Problems of Falsification of Medicinal products in the conditions of the COVID-19 Pandemic: Adaptation of Ukrainian legislation to the norms of the European Union.

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ABSTRACT:

The problem of distribution of low-quality medicinal products in Ukraine has become especially relevant against the background of the spread of the COVID-19 pandemic. The challenge to the national medical system became more tangible, as the fight against the virus and quarantine restrictions became heavy psychological blows for patients who sought appropriate treatment in an unofficial way. The purpose of the article is to analyze the problem of falsification of medicines in the conditions of a pandemic and to develop development models against the background of the study of European legislative norms. General scientific methods (synthesis, analysis, induction and deduction) became the main methods for writing the article. The methods of content analysis, systematic review of scientific literature, SMART and FINER principles were also used. The results highlighted one of the most important problems of the distribution of falsified and unlicensed drugs during the spread of COVID-19 - the semi-legal activity of pharmacies that work exclusively in the field of online sales. The requirements for their activities are quite loyal, and the distribution of low-quality or uncertified medicinal products is punished only administratively. The possibility of using European (primarily German) experience to counter the distribution of falsified medicines was discussed. Attention was also drawn to the geopolitical factor in the fight against COVID-19 – the use of the Russian vaccine “SPUTNIK V”, which in the conditions of Russian aggression can be assessed as a hybrid threat. The problematic nature of using this vaccine has been demonstrated, given the secrecy of the mechanism of conducting experiments. Resolutions of the European regulatory bodies allowed Ukrainian doctors not to use this vaccine either. This episode can be considered a positive moment of using European experience to establish medical rules for work in Ukraine. The conclusions note the need to reform Ukrainian legislation, take into account the European experience and harmonize with European regulations on the circulation of medical drugs. Such a step will make it possible to face modern challenges and significantly complicate the entry of counterfeit medicines into Ukraine.

Keywords: COVID-19, Ukraine, falsification of medicines, European development.

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REFERENCES:

1. Janvier S, De Spiegeleer B, Vanhee C, Deconinck E. Falsification of biotechnology drugs: current dangers and/or future disasters? Journal of Pharmaceutical and Biomedical Analysis [Internet]. 2018 Nov [cited 2022 Oct 20];161:175-91. Available from: https://doi.org/10.1016/j.jpba.2018.08.037

2. Corrie L, Muzaffar-Ur-Rehman M, Kukatil L, Manasa D, Shirisha A. Antifibrotic drugs for COVID-19: from orphan drugs to blockbusters? Current Respiratory Medicine Reviews [Internet]. 2021 May 5 [cited 2022 Oct 20];17(1):8-12. Available from: https://doi.org/10.2174/1573398x17666210304100043

3. Baker N. Coronapod: new hope from COVID antiviral drugs. Nature [Internet]. 2021 Nov 12 [cited 2022 Oct 20]. Available from: https://doi.org/10.1038/d41586-021-03441-2

4. Dwivedi S, Rawat A, Ranjan A, Agrawal R, Misra R, Gupta SK, Kishore S, Misra S. COVID-19 [Internet]. Boca Raton: CRC Press; 2022. Drug Repurposing and Novel Antiviral Drugs for COVID-19 Management; [cited 2022 Oct 20]; p. 74-95. Available from: https://doi.org/10.1201/9781003190394-7

5. Wakhlu A, Manoj M, Bafna P, Sahoo R, Hazarika K. Repurposing drugs: Lessons from rheumatology in the COVID-19 pandemic. Indian Journal of Rheumatology [Internet]. 2021 [cited 2022 Oct 20];16(2):179. Available from: https://doi.org/10.4103/injr.injr\_323\_20

6. Jacob S. The New Face of Medicine –care flow strategies developed during COVID. International Journal of Integrative Pediatrics and Environmental Medicine [Internet]. 2020 Jun 12 [cited 2022 Oct 20];5. Available from: https://doi.org/10.36013/ijipem.v5i1.83

7. Pocock L. Fake Covid vaccine found in Iran – and beyond? World Family Medicine Journal /Middle East Journal of Family Medicine [Internet]. 2022 Mar [cited 2022 Oct 20];20(3). Available from: https://doi.org/10.5742/mewfm.2022.9525016

8. Kanozia R, Arya R. “Fake news”, religion, and COVID-19 vaccine hesitancy in India, Pakistan, and Bangladesh. Media Asia [Internet]. 2021 May 17 [cited 2022 Oct 20];48(4):313-21. Available from: https://doi.org/10.1080/01296612.2021.1921963

9. Metil AS, Reshetnykova MY. Legal regulation of covid-19 in Ukraine. State and Regions. Series: law [Internet]. 2020 [cited 2022 Oct 20];(2):130-3. Available from: https://doi.org/10.32840/1813-338x-2020.2.22

10. Aborode AT, Awuah WA, Talukder S, Oyeyemi AA, Nansubuga EP, Machai P, Tillewein H, Oko CI. Fake COVID-19 vaccinations in Africa. Postgraduate Medical Journal [Internet]. 2021 Nov 23 [cited 2022 Oct 20]:postgradmedj—2021-141160. Available from: https://doi.org/10.1136/postgradmedj-2021-141160

