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Adoption of Identification of Medicinal Products Standards in Europe: Health Authorities and Industry Insights

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Summary: This article explores the adoption of the ISO Identification of Medicinal Products (IDMP) standards in Europe, aimed at establishing a unified framework for identifying medicinal products to enhance regulatory efficiency and patient safety. It provides a comprehensive overview of the regulatory landscape, implementation strategies, and the challenges faced by both health authorities and the pharmaceutical industry during the adoption process. Focusing on the European Union and key agencies like the EMA, the article highlights IDMP's potential to improve data interoperability, streamline regulatory processes, and support cross-border healthcare services, such as e-prescriptions. Despite the significant promise of IDMP, challenges such as technical integration, high resource requirements, and ensuring data quality remain critical hurdles. By examining regulatory developments, case studies, and best practices, this paper emphasizes the transformative potential of IDMP in achieving efficient, interoperable regulatory data management, ultimately contributing to safer and more effective healthcare delivery.

Keywords: Medicinal Product Identification, Global Pharmacovigilance, Data Interoperability, IDMP Implementation Challenges, ISO IDMP, SPOR

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1. Introduction

The Identification of Medicinal Products (IDMP), developed by the International Organization for Standardization (ISO), establishes a unified global standard for identifying and describing medicinal products. ISO IDMP unifies medicinal product information globally, covering elements such as substance identifiers, packaging, dosage forms, and routes of administration. The initial goal of IDMP has been to enhance

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pharmacovigilance activities, such as exchange of medicinal product information for adverse event reporting, but also to support wider regulatory activities and healthcare practices.[1] Leading regulatory organizations, including the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA), alongside multiple international stakeholders, played a pivotal role in the development of IDMP.

IDMP's objectives include promoting global interoperability of medicinal product information, supporting reduced medication errors, improved pharmacovigilance, and seamless cross-border e-prescription services. Additionally, IDMP provides standardized data models for regulatory authorities and contributes to enhanced public health by integrating data for drug research and monitoring.[2]

To achieve these goals, IDMP includes several key ISO standards that define the elements for medicinal product identification:

- ISO 11615: Data elements and structures for the unique identification and exchange of regulated medicinal product information.
- ISO 11616: Data elements and structures for pharmaceutical product identification and exchange.
- ISO 11238: Data elements for substances in medicinal products.
- ISO 11239: Information on dose forms, units of presentation, administration routes, and packaging.
- ISO 11240: Requirements for units of measurement for medicinal products.

IDMP is one of the largest and most complex regulatory data standardization initiatives, particularly for medicinal products. Adoption is advancing globally, with key regions like the European Union (EU), the United States, Japan, and Canada. The EMA has mandated IDMP compliance under its SPOR (Substance, Product, Organisation, and Referential) program, making IDMP adherence a regulatory requirement for pharmaceutical companies in the EU. In the United States, the FDA promotes IDMP alignment to enhance data consistency, though full compliance is not yet obligatory.[3] Japan's Pharmaceuticals and Medical Devices Agency (PMDA) and Health Canada are similarly moving toward IDMP-compatible systems, without imposing mandatory adoption. International bodies, including the World Health Organization (WHO) and the International Council for Harmonisation (ICH), are advocating IDMP standards to foster a unified approach to medicinal product information worldwide.

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[1] EUROPEAN MEDICINES AGENCY. *Data on Medicines (ISO IDMP Standards): Overview | European Medicines Agency (EMA)*. 2016 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview.

[2] EUROPEAN MEDICINES AGENCY. *Introduction to ISO Identification of Medicinal Products, SPOR Programme.* 2016 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview.

[3] U.S. FOOD AND DRUG ADMINISTRATION. *Identification of Medicinal Products (IDMP)*, *FDA.* 2022 [online]. Available at: https://www.fda.gov/industry/fda-data-standards-advisory-board/identification-medicinal-products-idmp.

While IDMP implementation promises substantial improvements in healthcare quality and safety, it also presents considerable challenges. Variations in healthcare systems, technological infrastructure, and regulatory environments complicate uniform IDMP adoption, particularly across the EU. The pharmaceutical industry faces operational and logistical challenges, from data management to aligning with evolving compliance requirements. Addressing these challenges is crucial to fully leverage IDMP's potential to enhance pharmacovigilance, streamline product lifecycle management, and improve overall public health outcomes.[4]

The aim of this paper is to provide a comprehensive overview of the adoption of ISO IDMP standards in the EU, focusing on their regulatory, operational, and technological aspects. It seeks to highlight the benefits of IDMP in enhancing data interoperability, pharmacovigilance, and patient safety while addressing the challenges faced by health authorities and the pharmaceutical industry. This paper also explores the progress made in the adoption of ISO IDMP standards in Europe, particularly by health authorities and the pharmaceutical industry, and examines the primary challenges and solutions associated with implementing IDMP standards, including technical, operational, and regulatory aspects. By analysing EU regulations, EMA guidelines, IDMP implementation project documents, industry reports, and case studies, the article aims to promote knowledge sharing and provide insights to support broader and more effective adoption of IDMP standards across stakeholders.

2. Current Initiatives and Progress in Europe

EU IDMP framework is based on Regulation (EC) No 726/2004, which governs the authorization and oversight of medicinal products for human and veterinary use. Amendments such as Directive 2010/84/EU and Regulation (EU) No 1235/2010 reinforced the need for a standardized system to enhance pharmacovigilance and drug safety monitoring.[5] The **EU's adoption of IDMP standards** began formally with the 2012 Commission Regulation. This regulation required Member States, Marketing Authorization Holders (MAHs), and the EMA to adopt ISO IDMP standards for the exchange and communication of medicinal product information. To facilitate the implementation of ISO IDMP standards, the EMA has established services to manage master data, collectively referred to as ‚SPOR' (Substance, Product, Organization, and Referential Management Services) throughout this guidance.[6]

[4] EUROPEAN MEDICINES AGENCY. *Introduction to ISO Identification of Medicinal Products, SPOR Programme.*

[5] EUROPEAN MEDICINES AGENCY. *Data on Medicines (ISO IDMP Standards).*

[6] EUROPEAN MEDICINES AGENCY. *Introduction to ISO Identification of Medicinal Products, SPOR Programme.*

The four SPOR services cover the four domains of SPOR master data:[7] Substance Management Service (SMS) – harmonised data and definitions to uniquely identify the ingredients and materials that constitute a medicinal product; Product Management Service (PMS) – harmonised data and definitions to uniquely identify a human medicinal product based on regulated information (e. g. marketing authorisation, packaging and medicinal information); Organisations Management Service (OMS) – data comprising organisation name and location address, for organisations such as marketing authorisation holders, sponsors, regulatory authorities and manufacturers; Referentials Management Service (RMS) – lists of terms (controlled vocabularies) to describe attributes of products, e. g. lists of dosage forms, units of measurement and routes of administration.

The implementation of the IDMP standards has experienced several delays since its inception. Initially, the EMA aimed for full IDMP compliance by 2016. However, due to the complexity of aligning diverse regulatory frameworks and the need for comprehensive data integration, this timeline was extended. The EMA released the first version of the EU IDMP Implementation Guide in February 2020, providing initial guidance for stakeholders to prepare for ISO IDMP standards adoption. Updated versions were published in 2021 and 2022, incorporating the latest agreements and prioritizing improvements in data management. The plan was for pharmaceutical companies to begin submitting product data in IDMP format by the first quarter of 2022, with mandatory compliance expected by the first quarter of 2023. Despite these efforts, full implementation faced further delays. In 2022, the EMA introduced the Digital Application Dataset Integration (DADI) project, focusing on replacing current electronic application forms with web-based versions to facilitate structured data submissions. The go-live for DADI was planned for October 2022, with a transition period extending to April 2023 for companies to adapt. By April 2023, the EMA continued to work on integrating IDMP standards, emphasizing the gradual rollout of the Product Management Service (PMS) and the Substance Management Service (SMS). To address drug shortages, additional packaging data elements critical for tracking product availability are expected to go live by **2025**, ensuring a more comprehensive regulatory system for managing medicinal products.[8]

[7] EUROPEAN MEDICINES AGENCY. *Substance, Product, Organisation and Referential (SPOR) Master Data | European Medicines Agency (EMA)*. 2016 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data.

