

Supporting patient access to quality medicines



U. S. Pharmacopeia (USP) is committed to support FDA's List of Off-Patent, Off-Exclusivity Drug Products without an Approved Generic (OPOE) to expedite greater access for important generic drug therapies and help ensure quality and scientific rigor during drug development and manufacturing. We recognize that the pharmaceutical manufacturing industry, FDA, public health community (patient organizations and healthcare practitioners) and USP all share a collective priority to expand patient access to safe, quality medicines. Through initial discussions with these key stakeholders, USP has prioritized FDA's OPOE list, and launched a Call for Collaboration to advance our shared priorities.

As an organization committed to patient access to quality medicines, we invite you to participate in the Call for Collaboration. The Call for Collaboration bridges the voice of the patient with the scientific and technical capabilities of FDA, USP and pharmaceutical manufacturers.

Successful implementation includes:

- Active engagement and communication with the patient community and their advocates who identify gaps in access to critical therapies
- Regular dialogue with USP's scientific staff
- Support for the pharmaceutical manufacturers efforts to develop new generic medicines from the OPOE list

USP has monitored the OPOE list to identify opportunities where public quality standards can help increase access to high impact public health medicines. We mapped our monograph development work, prioritized and identified areas where compendial standards can help increase access to quality medicines. Based on feedback from stakeholders, we developed a tiered approach to prioritize more than 450 drugs on the OPOE list, starting with candidate drugs that would have the greatest immediate impact. Join the collaboration to advance shared priorities and explore how our monograph development efforts can facilitate greater patient access to quality medicines.

The FDA Generic Drug Program values our close collaboration with USP and we look forward to continuing our work to advance our shared goals of improving public health and fostering generic competition.

Sally Choe, Ph.D., Director, Office of Generic Drugs and Michael Kopcha, Ph.D., R.Ph., Director, Office of Pharmaceutical Quality

Join the Call

The Call for Collaboration brings together USP, FDA, the patient advocacy community and pharmaceutical manufacturers who are committed to create quality generic medicines for legacy drugs without alternatives. Join us in this collective public health effort to increase access to quality medicines for patients who need them.

About USP

Founded in 1820, USP is an independent, scientific non-profit organization, committed to advancing public health and patient safety through standards and related programs that help to ensure the quality of medicines, dietary supplements and foods. USP standards are established by over 800 expert volunteers from academia, industry and the healthcare practitioner community. We are governed by a Convention of over 460 organizations representing the global healthcare community. Our staff of over 1000 scientists and dedicated professionals help to advance our mission for more than 2 billion people around the world.

For more information:

CallforCollaboration@usp.org