MONTHLY NEWS DIGEST

May 2021

SAFEMED'S HTA WEBINAR SERIES 2.0 COMES TO A CLOSE

This month, SAFEMed's Health Technology Assessment (HTA) Webinar Series 2.0, which began in February 2021, ended with **a total of eight online sessions completed**. The Webinar Series, originally launched at the height of COVID-19 restrictions, was designed to bring together well-known HTA thought leaders from around the world to share specific methods/experiences that could be useful to the Ukrainian setting. The Series comprised several key technical points of interest through online collaboration.

Participants at the Panel Discussion on Patients' Engagement and Ethics in HTA Webinar.

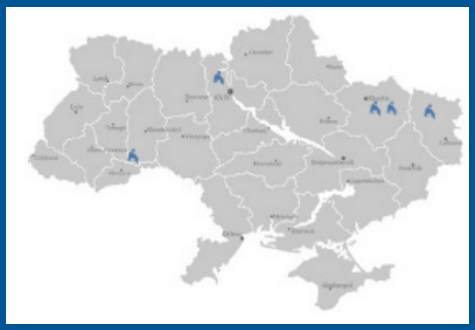
The eight sessions included international and local speakers and garnered **a total participation of 144 individuals**, as follows:

- 33% industry representatives
- 17% academia
- 16% State Expert Center (SEC)
- 14% patient organizations

Participants gained new information and improved their existing knowledge on various HTA topics. One of the most common issues participants raised was patient engagement in HTA. Questions concerning practical ways to involve patients, such as at what stage, how deeply, and who exactly could be involved in the process led to a lively and rich technical conversation. Considering the ongoing work on the legislative framework enabling HTA in Ukraine, this knowledge exchange among HTA professionals is critical to ensure a common understanding of the newly established process and its sustainability.

The webinars included short «knowledge tests» before and after each presentation to measure comprehension/concept mastery among attendees. Overall, the percentage of correct answers increased with each webinar, leading to greater confidence and understanding of HTA matters by the participants.

SAFEMED FINALIZES BIOEQUIVALENCE LAB ASSESSMENT



Clinical sites and laboratories performing bioequivalence studies in Ukraine.

During the spring of 2021, SAFEMed, together with the State Expert Center (SEC), assessed the capabilities, availability of resources, and regulatory compliance of organizations conducting bioequivalence studies in Ukraine. Bioequivalence studies are used to demonstrate that a generic drug is as safe and efficacious as a brand drug. SAFEMed is supporting the Government of Ukraine to strengthen its regulations to ensure generic drugs are bioequivalent.

Currently, manufacturers can conduct bioequivalence research both at international and Ukrainian centers. The cost of such research in Ukraine is lower than in other EU countries. Since we expect to see an increase in the need for bioequivalence studies in Ukraine, SAFEMed equipped manufacturers, especially local ones, with information and resources available in the country for conducting these types of studies safely and efficiently.

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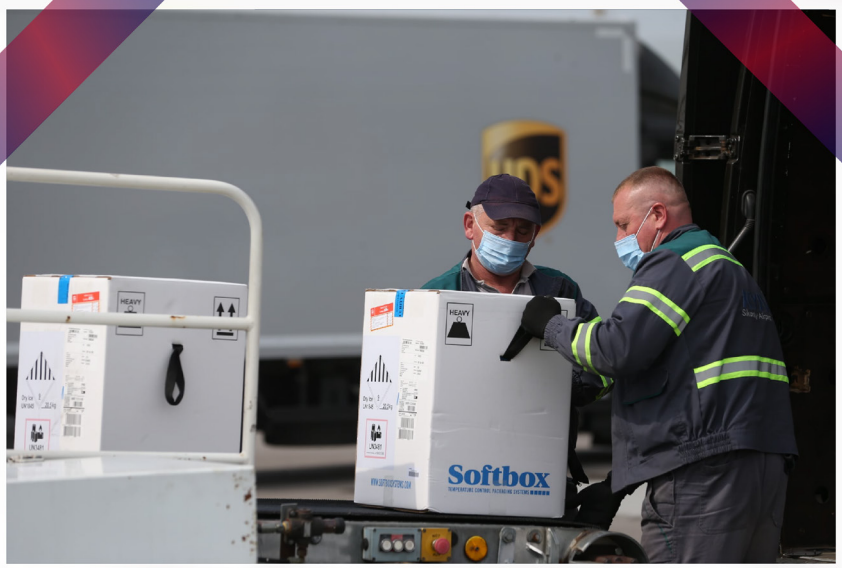
Although historically Ukraine has had the scientific and technical potential to conduct bioequivalence research, the capabilities of the Ukrainian laboratory network were unknown prior to this assessment. The assessment revealed that in Ukraine only **five** organizations are able to conduct bioequivalence studies in accordance with internationally recognized standards. All of them have a long record of operation and have the necessary experience in conducting research of this kind as well as premises and equipment to conduct all required study-related activities. In addition, two of the centers – the Clinical and Diagnostic Center (CDC) of the National University of Pharmacy and Laboratory of Pharmacokinetics and the SEC of the Ministry of Health of Ukraine – have been prequalified by WHO.

In addition, SAFEMed's work developing the Bioequivalence Strategy in Ukraine has earned regional recognition. The review of the strategy and the first results of its implementation, namely changes in legislation towards harmonization with the EU, were published in the European journal Die pharmazeutische Industrie: pharmind, 83, Nr. 4, 477-490 (2021).

USAID THROUGH THE SAFEMED ACTIVITY CONTINUES TO SUPPORT THE GOVERNMENT OF UKRAINE IN THE LOGISTICS OF THE PFIZER/BIONTECH VACCINE

The availability of effective and safe vaccines against COVID-19 is stated as a key milestone in Ukraine's strategy to combat the COVID-19 pandemic. In mid-May, Ukraine received almost half a million (473,850) additional doses of the Pfizer/BioNTech vaccine through the COVAX facility. SAFEMed will continue to support the Ministry of Health (MOH) with warehousing and logistics services for the vaccine with ultra-cold chain requirements to ensure safe delivery.



Airport staff unload a shipment of vaccines at the Kyiv international airport on May 18. Photo: UNICEF/Ukraine.

Stay Tuned for the Next Digest

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