

**COLLABORATION OF SERBIA IN WORK OF PH. EUR. AND OMCL NETWORK:
RESULTS, ACTIVITIES AND FUTURE**

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European pharmacopoeia (Ph. Eur.) is unique reference for quality of medicines in Europe (First issue, 1969). Collaboration of Serbia is done through expert groups, participation at Ph. Eur. Commission, quality control of medicines in National Control laboratory (NKL), and network of Official medicines control laboratories (OMCL). The aim of work was to present historical data on the collaboration between Serbia, Ph. Eur. and OMCL, by searching data from ALIMS database, which coordinates this collaboration. Collaboration started in 1991. when Yugoslavia ratified Convention on Ph. Eur. As an independent state, Serbia was participating in the work of Ph.Eur. Commission since 2003. Serbia has 7 representatives in expert groups: 10B,11 (Organic Chemistry), 15 (Human Vaccines and Sera), P4 (Patent medicines), PaedF (Pediatric Formulas), POW (Powders) and ST (Standard Terms). These experts have developed 16 new monographs, European Pediatric Formulas and participated in revision of over 10 existing monographs. Representatives of Serbia chair P4 and POW groups. NKL is a full member of the OMCL network since 2004, and in 2013 it was certified against ISO 17025. Since 2006, NKL was participating in the development of new chemical reference substances (CRS), monitoring their quality, doing laboratory performance studies, European systematic drug quality control and studies of suspicious and unknown samples. By active participation in development of monographs and quality control of medicines, the competence of experts has been improved. By application of the modern technologies this has enabled patients in Serbia to have available medicines of equivalent quality as on the EU market.

References

1. <https://www.coe.int/en/web/conventions/full-list?module=signatures-by-treaty&treatynum=050>
2. Izveštaj o radu ALIMS a za 2019.godinu

UČEŠĆE SRBIJE U RADU EVROPSKE FARMAKOPEJE I OMCL MREŽE: REZULTATI, AKTIVNOSTI I BUDUĆNOST

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Evropska farmakopeja (Ph. Eur.) je jedinstvena referenca za kontrolu kvaliteta lekova u Evropi (prvo izdanje, 1969). Saradnja Srbije sa Ph. Eur. se sprovodi kroz članstvo u ekspertskim grupama, učešće u Komisiji Ph. Eur. i kroz kontrolu kvaliteta lekova u Nacionalnoj kontrolnoj laboratoriji (NKL) u okviru mreže nacionalnih kontrolnih laboratorija za lekove (OMCL). Cilj rada je bio prikaz istorijskih podataka o saradnji Srbije sa Ph. Eur. i OMCL, pretragom podataka iz baze ALIMs-a, koji koordiniše tu saradnju. Saradnja počinje 1991. godine, kada je Jugoslavija ratifikovala Konvenciju o izradi Ph. Eur. Kao samostalna država, Srbija od 2003. godine učestvuje u radu Komisije Ph. Eur. Srbija ima 7 predstavnika u sledećim ekspertskim grupama: 10B i 11 (Organska hemija), 15 (Humane vakcine i serumi), P4 (Lekovi pod patentnom zaštitom), PaedF (Evropske pedijatrijske formule), POW (Karakterizacija praškova) i ST (Standardni termini). Ovi eksperti su do sada razvili 16 novih monografija Ph. Eur. i Evropskih pedijatrijskih formula i učestvovali u reviziji preko 10 postojećih monografija. Predstavnici Srbije predsedavaju grupama P4 i POW. NKL je punopravna članica OMCL mreže od 2004. godine, a 2013. je sertifikovana o usklađenosti sa standardom ISO 17025. Od 2006. godine NKL učestvuje u razvoju novih hemijskih referentnih supstanci (CRS), praćenju kvaliteta postojećih CRS, studijama provere performansi laboratorije, evropskoj sistematskoj kontroli kvaliteta lekova i studijama ispitivanja sumnjivih i nepoznatih uzoraka. Aktivnim učešćem Srbije u razvoju monografija i ispitivanju kvaliteta lekova, poboljšana je kompetentnost eksperata i uz primenu najsavremenijih tehnologija je omogućeno da pacijenti u Srbiji imaju dostupne lekove ekvivalentnog kvaliteta lekovima na tržištu EU.

Literatura

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