This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No. 875299

Project full title: Up-scaling the global univocal identification of medicines

Call identifier: H2020-SC1-DTH-2019

Deliverable D10.2:
Interim report on cost benefit data collection

Version:	1.0
Status:	Final
Dissemination Level[1]:	PU
Due date of deliverable:	30.11.2022
Actual submission date:	03.01.2023
Work Package:	WP10: Socio-economic impact, legal and governance aspects
Lead partner for this deliverable:	EMP
Partner(s) contributing:	na
Deliverable type[2]:	R

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[1] Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

[2] Type of the deliverable: R: Document, report; DEM: Demonstrator, pilot, prototype; DEC: Websites, patent fillings, videos, etc.; OTHER; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot

Revision History

Version	Date	Changes made	Author(s)
0.1	05.07.2022	Structure, content, and key messages	ST, MM
0.2	09.08.2022	Initial draft of Chapters 3-4	ST, MM
0.3	14.09.2022	Initial draft of Chapters 5 and 6	ST, MM
0.4	30.09.2022	Initial draft of Chapters 7 and 8	ST, MM
0.5	07.10.2022	Formatting changes, and increased content for Chapters 3 and 4	ST, MM
0.6	12.11.2022	Increased content for Chapters 5 and 6	ST, MM
0.7	20.11.2022	Revised content and structural changes to Chapter 5-8	ST, MM
0.8	29.11.2022	Completion of conclusion, executive summary, and abstract sections	ST, MM
0.9	30.11.2022	Ready for internal quality review	ST, MM, FD, VS
1.0	03.1.2023	Final after internal quality review	ST, MM, FD, VS

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

Deliverable Abstract

This deliverable describes the current state of efforts on data collection for the socio-economic impact assessment and cost-benefit analysis within the UNICOM context. It presents the methodological approaches employed and reports on the interim results of desk research and expert interviews on detailing expected impacts of ISO-IDMP adoption; followed by a discussion on policy perspectives, foreseen challenges, and related risks in the push towards IDMP implementation.

Keywords: UNICOM, IDMP, socio-economic impact, cost-benefit analysis

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List of Abbreviations

Abbreviation	Complete form
ADE	adverse drug event
ADR	adverse drug reaction
ASSIST	Assessment and evaluation tools for e-service deployment in health, care and ageing
ATC	anatomical therapeutic chemical
CBA	cost-benefit analysis
CDA	clinical document architecture
CESP	common European submission portal
CMDs	Coordination Groups for Mutual Recognition and Decentralised Procedures
CMDh	Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CTD	common technical document
CTS	communication and tracking system
DALY	disability-adjusted life year
DCP	decentralised procedure
DIC	drug information centre
EC	European Commission
eD	eDispensation
EDQM	European Directorate for the Quality of Medicines & HealthCare
EEA	European economic area
EESAM	Republic of Estonia Agency of Medicines
eHDSI	eHealth digital service infrastructure
EIF	European Interoperability Framework
EMA	European Medicines Agency
EMA CR	EMA common repository
EP	electronic prescription

EU	European Union
FHIR	Fast Healthcare Interoperability Resources
GIDWG	Global IDMP Working Group
GiMED	INFARMED National Repository of Medicinal Products
HALMED	Agency for Medicinal Products and Medicinal Devices of Croatia
ICSR	Individual Case Safety Report
IDMP	Identification of Medicinal Products
INFARMED	National Authority of Medicines and Health Products of Portugal
INN	International non-proprietary name
ISO	International Organisation for Standardization
JRC	Joint Research Centre
KPI	Key performance indicator
MAA	marketing authorisation application
MAH	marketing authorisation holder
MedDRA	Medical Dictionary for Regulatory Activities
MPA	Medical Products Agency of Sweden
MPD	Medicinal Product Dictionary
MPI	Medicinal Product Information
MPL	Maple Language File
MRP	Mutual Recognition Procedure
NCA	National Competent Authority
NP	National Procedure
NPL	National Repository for Medicinal Products (Sweden)
NRL	National Medicinal Products Registry of Croatia (Nacionalni Registar Lijekova)
PDF	Portable Document Format
PMS	Product Management Services
QA	Quality assurance
RDM	Reference data model

RMS	Referential Management Service
SEK	Swedish krona
SEMPA	Swedish Medical Products Agency
SMUH-AIM	Portugal's Portal of Medicinal Products for Human Use Management System
SMUH-ALTER	Portugal's platform for submission of variation applications
SNOMED CT	SNOMED Clinical Terms
SPIRA	Substances, Products, Intressent (Organisation), Referentials, Automation
SPMS	Shared Services of the Ministry of Health (Serviços Partilhados do Ministério da Saúde)
SPOR	Substances, Products, organisations and Referentials
STEP	Swedish MPA Case Management System
WHO-UMC	Uppsala Monitoring Centre
WP	Work Package
XML	Extensible Markup Language

1 Executive Summary

The present deliverable reports on data collection for the socio-economic impact assessment and cost-benefit analysis of UNICOM and ISO-IDMP implementation. It builds upon the multimodal socio-economic impact assessment framework developed in D10.1 *Assessment framework socio-economic impact* and its outputs feed directly into D10.3 *Cost-benefit analysis including spill-over effects*.

The scope of the deliverable relates to forecasting the costs and benefits of ISO-IDMP adoption through quantitative and qualitative methodologies in order to evaluate their impacts. Chapter 2 presents a brief introduction to the deliverable, including its context and objectives. Chapter 3 discusses the methodological approaches used for data collection, which include desk research, expert interviews, a regulatory survey, and collation of information from various UNICOM workshops and webinars. Chapter 4 begins reporting on the interim results by presenting information on the flow of medicinal product information through specific NCA systems setting the context for the key domains of impact. Chapter 5 expands upon selected impact indicators and domains of impact, which are modelled as:

- Improved interoperability, data quality and automation
- Enhanced pharmacovigilance and clinical care
- Enriched cross-border ePrescription and eHealth programs
- Capacity building of expertise

Chapter 6 presents a preliminary assessment of the monetary costs of IDMP implementation at the NCA level, based upon which a regulatory survey was subsequently developed. The next two chapters discuss specific issues pertinent to the final cost-benefit analysis. Chapter 7 focuses on the political drivers behind investment in IDMP adoption and Chapter 8 highlights foreseen challenges and their related risks in the push towards IDMP implementation. Chapter 9 then summarises the main findings to conclude the report.

2 Introduction and Deliverable Objectives

The UNICOM project aims to improve patient safety and healthcare through supporting the implementation of International Organization for Standardization's (ISO) suite of IDMP (IDentification of Medicinal Products) standards. These standards are vital for improving medical product life cycle management in pharmacovigilance, regulatory, clinical, and cross-border healthcare domains.

One of the main objectives of WP10 *Socioeconomic Impact, Legal and Governance Aspects* is to conduct a socio-economic impact assessment and cost-benefit analysis for the project, forecasting the potential impacts of the project's outcomes.

