PERSPECTIVE

Creating E-Labeling Platforms: An Industry Vision

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This perspective provides a vision for creating digital patient-centric regulatory platforms to share reliable, relevant, and current information while minimizing environmental impact. Current technologies provide opportunities for healthcare providers (HCPs) and patients to obtain approved product information in a personalized manner to meet individual needs. Electronic labels serve as a foundation for truly advanced information communication and telemedicine, allowing HCPs and patients to make informed decisions based on easily accessible, relevant, and current information.

BACKGROUND

Electronic labeling (or e-labeling) is the dissemination of approved product information in a digital format via a common structured format using global standards. This common format provides opportunity for each country or region to then create a platform to allow for the seamless sharing of information between manufacturers, regulators, HCPs, and patients. While creating these platforms, we must also work toward the eventual phaseout and elimination of the outdated, lengthy paper versions of labeling. Current paper copies of labeling can become outdated when new safety and/or effectiveness information is approved. Electronic platforms provide the opportunity to share recent changes in approved information more rapidly. Eliminating the paper versions would also simplify the process to quickly move product from one country to another during drug shortage situations. As regulators across the world begin to implement various forms of e-labeling, we need to continue to strive to build platforms using harmonized global standards to realize the full benefits.

BENEFITS OF E-LABELING

E-labeling brings significant benefits that support near-term implementation.

Enhanced patient safety

- *Better readability and searchability*—For some users it may be difficult to find information in the current paper format which, when unfolded to its full size, can be overwhelming to read and navigate due to the small font and large volume of text.
- *Faster sharing of new information*—Safety updates can be implemented in days versus months. Paper versions can be significantly outdated[1] due to the complexity of the supply chain, e.g., printing updated material, re-packaging, distributing, and potential replacement of stock. A dual system of paper and electronic labeling creates a discordance due to the delay in time before an update is present in the product on the market, which may create confusion.
- *Customizable information*—Opportunities to highlight, customize, and prioritize important changes in labeling in a timely manner and target the information for a specific patient population exist. Users could access information in the language and format they prefer, e.g., enlarged text for visually impaired patients and audio information for hearing impaired. Electronic information in standard formats provides the opportunity to develop "integrated" product information, i.e., combining information from multiple product leaflets to make a more user-friendly and complete resource. For example, users could more readily compare known indications and side effects of drugs to help make individual benefit–risk decisions. This customizable information may also help to drive efforts to improve health literacy.

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Saving resources and reducing burdens

Every year, millions of paper inserts are discarded without even being viewed. The elimination of paper and reduction of package sizes also advances many efforts globally to reduce our overall environmental impact. The professional labeling, i.e., labeling targeted to the HCP, is often discarded upon dispensing a product to the patient. When there is a labeling change, resources are required to ensure quality control, review graphic design, proofread, and conduct final release of the printed labeling. In some regions, packs are destroyed in order to implement labeling changes within a legally prescribed timeline, adding to the waste. At times, the actual packaging configuration may need to be enlarged due to the increased size of the paper labeling.

ANTICIPATED CHALLENGES

While many see the advantages of e-labeling, there are some challenges that must be addressed by companies and regulators.

Common global standards

Global standards for the transmission of labeling information should be followed, e.g., Health Level Seven / Fast Healthcare Interoperability Resources (HL7 FHIR),[2] to ensure consistent understanding of the labeling information in multiple geographies/languages and allow for easier sharing of information. A common standard also allows for exchange of information between computer systems in a way that cannot be accomplished with a portable document format and further facilitates customization of information with the ability to develop "integrated" product information for patients on multiple therapies by combining information from multiple product leaflets to make a more user-friendly and complete resource.

Ensuring access to electronic media

The adoption of e-prescribing practices shows that HCPs have access to the Internet, which supports the dissemination of labeling information digitally. The rate of e-prescribing continues to rise and is near 100% in many countries, e.g., 99% of pharmacies are using e-prescribing in the United States,[3] 99% in Estonia,[4] and 99% in Denmark.[5] Most importantly patients can continue to obtain information directly from their HCP (who has access to the latest information digitally) at the time their prescriptions are dispensed. Patients would also be able to view the information directly online should they wish. It is recognized that other solutions may be needed in certain regions to ensure patient access to product information when the pharmacist is not involved in providing information.

VARYING REGULATORY APPROACHES TO E-LABELING

Regulators are independently taking steps to implement e-labeling. Several countries/regions have ongoing initiatives advancing e-labeling, e.g., Australia, Belgium, Brazil, Canada, Europe, Germany, and Singapore. The United States' and Japan's health authorities have required the submission of structured product electronic labeling for many years, and approved labeling is available on a common portal recognized by the regulator. However, the various pilots and programs use differing approaches to e-labeling, e.g., different electronic standards, requiring companies to post labeling on their own websites rather than on a single shared portal, and timing of when updates to information should be made available.

Most regions also still require hard copies of labeling to accompany the product, and many do not have a single portal in their country to share the electronic labeling. While many companies provide electronic versions of approved labeling on their websites, patients on multiple therapies must navigate to multiple sites to find information. A single portal managed and widely communicated by the regulator in each country would provide the user confidence that they are viewing authoritative information and create the opportunity to easily link to regulator assessments for additional information. Product packaging should clearly identify the website where the most current and authoritative information is available. Since the content of labeling and regulator assessments of data may vary, we recognize that each country or region may need to have their own platform to share the labeling; however, approaches to implementing these platforms should be harmonized, and we should leverage best practices from the ongoing pilots and current platforms, such as common electronic standards and use of a single location within a country to post approved labeling information.

MOVING TOWARDS E-LABELING PLATFORMS

Despite progress being made on several fronts, we need to continue to advance the use of e-labeling and strive toward elimination of paper copies. There must be a stepwise approach as regulators create or recognize an authoritative portal in their country that is seen as a trusted source of approved information, such as:

1. Global structured product labeling standards for labeling information are adopted and electronic labels are submitted in dossiers.
2. The electronic label is accepted as the authoritative source of approved information.
3. Regulators develop or recognize multinational/national portals for approved prescription drug information.
4. Once we can be assured that stakeholders have access to electronic media, eliminate the requirement of paper labels to accompany the package. During the transition, we recognize that there may be a need for dual requirements, i.e., electronic and paper. However, any dual requirements should have a phaseout period for paper labeling.

Our hope is by 2030 every country has a system where a user can easily access information on multiple therapies to make informed decisions based on current digital approved information. We encourage regulators, legislators, and the pharmaceutical industry to take the necessary steps to make this happen.

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CONFLICT OF INTEREST

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