Gravitate-Health EU-China Workshop: Challenges and solutions for electronic labeling medications in the EU and China: collaboration opportunities

August 24, 2022, 08:00-11:00 (EU); 14:00-17:00 (CN)
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Meeting ID: 992 6738 7645 Passcode: 124752

Overview

A product information is a critical risk-minimization measure communicating benefit/risk and usage instructions. There are a variety of formats (paper, electronic) and types (patient, HCP) distributed according to national requirements. Also, there are differences of the products information not only contents, but also the template of the product information. Due to the COVID 19 pandemic, various electronic labeling initiatives have been accelerated worldwide following the full digitalization movement in health care and pharmaceuticals fields. E-labeling improves the accessibility and understanding of medical product information, thereby enhancing adherence to medicines and patient outcomes. The availability of the up-to-date labeling on a publicly accessible website is an important first step in improving patient safety and trust in medicines. Eventual removing paper labeling from the commercial packs will improve efficiencies on reducing operational steps for inserting paper labeling in packs, and support environmentally friendly process. The adoption of e-labeling in a structured format enhances the user's ability to navigate information on how to use, handle the product and to better understand safety information. In the future, e-labeling will be integrated with the wider digital healthcare system such as electronic medical record, electronic prescription, resulting to greater efficiencies, and opportunities lie within the healthcare sector. In this session, we will share the landscape of e-labeling initiatives around the world, the most up-to-date ePI initiatives led by EMA and the current situation and challenges on product information in China and Europe. Also, we will discuss the current technology landscape in medical informatic area which will be linked to digital health and the innovative research project on product information from patient centric point of view in China and Europe. In the closing panel, the speakers will join the discussion on collaboration opportunities between the EU and China.

Speakers

Co-Chairs

- Rie MATSUI, Senior Director, Head of Regional Labeling for APAC, Global Regulatory Affairs, Pfizer R&D Japan
- Catherine CHRONAKI, EFMI president, Gravitate-Health Interoperability Lead

Speakers

- Rie MATSUI, Senior Director, Head of Regional Labeling for APAC, Global Regulatory Affairs, Pfizer R&D Japan, *Landscape of current trends of product information (labeling) across regions*
- Juan GARCIA-BURGOS, Head of Public and Stakeholder Engagement Department, European Medicines Agency, *Electronic product information in the European Union (EU): the road ahead*
- Fakhredin SAYED TABATABAEI, Medicines Evaluation Board Agency (CBG-MEB) NL, *Challenges of delivering structured ePI (electronic labeling)*
- Jens Kristian VILLADSEN, Business Unit Leader at Trifork, Chairman of the board @ HL7 DK, *HL7 FHIR electronic Product Information (ePI) Implementation Guide*

- Lan ZHANG, Vice Director of national clinical test organization for medication, Chair for China alliance Pharmaceutical Federation, *Intelligent Pharmacy promoting the rational use of drugs.*
- Wenya WANG, Beijing Tsinghua Chang Gung Hospital, Tsinghua University, *Survey results from the Chinese PI project from Tsinghua university*
- Jing (Jason) CHEN, team lead of International Labeling Group at Pfizer
- Kitty JIN, Vice president, Medlive, *Process and experience sharing about digitalized and integrated doctor and patient management*

Comments -Discussion

- Lars LIDSKOLD, EFMI Institutions Officer,

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Preliminary Program

08:00 (CET)/14:00 (CN) Welcome and introduction to the session

Rie Matsui, Catherine Chronaki

08:05 (CET)/14:05 (CN) Keynote: Landscape of current trends of product information (labeling) across regions

Rie Matsui, Senior Director, Head of Regional Labeling for APAC, Global Regulatory Affairs, Pfizer R&D Japan

Abstract: There are various labeling regulations all over the world. In general, two types of labeling documents exist, one is the healthcare professionals and the other is the patient centric labeling. Much of the current focus around labeling is about the content and little attention has been paid to how the label is being accessed, used, understood, and adhered to in real life settings. We need to shift our mindset. There are three key related issues for the patients, accessibility, understanding, and adherence. Electronic product information will improve the accessibility and understanding of product information, thereby enhancing adherence to medicines and patient outcome. Due to the COVID-19 pandemic, various electronic labeling initiatives have been accelerated worldwide following the full digitalization movement in healthcare and pharmaceuticals fields. In the future, e-labeling will be integrated with the wider digital healthcare system such as electronic medical record, electronic prescription, resulting to greater efficiencies, and opportunities lie within the healthcare sector. The presentation will share the landscape of e-labeling initiatives and patient centric labeling all over the globe, and the current labeling situation especially the differences between China and Europe.