This deliverable D10.2 *Interim report on cost-benefit data collection* is one of the outputs of Task 10.2 *Data collection for cost-benefit analysis*. It builds on the socio-economic impact assessment framework developed in D10.1 *Assessment framework socio-economic impact* and its outputs will be further expanded upon in D10.3 *Cost-benefit analysis including spill-over effects*.

The specific objectives for D10.2 are as follows:

- Gather data and literature based on the framework developed in D10.1 on:
  - value propositions of stakeholders in the IDMP domain
  - the utility of data quality and interoperability as applicable to IDMP
  - the expected regulatory impact of IDMP and its measurement and operationalisation
  - nontangible and scenario-based indicators for impact assessment of IDMP
- Conduct interviews with experts and stakeholders to estimate foreseen costs and benefits of IDMP
- Elaborate on foreseen costs and benefits through quantitative and qualitative methodologies

3 Methodological Approaches and Data Collection

This chapter describes how the socio-economic impact assessment models impact by integrating the following diverse sources of data over the course of the project; namely, desk research, expert interviews, surveys and questionnaires, the community of expertise webinars, and best practice workshops for NCAs.

3.1 Desk Research

Desk research conducted so far focused on the continued elaboration of the socio-economic impact assessment framework in terms of narrowing down the preliminary impact indicators described in D10.1 and modelling their quantification where possible. The following research questions guided the desk research and data collection:

Focus of the desk research and data collection

- What are the use cases and applications of IDMP implementation across scientific, clinical, health, pharmaceutical, regulatory, and business domains?
- Who are the main institutions and institutions involved in the IDMP and medicinal product information ecosystem?
- What are the national policies or strategies associated with IDMP?
- Which cost-benefit analysis paradigms and frameworks are most applicable to evaluating the impact of IDMP implementation?
- How can the economics of standardisation be applied to evaluating the socio-economic impact of IDMP?
- What data sources and datasets are available on pharmacovigilance and adverse drug reporting in Europe? How can they be used to assess the impact of IDMP in the pharmacovigilance domain?
- What methods are available for assessing the impact of increased interoperability, more automation, and better data quality as it pertains to medicinal product information?
- What are the cross-border benefits associated with IDMP and how can they be evaluated?
- What is the progress of IDMP implementation across different member states in Europe?
- What are the available data sources and datasets on medicinal product information?

To address these research questions in the socio-economic impact assessment framework, the study team performed a literature search in Google Scholar and PubMed databases and screened the websites of relevant institutions and governments for relevant reports and publications. Multiple sources were consulted and included peer-reviewed articles, EU reports, reports by international organisations, academically published sources and datasets, European Medicines Agency (EMA), World Health Organization (WHO), European eHealth Network, International Organization for Standardization (ISO), Eurostat databases, Eudravigilance, and other UNICOM deliverables. The following key terms were used:

EU-level policies related to IDMP:

ISO-IDMP, IDMP regulation, medicinal product information regulations, eHealth Network, coordination, approach, support action, IDMP implementation, Member States, EEA countries, cross-border healthcare policies, MyHealth@EU, eHDSI,

guidelines for global pharmacovigilance, Global IDMP Working Group (GIDWIG), national competent authorities for medicinal products, European eHealth agencies, European pharmacovigilance, global pharmacovigilance, EMA SPOR, EMA Substances Management Services, EMA Products Management Services, EMA Organisations Management Services, EMA Referentials Management Services, Eudravigilance legislation, IDMP implementation guide Europe, EU directives IDMP, EU pharmaceutical policy

Assessing IDMP impact on pharmacovigilance and adverse drug reporting:

Pharmacovigilance in EEA, Eudravigilance, WHO-UMC pharmacovigilance, national adverse drug reactions databases, quantification of the impact of adverse drug events, adverse drug events in Europe, European adverse drug reporting, impact of adverse drug events, impact of pharmacovigilance, cost-benefit analysis of adverse drug events, cost-benefit analysis of pharmacovigilance, cost-effectiveness of adverse drug event reporting systems, socio-economic impact of standardisation of medicinal product information, combatting preventable adverse drug events, EU economic impact adverse drug events, epidemiology of adverse drug reactions in Europe, evaluation of drug regulations

Assessing the impact of standardisation, interoperability, automation, and data quality on medicinal product information:

Socio-economic impact of standardisation / interoperability / automation / data quality, assessment of standardisation / interoperability / automation / data quality, cost-benefit analysis of standardisation / interoperability / automation / data quality, evaluation of digital health technology, cost-benefit analysis of digital health, value of health information exchange, interoperability frameworks for healthcare data, use of medicinal product information data, interoperability assessment frameworks, WHO monitoring and evaluating digital health interventions, willingness-to-pay healthcare data, willingness-to-pay medicinal product information, healthcare data Europe, pharmaceutical data Europe.

Assessing the impact of IDMP on cross-border care and eHealth:

Socio-economic impact of cross-border healthcare, cross-border exchange of medicinal product data, eHDSI KPIs, eHDSI pilots, ePrescriptions and eDispensations cost-benefit analysis, cross-border healthcare programs in Europe, cross-border exchange of medicinal product information, cost-benefit analysis of eHealth, cost-benefit analysis of cross-border healthcare

3.2 Expert Interviews and Focus Groups

Strategic interviews were carried out with selected partners and experts in order to further refine the socio-economic impact assessment framework and narrow down the preliminary impact indicators presented in D10.1. The interviews were focused on validating the scope for impact assessment and collecting insights that could expand upon stakeholder perspectives. Several countries were approached for the interviews, representing different medicinal product information (MPI)-architectures and geographic locations.

Interviews were conducted with SE MPA, INFARMED, and SPMS to capture focus areas and relevant priorities for NCAs in terms of IDMP implementation. The semi-structured interview format included questions concerning the flow of medicinal product

information data at the NCA, potential benefits and other changes expected due to IDMP implementation, policy perspectives driving the push towards IDMP, and an initial stock-taking of operational costs associated with the shift towards IDMP (see Appendix 10.1). Interviews with HALMED and EESAM, conducted by WP12, focused on the perceived benefits of IDMP and the strategies employed by each agency in their migration towards IDMP implementation.

The interviews provided a stock-taking of barriers, enablers, success factors and decisional aspects in the development of IDMP at the NCA level. This information was further supplemented by discussions held during alignment meetings, strategy board meetings, and consortium meetings over the course of the project.

3.3 Regulatory Cost-Benefit Analysis Survey

A survey was prepared for launch among participating NCAs to collect data for the final cost-benefit analysis. The survey questions were presented to NCA colleagues for feedback during the UNICOM November 2022 Project Executive Committee meeting and will be launched early next year.

The survey, formatted as an online Microsoft form, asks for available data on marketing authorisation applications and costs associated with the transition towards IDMP at the NCA level (see Appendix 10.2). Data from the survey will be used in accordance with the ASSIST impact assessment evaluation framework as described in D10.1.

