NEEDS AND OPPORTUNITIES FOR COMPOUNDING OF MEDICINES FOR BIOIDENTICAL HORMONE REPLACEMENT THERAPY IN SERBIA

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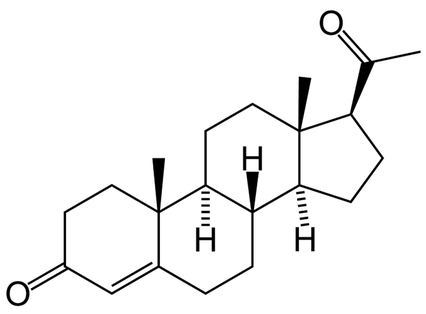
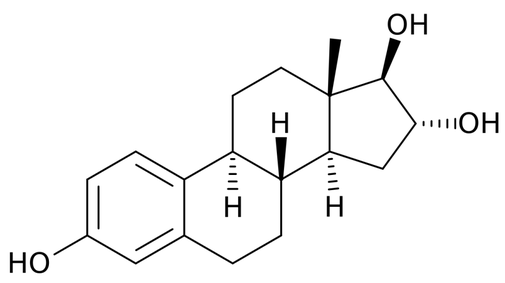
INTRODUCTION: Around 75% of women in menopause experience some symptoms and approximately one-third of these experience severe symptoms which affect their quality of life.[1] Postmenopausal hormone replacement therapy (HRT) is an effective, well-tolerated treatment for women with menopausal symptoms. Nationwide, a lot of women use compounded hormone replacement therapy. According to a study, usage of these compounded medicines made in pharmacy for an individual patient is increasing each year.[2]

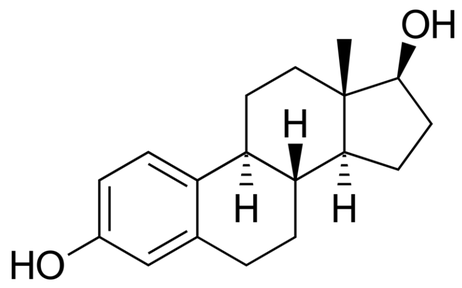
OBJECTIVES: The aim of this study was to determine needs and opportunities for bioidentical hormone replacement therapy (HRT) in Serbia.



Progesterone



Estriol



Estradiol

METHOD/DESIGN: Data about consumption of approved bioidentical monocomponent HRT medicines was obtained from official website of Medicine and Medical Devices Agency of Serbia in September 2021 for period of 2011-2019. Consumption was observed as defined daily dose (DDD) per 1000 inhabitants per day. Opportunities for compounding of extemporaneous hormone replacement medicines were considered according to Serbian Law on Medicines and Medical Devices and following regulations.

RESULTS: At the moment of obtaining these results, in Serbia there were 13 formulations registered with either progesterone, estradiol or estriol as the only active pharmaceutical ingredient. There are 8 formulations with progesterone (2 vaginal gels, 1 gel, 1 solution for injection and 4 soft capsule formulations). Estradiol is present in 2 transdermal spray formulations and one transdermal patch. Estriol is registered as one vaginal cream and one vagitoria.

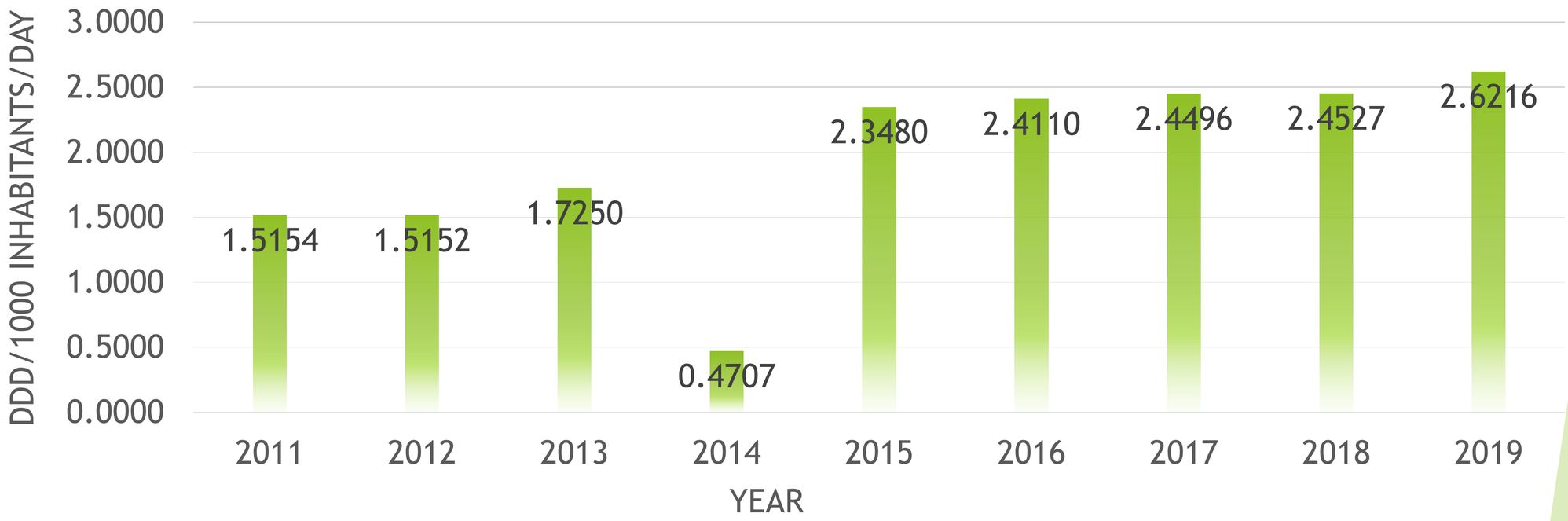


Figure 1. Consumption of approved monocomponent bioidentical hormone replacement medicines

Data about consumption are presented in Figure 1. Consumption trend in the observed period can be considered to be increment, with the exception in year 2014. During this year oral progesterone was not licensed in Serbia. Serbian drug law provides the possibility of compounding magistral medicines in situations like these, when an adequate medication is not available in the market. These medicines are proscribed by physicians and prepared in community pharmacies for each individual patient.

CONCLUSIONS: In the observed period there is increasing trend in consumption of approved bioidentical hormones. Extemporaneous medicines can be appropriate in situation when there is shortage of approved medicines or there are opportunities for individualization of HRT therapy concerning dose or specific combinations of bioidentical hormones. However, caution is advised as neither safety nor efficacy of compounded bioidentical hormone formulations has been proven.

REFERENCES

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2. MacArthur RB, Mattison D, Parker RM. Compounded bioidentical hormone products, a path forward. J Am Pharm Assoc. 2021;9:S1544- 3191(21)00346-0.