[8] EUROPEAN MEDICINES AGENCY. *Substance and Product Data Management Services | European Medicines Agency (EMA)*. 2024 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services. EUROPEAN MEDICINES AGENCY. *Substance, Product, Organisation and Referential (SPOR) Master Data | European Medicines Agency (EMA)*.

As of end of 2024, full mandatory compliance with IDMP standards has not yet been achieved. The EMA continues to adopt a phased approach, focusing on iterative steps to ensure a smooth transition for stakeholders. Stakeholders are encouraged to stay informed about these developments to prepare for future compliance obligations.[9]

2.1. SPOR (IDMP) Task Force

The EMA plays a key role in advancing ISO IDMP implementation across the EU, coordinating with National Competent Authorities (NCAs) and industry stakeholders to establish technical specifications and create guidance documents. The SPOR Task Force, established in 2015, includes representatives from the EMA, 20 NCAs, and 8 industry associations such as EFPIA and Vaccines Europe, along with technology vendors and consultancy firms, to address pharmaceutical industry needs for IDMP compliance.[10,11]

The SPOR Task Force developed the EU implementation guide and roadmap, facilitating alignment among regulatory bodies, pharmaceutical companies, and vendors on SPOR data standards. Initial priorities focused on launching the OMS and RMS in 2017 to provide reusable regulatory data.[12] The task force evolved the EU IDMP Implementation Guide and influenced EMA's transition to the PLM portal and DADI project, setting a foundation for additional IDMP components like the Product Management Service (PMS).[13,14] In 2022, with the SPOR program moving to an agile governance model, the task force concluded its formal role, though its contributions continue to impact SPOR and IDMP initiatives, advancing data interoperability and regulatory alignment across Europe.[15]

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9 JAMIL, Adnan. Assessing Pharma's Readiness for Digital Product Information Management, *European Pharmaceutical Review*. 2021 [online]. Available at: https://www.europeanpharmaceuticalreview.com/article/159996/assessing-pharmas-readiness-for-digital-product-information-management.

10 EUROPEAN MEDICINES AGENCY. *Substance and Product Data Management Services | European Medicines Agency (EMA)*.

11 UNICOM. *UNICOM Project, UNICOM* [online]. Available at: https://unicom-project.eu/.

12 EUROPEAN MEDICINES AGENCY. *SPOR (ISO IDMP) Task Force | European Medicines Agency (EMA)*. 2015 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/spor-iso-idmp-task-force.

13 EUROPEAN MEDICINES AGENCY. *Substance and Product Data Management Services | European Medicines Agency (EMA)*.

14 EUROPEAN MEDICINES AGENCY. *Substance, Product, Organisation and Referential (SPOR) Master Data | European Medicines Agency (EMA)*.

15 EUROPEAN MEDICINES AGENCY. *Referentials Management Service (RMS) | European Medicines Agency (EMA)*. 2016 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/referentials-management-service-rms.

2.2. UNICOM Project

The European Commission's (EC) UNICOM project (Up-scaling the Global Univocal Identification of Medicines) supports ISO IDMP adoption, seeking to standardize medicinal product data across the EU and to improve data interoperability in the healthcare sector. Launched in January 2020, UNICOM involves 11 National Competent Authorities, National eHealth Centers, Standards Development Organizations, and IT vendors, though industry is not represented.[16]

UNICOM aims to address data inconsistencies by implementing IDMP standards across EU healthcare systems, thereby enhancing data reliability and compliance for pharmacovigilance and patient safety. Its objectives include enabling standardized data exchange among EU Member States to provide „trusted data" about medicines for clinicians and patients, supporting the digital transformation of healthcare with unified data structures, and improving cross-border healthcare in alignment with the European Health Data Space initiative.[17]

UNICOM's key achievements include establishing IDMP-compliant digital infrastructures integrated with the EMA's SPOR program, running pilot projects in EU Member States to evaluate real-world implementation, and collaborating with HL7 and IHE (Integrating the Healthcare Enterprise) to ensure compatibility with global standards.[18]

The UNICOM project was finalized in 2024, with its accomplishments showcased at its April 2024 conference, where future applications for supporting the European Health Data Space were discussed. UNICOM resources, including white papers and webinars, offer guidance on IDMP adoption and data management practices.[19]

2.3. Pistoia Alliance's IDMP Ontology Project

The Pistoia Alliance's IDMP Ontology Project (IDMP-O), launched in 2022, helps pharmaceutical companies achieve IDMP compliance by enhancing data interoperability across regulatory, clinical, and manufacturing workflows. Partners include Bayer, Novartis, GSK, Merck KGaA, Roche, Johnson & Johnson, AstraZeneca, and others, as well as supporting organizations like the EDM Council and ACCURIDS.[20]

IDMP-O aims to develop an open-source, vendor-neutral ontology that enhances the usability of IDMP data. It also seeks to establish a FAIR (Findable, Accessible,

[16] UNICOM. *UNICOM Project.*

[17] UNICOM.

[18] WILLIAMS, A. What Lies Ahead for IDMP? *European Pharmaceutical Review* [online]. Available at: https://www.europeanpharmaceuticalreview.com/article/172039/what-lies-ahead-for-idmp/.

[19] EUROPEAN MEDICINES AGENCY. *Data on Medicines (ISO IDMP Standards).*

[20] MASKELL, C. Pistoia Alliance Launches Freely Available IDMP Ontology 1.0, Covering All Five Standards Set by ISO. *Pistoia Alliance* (blog). 2024 [online]. Available at: https://www.pistoiaalliance.org/news/press-release-pistoia-alliance-launches-idmp-1-0/.

Interoperable, and Reusable) data model to support regulatory and pharmacovigilance applications. Additionally, IDMP-O strives to reduce the costs and time involved in manual data management, particularly for achieving compliance across different jurisdictions.[21]

In its first phase, IDMP-O developed an ontology framework for aligning IDMP data with real-world applications. The project is now expanding to cover additional areas such as dose forms, packaging, and complex substances like vaccines. The Pistoia Alliance is seeking further funding and participation to broaden the ontology and establish a comprehensive IDMP data ecosystem for the pharmaceutical industry.[22]

3. Use Cases of IDMP in Europe: Aspirations, Early Impacts, and Current Progress

3.1. Pharmacovigilance and Safety Monitoring

A central objective of IDMP implementation is to strengthen pharmacovigilance systems by improving the quality and consistency of medicinal product data used for monitoring adverse events. Adoption of IDMP-compliant data structures seeks to standardize adverse event reporting and enable faster, more accurate identification of safety signals, thereby enhancing the traceability of adverse reactions across EU Member States.[23]

Significant progress has been achieved through the EMA's SPOR services, particularly the RMS, which provides a unified terminology framework essential for standardized adverse event reporting. Additionally, recent updates in the IDMP Implementation Guide specify further integration steps for IDMP data into pharmacovigilance processes, with pilot projects currently assessing interoperability and data quality consistency within these systems. However, transitioning from traditional reporting systems to an IDMP-compliant framework requires extensive data harmonization efforts, such as aligning disparate data formats and overcoming differences in regulatory requirements across Member States. Pharmaceutical companies must also

[21] MASKELL, C. Pistoia Alliance Launches New Identification of Medicinal Product Ontology Project to Align Data Standards, Accelerate Innovation, and Improve Patient Safety. *Pistoia Alliance* (blog). 2022 [online]. Available at: https://www.pistoiaalliance.org/news/pistoia-alliance-launches-new-identification-of-medicinal-product-ontology-project/.

