

## VIA ELECTRONIC SUBMISSION

January 15, 2021

World Health Organization  
The Director  
Department of Governing Bodies  
20 Avenue Appia  
1211 Geneva 27

### Re: USP Statement – 148th session of the Executive Board

I am Sireesha Yadlapalli, Senior Director of International Government and Regulatory Affairs at USP, the United States Pharmacopeia. Thank you for this opportunity to present USP's statement on the quality of hand sanitizers, or handrubs, as related to public health emergencies: preparedness and response.

Quality-assured handrubs are critical to decrease risks of transmission of infections caused by microorganisms. Quality issues, including potential contamination, can lead to adverse events requiring hospitalization, and may cause blindness and death. These are matters of global concern.

Enhanced demand during the pandemic created global shortages, with concomitant surges in production and poor-quality products. Global data from the Infectious Diseases Data Observatory's Medicine Quality Monitoring Globe indicates that there were over two hundred reports of quality issues related to hand sanitizers or handrubs in 2020. We must remain vigilant about the quality of alcohol-based handrubs across the life cycle, throughout production, labeling, packaging, transportation and storage.

The WHO guidelines on hand hygiene in health care and recommended handrub formulations for local production have undoubtedly helped address shortages and quality issues. USP supports and complements WHO's effort through a multi-pronged approach, including a toolkit<sup>1</sup> and stakeholder open forums. Specifically, our toolkit includes information for compounders, drug manufacturers, and other facilities that prepare handrubs. It refers to the WHO, FDA, and CDC guidelines and USP compendial standards for ingredients used in alcohol-based handrubs. USP also revised its alcohol monographs to address methanol contamination. We are currently planning regionally tailored seminar education series intended for manufacturers, compounders, regulators, healthcare professionals, and consumers. The series will provide information and raise awareness on quality issues related to handrubs throughout the life cycle. USP welcomes WHO participation.

USP continues supporting WHO in COVID-19 preparedness and response and is committed to support the global safeguard of handrub quality.

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<sup>1</sup> USP Hand Sanitizer Toolkit, <https://www.usp.org/covid-19/hand-sanitizer-information>.