Jinghe Xu
Deputy Commissioner
National Medical Products Administration
No. 1 Beiluyuan, Xicheng District
Beijing, 100037
China

November 27, 2023

Dear Deputy Commissioner Xu,

I am writing today to notify you, as chair of the Global Harmonization Working Party (GHWP), the United States Food and Drug Administration's (FDA) decision to officially withdraw as a member of GHWP.

For a few years, I have become increasingly concerned with the divergent harmonization efforts for medical devices and how some of these efforts do not align with FDA's priorities or international best practices. Therefore, I asked my staff to join GHWP and similar organizations to find alignment between all international medical device harmonization efforts and to expand our reach with global partners.

When FDA became a member of GHWP in December 2021, we did not realize how divergent the two organizations, GHWP and the International Medical Device Regulators Forum (IMDRF), had become and the major challenges that needed to be overcome for them to successfully work together.

Some of those challenges in GHWP include leadership that is not diverse or representative of a global perspective in the Steering Committee, Technical Committee and Strategic Advisory Board (SAB); the imbalance of regulator and industry participation in working groups often resulting in work items that do not represent the regulator's perspective; the lack of an alignment-based approach and transparency with processes and procedures in the creation, review, and finalization of documents; and GHWP's past and recent practices to duplicate and modify documents from other organizations leading to inconsistencies and undermining efforts to truly promote global harmonization and convergence for medical devices.

I would like to see GHWP and IMDRF collaborating on the common goals of fostering global regulatory convergence and leveraging resources to make safe and effective medical devices available globally, not trying to compete with one another. FDA's goal in joining GHWP was to provide a bridge between the two organizations. Unfortunately, GHWP does not offer the opportunity for FDA and other regulatory bodies to have our voices heard and considered.

Moving forward, FDA will spend the next few months refocusing its efforts and repositioning staff and resources to primarily work on IMDRF. FDA's efforts to advance global harmonization have been and will continue to be primarily through IMDRF. As chair of IMDRF in 2024, I will continue IMDRF's efforts to work collaboratively with as many entities as possible, including GHWP, the World Health Organization, Pan American Health Organization, African Medical Devices Forum, etc., to ensure alignment of medical device international harmonization efforts.

In your role as GHWP Chair, I would like to invite you to attend the March IMDRF meeting to continue the discussions between GHWP and IMDRF and to provide the GHWP update at the meeting. I am looking for a few champions to support this goal of alignment amongst the organizations and to build a solid bridge between GHWP and IMDRF. I hope I can count on your support and cooperation.

Official invitations for the IMDRF meeting will be sent in January 2024. My team is available if you have any questions regarding the planning of next year's meeting. We look forward to welcoming you to Washington, D.C. and to your participation in the meeting.

Sincerely,

Jeffrey E. Shuren -S

Digitally signed by Jeffrey E. Shuren -S
Date: 2023.11.26 10:09:24 -05'00'

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Director
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