[22] MASKELL, ibid.

[23] EUROPEAN MEDICINES AGENCY. *Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) Standards for the Identification of Medicinal Products (IDMP) in Europe.* 2022 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services.

implement substantial updates to their internal pharmacovigilance systems, adapting data management protocols and infrastructures to align with IDMP requirements.[24]

3.2. Regulatory Affairs – Improving efficiency

The IDMP framework seeks to streamline regulatory processes across Member States by establishing a single, standardized format for medicinal product information. By standardizing terminology and coding across all participants in the pharmaceutical supply chain—including manufacturers, distributors, and regulatory authorities—IDMP minimizes inconsistencies in regulatory processes and optimizes regulatory workflows. This standardization fosters a uniform regulatory environment, by eliminating redundant data entries, enhancing data quality, and mitigating administrative burdens. Assigning a unique identifier to each medicinal product allows comprehensive traceability throughout its lifecycle – from development to post-marketing surveillance. This traceability strengthens regulatory oversight and enhances pharmacovigilance by supporting efficient product tracking and monitoring across regions. Furthermore, IDMP accelerates approval processes by providing regulatory authorities with more efficient access to medicinal product data, streamlining review processes. By simplifying data submission and review, IDMP has the potential to expedite approval timelines, reduce time-to-market, and improve patient access to new treatments.[25]

The transition to Electronic Application Forms (eAF) under the EMA's Digital Application Dataset Integration (DADI) project represents a major step towards digital submissions. The project replaces electronic PDF forms with web-based applications that integrate directly with product databases, improving efficiency and accessibility. Additionally, the new online forms adhere to the EU Implementation Guidelines for describing human and veterinary medicinal product data, leveraging the Fast Healthcare Interoperability Resources (FHIR) data standard. This streamlined process not only accelerates review timelines but also enhances accessibility to critical product data, expediting market access and patient access to new treatments.[26]

3.3. Cross-Border Product Tracking and Recall Management

The implementation of standardized identifiers within the IDMP framework aims to improve cross-border traceability of medicinal products across the EU, improving

[24] VARDANYAN, L., KOCHARYAN, H., HAMUĽÁK, O., KERIKMÄE, T. Digital Sovereignty in the EU: Searching for Legal Mechanisms for Marking the Borders. *Digital Development of the European Union: An Interdisciplinary Perspective.* Springer International Publishing, 2023, 219–34.

[25] RAJENDRAN, M. Challenges and Benefits of Implementing IDMP in the Pharmaceutical Industry. *PharmaCommerce*. 2024 [online]. Available at: https://www.pharmaceuticalcommerce.com/view/challenges-and-benefits-of-implementing-idmp-in-the-pharmaceutical-industry.

[26] RAJENDRAN, ibid.

regulatory transparency and protecting public health. This capability streamlines the management of recalls, shortages, and batch-specific safety concerns within the interconnected EU market. The use of consistent, harmonized product data under IDMP allows a unified approach to product tracking, which is essential for timely regulatory action and consumer safety across Member States. Furthermore, by establishing a standardized system, IDMP reduces the risks associated with inconsistent product data and minimizes delays in cross-border tracking and recall efforts.

The EMA is launching European Shortage Monitoring Platform (ESMP), which leverages IDMP standards to harmonise data across various systems. The ESMP is intended to proactively manage the supply and demand of critical medicines in the EU, reducing the risk of shortages by providing regulators with real-time insights. It will also use PMS data to gather information about medicine supply and demand and to prevent, detect and manage shortages of human medicines.[27] IDMP data definitions have been used to transform EMA data from SIAMED and XEVMPD, aligning them with IDMP structures. This data is then made available in PMS, enriched with IRIS integration, and fed into ESMP. The combined data from these systems helps EMA monitor the supply, demand, and shortage risks of critical medicines.[28]

3.4. ePrescription and Patient Summary Management

Integrating the IDMP framework into ePrescription and patient summary systems enhances EU healthcare delivery by allowing patients to access prescribed medications across borders and ensuring essential health information is available for continuity of care. By applying standardized identifiers and terminology, IDMP aims to harmonize medicinal product data, ensuring that prescriptions and health information remain accurate and consistent across Member States. This capability is crucial for ensuring consistent and reliable healthcare across borders, particularly for mobile EU populations, by ensuring that medicinal products are consistently identified and accurately dispensed, regardless of the Member State.

This initiative is part of the broader European Health Data Space (EHDS), which aims to create a secure framework for health data sharing within the EU. Supported by projects like the UNICOM initiative and developed in alignment with the eHealth Digital Service Infrastructure (eHDSI) under the European Union's Connecting Europe Facility (CEF), cross-border ePrescriptions and patient summaries utilize IDMP standards to ensure accurate medicinal product identification across Member

[27] MERRILL, A. IDMP at the EMA: The European Shortage Monitoring Platform. *Ennov Software for Life* (blog). 2024 [online]. Available at: https://en.ennov.com/blog/regulatory-blog/idmp-ema-european-shortage-monitoring-platform/.

[28] STROETMAN, K. A. The Univocal Identification and Safe Dispensation of Medicinal Products across Europe – Challenges and Solution Proposal. *GMS Medizinische Informatik, Biometrie Und Epidemiologie*. 2017, vol. 13, no. 2: Doc09, DOI: 10.3205/mibe000176.

States.[29,30] This standardization reduces the risk of errors and enhances accessibility, fostering safer and more reliable cross-border healthcare.

Significant progress has been achieved in implementing cross-border ePrescription and patient summary services through the eHDSI. Integrating IDMP standards within these services allows healthcare providers and pharmacists to interpret prescriptions and patient summaries accurately, even with national language differences or regional product variations. This interoperability supports accurate dispensing, minimizes prescription errors, and aligns with the EHDS's goal of establishing a secure, harmonized health data sharing framework across the EU.[31]

The main challenges include variations in digital infrastructure, regulatory differences, inconsistent data privacy laws, and the need for extensive training for healthcare providers. These barriers complicate the integration process and necessitate coordinated efforts and significant investments. Cross-border data exchange also raises privacy and security concerns, as patient information must be safeguarded under diverse national regulations.[32] Compliance with GDPR and other privacy frameworks is essential, demanding robust security measures in managing ePrescription and patient summary data. Moreover, not all healthcare systems are technically ready to support IDMP integration with these services. Upgrading IT infrastructure and ensuring interoperability across Member States is a gradual process that requires significant financial investment and cooperation from both regulatory authorities and healthcare providers.[33,34]

3.5. Clinical Trials and Data Management

Another key objective of IDMP is to standardize data management in clinical trials across Europe, making regulatory submissions more consistent and reducing complexity for multicenter trials. The framework is designed to enable clinical trial sponsors to

[29] UNICOM WP5 Members. *D5.6: Guidelines to Implement IDMP in National eHealth Services. WP5 – IDMP Adoption by eHealth Services. UNICOM.* 2022 [online]. Available at: https://unicom-project.eu/wp-content/uploads/2023/11/UNICOM_D5.6_Guidelines-to-implement-IDMP-in-National-eHealth-Services_PU_approved-1.pdf

[30] VARDANYAN, L., KOCHARYAN, H., HAMUĽÁK, O., KERIKMÄE. T. Digital Sovereignty in the EU: Searching for Legal Mechanisms for Marking the Borders. *Digital Development of the European Union: An Interdisciplinary Perspective.* Springer International Publishing, 2023, 219–34.

[31] UNICOM WP5 Members. *D5.6: Guidelines to Implement IDMP in National eHealth Services.*

[32] HAMUĽÁK, O. *National Sovereignty in the European Union: View from the Czech Perspective.* Springer, 2016.

[33] STROETMAN. The Univocal Identification and Safe Dispensation of Medicinal Products across Europe – Challenges and Solution Proposal.

