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Drug Policy in Croatia

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ABSTRACT

We presented a general overview of the health care system as well as the pricing and reimbursement environment in Croatia. In Croatia, most of the public funding for health care is collected from employers, through mandatory health care contributions for all the employed citizens. This contribution is a dedicated tax reserved for the health care system derived from employees' salaries. The rest of the public funds is mainly from taxes used by the Ministry of Finance to complement the overall health budget each year. The population is covered by a basic health insurance plan provided by statute and optional insurance, administered by the Croatian Health Insurance Fund. Reimbursement decisions are based on the Ordinance of Ministry of Health issued in 2013, which is an ordinance establishing the criteria for inclusion of medicinal products in the Croatian Health Insurance Fund basic and supplementary drug lists. A health technology assessment agency was established in 2007 as a legal, public, independent, nonprofit institution under the Act on Quality of Health Care. Budget impact analysis is obligatory, and cost-effectiveness analysis is beneficial. Two reimbursement lists exist: the basic (100% drug coverage) and the supplementary (co-payment from 10% to 90%) lists. The basic list covers both hospital and retail drugs. There is also a special drug list for expensive drugs (mainly hospital drugs). International reference pricing is also in place. List updates are done on an yearly basis. Real-world evidence can be required for health technology assessment as evidence for the budget impact models and cost-effective analysis; it is, however, not mandatory.

Keywords: Croatia, health care system, pharmaceutical system, pricing, reimbursement.

Introduction

Observing the complexity of decisions in health care system, the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) Central and Eastern Europe Network Publication working group initiated a multinational project to review and describe the drug policies in several European countries. There are several areas of special interest when looking at health care systems and at the basis for reimbursement decisions. These include factors from the environment that could influence or support decisions, for example, use of real-world data as additional information, as well as social aspects, patients' insurance, and co-payments.

The aim of this study was to present an overview of the health care system and the pricing and reimbursement environment in Croatia. The article was prepared as part of a project conducted by the working group under the ISPOR Central and Eastern European Network.

According to the Croatian Central Bureau of Statistics [1], the data from the initial results of the population census (published on June 30, 2011) showed that Croatia had a population of 4,465,096 people. Years of decline in the number of births, an increase in mortality among younger age groups during the war, and negative migration trends over the last decade have influenced the overall population trends. In 1991, Croatia entered a depopulation stage. In 2011, Croatia had 41,197 births and 51,019 deaths, that is, 9,822 more deaths than births. The natality, mortality, and general fertility rates were 9.4/1000, 11.6/1000, and 40.4/1000, respectively. Croatia's natural population increase rate was negative (–2.2). Like most European countries, Croatia is among the countries with an exceedingly old population. According to a population estimate by the Central Bureau of Statistics, in mid-2011, Croatia had 756,698 inhabitants aged 65 years or older (17.2%). Average life expectancy at birth in the year 2011 was 77.0 years for both sexes, 73.9 years for men and 80.0 years for women. The number of people employed at the age of 50 years or older was 54,300, and the number of people employed at the age 65 years or older was 54,000.

Health Care System

The total amount spent on health care in Croatia in 2013 was €2.7 billion and the amount spent on pharmaceuticals represented 1.5% of the gross domestic product per capita, which was US $21.351. In 2013, the pharma market was valued at €0.71 billion and the health care spending per capita was US $982 [2–5].

Conflicts of interest: The authors have indicated that they have no conflicts of interest with regard to the content of this article.

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The national approval body in Croatia is the Ministry of Health and there is one national health insurance fund—the Croatian Health Insurance Fund (CHIF) [2]. The CHIF has its own consultative body, the Committee for Medicinal Products (CMP), that consists of 13 members and is accountable for drug assessment and reimbursement. The Croatian Chamber of Physicians is accountable for reviewing the decisions made by the CMP and for providing its opinion on the drug list.

The Administrative Committee of the CHIF is responsible for confirming the decisions of the CMP and taking a final decision. Decisions are mainly driven by budget impact analysis results according to ISPOR guidelines. Full health technology assessment (HTA) analysis is required only on the payer's specific request and there is no official threshold in place for incremental cost-effectiveness ratio.

The annual budget for the year 2014 was increased in relation to 2013. It was 23.5 billion Croatian kuna (HRK) (i.e., ~€3.1 billion) [6].