3.4 Workshops and Webinars

The UNICOM “Community of Expertise” webinar series, led by WP1, have been a rich source of data for delineating the benefits of IDMP implementation, highlighting discussions with experts on specific use-cases. The following webinars were used for gathering data on the pharmacovigilance and clinical care applications of IDMP:

- UNICOM Community of Expertise: Clinical Applications for IDMP
- UNICOM Community of Expertise: Draft Guideline for Medicinal Product Dictionary
- UNICOM Community of Expertise: Using IDMP in Adverse Event reporting and Individual Case Safety Reports
- UNICOM Community of Expertise: Navigating global and national identifiers using IMDP and FHIR
- UNICOM Community of Expertise: Representation of Clinical Information

Beyond collating the benefits, these webinars provided information on the technical challenges associated with IDMP utilisation in the domain. They included detailed discussions on how IDMP-related global and national identifiers could be used in practice and be mapped to existing coding systems such as EDQM and ATC.

Similarly, the WP4 “Best Practice and Knowledge Sharing Workshops” for NCAs have been instrumental in understanding the flow of medicinal product information in participating member states, their various medicinal product information management systems, and their efforts in moving towards IDMP implementation; all of which inform the development of impact indicators for the final cost-benefit analysis. Summarised results from the workshops are provided in D4.16 *Best-practise ISO IDMP workshops according to needs of the NCAs*.

4 Understanding the Dataflow of Medicinal Product Information

In order to be able to assemble issues related to the benefits and costs of the ISO IDMP (IDentification of Medicinal Products) suite of standards, it was first necessary to understand the dataflow of medicinal product information in various member states. As an exemplar, we present here information collected from Sweden and Portugal.

In Sweden, medicinal product information is the primary purview of the Swedish Medicinal Products Agency (SE MPA), acting under the Swedish Ministry of Health and Social Affairs. SE MPA includes a drug information centre (DIC) responsible for providing information to the public and is aimed towards both citizens and health professionals. The DIC is setup with an open-call centre format which provides a 24-hour service to health professionals and citizens and is connected to their emergency medical services. SE MPA also includes an in-house MPA laboratory for the analysis of medicinal products, thereby being involved in all aspects of a medicinal products lifecycle (Figure 1).

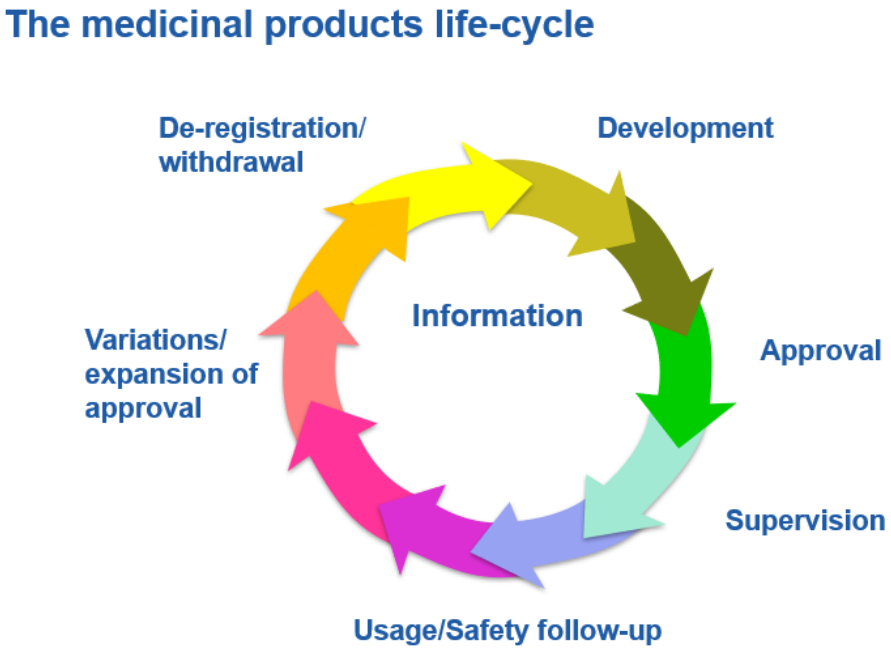

Figure 1. Medicinal products lifecycle

The agency´s main responsibilities include the safety, regulation, licensing, and quality assurance of medicinal products, including counteracting their misuse and falsification. The agency also provides and administers quality assured, producer independent information about medicinal products in relevant databases connected to the wider Swedish pharmaceutical and healthcare-related infrastructure. Conversely, ePrescriptions, cross-border prescriptions, and the supervision of hospitals or doctors remains outside the agency's remit.

Within the European framework, SE MPA leads the expert assessment of medicinal products and licensing, including centralised and decentralised procedures. A key point to note is that even for centralised procedure applications, the assessment itself is done by the Member States´ NCAs, such as SE MPA, whose assessment results are then sent onwards to EMA's expert groups. SE MPA, through bilateral agreements, has a number of joint global ventures involved in the exchange of medicinal product, pharmacovigilance, and clinical trial information with select countries.

Applications to SE MPA are submitted either through the electric Common Technical Document (eCTD) (Figure 2) via the CESP portal or the EMA Common Repository (EMA CR). The applications are first downloaded into the SE MPA repositories by their administrative unit, whereupon the relevant portions are forwarded to the various assessment groups (Figure 3):

- Quality assessment
  - Entails quality of the manufacturing and pharmaceutical information, including description of active substance, production chemistry and method, excipient production, testing of active substance and final product, i.e., both production and quality processes are assessed.
- Non-clinical assessment
- Pharmacokinetic assessment
- Clinical and RMP assessment
- Product information
  - Entails assessment of SmPC, package leaflets, package characteristics and includes a pharmacovigilance plan.
- Regulatory assessment