[34] VARDANYAN, L., KOCHARYAN, H., HAMUĽÁK, O., KERIKMÄE. T. Digital Sovereignty in the EU: Searching for Legal Mechanisms for Marking the Borders. *Digital Development of the European Union: An Interdisciplinary Perspective.* Springer International Publishing, 2023, 219–34.

submit product-related data in a harmonized format, supporting streamlined regulatory review and approval processes across multiple EU jurisdictions. This standardization is particularly advantageous for multicenter trials, where coordinating regulatory requirements between countries can be complex and resource intensive.

SPOR services, particularly PMS and SMS, provide a foundation for consistent data handling in clinical trials. Enhanced SPOR APIs now support real-time data exchange, allowing clinical trial information to be dynamically updated. Furthermore, updated submission pathways enable sponsors to submit investigational product data in IDMP-compliant formats, providing streamlined data processing and regulatory review across jurisdictions. These advancements represent a crucial step toward fully standardized clinical trial submissions.

3.6. Electronic Product Information

EMA in collaboration with the EC, aims to advance patient safety and accessibility through the Electronic Product Information (ePI) initiative. ePI offers healthcare professionals and patients up-to-date, standardized information on medicinal products, digitizing what has traditionally been available in leaflets and labels, and making it readily accessible through electronic platforms. Supported under the EU's Digital Health and Care Strategy, the ePI initiative aligns with the IDMP framework and the UNICOM project, which promote cross-border healthcare interoperability. By standardizing product information and utilizing a common EU format, ePI enables healthcare providers and patients to make informed decisions based on accurate, accessible information across the medicinal product lifecycle.[35, 36, 37]

The ePI initiative, developed by the EMA in collaboration with the Heads of Medicines Agencies (HMA) and EC, has made substantial progress. This standard, based on Fast Healthcare Interoperability Resources (FHIR), supports efficient electronic handling and dissemination across digital platforms, enabling easy access via web, e-platforms, and printable formats. Initial pilot projects conducted by the EMA and national competent authorities have demonstrated that ePI can improve

[35] EUROPEAN MEDICINES AGENCY. *Electronic Product Information (ePI) | European Medicines Agency (EMA).* 2022 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi"language":"en","title":"Electronic product information (ePI

[36] EUROPEAN MEDICINES AGENCY. *Electronic Product Information for Human Medicines in the European Union – Key Principles* | European Medicines Agency (EMA). 2020 [online]. Available at: https://www.ema.europa.eu/en/electronic-product-information-human-medicines-european-union-key-principles

[37] Welzijn en Sport Ministerie van Volksgezondheid. *Electronic Product Information: A Paradigm Shift for Better Use – Regulatory Scienc* [online]. Available at: https://www.regulatoryscience.nl/editions/2022/14/electronic-product-information-a-paradigm-shift-for-better-use

regulatory processes by providing a uniform and consistent product data source across the EU.[38]

ePI enhances accessibility and safety by providing patients and healthcare professionals with on-demand access to accurate medicinal product information, promoting safe use and improving health outcomes. With multilingual capabilities, ePI also addresses language barriers, making it more accessible across the EU's diverse patient population. Increased regulatory efficiency is another advantage, as the ePI format enables marketing authorization holders (MAHs) and regulatory bodies to update product information swiftly, allowing quicker responses to safety concerns and streamlining data management across Member States. This efficiency reduces paperwork and improves data traceability for regulatory authorities and the pharmaceutical industry. Furthermore, the ePI framework is designed for future integration with electronic health records (EHR) and other e-health systems, facilitating seamless connection with healthcare workflows and enabling automated access to the latest product information directly within clinical and pharmacy systems.[39]

Implementing ePI within the IDMP framework involves several challenges. Differences in digital infrastructure, such as outdated IT systems and varying levels of digital maturity among Member States, have affected uniform ePI deployment. The transition to digital product information necessitates robust data privacy measures, especially as ePI integrates with e-health systems. [40]

4. Progress and Challenges in IDMP Implementation

4.1. Progress and Challenges – Health Authorities perspective

The implementation of ISO IDMP standards is transformative for national health authorities (NHAs), requiring significant updates to medicinal product data management. To meet IDMP standards, NHAs must standardize data, upgrade IT systems, migrate legacy data, align regulatory processes, and support cross-border and digital health services. This involves harmonizing data across substances, products, and organizations, while incorporating the EMA's SPOR services.[41]

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38 EUROPEAN MEDICINES AGENCY. *Electronic Product Information for Human Medicines in the European Union – Key Principles | European Medicines Agency (EMA)*.

39 EUROPEAN MEDICINES AGENCY.

40 Ministerie van Volksgezondheid. *Electronic Product Information.*

41 EUROPEAN MEDICINES AGENCY. *Product Management Service (PMS) – Implementation of International Organization for Standardization (ISO) Standards for the Identification of Medicinal Products (IDMP) in Europe* online]. Available at: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/product-management-services-pms-implementation-international-or

Achieving IDMP compliance requires NHAs to undertake extensive IT system upgrades. This process involves two main actions: database refactoring, where databases are restructured to align with IDMP standards for consistent data management, and integration with the EMA's SPOR system. Full IDMP implementation requires synchronizing national data with European standards through API connections and data migration tools, enabling seamless data exchange between national databases and the EMA's SPOR services.[42]

Legacy data migration is essential for NHAs to achieve IDMP compliance. This includes mapping existing data to IDMP-compliant fields for substances, products, and referentials. NHAs must also cleanse and standardize historical medicinal product data, such as marketing authorizations and packaging details, to align with IDMP standards. This often entails significant data verification and transformation efforts.[43]

NHAs must also update regulatory submission processes to align with IDMP standards, which includes adapting eAF to incorporate IDMP-compliant data structures. This standardization promotes consistent regulatory submissions across the EU and enhances communication between authorities. Additionally, IDMP compliance is crucial for cross-border healthcare services such as e-prescriptions and patient summaries, which require data interoperability to ensure medicinal products prescribed in one country are recognized in another.[44]

Collaborative efforts among NHAs, EMA, and international entities are critical for IDMP implementation. NHAs are participating in European initiatives such as UNICOM to develop best practices for data migration, system updates, and regulatory alignment.[45] Collaboration with the EMA and other NHAs ensures system compatibility across countries, enhancing the standardization process.

4.2. Progress and Challenges – Pharmaceutical Industry

For pharmaceutical companies, IDMP initially represents regulatory requirements that must be adhered to. Failure to comply with these requirements could result in

ganization-standardization-iso-standards-identification-medicinal-products-idmp-europe-chapter-2_en.pdf

42 KUIVAMÄKI, Mika, KALLIO, Marko. *D4.3: Finland: Progress Report on Refactoring or New Build of National IT Systems, Migration of National Data, and Data Interfaces to EMA's SPOR, UNICOM, WP4 IDMP Implementation at National Drug Agencies.* 2021 [online]. Available at: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.3_Finland_Progress-report-on-implementation_20210131.pdf

43 Ministerie van Volksgezondheid. *Electronic Product Information.*

44 Ministerie van Volksgezondheid.

45 NEUWIRTHER, Geord, LAIMER, Harald. *D4.1: Austria: Progress Report on Implementation. WP4 IDMP Implementation at National Drug Agencies. UNICOM.* 2021 [online]. Available at: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.1_Austria_Progress-report-on-implementation_20210201.pdf

penalties, delays in product approvals, and hindered ability to bring products to market.[46]

Traditionally, regulatory departments in pharmaceutical companies submitted documents, rather than data, to regulatory authorities. In 2012, the industry began providing some data for Marketing Authorization Applications (MAAs) under xEVMPD. With the introduction of IDMP requirements, companies must now prepare to submit data at the beginning of regulatory activities for new medicines or variations.[47] These requirements also extend beyond regulatory data, potentially including information from various other sources.

