product in all EU Member States.

Reimbursement requirements (2)

The analysis is necessary only for new molecules applying for reimbursement.

For generics are required only lower prices.

The final decision on granting reimbursement is primarily driven by the impact of inclusion of the new medicine on CHIF's budget.

Level of drug reimbursement

Like in most EU countries, CHIF reimburses specific medicines at 100%, whereas patients are charged co-payments for other reimbursable medicines.

Criteria for reimbursement include the medicine's importance from the public health perspective, its therapeutic value, and relative effectiveness.

Reimbursement is based on a reference price system.

Level of generic drug reimbursement (1)

The generic drug has to be applied on the Baseline List in order to be reimbursed.

The level of reimbursement for generic medicines is higher than for the originator. Since 2013 there is a political system encouraging the use of generic drugs.

CHIF brings the Guide through a new referral model - it is recommended that doctors prescribe the lowest generic drug on the Baseline List.

Level of generic drug reimbursement (2)

The cost of the lowest generic is 100% reimbursed, while the patient pays additionally the price difference between the reimbursed price and the price of the originator. Sometimes the originator lowers the price in order to have the same as generic drugs.

It is important to note that in the Reimbursement System the referent drug has not to be the originator. It is considered as the first entered drug on the List.

Generic entry

According to the law, the cost of the first generic drug must not exceed 70% of the cost of the originator medicine listed on the Baseline List (under the same INN).

The cost of the second generic drug must not exceed 90% of the cost of the first generic, and the cost of every next generic drug must not exceed 90% of the previous generic drug from the List.

There are no limits in the price or number of generics, the rule can be applied endlessly.

Price revision

There is a regular revision of already reimbursed products, both originators and generics. Price cuts are expected on an annual basis.

The manufacturers are obliged to calculate each year the average comparative price of the referent drug in referent countries (Italy, Slovenia and Czech Republic; in case that there is no parallel drug in these three countries, a reference is taken from Spain and France).

The price of the drug must not exceed the average comparative price.

The level of price cuts is unknown and cannot be foreseen since it depends on referent countries.

Especially expensive drugs (1)



Very expensive medicines are financed from funds for especially expensive products (separate CHIF funds that are excluded from hospital budgets).

In 2010, CHIF defined financial limits to the funds that can be spent on especially expensive products within each therapeutic indication, and entered into multilateral volume-cap agreements with the marketing authorization holders supplying such expensive products.

Especially expensive drugs (2)

Any new product proposed for financing from funds for especially expensive products should first be added to the existing volume-cap agreement, with a condition that its price is lower than the price of the cheapest product listed in the existing agreement (Innovative Health Initiative, 2012).



Substitution

There is a possibility by law that a GP substitute originators with generics.

The pharmacist is able to issue a parallel drug only in case that the prescribed drug is missing in stock.