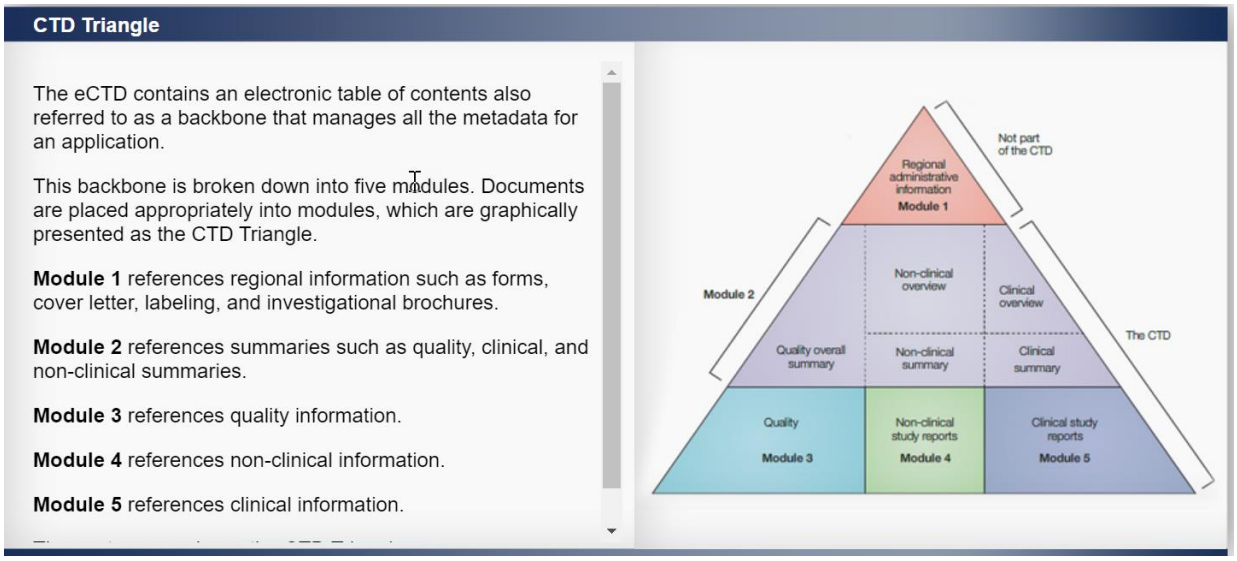

Figure 2. Modules of the eCTD

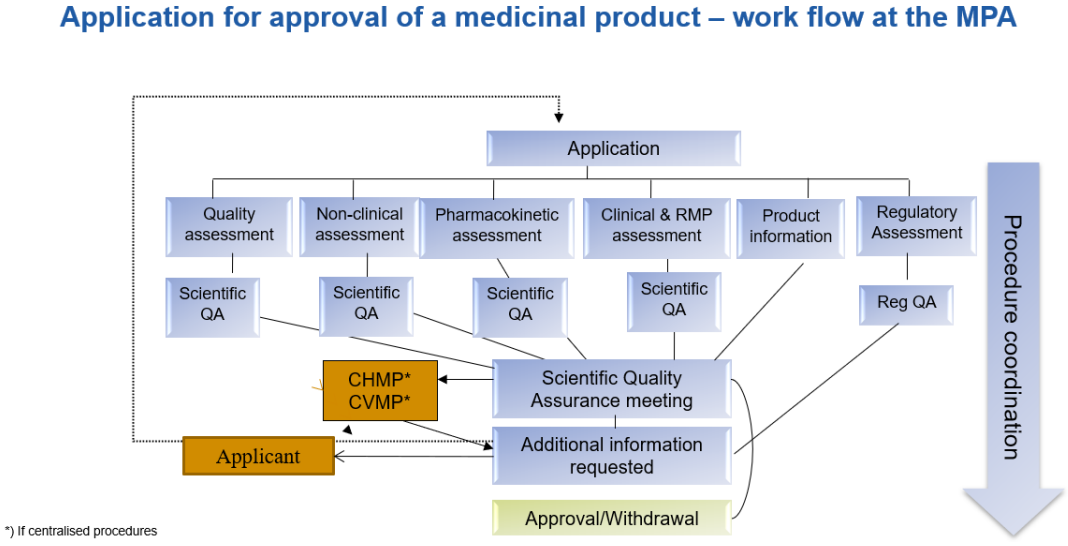

Figure 3. MAA Workflow

Following the application´s assessment by the various groups, the next step is Scientific QA, i.e. assessment of the quality of the previous assessments, where expert groups assess the previous assessment itself, discussing any problems or questions that need to be put to the applicant. Following Scientific QA, a Scientific Quality Assurance meeting is held where all information is compiled together and a benefit-risk assessment of the product is conducted, including a comparison of its therapeutic value and potential adverse side effects. Any additional questions that arise are then sent to the applicant for further clarification. As such, the whole assessment procedure lasts for 12 to 18 months. Following assessment, if the application was made with the centralised procedure, the finalised report is sent to the expert groups at EMA. The application´s workflow is managed by STEP, SE MPA`s queryable case management software system, which bundles relevant information together (Figure 4).

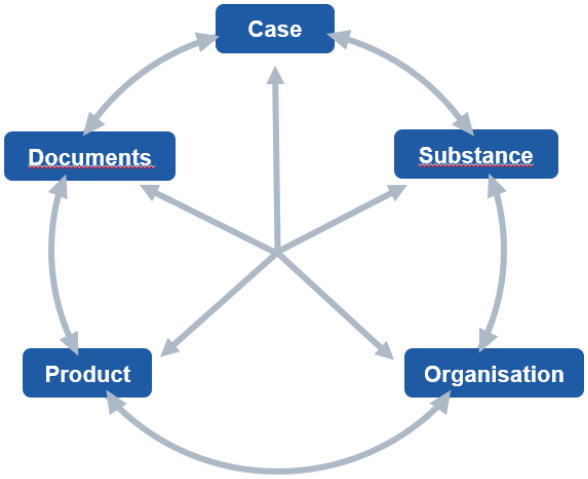

Figure 4. STEP- Swedish MPA Case Management System

However, it is key to note that in terms of MAA, SE MPA does not exchange medicinal product data directly with other NCAs. Instead, they assess only incoming applications, and all NCAs receive the same data in the application dossier. Once the application is assessed and finalised, the information (including the SmPC, substance data, and product information) is uploaded to the common case management system, CTS, which handles the decentralised procedures, which are not EMA procedures.

Once marketing authorisation is granted, the product is added to the national product database (NPL), where it is available in structured XML format, for use by eHealth agencies and other actors in Sweden (Figure 5).