08:30 (CET)/14:30 (CN) Keynote: Electronic product information in the European Union (EU): the road ahead

Juan García Burgos, Head of Public and Stakeholder Engagement Department, European Medicines Agency

Abstract: *The product information (PI) of an EU medicine includes the package leaflet for patients and the summary of product characteristics for healthcare professionals. These documents accompany every medicine authorised in the EU and explain how the medicine should be used and prescribed. While today the PI is generally provided by regulators in pdf format, and the package leaflet included as a printed copy in the medicines pack, there is a need to provide a semi-structured electronic format of PI (ePI) for EU medicines. Harmonised implementation of ePI in the EU will widen the dissemination of up-to-date medicines information to patients and healthcare professionals at the point of need. ePI will increase accessibility of medicines to users with diverse abilities. In addition, ePI offers opportunities to enable administrative efficiencies in handling of product information. EU regulators have adopted the EU ePI Common Standard, based on the global FHIR standard for healthcare applications, paving the way for harmonised implementation. The presentation will describe the road to ePI implementation and progress in building the tooling and business processes needed to introduce ePI into EU regulatory processes. Expansion of use of ePI and future evolution to facilitate advanced use cases will also be discussed.*

08:50 (CET)/14:50 (CN) Challenges of delivering structured ePI (electronic labeling)

Fakhredin Sayed Tabatabaei, CBG-MEB, The Netherlands

Abstract: *The goal of developing an electronic version of Product Information (PI) is to improve the shortcomings of paper version sensed in the 21st century health system. Although the definition of PI is relatively straightforward, the definition of 'electronic' could be misleading. In fact, any format beyond paper version may be considered electronic. However, formats such as PDF, Word or other free text files do not deliver the benefits that are expected from the electronic Product Information (ePI). In addition to the electronic characteristic of ePI, there are a few essential elements still to be taken into consideration. The first unmissable criterium is 'Structured' format, meaning that ePI has to contain some structured data elements (e.g. consistent, fixed headings and controlled vocabularies), although some unstructured elements (e.g. free text and graphics) may still be present. Nonetheless, inconsistencies and divergence of the information are part of paper version shortcomings, which cannot be resolved only by an structured electronic format. For this reason, the structured data elements have to be 'Coded,' in order to facilitate standardization. Last, but not least, those structured and coded elements need to be 'Connected' to some high-level data sources. This will facilitate seamless harmonization of product information at regional and international level, and ultimately deliver the maximum benefit to the health system and ultimately to the patients.*

09:05 (CET)/15:05 (CN) HL7 FHIR ePI Implementation Guide

Jens Kristian Villandsen, Business Unit Leader at Trifork | Chairman of the board @ HL7 DK

Abstract: *The Gravitate-Health initiative has launched the ePI/eLabeling Project, under the HL7 FHIR accelerator, in an effort to create a global standard consistent to EMA's ePI common standard specification. This presentation will describe the current status of the HL7 FHIR implementation guide and relate it to developments around the world.*

09:25 (CET)/15:25 (CET) break

09:35/15:35 Keynote: Intelligent Pharmacy promoting the rational use of drugs

Dr. Lan Zhang, Vice Director of national clinical test organization for medication, Chair for China alliance Pharmaceutical Federation

10:00 (CET)/10:00 (CN) Survey results from the Chinese PI project from Tsinghua university

Jason Chen, Pfizer & Wenya Wang, Tsinghua university

In China per regulation there is only one labeling document (also called 'product information') approved for a drug. This PI is supposed to be used by both healthcare professionals and indicated patients. Although there is the general requirement per labeling regulation (Order 24) that fluent easy language should be used in authorizing the document for better understanding. However, in reality it may not be the case. There is always PI related enquiries and complaints from the patients. To know the overall feedback an on-line survey was designed and conducted in China. There are totally 17 questions in this survey, including 4 demographic questions, 13 PI related questions related to how PI is used, how much PI is understood, and what future labeling is expected ie patient labeling or e-labeling. By end of date, totally 7000 subjects' responses were collected which mainly come from Beijing and Shenzhen (two tier 1 cities). Among them 6953 responses were finally analyzed. In this presentation we are going to share some of the survey results.

