

ACCESS TO ORPHAN DRUGS: A CROSS COUNTRY COMPARISON OF LEGISLATIVE APPROACH AMONG SERBIA, CROATIA AND MACEDONIA

*Dušana Krajnović¹, Jasmina Arsić², Ljiljana Tasić¹,
Guenka Petrova³, Svetlana Milijić⁴*

¹University of Belgrade, Faculty of Pharmacy, Department of Social Pharmacy and Pharmaceutical Legislation, Belgrade, Serbia,

²At the time of the research student at postgraduates specialization programme, University of Belgrade, Faculty of Pharmacy, Department of Social Pharmacy and Pharmaceutical Legislation, Belgrade, Serbia

³Medical University of Sofia, Faculty of Pharmacy, Department of Social Pharmacy, Sofia, Bulgaria

⁴Republic Fund for Health Insurance, Niš, Serbia

Contact: Dušana Krajnović
450 Vojvode Stepe Str, 11221 Belgrade, Serbia
E-mail: parojcic@pharmacy.bg.ac.rs
dusica.krajnovic@pharmacy.bg.ac.rs

Access to orphan drugs (In EU regulation Orphan Drugs are referred as Orphan Medicinal Products (OMP)) is a key role in determining whether patients with rare diseases (RDs) will receive adequate and efficient treatment. The objective of this article is to identify differences in patient access to orphan drugs in 3 pharmaceutical markets: Serbia, Croatia and Macedonia. Patient access was defined: as the market access (availability) and affordability (financial accessibility). We analysed the legislative requirements for the authorisation process and made a cross country comparison. Retrospective cross-sectional analysis was done on drug lists in selected countries and a cross-comparison between the List of Orphan Drugs in Europe (LODE) for a six-month period (May 2014-October 2014). We included all 179 OMPs marketed in EU in our analysis, which had received market authorization in Croatia upon its membership in the EU. Total number of marketed drugs in Serbia was 59 (32.96%) drugs and in Macedonia 52 (29.05%) drugs. However, market authorization does not guarantee patient access to any given drug, so only 39.11% of OMPs could be accessed by Croatian patients (70 drugs). The number of refunded drugs in Serbia and Macedonia was smaller (32 and 20, respectively) which makes respectively, 17.88% and 11.17% of drugs on the LODE. The present study showed some variations between countries in selected indicators of availability and access to orphan drugs. Patients in Croatia had greater number of registered and refunded drugs, but in Serbia more than a half of registered OMPs could be refunded from National Health Insurance Fund. Macedonia had smaller number of inhabitants and also had the smaller number of patients from certain RDs which results in lower total number of OMPs.

Acta Medica Medianae 2018;57(4):43-51.

Key words: orphan medicinal product (OMP), affordability, availability, rare diseases, legislative requirements