Beyond compliance, more companies are beginning to explore the additional value that IDMP can provide. For pharmaceutical companies, IDMP enables data connectivity along the entire value chain, including research and development, clinical, manufacturing, and commercial operations. IDMP data standards bridge the gap between regulatory and supply chain, enabling a unified language for products and active substances. Previously, the supply chain, regulatory, pharmacovigilance, and clinical functions often used different names for the same products and active substances.[48] With IDMP, these domains can adopt a unified language, enabling shared data and terminology that streamline manufacturing, supply chain operations, and patient information exchange.

The transition to IDMP compliance is challenging for the pharmaceutical industry, as companies must address issues related to data management, system integration, and regulatory coordination. Data must be collected from several functional areas, including regulatory affairs, pharmacovigilance, supply chain, and quality assurance. Unlike xEVMPD, existing processes within life sciences companies need to be amended to collect more data from an earlier stage in the process.[49] A primary challenge lies in the migration and standardization of legacy data, given the historical diversity in data formats across regions. Harmonizing product names, ingredients, dosages, and packaging information requires extensive data cleansing and standardization, particularly

[46] DELOITTE. *The Building Blocks of IDMP Implementation | Deloitte | Life Sciences and Health Care* [online]. Available at: https://www2.deloitte.com/lk/en/pages/life-sciences-and-healthcare/articles/building-blocks-of-idmp-implementation.html2023, [online]. Available at: <https://www2.deloitte.com/lk/en/pages/life-sciences-and-healthcare/articles/building-blocks-of-idmp-implementation.html>.","plainCitation":"DELOITTE, "The Building Blocks of IDMP Implementation | Deloitte | Life Sciences and Health Care," Deloitte, accessed October 29, 2023, [online]. Available at: <https://www2.deloitte.com/lk/en/pages/life-sciences-and-healthcare/articles/building-blocks-of-idmp-implementation.html>.","noteIndex":46},"citationItems":[{"id":3,"uris":["http://zotero.org/users/12860252/items/UT974UGM"],"itemData":{"id":3,"type":"webpage","abstract":"The benefits of meeting the evolving Identification of Medicinal Product (IDMP

[47] THOMAS, Felicity. Coming Up to ISO IDMP Standards. *Pharmaceutical Technology*, Pharmaceutical Technology, 2021, vol. 45, no. 1 [online]. Available at: https://www.pharmtech.com/view/coming-up-to-iso-idmp-standards

[48] JAMIL. Assessing Pharma's Readiness for Digital Product Information Management.

[49] THOMAS. Coming Up to ISO IDMP Standards.

for companies operating in multiple markets with varying regulatory requirements. Furthermore, inconsistent data sources and poor-quality data exacerbate these difficulties, requiring thorough data verification and restructuring to ensure compliance.[50, 51]

The global nature of the pharmaceutical industry adds to the complexity of IDMP compliance, requiring alignment with both global standards and regional regulations, such as those of the EMA and the FDA. This necessitates standardizing regulatory submissions via IDMP-compliant eAFs and ensuring that data meets varying regional standards. Additionally, the evolving nature of IDMP guidelines – with ongoing updates from the EMA's SPOR services and other evolving requirements such as eCTD 4.0, the regulation on medical devices (MDR), and in vitro diagnostic devices (IVDR) – poses compliance challenges for companies as they strive to adapt to these changing requirements.[52]

Pharmaceutical companies must upgrade or replace IT systems to handle IDMP-compliant data. This typically involves updating Regulatory Information Management (RIM) and/or Product Lifecycle Management (PLM) systems and integrating them with external databases such as the EMA's SPOR portal to facilitate regulatory submissions and data exchange.[53] To enable data exchange with EMA's SPOR services, typically **Application Programming Interfaces (**API) development is required for data transfer between internal databases and external regulatory systems, allowing for the consistent sharing of product data. Also, companies should consider cross-functional reporting capabilities that will allow different departments and systems to share SPOR data.

Implementing IDMP requires significant resource and budget allocation, as well as extensive cross-functional collaboration. Companies must invest in technology upgrades, data migration, and staff training. Budgets need to be allocated for IT system refactoring, purchasing new software tools, and integrating with external regulatory databases. Compliance with IDMP is not a one-time effort and requires sustained resource allocation, including continuous data management and system updates.[54] Effective implementation also requires cross-functional coordination, with regulatory,

[50] MUNNIK, Remco. EMA's New Guide to Implementing IDMP Triggers the Countdown to Change. *European Pharmaceutical Review*. 2021 [online]. Available at: https://www.europeanpharmaceuticalreview.com/article/144651/emas-new-guide-to-implementing-idmp-data-standards-triggers-the-countdown-to-change

[51] STULP, Frits. IDMP – Transforming Medicine Management with Global Data Standards. *American Pharmaceutical Review – The Review of American Pharmaceutical Business & Technology*. 2021 [online]. Available at: https://www.americanpharmaceuticalreview.com/Featured-Articles/573336-IDMP-Transforming-Medicine-Management-with-Global-Data-Standards

[52] DELOITTE. The New European Union Medical Devices Regulation. *Deloitte | Life Sciences and Healthcare.* 2016 [online]. Available at: https://www2.deloitte.com/lk/en/pages/life-sciences-and-healthcare/articles/new-european-union-medical-devices-regulation.html

[53] UNICOM. *Implementing IDMP to Improve Patient Safety and Facilitate Better Healthcare for All* [online]. Available at: https://unicom-project.eu/wp-content/uploads/2020/10/snomed-CT-1.pdf

[54] MUNNIK. EMA's New Guide to Implementing IDMP Triggers the Countdown to Change.

IT, and supply chain departments collaborating. Since IDMP introduces new data standards and workflows, companies must invest in training employees and change management programs to ensure successful implementation. Staff need to be trained on using new data formats, handling updated submission procedures, and maintaining consistent compliance.[55]

4.3. Progress and Challenges – Third party vendors

Third-party vendors play a critical role in helping pharmaceutical companies achieve IDMP compliance through providing specialized software tools, such as advanced RIM (Regulatory information management) systems. RIMs are IT solutions used by regulatory affairs to oversee the regulatory approval process and ongoing maintenance of products for commercial use. These systems support regulatory content management, dossier creation, submission publishing, market registration tracking, product labelling, and interactions with health authorities, including commitment monitoring.[56] Several RIM vendors are trying to upgrade their RIM systems to support IDMP data structure and prepare data for submission to EMA.

Some software vendors provide tools that help extract, standardize, and structure the required data elements from IDMP-relevant unstructured text documents, including Summary of Product Characteristics (SmPC); Manufacturing licenses; and the regulatory dossier, e. g. Chemistry, Manufacturing and Control (CMC) documents, e. g. by using natural language processing (NLP) technology.[57] Vendors also offer data integration and migration tools to consolidate information from various sources and ensure that legacy data aligns with IDMP requirements. Additionally, consultancy companies assist pharmaceutical companies in managing RIM implementation or upgrade projects by assessing needs, developing strategies, selecting vendors, and managing IT system implementation projects.

The demand for third-party vendors providing IDMP-compliant software, particularly RIM systems, is substantial. The pharmaceutical industry is expected to continue its heavy investment in these technologies as regulatory compliance becomes more complex and international. However, software vendors face challenges in real-time RIM system integration and customization, as they must adapt systems to meet the diverse regulatory needs of pharmaceutical companies operating in various international markets. Balancing standardized RIM offerings with flexibility for regional adaptations remains a vendor challenge.

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[55] STEGWEE, Robert. Implementing IDMP to Improve Patient Safety and Facilitate Better Healthcare for All.