10:15 (CET)/16:15 (CN) Process and experience sharing about digitalized and integrated doctor and patient management

Kitty Jin, Vice president, Medlive

Abstract: *Medlive utilized the deep understanding of 310 million doctors in past 26 years, create a new module about digitalized patient management. Based on the core element of patient management—patient education and patient follow up, create a convient digital patient management tool, use multipal media to deliver the patient education material in public and private way. By linking the doctor and patient, patient's understanding about disease, diagnose and treatment has improved, and improve the patient compliance. In addition, doctors' scientific need, clinical need, and branding need have also been considered, and realize a win-win solution for both doctor and patients*.

10:30 (CET)/16:30 (CN) Discussion

10:55 (CET)/16:55 (CN) Closing remarks

11:00(CET)/ 17:00 (CN) End of Workshop

Speakers Biography

Rie Matsui *is Senior Director, Regional Labeling Head for APAC within the International Labeling Group (ILG) at Pfizer as well as the Head for External Engagements within ILG. She is the founder of the Asian Labeling Hub in Pfizer that is responsible for creation of local labels for more than 25 countries in Asia. She has been with Pfizer for over 25 years in labeling, pharmacovigilance and risk management roles. She has been actively involved in a number of conferences in Japan, China, Singapore, and the U.S., both as a session chair and speaker. Her papers were published in scientific journals such as Therapeutic Innovation & Regulatory Science. She received the DIA Japan regional award in 2015 and was a member of the Advisory Council of DIA Japan until 2020. Also, she was the vice chair of the 2021 DIA Japan Annual Meeting Program Committee. Rie is the chair of the DIA Asia labeling community and the leader of the APAC e-labeling expert working group. Very recently, Rie received the DIA Global Inspire Award Connector in 2022. She is a pharmacist.*

Juan García Burgos *is the Head of Public and Stakeholders Engagement Department, European Medicines Agency (EMA). Juan García Burgos is a Qualified Medical Doctor from the University of Autonoma in Madrid, specialised in urology. Juan worked as a urologist surgeon at the hospital Gregorio Maranon in Madrid. He joined the European Medicines Agency in 2002 in the scientific Units and was responsible for coordinating the preparation of EU clinical guidelines for drug development. He took up new responsibilities in 2005 where he was appointed Head of Medical and Health Information, being directly involved in the interaction with Patients, Consumers and HealthCare Professionals' Organisations and the preparation of information on benefit-risk of medicines for lay audiences. In January 2017, he was appointed Head of Public and Stakeholders Engagement Department and is Co-chair of the EMA patients' and healthcare professionals' working party.*

Fakhredin Sayed Tabatabaei *is a medical doctor and an epidemiologist. He has worked as a senior assessor at the pharmacovigilance department of the Dutch national agency (MEB) for more than 16 years. Since 2017, he is part of the 'Better Use Programme,' initiated within the MEB, focusing on improving access to product information, so that both patients and healthcare providers can search for, find, consult, and use information about medicines. He is also a member of the 'electronic Product Information (ePI)' and the chairman of the 'Harmonisation of RMP (HaRP)' projects in Europe.*

Jens Viladsen *is Business Unit Leader at Trifork and Chairman of the board @ HL7 DK. He is instrumental in the development of the ePI/eLabeling HL7 FHIR Implementation Guide.*

Dr. Zhang *Lan is the Vice Director of national clinical test organization for medication, Chair for China alliance Pharmaceutical Federation. She is Researcher, supervisor of postgraduate, the director of department of pharmacology, Xuanwu Hospital of Capital Medical University. She received Ph. D of Pharmacology, Master of Hospital Pharmacy Administration, and she studies Harvard Medical School and received Postdoctorate in 2007-2009. She is selected in Beijing Health and Technical Personal of High-level Plan-academic pacesetter, New Star Program of Beijing Science and Technology Committee and the New Centuary Hundred, Thousand and Ten Thousand Talent Project –candidates in Beijing. She has been working on the Pharmacological Research and New Drug R&D for Neurodegenerative diseases of the elderly from 1997. She did systematic research and evaluate for the active ingredients of Kidney-reinforcing herbal medicine, like dogwood, polygonum multiflorum and epimedium. As a principal investigator, she took 22 projects, includes 4 national research projects, 6 provincial research projects and over 12 other projects. And she get many other achievements, like Beijing municipal science and technology first prize, national scientific and technological progress second prize, 11 new drug patents. She took part in three new drug preclinical studies, and all of these three studies have got clinical trial permission. Besides that she has published over 100 papers, she is the first author or corresponding author of 46 of them.She started to research for the rational use of drugs in the elderly*