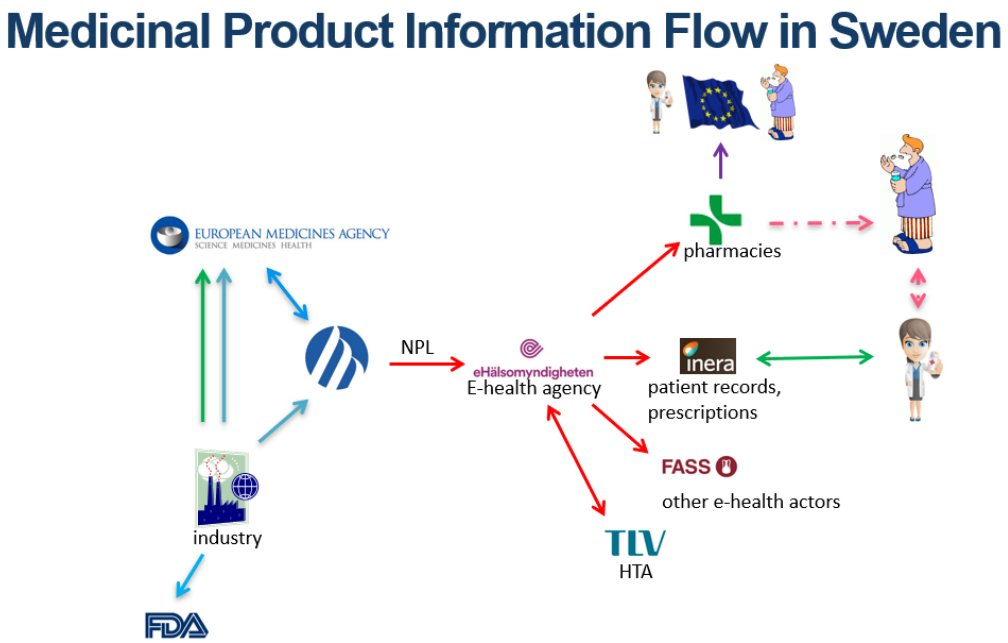

Figure 5. MPI flow Sweden

With regard to Portugal, applications to INFARMED for almost all their procedures are submitted through the eCTD except for simple applications such as parallel imports. Applicants of Marketing Authorisation Applications (MAA) by national procedures (NP), mutual recognition and decentralised procedure must pre-submit their application in the Portal of Medicinal Products for Human Use Management System (SMUH-AIM). This data gets automatically transferred to the medicines database (GiMed), after which it is manually checked and updated according to the outcome of the assessment. After the pre-submission phase, the applicant submits the MAA dossier via CESP. Any communication with Marketing Authorisation Holders (MAH) and assessors is made via email. For the case of a centrally authorised product, the documentation is accessed through the EMA central repository. In this case, there is no submission portal, and all data is filled out manually in the medicines database.

The major steps followed in the process are:

- Validation
- Assessment
- National Phase (when applicable DCP, MRP)
- Decision

In the validation phase, companies applying for authorisation fill the information for the active substance and excipients in the national portal, a national repository not linked to SPOR. There are cases where the information is incomplete as the substances are not in the national database. In this case, the data is corrected or completed during the validation phase. Given that Portugal has a single submission, the Portuguese NCA must consult any missing information in the marketing dossier, as companies can not change their submissions.

For the case of variations and renewals, a different portal is used for submissions (SMUH-ALTER). The documentation can be uploaded through the online portal or CESP. In this case, the major steps are the same as with the national phase. The update of data in the medicines database is made automatically in some types of variations but manually in others, which also requires the use of significant human resources and time.

In the same way as Sweden in terms of MAA, Portugal does not exchange data or documentation with other NCAs. When a marketing authorisation is in several countries, all NCAs receive the data and dossiers through their national portals. During the assessment phase for MAA, variation and renewals, there is an exchange of information through email and CTS procedural documentation, such as assessment reports shared with NCAs and/or EMA by email or Eudralink. Also, data for procedural aspects are shared through CTS. Furthermore, in the context of CMDh and for specific purposes, e.g., identification of medicines available in different member-states, preparation of referral procedures and data concerning medicines is exchanged via email with NCAs and EMA.

5 Modelling Domains of Impact for UNICOM and IDMP Adoption

This chapter models the key domains of impact for UNICOM by collating the interim results of the ongoing data collection processes related to the socio-economic impact assessment and cost-benefit analysis. The aim of this process is to narrow the impact indicators presented in D10.1 to focus on those most relevant for stakeholders and their use cases. The key domains of impact for UNICOM and IDMP adoption, elucidated through expert interviews and desk research, are categorised as:

- Improved interoperability, data quality and automation
- Enhanced pharmacovigilance and clinical care
- Enriched cross-border ePrescription and eHealth programs
- Capacity building of expertise

5.1 Improved Interoperability, Data Quality and Automation

In evaluating the expected impact of IDMP implementation, both desk research and expert interviews highlighted the benefits in terms of improved interoperability, better data quality, and facilitated automation.

IDMP standards stipulate guidance for the structuring of medicinal product data. As described previously, MP assessment can consist of different competences. In terms of MAAs at SE MPA, from the perspective of a clinical assessor, IDMP would not directly add additional benefits to the clinical assessment itself. However, IDMP would play a role in the quality assessment and product information portions, where the better structuring of data would provide efficiency gains. In these assessment portions, the SE MPA receives documentation from pharmaceutical companies, which are formatted according to each company´s language and terminology. After which, they must be interpretated and added to the STEP case-management system by assessors. A structured IDMP format would help with understanding and interpretating this information. IDMP can describe the composition of a product, where it´s produced, how it´s packaged, and what it´s shelf life is. Currently, this data is received in tables and text and structured according to each company´s own process and workflow. Having this data structured in a standardised format would help assessors in terms of efficiency and improved data quality, where improved data quality refers to both accuracy and completeness of data sets. Furthermore, IDMP can also provide guidance on how to structure information for new data fields or elements which may need to be added to the Swedish NPL, such as those for therapeutic indications. Previously, SE MPA has had to develop these fields without guidance, and IDMP can offer a roadmap on what characteristics to include. The improvements in data quality and structure, however, do not mean that IDMP will remove all free text or PDFs from the MAA workflows. Despite the structured data, there will be components requiring text to be read.

Similarly, Portugal expects significant benefits in their assessment of medicines step. Currently, Portugal has an organisations database (GEnt) and substance database (GSub), with severe data quality issues and little information available. The implementation of IDMP would enrich their substance information and tackle quality issues that would help solve these problems. Furthermore, there is no submission portal for centrally authorised products CAPs and the documentation is accessed in the central repository, where updates in the medicines database are manually made. Implementing PMS is expected to significantly reduce the burden of manually entering information in the systems.

In terms of structured data, while IDMP-formatted information allows for the better exchange of medicinal product information, thus leading to benefits from a sdigitalisation perspective, the IDMP standard itself isn´t a 'structured document.' SE MPA notes that a key priority for the Swedish authority is to create structured medicinal product information, and the advent of IDMP, including related legislation, helps provide a driver for this change, allowing for the development of more integrated digital processes.

SE MPA further highlights that improved semantic and technical interoperability is where they see the key benefits of IDMP implementation. The immediate impact of interoperability is in the linking of the Swedish MPA MPDs to EMA SPOR. Here, this should allow for the easier exchange of information between all stakeholders, including NCAs, EMA, and eHealth organisations. More complete information on medicinal products in MPDs, provision of more accurate information earlier in the MAA process, and less opportunities for inconsistencies in MPI will all be facilitated by improved interoperability between medicinal product databases. Likewise, Portugal sees improved interoperability as a long-term benefit that will facilitate the linking and exchange of information between stakeholders, including EMA. This would allow them to have a more streamlined process and reduce costs. Furthermore, by improving the interoperability of systems, they could reuse data received from companies without needing to retype it.

Facilitated automation also serves as a major driver for IDMP implementation. SE MPA notes that the push for IDMP implementation at SE MPA has a number of key drivers, one of which is that the organisation needs to be 2 to 3% more effective and productive each year to meet their yearly increase in costs. Automation provides a solution as it allows the organisation to be more productive, cutting human resources related costs in certain areas, and repurposing them to other areas. IDMP supports automation through the increased provision of structured medicinal product data in MAAs as described above and improved interoperability, thereby requiring fewer human resources for data cleansing and maintenance related tasks. IDMP allows for MPI in national databases to reach the level of standardisation in information structures necessary for setting up automated workflows, such as those for communicating between different MP databases. It is, however important to note that the Swedish authority does not envision that automation will lead to continuous application workflows through the whole MAA process, as the assessors will still require the necessary prerequisite time for MP assessment.

