SIDLEY

WHO May Affect the National Pricing of Therapeutic Products

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Pricing of pharmaceuticals and medical devices is a hot topic. Governments increasingly seek to reduce spending in an attempt to ensure that patients have access to products that are life-enhancing and often life-saving. At the same time, incentives must be maintained in order for companies to continue to innovate. Questions on pricing often surround one question: What is a "suitable" or a "fair" price?

Whilst companies are focused on national regulations, they often overlook developments at the international level which may affect the way pharmaceutical companies set their prices in the future.

The global standard-setting body for health, the World Health Organization (WHO), has been active in the "fair pricing" debate for some time. In 2017 and 2019, the WHO co-convened two Fair Pricing Forums to shed more light on the question of what should and should not be considered a "fair" price. At the 2019 forum, participants acknowledged difficulties in defining what constitutes a fair price. To address this issue in more detail, the WHO recently established a set of technical working groups that will focus on specific areas of pricing to determine what is achievable in the short- and medium-term. To aid in its deliberations, the WHO launched a survey where it sought input on a number of questions, including the definition of "fair price" and the terms of reference of the technical working groups that will examine different areas of pricing.

In the meantime, Ministers of Health at the 2019 World Health Assembly, the WHO's highest decision-making body, adopted a resolution on improving the transparency of markets for medicines, vaccines, and other health products (Transparency Resolution). Resolutions constitute recommendations for national governments and are often used as a blueprint for domestic regulation. The scope of the Transparency Resolution is all-encompassing and includes not only medicines but also "vaccines, medical devices, diagnostics, assistive products, cell- and gene-based therapies, and other health technologies."

The Transparency Resolution calls on national governments to adopt "appropriate" domestic regulation, with the aim "to publicly share information on the net prices of health products," and on "aggregated results data and …. costs from clinical trials." The resolution also calls on governments to "work collaboratively to improve the reporting of information by suppliers … on sales revenues, prices, units sold, marketing costs, and subsidies and incentives…"

As well as focusing on developments at a national level, companies need to engage constructively at an international level, otherwise they will find that they have missed the opportunity to influence pricing regulation.