from 2000. As a project management coordinator, she worked with WHO, INRUDs and Harvard Medical school to win Harvard-China Fund. And she also worked with National Ministry of Health, WHO-China and Beijing medical insurance affairs management center to promote many global projects. She was charge of key national projects on Phase 3 trial of Tai Si Capsule for Alzheimer's disease. She was also many other project leaders, such as Rational use of training and science campaign of essential drugs on primary health care institutions and Science healthy people. As the main participants, she completed National science and technology support project "Rational use of evaluation and research of the main essential drugs on primary health care institutions" with others. Meanwhile, she conducted a project for promotion of rational drug use by medical insurance with pharmacy department, medical insurance office and Beijing health care center. And she published 2 papers for this project. She is also the associate editor of one Clinical pharmacy monograph. She served as the vice chairman and secretary-general of Branch of Elderly rational drug use, Chinese Association of Geriatric Research, the vice chairman and secretary general of Beijing Pharmacological Society, director of Chinese Pharmacological Society, Standing Committee of Experimental Medicine Professional Committee, Chinese Association of Integrative Medicine, committee of Elderly Pharmaceutical Professional Committee, Chinese Pharmaceutical Association, director of Scientific Committee of Aging and Antiaging, Gerontological Society of China. She is the editoral of Restorative Neurology and Neuroscience and Journal of Alzheimer's disease.

Dr. Wenya Wang *is a medical doctor. She is now working in Beijing Tsinghua Chang Gung Hospital affiliated to Tsinghua University in preparation for the establishment of Biotherapy Research Center. Before that, she worked in Ding Sheng's research group at the School of Pharmacy, Tsinghua University and engaged in drug regulatory scientific research and drug science curriculum system planning, focusing on regulatory scientific research and cooperation in precision medicine and emerging therapeutic areas. As the main person in charge or responsible person of the project, she participated in the first batch of key projects of the National Medical Products Administration's China Drug Regulatory Science Action Plan - cell and gene therapy evaluation and regulatory policy research, drug-device combination product evaluation system research, etc., organized and completed the Shenzhen Development and Reform Commission Cell Treatment legislation research and other topics. From 2017 to 2018, he served as the deputy secretary general of China Pharmaceutical Quality Management Association, responsible for external affairs and scientific and regulatory affairs. As a core member, participate in the work of the generic drug branch. He took the lead in completing the research report on reference preparations for the evaluation of the consistency of quality and efficacy of generic drugs in China, and put forward the proposal for the establishment of the implementation plan of the Chinese generic drug reference drug catalog (Orange Book). Participate in regulatory policy research for cell and gene therapy, and support the development and discussion of technical guidelines for cell products. She also used to work in multinational pharmaceutical company (BMS) responsible for the drug registrations. Dr Wang used to worked in the State Food and Drug Administration from 2005 to 2011, and successively served as the chief staff member of the Drug Safety Supervision Department and the Drug Registration Department (2005) and deputy investigator (2007).*

Jing (Jason) Chen *is the team lead of International Labeling Group at Pfizer. He is mainly supprting regional labeling lead with the labeling related strategy development/implementation. He is also supporting the regulatory colleagues with the required labeling updates across APAC markets in the company. Before joining pfizer as labeling experts, he managed various regulatory activities in other multi-national pharmaceutical companies in China.*

Kitty **Jin** *is Vice President of clinical research at Medlive. She has 15 years clinical research experience with the expertise of clinical development, project management, clinical operation, quality management and training. Currently, she leads the cross function clinical development team including clinical operation, medical team, DM and Bios, patient recruitment and patient management team. She as led 20+ phase I III successful studies, and multiple BE and phase IV studies and played as clinical development lead role to realize the successful NDA approval of a precise medication, and project lead role to realize. Before she joined Medlive, she played the clinical development lead and project management director in Cstone from 2019 2021, deputy GM and audit director in 3Audit from 2017 2019, senior project manager and clinical operation role in Quintiles,Roche and Jingsuhengrui. She served as Chief editor: 2022 DIA China "RBQM position paper", author 2022 DIA "DCT expert consensus", 2021 DIA "DCT bluepaper", Corresponding author 2021 "Optimization*

of quality management of anti tumor clinical trials through centralized monitoring based on risk assessment statistical model" cited by CDE guideline. She has also published on quality management in the "China Food&Drug administration Magazine" and "China new drug regulation and registration double yearbook"

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