Similarly, the Portuguese NCA highlights that increasing automation is a significant benefit of IDMP implementation from their perspective. One of the main challenges they face is reducing response times in the MAAs and improving organisational efficiency. Having structured IDMP data in MAAs would help automate processes at the end of the assessment process, whereupon at the moment the process has to be manually updated. It is expected that automation would further decrease operation costs in the long term and, in the same case as Sweden, will allow them to repurpose resources to other areas.

To quantify the expected impact of IDMP for the impact indicators of interoperability, data quality, and automation, the final cost-benefit analysis (CBA) will incorporate the principles of the European interoperability framework (EIF)[3] and adapt the

[3] Interoperability solutions for public administrations, businesses and citizens. The New European Interoperability Framework, https://ec.europa.eu/isa2/eif_en/

methodology of the European Commission Joint Research Centre's (JRC) 2022 report on quantifying the benefits of location interoperability in the EU[4]. The JRC report conducted an economic impact analysis by first estimating the economic impact of interoperability generally in the EU, followed by calculating the specific share of location interoperability. More specifically, the analysis compared available datasets specific to location interoperability as a means of deriving the proportion of location interoperability attributable to overall interoperability within the EU. By employing this method in the medicinal product information domain, the final socio-economic impact assessment will similarly provide an estimate of the relevant impact indicators from a societal perspective.

5.2 Enhanced Pharmacovigilance and Clinical Care

In the pharmacovigilance and clinical care domain, experts reported that IDMP standards improve pharmacovigilance systems by helping them to better identify the right medicinal products, as products could be expressed in a structured way. NCAs report that the univocal identification of medicinal products is in itself a key driver for IDMP implementation and pharmacovigilance legislation stipulates its necessity, placing IDMP as a facilitator of better global health. In their interviews, INFARMED and SPMS highlighted how IDMP implementation in pharmacovigilance systems will improve data quality and further streamline the flow of data when it comes to adverse event reporting, thereby improving the identification of patterns and new risks associated with medicinal products. As a specific example, they state that it is often challenging for them to receive the correct information on the batch number for MPs according to their current format, but since IDMP will necessitate a specific field for this, it will make data collection for this field easier.

To formalise the cost-benefit analysis of IDMP in the pharmacovigilance and clinical care domains, the final socio-economic impact assessment will capitalise on research published on the rates of adverse event events (ADEs) as part of the overall model. According to estimates, ADEs account for about 5% of all hospital admissions in Europe, with around 5% of shospitalised patients experiencing an ADE during their hospital stay, and ADEs resulting in approximately 197,000 fatalities each year across the EU, representing a significant contribution to morbidity and mortality in Europe[5,6]. The impact of adverse drug events can be quantified by estimating the direct healthcare costs that result from ADEs and the indirect effects linked to the loss of health, measured in disability-adjusted life years (DALYs)[7]. The final cost-benefit analysis will use this data to model the effect of selected criterion values, e.g., 1%, 2.5%, 5%, and 10%, on the value added from IDMP implementation.

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[4] Ulrich, P., Duch Brown, N., Kotsev, A., Minghini, M., Hernandez Quiros, L., Boguslawski, R. and Pignatelli, F., *Quantifying the Benefits of Location Interoperability in the European Union*, EUR 31004 EN, Publications Office of the European Union, Luxembourg, 2022, ISBN 978-92-76-48846-0, doi:10.2760/72064, JRC127330.

[5] Bouvy, J. C., De Bruin, M. L., & Koopmanschap, M. A. (2015). Epidemiology of adverse drug reactions in Europe: a review of recent observational studies. *Drug safety*, *38*(5), 437-453.

[6] Kongkaew, C., Noyce, P. R., & Ashcroft, D. M. (2008). Hospital admissions associated with adverse drug reactions: a systematic review of prospective observational studies. *Annals of Pharmacotherapy*, *42*(7-8), 1017-1025.

[7] Agbabiaka, T. B., Lietz, M., Mira, J. J., & Warner, B. (2017). A literature-based economic evaluation of healthcare preventable adverse events in Europe. *International Journal for Quality in Health Care*, *29*(1), 9-18.

5.3 Enriched Cross-Border ePrescription and eHealth Programs

Implementation of ISO IDMP standards further supports cross-border ePrescription and related eHealth programs, the expansion of which constitutes a key use case for European healthcare. The ISO IDMP data model establishes definitions and concepts to represent data elements and their structural relationships for medical product identification, improving the safety of ePrescriptions, eDispensations, and Patient Summaries in national and cross-border scenarios. UNICOM participation has helped key eHDSI stakeholders to adopt the inclusion of IDMP attributes in the eHDSI pre-production testing for ePrescription, eDispensation and Patient Summaries, aligning them to EMA – SPOR processes, eHDSI specifications, and the CDA Implementation Guides and ValueSets.

In terms of modelling, desk research shows that the impact of IDMP in the cross-border eHealth domain at the pharmacy level can be extrapolated from case studies on the impact of ePrescription. A Finnish study explored the impacts of ePrescriptions on pharmacists' opinions regarding medication safety in community pharmacies. According to the respondents, ePrescriptions increase medication safety in a variety of ways, including lowering the incidence of prescription forgeries, lowering the chance of dispensing errors, encouraging better patient medication management, making it easier to keep track of drug interactions and duplicative therapies, and lowering the chance of incorrect interpretations of prescriptions. Additionally, respondents noted that, on average, they often encountered ePrescriptions with ambiguities or inaccuracies that necessitated further clarifications during dispensation. The most frequent ambiguities or errors in ePrescription were reported as being the incorrect total amount of medication, missing notation of exceptional dosage instructions or exceptional purpose of use, unclear or incorrect dosage instructions, incorrect strength, and incorrect pharmaceutical form[8]. IDMP-structured medicinal product information is expected to reduce these errors. D5.2 *Guidelines for IDMP-based Cross-Border ePrescription / eDispensation & Patient Summary* further describes additional impact-based scenarios for eHDSI and cross-border healthcare use cases.

