PROGRAMS FOR RARE DISEASES IN SERBIA AND EUROPE

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Background: At the end of the 20th century, in the countries of the European Union (EU), the need to define a European policy in the field of rare diseases (RD) was recognized, which resulted in the adoption of a series of strategic documents, the opening of the first expert centers and registries for RD.

Methods and Objectives: In order to assess the health care of patients with RD, a situational analysis of the available strategic/program documents in the field of RD in our country and in Europe was done.

Results: Regulation on orphan drugs no. 141/2000 of the European Parliament and the Council on orphan drugs from 1999, the European definition of RD was adopted and the criteria for the designation of orphan drugs in the EU were established. The regulation provided basic guidelines for the development of strategies for RD in EU countries with the aim of encouraging research, diagnosis, treatment and care of people with RD. In 2008, the European Commission published a report on RD, on the basis of which the European Council of Ministers of Health adopted Recommendations in the field of RD in 2009. The recommendations emphasized the importance of: developing and adopting national plans/strategies for RD, encouraging research, strengthening patient organizations and sustainability information, research and health infrastructures. By the end of 2014, 20 national plans/strategies for rare diseases were adopted in the EU. In 2019, the government of our country adopted the first National Development Program for RD for the period 2020-2022, with the main goal of improving the health care of patients with RD.

Conclusions: The recommendation of the two-year study "Rare 2030" initiated by the European Parliament is the development of a broader strategy on RD, and this initiative is supported by 21 EU member states. In Serbia, the development of a new National Program for RD is underway.

Keywords: rare diseases, programs, Serbia, Europe