

Rebooting the Harmonized System: An Opportunity for Life Sciences to Facilitate Trade

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The global life sciences industry stands at the forefront of innovation and technological development. The increased rate at which novel products are developed and commercialized, however, raises concerns about their efficient regulation and taxation. It is crucial that regulatory regimes remain receptive to these changes so as to not stunt growth and discourage investors. The ongoing review of the Harmonized Commodity Description and Coding System (Harmonized System or HS) is one such opportunity for life science companies to act and protect their interests.

The HS is the common language of world trade. It establishes a global uniform framework of classification that facilitates the trade in goods, especially import and export. The classification of goods is also important because it determines the applicable import duty rate. Through regular updates, the HS accommodates technological developments and changes in trade patterns. The updates follow suggestions from states and national organizations.¹

That is not to say, however, that the HS is perfect. Many stakeholders have challenged the HS regime, given its complexity and inability to keep up with the pace of advancement and development in global commerce. An important example of such difficulties lies in the growth of the biotechnology industry. When the HS was developed in the 1980s, biotechnology was a mere developing field of research, not the globalizing industry branch with trade volumes in the billions of U.S. dollars it is today.² The HS, however, has, as of now, failed to accommodate such changes. The identification and classification of biotechnology items remains unspecific and ambiguous, with companies using various codes for the same items of equipment.³ Cell therapy products, for instance, a market expected to grow to US\$8.21 billion by 2025,⁴ still do not benefit from a clear and uniform classification.⁵ Biotechnology companies operate amid uncertainty and rapid change,

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- ¹ See preamble of the HS Convention, available at http://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs_convention.aspx#preamble.
 - ² Hunger and Gunnar, "Building Transparency in the World Wide Trade in Biological Dual Use Equipment," *Research Group for Biological Arms Control*, Occasional Paper No. 12, December 2010 p. 16.
 - ³ Ibid.
 - ⁴ Frost & Sullivan, "Growth Opportunities in the Global Cell Therapy Market, Forecast to 2025: A Robust Product Pipeline Creating Opportunities for Ground-breaking Combination Therapies is Set to Revolutionize the Global Cell Therapy Market," Global Transformational Health Research Team at Frost & Sullivan, October 2018
 - ⁵ World Customs Organization, Revitalizing the Harmonized System: What is needed for a 21st century Harmonised System? WCO Conference on the future direction of the HS, May 2-3, 2019.

adhering to ever shorter innovation cycles to beat out global competition.⁶ The relatively long HS review cycles and limited mechanisms for private sector engagement are inadequate in effectively transposing this surge of innovation and technological advancement into the HS.⁷ Other life science companies are facing comparable challenges.

Some concerns have recently been brought up during the World Customs Organization Conference on the future direction of the HS, which took place in May of this year. The conference aimed to identify the problems of the system and brainstorm on how to better suit the realities of 21st century world trade. A central tenet to the conference was a focus on the views, experience and proposals of different stakeholders. The consultation process with the private sector is ongoing. This represents a unique opportunity for life sciences companies to engage and promote the efficient and uniform classification of their products.

This is the moment to evaluate the language used for the description of particular goods, review the adequacy of the interpretations endorsed in the explanatory notes and identify any discrepancies in the application of tariff lines to biotechnology and pharmaceutical products.

http://www.wcoomd.org/-/media/wco/public/global/pdf/events/2019/hs-conference/hs-conference_guidance-document.pdf?la=en; p 15.

⁶ Khilji, Mroczkowski, and Boaz Bernstein. “From Invention to Innovation: Toward Developing an Integrated Innovation Model for Biotech Firms,” *Journal of Product Innovation Management* 2006; 23: p. 528-540.

⁷ CompTIA, “What is needed for a 21st century Harmonized System,” WCO Conference on the Future Direction of the Harmonized System: Revitalizing the Harmonized System, May 2-3, 2019. http://www.wcoomd.org/-/media/wco/public/global/pdf/events/2019/hs-conference/wcohsconference2019_comptiahighlevelrecommendations_final.pdf?la=en.