[56] SMITH, Jeff. Market Guide for Life Science Regulatory Information Management Solutions. *Gartner.* 2024 [online]. Available at: https://www.gartner.com/doc/reprints?id=1-2JBWS6S8&ct=241112&st=sb&submissionGuid=a43b4fcf-0799-46f8-8fe4-971724f78efd

[57] LINGUAMATICS. *Regulatory Affairs | Linguamatics* [online]. Available at: https://www.linguamatics.com/solutions/team/regulatory-affairs

5. Case studies

5.1. IDMP Implementation in Austria

Austria has taken a comprehensive approach to implementing ISO IDMP standards through its national regulatory authority, the Austrian Medicines Agency (AGES), as part of UNICOM. Central to Austria's efforts is the refactoring of its PHAROS data system, which manages medicinal product data. This refactoring involves updating core data elements, including ingredients, manufactured items, and packaging information, to comply with IDMP specifications. The goal is to ensure that Austria's national product database aligns seamlessly with other European databases, such as the EMA's SPOR system, including integration with the SPOR portal managed by the European Medicines Agency (EMA).[58]

Austria's participation in the UNICOM project further supports its goals, particularly in cross-border e-prescription services and interoperable digital health solutions. AGES has been working closely with other national and European agencies, as well as participating in workshops and collaborations through the UNICOM Work Packages. This cooperation focuses on developing best practices for IDMP data migration, creating user stories and use cases for IDMP-compliant systems, and ensuring a smooth transition to a fully IDMP-compliant medicinal product database.[59]

The implementation of IDMP in Austria has faced challenges, including the complexity of data migration and ensuring alignment with European standards. Despite these challenges, Austria has made significant progress by initiating data cleansing processes, adjusting its PHAROS system to accommodate IDMP data structures, and conducting pilot projects to test IDMP compatibility with national and cross-border eHealth services.[60]

5.2. IDMP Implementation in Finland

Finland has made substantial progress in implementing ISO IDMP standards, an effort led primarily by the Finnish Medicines Agency (Fimea) as part of the UNICOM project. Central to this process is updating national medicinal product registers, enhancing data accuracy, and facilitating cross-border healthcare services such as e-prescriptions.

A key component of Finland's implementation strategy is the deployment of a new marketing authorisation and medicines register, Saga, which replaced the old Fimea's iRis system to align with ISO IDMP standards. This also included implementation of 14 data integrations. Additionally, Fimea has taken significant steps by migrating and cleansing legacy data between iRis and Saga. Another critical step in Finland's

[58] NEUWIRTHER, LAIMER. *D4.1: Austria: Progress Report on Implementation.*
[59] NEUWIRTHER, LAIMER.
[60] NEUWIRTHER, LAIMER.

approach to IDMP compliance is the integration with the EMA's SPOR system. Finland has already established test access to SPOR services and is working toward finalizing production APIs to ensure that medicinal product data in Fimea's registers conforms with EMA standards. [61]

Fimea is collaborating with Kela, the Finnish Social Insurance Institution, to create an IDMP compliant pharmaceutical register. This database will support various eHealth services, including e-prescriptions, by standardizing medicinal product information. Ensuring IDMP compliance aims to improve the accuracy of medicinal product information used in healthcare.[62]

A critical aspect of Finland's IDMP integration process involves data cleansing and mapping to meet IDMP specifications. Fimea has undertaken data mapping and cleansing to harmonize its existing medicinal product data with IDMP requirements. Future tasks will involve working with Substance Management Services (SMS) and Product Management Services (PMS) once the EMA publishes the final guidelines, which will enable Finland to fully implement these systems in compliance with IDMP standards.[63]

Despite progress, Finland was facing challenges related to data migration and system integration. However, ongoing efforts aim to address these hurdles, with further tasks including finalizing data models, enhancing e-prescription systems, and refining data exchange processes with Kela and other national stakeholders. Finland remains committed to achieving a fully integrated IDMP-compliant healthcare and regulatory system, with key future initiatives focused on supporting cross-border health services, ensuring data interoperability, and continuing collaborations within the European regulatory framework.

5.3. IDMP Implementation in Estonia

Estonia has made significant progress in the implementation of ISO IDMP standards, primarily through the **Estonian State Agency of Medicines (EESAM) participating in the UNICOM project.**

The medicinal product data, previously managed in SamTrack database – Estonia's central repository for medicinal product data – has been cleansed and mapped in order to prepare for a new SamTrack II IT system. Estonia has also started migrating legacy data into IDMP-compliant formats, including cleansing and mapping existing medicinal product information to align with ISO IDMP and SPOR requirements.[64] The

[61] KUIVAMÄKI, KALLIO. *D4.3: Finland: Progress Report on Refactoring or New Build of National IT Systems, Migration of National Data, and Data Interfaces to EMA's SPOR.*

[62] KUIVAMÄKI, KALLIO.

[63] KUIVAMÄKI, KALLIO.

[64] SILLA, Toomas, MÄESALU, Triin, MIRJOZEV, Raheeli. *D4.2: ESTONIA: Progress Report on Implementation. WP4 IDMP Implementation at National Drug Agencies. UNICOM: EESAM.* 2021

focus of mapping and cleansing activities has been mainly related to organisations and referentials.

Estonia's initiatives also include developing a prototype of an IDMP-compatible data feed for the Medicinal Product Register, which supports e-prescription and e-dispensation services. This ensures that medications prescribed or dispensed in one country are identified consistently and recognized in another, enhancing cross-border healthcare. Furthermore, Estonia is contributing to the broader European effort to enable cross-border digital health services by integrating IDMP standards into their eHealth Digital Service Infrastructure (eHDSI). This integration facilitates streamlined services, such as e-prescriptions and patient summaries, across EU member states.

Estonia was facing challenges in data migration and ensuring full interoperability with European systems, however significant progress has been made in implementing the SamTrack II database. Furthers steps involved integration with the EMA's SPOR services and continuing the data cleansing efforts, particularly in pharmaceutical substances and products.[65]

5.4. IDMP Implementation in Pharma Industry – Novartis

Novartis began implementation of IDMP in 2014, with an initial plan to be ready by 2016, focusing on RIM implementation. During the early implementation phase (2014–2015), Novartis launched IDMP workstreams to establish structured data practices and plan for alignment with the EMA's SPOR (Substance, Product, Organization, and Referential) data management requirements, building foundational support for IDMP compliance by 2016. From 2017 to 2022, Novartis expanded its efforts for enterprise-wide adoption by involving non-regulatory associates and launching the RIM replacement project. This project, however, had to be terminated and evolved into a RIM solution upgrade, that was creating 45% of necessary data. Novartis also implemented an additional Master Data Management (MDM) solution to collect the remaining required data. It was identified that the terms between regulatory and manufacturing are not aligned and therefore there is a strong need to establish a master data management with data governance.

To address these challenges, a dedicated SPOR team was established to oversee the onboarding process and to align data governance across both existing and new systems. In 2021, cross-functional teams from Regulatory Affairs operations, Product Lifecycle Management (PLM), and MDM were engaged, supported by training, knowledge-sharing sessions, and a centralized SharePoint resource that includes newsletters, external links, documents, and contact points for staff guidance. With the EMA's revised strategy in 2022, including the DADI and PLM portal for CAPs,

[online]. Available at: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.2_Estonia-Progress-report-on-implementation_20210131.pdf

[65] SILLA, MÄESALU, MIRJOZEV.

Novartis focused on further alignment to integrate evolving standards for data submission and packaging requirements related to drug shortages, with a target completion by 2025.

Novartis faced several key challenges and cultural shifts in its transition to a data-driven regulatory approach. Ensuring master data management and governance was crucial, as robust data governance practices were needed to break down silos and promote consistent data usage across regulatory and manufacturing domains. Stakeholder and change management also played a central role, with senior management actively engaged and structured change management practices in place. Regular communication on the benefits of moving from document-based to data-centric models has helped maintain alignment across the organization. Additionally, Novartis remains focused on ongoing maintenance and adaptability, especially as standards continue to evolve with expected IDMP updates in 2024. Feedback from stakeholders is continuously leveraged to refine and enhance data governance and data submission processes.