General Information

Health care contributions in Croatia are mandatory for all employed citizens, which are collected from their employers. The dependents obtain their health care coverage through contributions made by working members of their families. Self-employed workers in Croatia are also obligated to make health care contributions. Croatian citizens who belong to a particularly vulnerable category are exempt from making health care contributions; retired people and persons with low income are insured and have access to health care facilities—contractual partners—of the CHIF. Croatian citizens are required to participate in health care expenditures, except for certain categories of insured persons (e.g., children younger than 18 years) or insured persons suffering from certain diseases, when health care services are being rendered because of complications caused by those diseases (e.g., malignant diseases or chronic mental illnesses). For some health care services, such as plastic surgery, insured persons are obligated to pay on their own; that is, the cost is not covered by mandatory health insurance. A family doctor or a general practitioner may further suggest secondary or tertiary level health care service for a patient if needed, which allows the patient free access to hospitals and polyclinics that have signed contracts for rendering health care services from mandatory health insurance (contractual partners).

Health care services on secondary and tertiary levels in major cities are mainly rendered in hospitals. Hospitals can be classified as clinical, general, and special hospitals. They are mainly financed by CHIF, but also from several other sources like local governments.

Most of the public funding for health care is collected from employers, through mandatory health care contributions for all the employed citizens. This contribution is a dedicated tax reserved for the health care system derived from the salaries of the employees. The rest of the public funds are mainly from taxes (mainly income tax, value-added tax, etc.) used by the Ministry of Finance to complement the overall health budget each year. Almost the entire private fund for health care is citizens' own funds [2].

General, county, and university hospitals are public hospitals. There are also private clinics in specialty fields (e.g., orthopedic, cardiosurgery, and obstetrics). Primary health care doctors are public employees, and even when they work in the private sector they are contracted from the CHIF.

The population is covered by a basic health insurance plan provided by statute and optional insurance and administered by the CHIF. In 2012, annual compulsory health care–related expenditures reached 21.0 billion HRK (~€2.8 billion). Health care expenditures comprised 0.6% of private health insurance and public spending. In 2012, Croatia spent 6.8% of its gross domestic product on health care, down from approximately 8% as estimated in 2008, when 84% of health care spending came from public sources. There are hundreds of health care institutions in Croatia, including 79 hospitals and clinics with 25,285 beds, caring for more than 760,000 patients per year. The ownership of hospitals is shared between the state and the counties of Croatia. There are 5,792 private practice offices and a total of 46,020 health workers in the country, including 10,363 medical doctors. There are 79 emergency medical service units that performed more than 1 million interventions in 2012 [7].

Decision-Making Process

Reimbursement decisions are based on the Ordinance of Ministry of Health issued in 2013 [8], which is an ordinance establishing the criteria for inclusion of medicinal products in the basic and the supplementary drug lists of the CHIF. Budget impact analysis is obligatory, and cost-effectiveness analysis is beneficial. The basic list covers both hospital drugs and retail prescription drugs (essential medications with 100% drug coverage). Medicines on the supplementary list can be partially reimbursed (co-payment

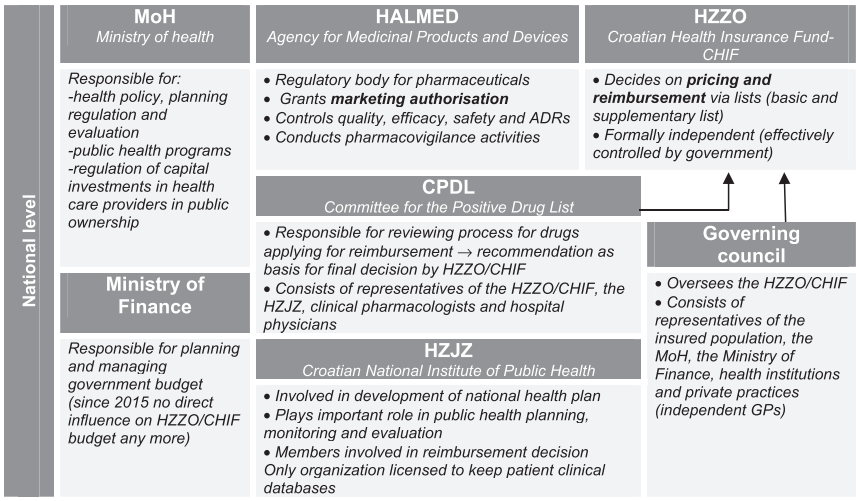

Fig. 1 – Reimbursement process in Croatia. ADR, adverse drug reaction; GP, general practitioner.