5.4 Capacity Building of Expertise

Stakeholders semphasised the role of UNICOM in helping them further build their capacity in terms of expertise in the IDMP domain. They highlighted the value of scaling up expertise through the support provided by UNICOM in terms of both knowledge exchange and the implementation guidance. SE MPA reported that they had been motivated to assign more resources in terms of both human resources and technical expertise to figure out how to align IDMP to existing national and European databases. Their experience in providing data for the UNICOM demonstrators has been instrumental in helping them learn what needs to be adapted for IDMP integration. Similarly, INFARMED and SPMS reported that UNICOM has created the opportunity for them to dedicate resources to understanding IDMP. It has allowed them to develop in-house knowledge of IDMP adoption, which was further compounded through knowledge exchange with other NCAs. The Estonian NCA explained how, in order to implement IMDP, additional resources were needed in terms of time, money and expertise. Through UNICOM, they have been able to dedicate specific resources to organise and map legacy data to SPOR, learn how to use FHIR messages and

[8] Kauppinen, H., Ahonen, R., & Timonen, J. (2017). The impact of electronic prescriptions on medication safety in Finnish community pharmacies: a survey of pharmacists. *International Journal of Medical Informatics*, *100*, 56-62.

implement IDMP in a practical way. All stakeholders interviewed agreed that UNICOM has enabled them to leverage UNICOM's network of interdisciplinary expertise to significantly build their capacity for IDMP adoption, moving beyond theoretical discussions to technical adoption and practical implementation.

6 Operationalising Costs

Collecting relevant cost data is essential for the final cost-benefit analysis. An initial assembly of costs related to IDMP implementation was conducted through expert interviews with NCAs and information provided by SE MPA and INFARMED is highlighted below. Based on this, a survey for operationalising and estimating the costs of IDMP implementation from the regulatory perspective was created and will be launched in 2023 (see Appendix 10.2).

Implementation of IDMP at the SE MPA is framed within their SPIRA project, a project to develop new EMA SPOR compatible IT systems for MPI at the agency, which aims to replace their old legacy medicinal product information IT systems. The SPIRA project was started in 2018 and is expected to be completed by the end of 2023. The total budget for the project is 6 million euros, out of which roughly a third is associated with IDMP adaptation, approximately 2 million euros. Regarding overall cost savings at the agency, interviewees note that while IDMP implementation may decrease some costs during the initial phases for MAA processing, e.g. due to increased automation of information exchange, there will be increased costs associated with informatics and technical development, leading to no net cost savings.

The Swedish MPA was queried about the costs associated with their MAA and the following information was obtained. For 2020, the SE MPA processed 498 total MAA including through the centralised and mutual recognition/decentralised procedures. The associated costs for these applications in 2020 were 14,566 EUR (147,866,000 SEK), with an average cost of 29,257 EUR (297,000 SEK) per application.

Table 1. Number of Applications at SE MPA

	2020	2019	2018
Before approval			
Scientific advice, centrally, with SE as coordinator [3]	119	86	80
Scientific advice, national [3]	144	171	178
Klinisk prövning, ansökningar [4,7] (Clinical Trial Applications)	275	267	313
Licenser, ansökningar [4] (License Applications)	55 761	54 431	49 978
Marketing Authorisation Applications			
New application, complete [1,3]	146	152	161
New application, abridged [1,2,3]	298	285	327
Line extension [1,3]	54	47	53
Total	498	484	541

Table 2. Aggregate Costs of Marketing Authorisation Applications at SE MPA

Costs for Approval (Thousand SEK)	2020	2019	2018
New applications [1,2,3]	147 866	151 095	144 160 [4,7]
Parallel import [5]	8 784	8 209	7 923
other [6]	16 777	17 606	21 394 [7]
TOTAL	173 427	176 910	173 477

Table 3. Costs of Marketing Authorisation Applications at SE MPA Specified by Application Procedure

Procedure	Ack Utfall m sek	Ack Timmar (Hours)	Antal ärenden	Average Cost (Thousand SEK)	Average Cost (Thousand EUR)
CENTRAL	-70	64 924	159	-441	-43
DCP	-52	50 523	238	-220	-22
MRP	-11	10 377	84	-129	-13
NATIONAL	-15	13 581	17	-857	-84
Total	-148	139 405	498	-297	-29

*using a currency conversion rate of 1 EUR = 10.1515 SEK

Table 4. 2020 Costs Associated with the Different Stages of Medicinal Product Information Management at SE MPA

	Costs (SEK)	Average (Thousand SEK)	Average (Thousand EUR)
Product information	-14 173	-28	-3
Regulatory department	-15 248	-31	-3
Administration of applications	-13 539	-27	-3

*using a currency conversion rate of 1 EUR = 10.1515 SEK

Table 5. 2020 Costs for the Maintenance and Development of IT at SE MPA

	T sek	T eur	Average (Thousand SEK)	Average (Thousand EUR)
1146 IT Maintenance applications	-19 049	-1 876	-38	-4
1541 STEP GK Maintenance	-19 802	-1 951	-40	-4
1502 Spira product	-4 987	-491	-10	-1
Chosen parts	-43 838	-4 318	-88	-9

*using a currency conversion rate of 1 EUR = 10.1515 SEK

The Portuguese NCA, INFARMED, estimates the cost of refactoring the system is 922.500,00€. These costs cover the refactoring of their national medicinal products database, their national repositories (organisations and substances) and the addition of the referentials. Although no costs for the MAA could be provided during the interview, the interviewees stated that they foresee a decrease in their operational costs through IDMP implementation. The number of days to process applications for the national phase should be 30 days. However, at the moment, they are operating significantly above this with 149 calendar days for mutual recognised procedures (MRP), 139 for decentralised procedures (DCP) and 121 when Portugal is the reference member state (RMS). While several measures have been taken to simplify this phase and reduce the days it takes to process an MAA, the most significant activity in the national phase is checking the quality of data which continues to be resource intensive. IDMP can improve this area and help streamline the process. In this sense, if the number of days needed to process an application is reduced, it will lead to a decrease in operational costs.

7 Policy Perspectives Driving IDMP Adoption

The policy priorities of an organisation, namely the priorities and perspectives of its upper management, are ultimately responsible for its funding decisions. Therefore, understanding the key drivers for investment in IDMP, as seen by the business and management units, provides a wider context for cost-benefit analysis.

Interviewees were asked about what was guiding the investment perspective behind funding IDMP implementation at SE MPA. Different levels of objectives were highlighted in response. As a prelude, the interviewees note that the organisation´s legal obligations in the pharmacovigilance arena combined with the European Commission's (EC´s) implementation regulation on standardisation (reg 520/2012) necessitate IDMP implementation. IDMP is a global standard, and through the legislation, it serves as a driver for change. While more work still needs to be done to fully understand the specific benefits that IDMP implementation would bring and what it would mean in Sweden and in Europe, the regulations have provided the push for Sweden to change its legacy MP systems, which was a long-pending goal. Thus, for the SE MPA, IDMP implementation has been a technical driver for updating their systems. Because of the ever-prevalent competition for project funding, without the regulatory stipulation, it would have been more difficult to get the necessary funding for IDMP. and UNICOM has helped to accelerate and fund this change by providing focus on it through a specific project.

Stemming from that, IDMP implementation thereby provides support for what the organisation sees as key business objectives, and these business objectives are driving the change towards IDMP, more so than the concept of IDMP itself.

