HBW INSIGHT
CITELINE COMMERCIAL

29 Mar 2022 | **News**

Learn From Regulatory Innovation During COVID-19, Urges Global Self-Care Industry

by David Ridley

The Global Self-Care Federation has published three papers outlining how regulatory flexibility and innovation seen during the cornavirus pandemic can be brought forward to a post-pandemic consmer heathcare sector.

The Global Self-Care Federation is urging authorities across the world to reflect on the regulatory innovations introduced during COVID-19 to keep medicines on the market and to retain those that will continue to benefit consumers in the post-COVID era.

Analyzing the changes and trends in regulation during the coronavirus pandemic, GSCF has outlined recommendations for future policy and regulation in three papers covering the following areas:

- Regulation of e-commerce of non-prescription medicines;
- Modernizing regulation of non-Prescription medicines through increased flexibility and digitalization;
- Enhancing supply chains to ensure consumer access to non-prescription medicines.

Taken together, the papers advocate for an assessment for potential adoption of many of the innovative policies and regulation changes seen during the pandemic into normal practice, to benefit enhanced access to non-prescription medicines.

“There is an opportunity for governments and regulators to take a fresh look at the policies and regulations associated with non-prescription medicines,” GSCF’s regulatory affairs committee chair, Ian Urquhart, told HBW Insight.

"Whether it is making some of the beneficial changes implemented during the COVID-19 pandemic permanent, or by identifying other ways to evolve regulatory ecosystems to make the delivery of self-care more effective and efficient," he said. Urquhart – who is also leads global regulatory intelligence and policy at GlaxoSmithKline Consumer Healthcare – said that undertaking such a project would "ultimately benefit individuals and health systems alike."

Virtual Inspections, Regulatory Simplification

Among the suggestions put forward by GSCF is retaining virtual inspections, which were used out of necessity during the pandemic "despite a preference by the regulatory authorities and the industry for onsite visits."

"These virtual visits were shown to be as rigorous as on-site visits, where documents were submitted well in advance for inspectors to review, and included historical reports of previous inspections," GSCF explained. "They emerged as an innovative approach to maintaining high manufacturing, clinical and pharmacovigilance practice (GMP, GCP and GVP) standards, while optimizing agency resources."

Regulatory simplification is another key area that GSCF believes could be taken forward in future, seen particularly in the rapid approval of COVID-19 vaccines and described in a *2020 joint report* from the International Coalition of Medicines Regulatory Authorities (ICMRA) and the World Health Organization (WHO).

"COVID-19 led to regulatory pragmatism in some markets regarding the life-cycle management activities for self-care products," the GSCF pointed out. "This, in turn, demonstrates that regulation of non-prescription medicines can be adjusted to the risk levels without a reduction in quality or consumer safety."

Post-approval regulation of non-prescription medicines, particularly simplifying approvals of variations, is for the federation an area for future improvement "since risk management measures for these well characterized products are generally understood," it said.

"From a global perspective, where possible, post-approval changes should follow a common international system, which is evidence and risk-based, and which establishes unified data requirements across regulatory authorities," GSCF suggested.

"Minor quality variations and other modifications requiring purely administrative changes should not require regulatory approval prior to implementation," it continued. "Agencies could either be notified in a periodic report or such changes should be maintained within the manufacturer's quality system and reviewed during inspections."

Shoring Up The Supply Chain, But No Protectionism Please

Virtual inspections and simplified variations are also two important ways that the global supply chain could be adapted to ensure that the kinds of shortages seen during the early months of the pandemic do not happen again, the federation argued.

"Initially, there was a surge in demand for popular non-prescription medicines across the globe, which, in turn, led to shortages in some geographies," GSCF reflected. "At the same time, international freight shipment, both air and sea, was severely restricted and, consequently, the cost of international transportation of finished goods and product components reached record heights."

"Supply chain resilience was further tested, with product shortages exacerbated by exporter restrictions of starting materials and active substances," it continued. "In addition, some governments began stockpiling certain products and many consumers filled their pantries in expectation of future shortages."

On top of the above measures, making it easier for OTC drug manufacturers to switch suppliers of active pharmaceutical ingredients and critical starting materials would make the supply chain far more resilient, the federation insisted.

In the European Union, it noted, manufacturers can in exceptional circumstances source starting materials, reagents, intermediates or active substances from suppliers not specifically mentioned in a product's marketing authorization.

Also in Taiwan, the country's Food and Drug Administration allows a fast-track for registering additional active pharmaceutical ingredient (API) sources if there is concern of the sufficient product supply for the original API, the federation pointed out.

One thing that the GSCF does not want to see, however, are "protectionist measures," such as "mandatory purchasing of locally produced products." (Also see "*Coronavirus-Related Free Trade Blocks Placing Strain On EU Food Supplements Supply Chain*" - HBW Insight, 8 Apr, 2020.) (Also see "*COVID-19 Prompts OTC Sales Restrictions Across Europe*" - HBW Insight, 26 Mar, 2020.)

"It is critical that governments do not mandate the localisation of components of the supply chain and do not implement policies that would destabilize the supply chain for currently available medicines or take any measures that could undermine the complex arrangements between firms which allow for efficient delivery of medicines," the GSCF maintained.

E-Commerce, ePILs And Digital Consultations

Finally, GSCF is keen to extend the liberalization of online sale of OTCs that occurred in some countries during the pandemic, in Switzerland for example. (Also see "*Swiss Federal Council Wants To Liberalize Online OTC Market*" - HBW Insight, 6 Jan, 2022.)

“During the pandemic, many governments and regulatory authorities implemented several policies specifically designed to aid consumers in their efforts to purchase non-prescription medicines via e-commerce,” GSCF explained.

“Post-pandemic, GSCF believes that governments and regulatory authorities have the opportunity to support the safe growth of on-line purchasing of non-prescription medicines by making permanent some of the policy and regulatory changes approved during the pandemic,” it added.

Specifically, GSCF urged regulatory authorities to develop frameworks that enable the growth of e-commerce by introducing risk appropriate approaches specific to the particulars of e-commerce versus traditional brick-and-mortar retail.

Within such approaches, regulators should develop guidance or standards on how information should appear to consumers as they browse the digital non-prescription medicines shelf, taking into account innovations in labeling such as e-Product Information. (Also see "*EU Regulatory Round-Up: RWE Platform Proposed, Brexit Transition Update, EPI Principles Published*" - HBW Insight, 23 Mar, 2020.)

Regulators should also support healthcare professionals in offering online consultations, GSCF suggested, pointing to *a recent report* by the European self-care trade association, the AESGP, which foresees “a future where more and more (physician and pharmacist) consultations will happen online.”