11. Choudhary OP, Priyanka, Singh I, Mohammed TA, Rodriguez-Morales AJ. Fake COVID-19 vaccines: scams hampering the vaccination drive in India and possibly other countries. Human Vaccines & Immunotherapeutics [Internet]. 2021 Aug 6 [cited 2022 Oct 20]:1-2. Available from: https://doi.org/10.1080/21645515.2021.1960770

12. Bakker-’t Hart IM, Ohana D, Venhuis BJ. Current challenges in the detection and analysis of falsified medicines. Journal of Pharmaceutical and Biomedical Analysis [Internet]. 2021 Apr [cited 2022 Oct 20];197:113948. Available from: https://doi.org/10.1016/j.jpba.2021.113948

13. Ahmad A, Hussaan M, Batool F, Mumtaz S, Rehman N, Yaqoob S, Kausar H. The Covid-19 Pandemic [Internet]. Boca Raton: Apple Academic Press; 2022. Social Distancing and Quarantine as COVID-19 Control Remedy; [cited 2022 Oct 20]; p. 145-78. Available from: https://doi.org/10.1201/9781003283607-7

14. Tsekhmister YV, Konovalova T, Tsekhmister BY, Agrawal A, Ghosh D. Evaluation of Virtual Reality Technology and Online Teaching System for Medical Students in Ukraine During COVID-19 Pandemic. International Journal of Emerging Technologies in Learning (iJET) [Internet]. 2021 Dec 8 [cited 2022 Oct 24];16(23):127-39. Available from: https://doi.org/10.3991/ijet.v16i23.26099

15. Tsekhmister Y, Stepanenko V, Konovalova T, Tsekhmister B. Analysis of Physicochemical Natures of Modern Artifacts in MRI. International Journal of Online and Biomedical Engineering (iJOE) [Internet]. 2022 Mar 8 [cited 2022 Oct 24];18(03):89-100. Available from: https://doi.org/10.3991/ijoe.v18i03.25859

16. Tukaiev S, Vasheka T, Rizun V, Enzminger A, Havrylets Y, Palamar B, Dolgova O, Pravda O, Makarchuk M. Media trust during the COVID-19 pandemic in Ukraine. European Psychiatry [Internet]. 2022 Jun [cited 2022 Oct 20];65(S1):S378. Available from: https://doi.org/10.1192/j.eurpsy.2022.959

17. Abdellatif OS, Behbehani A, Behbehani M. Ukraine COVID-19 Governmental Response [Internet]. [place unknown]: UN Compliance Research Group; 2021 Apr [cited 2022 Oct 20]. Available from: https://doi.org/10.52008/ukr0501

18. Napryeyenko O, Napryeyenko N, Marazziti D, Loganovsky K, Mucci F, Loganovskaja T, Tsekhmister Y. Depressive Syndromes Associated with Alcohol Dependence. Clin Neuropsychiatry [Internet]. 2019 Oct [cited 2022 Oct 22];16(5-6):206-212. Available from: https://doi: 10.36131/clinicalnpsych2019050603

19. Holt E. COVID-19 vaccination in Ukraine. The Lancet Infectious Diseases [Internet]. 2021 Apr [cited 2022 Oct 20];21(4):462. Available from: https://doi.org/10.1016/s1473-3099(21)00156-0

20. Dhanashri A, Sachin R. A Role of Herbal Drug as an Immunity Booster during Covid-19 Pandemic. Asian Journal of Pharmaceutical Research [Internet]. 2021 Apr [cited 2022 Oct 20];11(3):206-211. Available from: https://doi: 10.52711/2231-5691.2021.00037

21. Vivekanandan K, Aishwarya G, Ashish S. Medical device’s regulation in South-East Asian countries: Current status and gap areas. Asian Journal of Pharmaceutical Research [Internet]. 2021 Apr [cited 2022 Oct 20];11(3):173-179. Available from: https://doi: 10.52711/2231-5691.2021.00032

22. Raza A, & Hussain N. Problems and challenges of future medical education: current state and development prospects. FeD [Internet]. 2022;31–43. Available from: http://dx.doi.org/10.57125/fed/2022.10.11.32

23. Tsekhmister Y. Education of the future: from post-war reconstruction to EU membership (Ukrainian case study). FeD [Internet]. 2022;42–52. Available from: http://dx.doi.org/10.57125/fed/2022.10.11.28

24. Gushchyn O, Kotliarenko O, Panchenko I, & Rezvorovych, K. Cyberlaw in Ukraine: current status and future development. Futurity Economics&Law [Internet]. 2022;4–11. Available from: http://dx.doi.org/10.57125/fel.2022.03.25.01

25. Kumar A. Analysis of the principle of subsidiarity as a principle of EU law: Future perspectives. Futurity Economics&Law [Internet]. 2021;18–27. Available from: http://dx.doi.org/10.57125/fel.2021.12.25.03