Global Electronic Labeling Initiatives: Updates from Japan, Canada, Europe, US, and Asia

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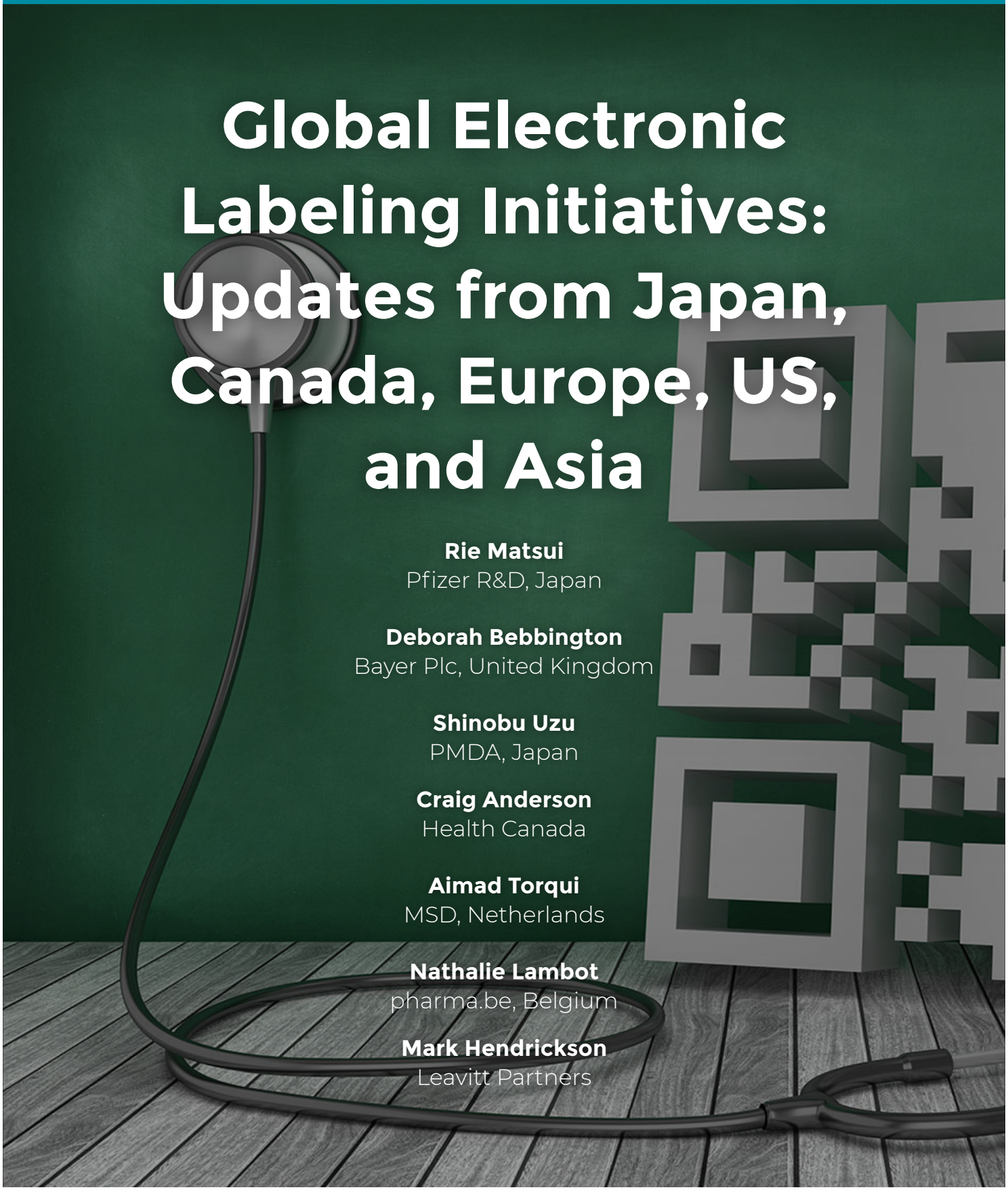

Electronic labeling is the focus of many ongoing initiatives across regions. eLabeling can deliver the latest labeling information immediately and in an efficient and customer-friendly way for patient safety. Also, eLabeling is driven by the acceleration of digital disruption and must consider patient-centricity.

DIA's recent *Global Labeling Conference 2020* opened with industry and regulatory experts discussing the current landscape of electronic labeling initiatives in Japan, Canada, Europe, Belgium and Luxembourg, US, and Asia.

