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COMMENTARY

A vision for integrated publicly available information on regulated medical products

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This perspective provides a vision for seamless access to publicly available information on regulated medical products supporting innovation and informed decision making. Current information shared by regulators postapproval is generally available on individual, siloed, and non-interoperable platforms. We believe there is great value in regulators to modify or create integrated platforms in their respective regions to share publicly available information on medical products in an accessible and manageable format to drive innovation and informed healthcare decisions.

BACKGROUND

Often, when seeking information on medical products, a web search is initiated leading the user to disconnected statements from varied sources, many of which are not based on robust data or trusted sources of information. Trusted information on medical products includes, but is not limited to, approved product leaflets, publicly available regulator assessments, and other regulator statements (e.g., safety statements, drug shortages, and recalls). Although the internet provides a vast number of

resources, it is not always possible to confirm whether information is accurate, comprehensive, or up to date.[1]

Regulators are trusted sources of information and as authorities are responsible for protecting public health through their review, approval, and regulation of medical products. They serve as the recognized source for authoritative information once a product is approved/authorized and must continue to serve as the providers of trusted information. Stakeholders (e.g., patients, healthcare providers [HCPs], academia, and drug developers) have a range of uses and needs when seeking out authoritative medical product information (e.g., safety, drug interactions, pediatric, geriatric, diversity, genomic, patient experience, and real-world evidence). They also rightfully expect the information they are accessing, particularly when made available by a regulator, is integrated, timely, and valid (i.e., authoritative). Access to publicly available information after approval also supports the creation of a learning healthcare system[2] and helps advance research and development of medical products.

Everyone should be able to easily access publicly available information in a timely manner and in a format that is easy for them to access and navigate. Many regulators already provide some information (e.g., labeling, safety data, and assessments) on their websites, but do so in a nonintegrated manner leading to the proliferation of stand-alone webpages that require users to navigate to different sites for information (see Table 1). Although a good first step, the information is disconnected, static, and not thought of holistically or with an eye toward standardization/efficiency. We recognize that information posted by regulators varies among countries/regions, and we are not necessarily proposing a single global platform, rather each individual regulator can and should develop their own integrated platform, while using globally harmonized technology standards and continue to increase transparency of publicly available information.

Existing technology can provide for more coordinated and customized access to information on approved medical products on a regulator's website. For example, worldwide initiatives already exist to share approved labeling in structured content and format so the information can be customized.[3,4] Regulators also are encouraged to share their public assessments, when they exist, of regulated medical products.[5] The coronavirus disease 2019 (COVID-19) pandemic has further enhanced the expectations for trusted information and regulators are seizing opportunities to make information available and we applaud those efforts. However, as regulators embark on modernizing their infrastructures and information sharing, they should work with stakeholders to understand their needs and leverage existing and new technologies to create or enhance existing websites using global standards to effectively share publicly available medical product information and continue to serve as the trusted source of information for medical products.

ADVANTAGES OF CREATING AN AUTHORITATIVE SOURCE OF MEDICAL PRODUCT INFORMATION

Stakeholders will benefit from having access to a versatile platform for regulated medical product information. Here, we start to explore those benefits.

Patients and healthcare providers

Regulator viewpoints are useful for patients and prescribers to help inform healthcare decisions. For example, patients often want to understand the experiences of patients in a clinical trial with similar attributes (e.g., race, gender, and age). All regulators require some type of labeling for HCPs, and regulators may also require specific patient labeling for certain medical products. However, quite often both patients and HCPs require additional trusted information to make informed healthcare decisions. Although the information may be available (see Table 1), it is not easy to find or is available through platforms not widely known, and if available can be difficult to understand. Different sources of information can result in complicating discussions between HCPs and patients rather than facilitating dialogue.

Additionally, sharing of new safety information could be optimized with a more holistic and integrated presentation of information regarding regulated products. Currently, safety updates are added to a label and sometimes regulators require issuance of additional communications and post the information to their websites (see Table 1). Safety information should be integrated with all information about a product in a more dynamic and accessible platform that would allow for a more contextual presentation (i.e., what is the genesis of the safety update, and what does it mean in relation to prior information and earlier assessments of benefit–risk).