The journey is not merely a technical upgrade but is reshaping Novartis‘ internal culture, promoting cross-functional collaboration, encouraging feedback, and creating development opportunities to ensure a sustainable transition to a fully data-driven organization.[66]

6. Technology and Future directions

The implementation of the Identification of Medicinal Products (IDMP) standards is closely linked to broader trends in digital transformation, particularly in healthcare. Application of key technologies such as artificial intelligence (AI), machine learning, and big data analytics could benefit significantly from standardized data formats like those provided by IDMP.

With IDMP-compliant data, healthcare stakeholders can explore novel applications in data analytics, enabling more sophisticated insights into medicinal product trends and patient outcomes. The structured data provided by IDMP will be able to support big data initiatives across healthcare systems, enabling predictive analytics and advanced drug monitoring.[67] Health authorities and pharmaceutical companies could have access to aggregated data across borders, enabling to assess patterns in drug utilization, efficacy, and safety. Pharmaceutical companies could leverage IDMP-compliant data in AI models to identify potential safety signals earlier in the product lifecycle, accelerating the drug development process. Furthermore, the integration

[66] CAHEN, Jean-Michel. Industry Case Study: How to Prepare the Organization in View of IDMP/SPOR/PLM. Novartis Pharma AG. *GRPAS 2023*, Brussels, October 24, 2023.

[67] ELZ, Sheila R. et al. The IDMP Ontology – A Catalyst to Unleash the Potential of AI and Accelerate Data-Driven Decisions with Industry-Wide Standards. *Drug Discovery Today*. 2024, vol. 29, no. 6, pp. 104017, DOI: 10.1016/j.drudis.2024.104017.

of machine learning algorithms into IDMP data will allow companies to simulate real-world outcomes, refining product safety protocols before market entry.

IDMP-compliant data can also contribute to interoperability between different health IT systems, such as electronic health records (EHRs), clinical trial management systems (CTMS), and pharmacovigilance databases. This enhanced interoperability supports a holistic view of medicinal products and their impact, not only in clinical settings but throughout the entire lifecycle of the product. Support of cross-border e-prescriptions and patient summary services facilitates healthcare interoperability and ensures continuity of care for mobile populations within the European Union and beyond. Cross-border interoperability facilitated by IDMP improve speed and coordination of responses to global health challenges, such as pandemics or medication shortages.

Moreover, IDMP's structured framework can enhance digital health applications, such as telemedicine and mobile health apps, by ensuring accurate and consistent drug information. Patients will benefit from more reliable tools for medication management, reminders, and adherence tracking. These advancements will empower patients to take a more active role in their healthcare, improving engagement and outcomes. In the long term, the integration of IDMP-compliant data with emerging technologies like blockchain, IoT, and AI could reshape the pharmaceutical landscape. Blockchain can ensure secure and transparent data sharing across stakeholders, while IoT devices equipped with IDMP identifiers can monitor medication usage in real time. Together, these innovations will drive a future where healthcare systems are interconnected, patient-centric, and continuously optimized to deliver superior care.

7. Conclusions

The adoption of the Identification of Medicinal Products (IDMP) standards marks a major milestone in harmonizing healthcare data, improving safety, and driving efficiency within the pharmaceutical and healthcare sectors. By establishing a unified framework for medicinal product identification, IDMP addresses key challenges such as inconsistent data standards, fragmented regulatory processes, and barriers to interoperability.

IDMP facilitates the exchange of structured medicinal product information across systems, organizations, and borders, ensuring consistency in data formats. This harmonization enhances collaboration among stakeholders and strengthens the reliability of healthcare information. By standardizing drug identification and enabling real-time data sharing, IDMP is anticipated to reduce medication errors and improve pharmacovigilance, ultimately contributing to enhanced patient safety through quicker responses to adverse drug reactions and more informed clinical decision-making.

Furthermore, the adoption of IDMP is expected to streamline regulatory processes, from drug approval to post-market surveillance. Leveraging IDMP-compliant data within digital platforms helps pharmaceutical companies and regulatory bodies reduce administrative burdens, increase accuracy, and accelerate the time-to-market for medicinal products. The integration of IDMP standards across healthcare and pharmaceutical operations not only bolsters the global healthcare ecosystem but also lays the foundation for future innovations.

As IDMP adoption accelerates, especially in the EU with the EMA‘s SPOR portal, its true impact lies in cross-border application, ensuring consistent product identification and monitoring globally. For multinational pharmaceutical companies, IDMP can streamline submissions, reduce costs, and accelerate registrations. However, achieving truly global benefits of IDMP requires addressing regional differences in regulations, such as Europe‘s GDPR. Ongoing collaboration and adaptive guidelines are crucial for effective implementation across diverse regions.

The adoption of the ISO IDMP standards marks a significant step toward achieving a unified, interoperable, and standardized medicinal product framework globally. However, realizing the full potential of IDMP requires overcoming several critical challenges. Widespread implementation necessitates robust and scalable IT infrastructure, especially for smaller pharmaceutical companies and national health authorities that lack the necessary resources for compliance. Addressing these disparities is essential to ensure equitable adoption and prevent gaps that could compromise data quality and interoperability. NCAs play a crucial role in ensuring the effective implementation of IDMP to unlock its full potential. Additionally, IDMP compliance is vital for cross-border healthcare services such as e-prescriptions and patient summaries.

The constantly evolving regulatory landscape means that IDMP standards must remain agile. Regular updates and revisions are necessary to align with new therapeutic developments, such as cell and gene therapies. A coordinated approach to updating IDMP standards – featuring contributions from regulatory bodies, industry players, and other stakeholders – will be essential for maintaining their relevance.

A shift in mindset is also essential across the pharmaceutical industry. Beyond mere compliance, the industry must recognize the broader value of IDMP in streamlining processes, enhancing patient safety, and enabling seamless data exchange across the value chain. Integrating IDMP into organizational digital strategies, rather than viewing it as a regulatory burden, could yield significant long-term benefits, including improved operational efficiency and data quality.

Collaboration among stakeholders – including health authorities, pharmaceutical companies, and third-party vendors – is central to the successful implementation of IDMP. Initiatives such as UNICOM highlight the importance of aligning regional efforts and sharing best practices to create a cohesive implementation roadmap.

As IDMP matures, its integration with advanced digital technologies will not only optimize pharmaceutical processes but also redefine patient safety and healthcare

delivery on a global scale. Stakeholders in healthcare must invest in these intersections to fully realize the potential of IDMP in transforming the pharmaceutical and regulatory landscapes.

Future research should focus on ensuring compatibility between IDMP and other global health data standards while addressing the challenges of data privacy and security. As IDMP standards evolve, leveraging advanced digital technologies such as artificial intelligence and machine learning will further enhance their impact, optimizing pharmacovigilance, regulatory processes, and, ultimately, patient care.

List of references

CAHEN, Jean-Michel. Industry Case Study: How to Prepare the Organization in View of IDMP/SPOR/PLM. Novartis Pharma AG. GRPAS 2023. Brussels, October 24, 2023.

DELOITTE. The Building Blocks of IDMP Implementation. Deloitte | Life Sciences and Health Care [online]. Available at: https://www2.deloitte.com/lk/en/pages/life-sciences-and-healthcare/articles/building-blocks-of-idmp-implementation.html

DELOITTE. The New European Union Medical Devices Regulation. Deloitte | Life Sciences and Healthcare. 2016 [online]. Available at: https://www2.deloitte.com/lk/en/pages/life-sciences-and-healthcare/articles/new-european-union-medical-devices-regulation.html

ELZ, Sheila R., KLEEMANN, Gerd R., OSTHUS, Torsten, PETRACCHI, Martin, SERGENT, Raphael. The IDMP Ontology – A Catalyst to Unleash the Potential of AI and Accelerate Data-Driven Decisions with Industry-Wide Standards. Drug Discovery Today. 2024, vol. 29, no. 6, pp. 104017. DOI: 10.1016/j.drudis.2024.104017.