Key Takeaways

- Japan's Pharmaceuticals and Medical Devices Act was amended to introduce eLabeling officially, replacing paper labeling and adding a necessary scheme that allows all healthcare professional access the up-to-date labeling information.
- Health Canada is taking steps to transition the product monograph to a new structured format based on Extensible Markup Language (XML), Health Level 7 (HL7) standards, and controlled vocabularies.
- Together with other relevant stakeholders, European regulators have established high level key principles that will guide future work in establishing, for example, common electronic standards, processes, and governance that all need to benefit public health.
- The US Food and Drug Administration (FDA) has long sought to leverage digital platforms for prescription drug labeling intended for physicians and pharmacists, allowing for distribution of prescribing information in a timely manner.

eLabeling Regulation in Japan

Paper labeling for healthcare professionals is currently required to be inserted in each commercial pack. Also, healthcare professional labeling is available in PDF format, HTML and SGML or XML as structured product labeling on the Pharmaceuticals and Medical Devices Agency (PMDA) website. Patient medication guides are also available in PDF format on PMDA's website. In December 2019, the Pharmaceuticals and Medical Devices Act was amended to introduce eLabeling officially, replacing paper labeling and adding a necessary scheme that allows all healthcare professionals access to up-to-date labeling information. A code will be printed on the outer box so that the healthcare professional can access labeling information. Paper labeling should be provided at initial delivery and at the time of labeling revision by the Marketing Authorization Holder (MAH)/Wholesaler outside the commercial pack. The enforcement of the amendment is planned for August 1, 2021.

Health Canada's XML Product Monograph Project

Health Canada is taking steps to improve the quality and accessibility of drug product information available to Canadians. As part of this work, Health Canada is taking steps to transition the product monograph to a new structured format based on Extensible Markup Language (XML), Health Level 7 (HL7) standards, and controlled vocabularies. In this context, "structured format" refers to the process of using XML to encode the product monograph's content in such a way that it is searchable and machine readable. The structured format encodes narrative content (e.g., section headings, text, tables, and figures); drug product metadata (e.g., ingredients, strengths, dosage forms, packaging); and applies standardized terminology (e.g., dosage forms, routes of administration, units of measure). The XML product monograph will allow Health Canada to deliver benefits not previously possible with PDF-based product monographs (for example, improved search and consistency, and support for mobile applications).

European Product Information (ePI): Hot Air or Real Opportunities?

In Europe, there is ongoing work to improve communication to patients, amongst others through electronic product information (ePI). The European regulators together with relevant stakeholders have established high level key principles that will guide future work in establishing, for example, common electronic standards, and processes/governance that need to benefit the public health. However, it is important to note that moving complex information to a digital/electronic format is not in itself sufficient from a health literacy perspective. Therefore, next to the technical nature of establishing ePI, there is a need to further improve the readability of product information especially in the context of presenting information on a screen and utilizing the advantages that structured data or other features can bring. Overall, there is great momentum within Europe, and industry is committed to work with regulators, patients, and healthcare professionals to ensure successful development and implementation.

The Electronic Patient Leaflet Project (e-PIL): A Pioneer Pilot in Belgium and Luxembourg

The e-PIL pilot is a collaboration between the pharmaceutical industry and the regulatory authorities in Belgium and Luxembourg. It is supported by the European Commission. In this 24-month pilot, the paper leaflet of a selection of medicines restricted to hospital use and marketed in Belgium and Luxembourg is no longer included in its paper version but can be consulted online via trusted websites. The objective is to demonstrate that the electronic format provides sufficient, adequate, and tailored information on the use of medicines to healthcare professionals and patients in a hospital setting. The interim results have shown that for 98 percent of pharmacists, the absence of the paper leaflet in the packaging has not generated any inconvenience in their daily practice, nor has it affected the requests from other healthcare professionals in the hospital. Based on these positive results, the authorities in Belgium and Luxembourg have asked the European Commission to allow the expansion of the pilot to further consolidate the results.

Electronic Labeling: A US Perspective

It is time to modernize prescribing information (PI) in the US to improve patient safety and reduce waste by leveraging digital platforms for prescription drug labeling intended for physicians and pharmacists. Prescribing information—information intended to provide the healthcare professional the most current information necessary for the safe and effective use of the product—is currently shared with healthcare providers in a bulky paper attachment to the medicine bottle. When there is an update to the prescribing information, it can take up to a year or more for that updated information to be circulated in paper form. FDA proposed a rule in 2014 to modernize information delivery to prescribers but Congressional action has halted FDA's work to implement the rule. FDA has long sought to enable the electronic distribution of prescribing information to ensure accurate information is available in a timely manner; we have an opportunity to work together collaboratively to do something positive and constructive, ensuring the most updated information is available to prescribers.

Asia Updates for eLabeling

Approximately half of the countries in Asia have published labeling in PDF format on their Health Authority (HA) websites, but not structured product labeling except for Japan. In Singapore, HSA issued Guidance for electronic labeling on August 19, 2019. In the guidance, eLabeling refers to product information, including the package insert (PI) and patient information leaflet (PIL), which is distributed via electronic means, such as through a machine-readable code or URL on the product carton that links to a secure online system that publishes the product information in digital format. In Taiwan, the Taiwan Food and Drug Administration (TFDA) posts labeling information on its website. TFDA developed an app in 2016 and through the app one can use a mobile device to connect with drug information on the TFDA website. In addition, the trade associations in some Asian countries such as Malaysia and Thailand have started to establish eLabeling working groups and are planning to discuss eLabeling initiatives with the HA further. Although no initiatives for eLabeling harmonization have started in Asia, there may be opportunities to collaborate within the region.