Both patients and HCPs need a trusted and timely source of information that can be made more understandable and accessible. The ability to integrate siloed information from an authoritative source (i.e., the regulator) provides more accessibility and transparency which not only enhances informed healthcare decisions but may help efforts to build trust.[6]

TABLE 1 Examples of publicly available information shared by regulators on approved medical products[a]

Information	US	EU	UK	Japan	Brazil	China	India
Assessments	https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm	https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human	https://products.mhra.gov.uk/	https://www.pmda.go.jp/PmdaSearch/iyakuSearch/	https://consultas.anvisa.gov.br/#/pareceres/	https://www.nmpa.gov.cn/datasearch/search-result.html https://www.cde.org.cn/main/xxgk/listpage/9f9c74c73e0f8f56a8bfbc646055026d https://www.cde.org.cn/main/xxgk/listpage/2f78f372d351c6851af7431c7710a731	https://cdsco.gov.in/opencms/opencms/en/Approval_new/Approved-New-Drugs/
Labeling	https://nctr-crs.fda.gov/fdalabel/ui/search https://labels.fda.gov/	https://www.ema.europa.eu/en/medicines/national-registers-authorised-medicines https://ec.europa.eu/health/documents/community-register/html/reg_hum_act.htm?sort=n	https://www.medicines.org.uk/emc#gref https://www.emcmedicines.com/en-GB/northernireland/	https://www.pmda.go.jp/PmdaSearch/iyakuSearch/	https://consultas.anvisa.gov.br/#/bulario/	https://zldj.cde.org.cn/home	https://cdsco.gov.in/opencms/opencms/en/Notifications/Prescribing-Information/

(Continues)

TABLE 1 (Continued)

Information	US	EU	UK	Japan	Brazil	China	India
Safety Information	https://www.accessdata.fda.gov/scripts/cder/safetylabelingchanges/ https://www.fda.gov/drugs/drug-safety-and-availability/drug-safety-communications https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/index-drug-specific-information https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-podcasts https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/potential-signals-serious-risks new-safety-information-identified-fda-adverse-event-reporting-system https://www.fda.gov/medical-devices/medical-device-safety/letters-health-care-providers https://www.fda.gov/drugs/resources-information-approved-drugs/drug-information-soundcast-clinical-oncology-disco	https://www.adrreports.eu/index.html https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/signal-management/prac-recommendations-safety-signals https://www.adrreports.eu/en/ https://www.ema.europa.eu/en/human-regulatory/post-authorisation/pharmacovigilance/direct-healthcare-professional-communications	https://www.gov.uk/drug-safety-update https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/	https://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html	https://www.gov.br/anvisa/pt-br/acessoainformacao/dadosabertos/informacoes-analiticas/notificacoes-de-farmacovigilancia https://www.gov.br/anvisa/pt-br/assuntos/fiscalizacao-e-monitoramento/farmacovigilancia	https://www.nmpa.gov.cn/yaopin/ypanqjsh/index.html	
Clinical Trial Information	https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshots	https://eudract.ema.europa.eu/	https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/	https://jrct.niph.go.jp/	https://ensaiosclinicos.gov.br/ http://antigo.anvisa.gov.br/pesquisa-clinica	https://www.chictr.org.cn/about en.aspx	https://cdsco.gov.in/opencms/opencms/en/Approval_new/CT-Approvals/

TABLE 1 (Continued)

