



For immediate release:

Response from DKT International regarding the August 1, 2023 articles in Bloomberg News (online) and Bloomberg Law (online)

The article, *“Global Abortion Pill Provider Buys From Manufacturer With Shoddy Quality Record”* by Bloomberg News, published on August 1, 2023, connects our organization to an India-based manufacturer of misoprostol, Synokem Pharmaceuticals, Ltd. DKT has been actively engaged and transparent with Bloomberg over the course of its reporting, which was originally presented to us as a story on misoprostol in general. Over seven months, DKT provided multiple interviews with personnel from DKT headquarters and field offices; made introductions to manufacturers and thought leaders; and shared details about our quality protocols, procurement data, pharmacovigilance policy, product test results, and significant other business data.

We engaged with Bloomberg and the reporter because – as one of the largest distributors and promoters of contraception in the world – DKT takes issues and questions around quality with the utmost seriousness. The data raising questions about product quality was first shared with DKT in April 2023 – but we were unaware of these findings before that time. When DKT was made aware of both of these studies in April 2023, we immediately engaged with the manufacturer to address all concerns raised. Throughout this time, DKT shared a wide range of information with Bloomberg regarding our approach to quality assurance and we were very surprised to learn in June 2023 that after several months of openly sharing information, the reporter advised us that the story had become focused on DKT India. Nevertheless, DKT continued to engage with the reporter and provided additional information which we believed clearly outlined DKT’s approach to quality assurance.

There are several factual problems with the story that warrant clarification. The Bloomberg story implies that funding from one of our donors – the Bill and Melinda Gates Foundation – is linked to DKT’s relationship with Synokem, misoprostol and abortion care. This is incorrect. The foundation does not support DKT’s efforts in this area in India or elsewhere.

The story claims that “DKT hasn’t adopted some common safeguards to ensure medicine quality,” but we carefully outlined the range of steps that we take related to ensuring quality in all countries to Bloomberg. These include relying on National Regulatory Oversight bodies in the country of manufacturing; audits of manufacturers (including by WHO PQ and SRA bodies); the

local FDA body in the country of registration; a manufacturer's own in-house quality testing; and external testing by independent third-party laboratories.

In the case of the misoprostol tablets manufactured by Synokem in India, DKT has relied on local regulatory oversight bodies in India to ensure compliance with Indian quality standards. DKT believes in supporting and working with local governments and agencies; this is also a requirement and standard practice with regards to regulatory and quality assurance issues. Every batch of medication sold by DKT India is tested by the in-house laboratory of the manufacturer. Those medicines are then tested by an external, independent, WHO-approved laboratory. DKT's products and test results passed through all these QA checks and the results were shared with Bloomberg. These and other compliance tests, as well as the approvals from the Indian FDA have all been such that we have felt confident selling Synokem's products.

The Bloomberg story implies that DKT may have sold Synokem products in the Democratic Republic of the Congo, Nigeria, Cambodia and Uganda. This is not the case. Synokem is not the manufacturer of DKT products distributed in those countries.

The Bloomberg story also references two reports specific to the products sold in India: one from the Central Drugs Standard Control Organization (CDSCO) and another from the Concept Foundation. As explained to Bloomberg, the misoprostol drugs tested in February 2019 by CDSCO (from Synokem) were not from batches ever received or sold by DKT. Bloomberg correctly states that The Concept Foundation study cited in the story has not been peer reviewed, but failed to mention that it also contains bold red language which explicitly states that it should not be referenced by the media.

The Bloomberg story additionally references products being sold in the USA. As made clear in the story, DKT is not associated in any way with any products being illegally imported into the United States.

DKT International markets and distributes thousands of products around the world. We are proud of the work our teams on the ground do everyday in more than 100 countries. They make a difference to the people they serve. While we take all quality concerns with the utmost seriousness, we do not believe that this article accurately reflects DKT's commitment to ensuring quality assurance globally or in India. As the article makes clear, DKT has received no complaints from our distributors, retail customers, government and NGO partners, or final end users about the efficacy or quality of the misoprostol that we have sold in India or anywhere else. Our organization stands by our policies on this issue and our long standing track record spanning more than 30 years around the world.

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