EUROPEAN MEDICINES AGENCY. Data on Medicines (ISO IDMP Standards): Overview | European Medicines Agency (EMA). 2016. [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview

EUROPEAN MEDICINES AGENCY. Electronic Product Information (ePI) | European Medicines Agency (EMA). 2022 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/marketing-authorisation/product-information-requirements/electronic-product-information-epi

EUROPEAN MEDICINES AGENCY. Electronic Product Information for Human Medicines in the European Union – Key Principles | European Medicines Agency (EMA). 2020. [online]. Available at: https://www.ema.europa.eu/en/electronic-product-information-human-medicines-european-union-key-principles

EUROPEAN MEDICINES AGENCY. Introduction to ISO Identification of Medicinal Products, SPOR Programme. 2016 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview

EUROPEAN MEDICINES AGENCY. Product Management Service (PMS) – Implementation of International Organization for Standardization (ISO) Standards for the Identification of Medicinal Products (IDMP) in Europe. 2022 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-stand

ards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services

EUROPEAN MEDICINES AGENCY. Referentials Management Service (RMS) | European Medicines Agency (EMA). 2016 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/referentials-management-service-rms

EUROPEAN MEDICINES AGENCY. SPOR (ISO IDMP) Task Force | European Medicines Agency (EMA). 2015 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/spor-iso-idmp-task-force

EUROPEAN MEDICINES AGENCY. Substance and Product Data Management Services | European Medicines Agency (EMA). 2024 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data/substance-product-data-management-services

EUROPEAN MEDICINES AGENCY. Substance, Product, Organisation and Referential (SPOR) Master Data | European Medicines Agency (EMA). 2016 [online]. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/research-development/data-medicines-iso-idmp-standards-overview/substance-product-organisation-referential-spor-master-data

HAMUĽÁK, O. *National Sovereignty in the European Union: View from the Czech Perspective*. Springer, 2016.

JAMIL, Adnan. Assessing Pharma's Readiness for Digital Product Information Management. European Pharmaceutical Review. 2021 [online]. Available at: https://www.europeanpharmaceuticalreview.com/article/159996/assessing-pharmas-readiness-for-digital-product-information-management

KUIVAMÄKI, Mika, and Marko KALLIO. D4.3: Finland: Progress Report on Refactoring or New Build of National IT Systems, Migration of National Data, and Data Interfaces to EMA's SPOR. UNICOM. WP4 IDMP Implementation at National Drug Agencies. Fimea. 2021 [online]. Available at: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.3_Finland_Progress-report-on-implementation_20210131.pdf

LINGUAMATICS. Regulatory Affairs | Linguamatics [online]. Available at: https://www.linguamatics.com/solutions/team/regulatory-affairs

MASKELL, Catherine. Pistoia Alliance Launches Freely Available IDMP Ontology 1.0, Covering All Five Standards Set by ISO. Pistoia Alliance (blog). 2024 [online]. Available at: https://www.pistoiaalliance.org/news/press-release-pistoia-alliance-launches-idmp-1-0/

MASKELL, Catherine. Pistoia Alliance Launches New Identification of Medicinal Product Ontology Project to Align Data Standards, Accelerate Innovation, and Improve Patient Safety. Pistoia Alliance (blog). 2022 [online]. Available at: https://www.pistoiaalliance.org/news/pistoia-alliance-launches-new-identification-of-medicinal-product-ontology-project/

MERRILL, Alice. IDMP at the EMA: The European Shortage Monitoring Platform. Ennov Software for Life (blog). 2024 [online]. Available at: https://en.ennov.com/blog/regulatory-blog/idmp-ema-european-shortage-monitoring-platform/

Ministerie van Volksgezondheid, Welzijn en Sport. Electronic Product Information: A Paradigm Shift for Better Use – Regulatory Science. Ministerie van Volksgezondheid, Welzijn en Sport [online]. Available at: https://www.regulatoryscience.nl/editions/2022/14/electronic-product-information-a-paradigm-shift-for-better-use

MUNNIK, Remco. EMA's New Guide to Implementing IDMP Triggers the Countdown to Change. European Pharmaceutical Review. 2021 [online]. Available at: https://www.europeanpharmaceuticalreview.com/article/144651/emas-new-guide-to-implementing-idmp-data-standards-triggers-the-countdown-to-change

NEUWIRTHER, Georg, LAIMER, Harald. D4.1: Austria: Progress Report on Implementation. WP4 IDMP Implementation at National Drug Agencies. UNICOM: AGES. 2021 [online]. Available at: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.1_Austria_Progress-report-on-implementation_20210201.pdf

RAJENDRAN, Mallikaarjunan. Challenges and Benefits of Implementing IDMP in the Pharmaceutical Industry. PharmaCommerce. 2024 [online]. Available at: https://www.pharmaceuticalcommerce.com/view/challenges-and-benefits-of-implementing-idmp-in-the-pharmaceutical-industry

SILLA, Toomas, MÄESALU, Triin, MIRJOZEV, Raheeli. D4.2: ESTONIA: Progress Report on Implementation. WP4 IDMP Implementation at National Drug Agencies. UNICOM: EESAM. 2021 [online]. Available at: https://unicom-project.eu/wp-content/uploads/2022/01/UNICOM_D4.2_Estonia-Progress-report-on-implementation_20210131.pdf

SMITH, Jeff. Market Guide for Life Science Regulatory Information Management Solutions. Gartner. 2024 [online]. Available at: https://www.gartner.com/doc/reprints?id=1-2JBWS6S8&ct=241112&st=sb&submissionGuid=a43b4fcf-0799-46f8-8fe4-971724f78efd

STEGWEE, Robert. Implementing IDMP to Improve Patient Safety and Facilitate Better Healthcare for All. 2020.

STROETMAN, Karl A. The Univocal Identification and Safe Dispensation of Medicinal Products across Europe – Challenges and Solution Proposal. GMS Medizinische Informatik, Biometrie Und Epidemiologie. 2017, vol. 13, no. 27, Doc09. DOI:10.3205/mibe000176.

STULP, Frits. IDMP – Transforming Medicine Management with Global Data Standards. American Pharmaceutical Review – The Review of American Pharmaceutical Business & Technology. 2021 [online]. Available at: https://www.americanpharmaceuticalreview.com/Featured-Articles/573336-IDMP-Transforming-Medicine-Management-with-Global-Data-Standards

THOMAS, Felicity. Coming Up to ISO IDMP Standards. Pharmaceutical Technology, 2021, vol. 45, no. 1 [online]. Available at: https://www.pharmtech.com/view/coming-up-to-iso-idmp-standards

UNICOM. UNICOM Project [online]. Available at: https://unicom-project.eu/

UNICOM. Implementing IDMP to Improve Patient Safety and Facilitate Better Healthcare for All [online]. Available at: https://unicom-project.eu/wp-content/uploads/2020/10/snomed-CT-1.pdf

UNICOM WP5 Members. D5.6: Guidelines to Implement IDMP in National eHealth Services. WP5 – IDMP Adoption by eHealth Services. UNICOM. 2022 [online]. Available at: https://unicom-project.eu/wp-content/uploads/2023/11/UNICOM_D5.6_Guidelines-to-implement-IDMP-in-National-eHealth-Services_PU_approved-1.pdf

U.S. FOOD AND DRUG ADMINISTRATION. Identification of Medicinal Products (IDMP). FDA. 2022 [online]. Available at: https://www.fda.gov/industry/fda-data-standards-advisory-board/identification-medicinal-products-idmp

VARDANYAN, L., KOCHARYAN, H., HAMUĽÁK, O., KERKIMÄE, T. Digital Sovereignty in the EU: Searching for Legal Mechanisms for Marking the Borders. *Digital Development of the European Union: An Interdisciplinary Perspective.* 219–34. Springer International Publishing, 2023.

WILLIAMS, Amy. What Lies Ahead for IDMP? European Pharmaceutical Review [online]. Available at: https://www.europeanpharmaceuticalreview.com/article/172039/what-lies-ahead-for-idmp/