Information	US	EU	UK	Japan	Brazil	China	India
Post-marketing Requirements information	https://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm	http://www.encepp.eu/encepp/studiesDatabase.jsp		https://www.pmda.go.jp/english/safety/index.html			
Recalls	https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts	https://www.ema.europa.eu/en/human-regulatory/post-authorisation/compliance/quality-defects-recalls	https://www.gov.uk/drug-device-alerts	https://www.pmda.go.jp/safety/info-services/drugs/calling-attention/recall-info/0002.html		https://www.nmpa.gov.cn/xxgk/chpzhh/index.html	https://cdsco.gov.in/opencms/opencms/en/consumer/Product-Recall/
Shortages/Supply	https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-regulated-products-current-shortages	https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines/shortages-catalogue#ema-shortages-catalogue-section		https://www.mhlw.go.jp/stf/newpage_10314.html	https://www.gov.br/anvisa/pt-br/acessoainformacao/dadosabertos/informacoes-analiticas/descontinuacao-de-medicamentos https://www.gov.br/anvisa/pt-br/assuntos/fiscalizacao-e-monitoramento/mercado/descontinuacao-de-medicamentos	http://english.nmpa.gov.cn/2020--01/17/c_448620.htm	
Expert Advice Panels	https://www.fda.gov/advisory-committees/committees-and-meeting-materials	https://www.ema.europa.eu/en/committees-working-parties-other-groups					https://cdsco.gov.in/opencms/opencms/en/Committees/SEC/

Abbreviations: EU, European Union; UK, United Kingdom; US, United States.

[a]Some sources contain additional information; however, the link provided highlights the location of the specific type of information.

Regulators

Transparency behind the process that leads to regulatory decision making is important beyond patients and HCPs. An integrated platform that includes public assessment reports can build trust among regulators and share knowledge and insights into innovative development programs.[5] This trust can increase reliance and work-sharing models, potentially creating more efficient medical product assessments globally and improving access to patients. Additionally, within a single country or region, regulators can use these integrated platforms to build or strengthen institutional memory to increase their knowledge and ensure consistency in decision making.

Researchers/drug developers

Drug developers and researchers often learn from each other, and a country-specific integrated platform of publicly available information would help drive innovation and efficiency. The ability to readily search across products and innovations can help to promote a learning healthcare system and create efficiencies.[2] Rather than posting pdf files or other static information, an interoperable platform that shares all publicly available regulated product information would allow developers to utilize modern technology to query across products and help inform future clinical trials. Decisions underpinning drug development programs, and sponsor interactions with regulators, also would be enhanced through access to a more effective, versatile collection and presentation of regulated medical product information. The increased usability of public information would further build trust among all researchers and avoid unnecessary duplication of work.

CHALLENGES IN CREATING A VERSATILE REGULATORY MEDICAL PRODUCT PLATFORM

Regulator resources and infrastructures and lack of harmonized standards are the biggest challenges in creating interoperable platforms to share approved medical product information. The first step for any regulator is to understand the needs of the stakeholders and make available all publicly available information in a format best suited to their needs and then modernize their information technology infrastructure and processes to create integrated platforms (i.e., create the ability to develop customized queries). Regulators and industry can work together to harmonize on global standards for sharing publicly available information in a structured content and format. The availability of information in searchable formats creates the opportunity for all stakeholders to customize information to their needs. Although resources can be a challenge, regulators around the world are taking notice of lessons learned from the COVID-19 pandemic and are beginning to upgrade their infrastructures. The COVID-19 pandemic identified the need for all countries to improve their broadband access and infrastructure. As these improvements take hold, the public at large will be able to reap the benefits as described above from increased and enhanced availability of trusted publicly available medical product information.

CONCLUSION: A VISION FOR AN INTEGRATED PLATFORM TO SHARE MEDICAL PRODUCT INFORMATION

We are in a unique time where we have learned from the recent pandemic the need for rapid, useful, and tailored access to approved and authoritative medical product information. We congratulate regulators for the increased sharing of information during the COVID-19 pandemic and are ready to work with them to embrace the global need for more timely, trusted, and credible information and utilize available globally recognized technologies and standards to develop integrated platforms for the sharing of publicly available information on medical products to enhance knowledge and drive innovation. As regulators improve their own infrastructures, increased sharing of public information can begin immediately via publication in an electronic format, with the ultimate goal of having integrated platforms by 2030 in their respective regions.

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CONFLICT OF INTEREST

All authors are employed by multinational biopharmaceutical companies, as indicated in their affiliations. The authors declared no competing interests for this work.

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