First is interoperability in the regulatory community. The Swedish MPA needs to be interoperable with EMA and other NCAs, and the organisation regards IDMP as an acceptable standard for the different related terminologies. Regarding the various reference terms in the EU and globally across medDRA and SNOMED, it is important that these terms are mapped accurately to allow for the correct use of terms in IDMP. Therefore, IDMP then acts as a driver of harmonised terms. Sweden contributes to the EU system because, on a governmental level, this is a strategic choice to position Sweden as one of the leading countries for this work and to be seen as an innovator in the digitalisation space. The Swedish government has set for itself the goal that Sweden will lead in digitalisation in the European space. Therefore, the experts at the MPA aim to position themselves to support the government in understanding the need for interoperability and its implementation. Thus, IDMP has allowed the experts to make the benefits of interoperability clearer, and show that IDMP as a set of defined standards works as an enabler for interoperability. Enablers are objectives in and of themselves. As such, at the board level, information exchange and interoperability are becoming big leverages for digitalisation in the eHealth arena. For SE MPA, it is beneficial if all involved agencies working with medicinal product information talk and understand the language in the same way. Interviewees note, that if the Swedish MPA can, as a regulatory community, take the lead to show the way forward, they also reap the benefits coupled to cross-border prescriptions, MP shortages, and risk assessments. They highlight that it is a common misconception that digitalisation and interoperability will always lead to economic benefits. Still, for the agency itself, the focus is more on the semantic understanding arising out of improved interoperability.

Following from the above, secondly, the organisation wants to make use of the technical benefits provided by IDMP formatted infrastructure. These could be, in

certain areas, the improved quality of information through the use of standard terminologies, extra guidance for missing data elements, increased effectiveness of information exchange workflows, and specific processes enhanced by automation.

Third, IDMP has benefits for their national healthcare system. IDMP would enrich medicinal product information across the data flow, including to their eHealth agency, pharmacies, and healthcare providers, and thereupon improve their pharmacovigilance systems as well. Healthcare provision for the Swedish population is a key focus for the government and is also seen as a moral obligation, providing an impetus for improving their technological infrastructure. The Covid-19 pandemic highlighted the need for better communication among and interoperability between health informatics related systems; they had staff working weekends and night simply to transfer data manually, as the information exchange between Swedish health authorities was crucial for a timely response.

In the case of INFARMED in Portugal, the interviewees highlighted that joining UNICOM was a strategic decision to join efforts between INFARMED and Portugal's e-health agency SPMS to support the cross-border use case with ePrescription and eDispensation. Furthermore, they also see the implementation of IDMP as an opportunity to improve the alignment of their national systems with EU telematics projects. This will allow them to improve their internal processes by benefiting from better national and European dataflows. In addition, IDMP will enrich their systems with quality data improving their pharmacovigilance systems by generating more robust outport from reports their system collects and improving their ICSR processing efficiency.

For HALMED, the Croatian NCA for human medicines and medical devices, the decision to implement IDMP came from the need to satisfy their business processes. HALMED started building their IT system Nacionalni Registar Lijekova, i.e., National Medicinal Products Registry(NRL) in 2010 to support the marketing authorisation process. The system has been developed and, over the years, has integrated other systems that rely on medicinal product data including pharmacovigilance and laboratory processes. One of the agency's goals is to comply with ISO-IDMP to capture the necessary data for their different systems, e.g., their current data is not enough to exchange ePrescriptions at the cross-border level. Since their existing business processes were supported by their system, they decided to refactor their current system, reconstruct their data model, update their user interface, and modify their synchronisation processes. Additionally, the decision to go forward with IMDP implementation and be part of UNICOM was driven by the agency's desire to impact decisions being implemented at the EU level.

When asked about the opportunity for new business activities offered by IDMP implementation, experts at SE MPA stated that new opportunities may rise out of the Swedish MPA´s role as a central information provider for structured medicinal product information to eHealth organisations. Here, they state that their role needs to be more established and better known to actors outside Sweden, and an IDMP-formatted technical infrastructure would strengthen the agency´s role as central provider of medicinal product information and set itself up as a key collaboration agency across both national boards of healthcare and various EU groups. From there, SE MPA would like to help establish further agencies within this domain.

Contrastingly, INFARMED and SPMS do not foresee significant new business opportunities directly arising out of IDMP adoption. However, they do consider that the implementation of IDMP would improve their business intelligence as it will facilitate

the extraction of markers and indicators from the structured MPI data to build dashboards. Also, as part of business intelligence, they would be able to provide enriched structured information in IDMP formats for ePrescription and eDispensation use cases.

8 Key Challenges and Related Risks to IDMP Adoption

Developing IDMP infrastructure across both national and international medicinal product systems in Europe promises to be an immense task and throughout the interviews experts discussed foreseen challenges towards integrated IDMP implementation.

For the Swedish MPA, interviewees pointed out that migration towards IDMP would require further transformation and development of the SE MPA's core businesses and competences, especially as there is a risk in the difficulty of fully understanding and implementing IDMP. They would need more information architecture experts with cross-disciplinary competences as well as business specialists with expertise in medicinal product information such as substances and ingredients. They will need to combine competences and specialities in ways which presents a hiring risk, as people who possess these specific cross-disciplinary expertise, namely in pharmaceutical informatics, are not easy to find.

Apart from obtaining the necessary expertise, migrating NCA's medicinal product databases, and from that the national flow of MPI also presents challenges. One of those is that available IDMP implementation guidance is relevant to only about half of the agency´s databases. The other half includes data about invoicing, organisations, information they provide to pharmacies about substitutions, etc. When they have to update a data element outside the purview of IDMP, but which nevertheless must be compatible, it can lead to technical issues. For SE MPA, there are areas with over 30 years of legacy data, especially for products that are no longer available, and it has been a challenge to reconcile that data with IDMP. Most of the formats for the legacy data, such as the MPL format, incorporate controlled vocabularies and data structures that the Swedish MPA itself has created. Each downstream agency, such as the eHealth organisations and pharmacies, have been integrated with these formats. For new vocabularies from EMA, the agency has been facing some issues with mapping, due to the fact that their vocabularies have been in use for so long, and even with structured data it is often difficult to transform it into IDMP formats.

As such, the experts point out that clear communication with all agencies within the medicinal product information dataflow is paramount. The NCA must communicate when they are changing their systems, what exactly will be changing, the interim periods between implementation, as well as the reasoning behind changes. IDMP implementation will have an impact on the medicinal product packages that are sold on the market, as specific data elements, e.g., the strength of composition, are expressed differently in IDMP. The technical implementation is not as simple as changing one data field for another and changing these things can have risks for patients as well. The plan, therefore, is to work in parallel streams of medicinal product information until full migration of legacy standards towards IDMP, which will likely take a number of years.

A second set of challenges arise out of the various requirements of NCAs and EMA. As it stands, the quality of data in the PMS of EMA SPOR is currently not ensured, making it unreliable for NCAs. The Swedish and Norwegian MPAs amongst others are therefore discussing the steps that would need to be taken before migration to and integration with PMS. It is easier to link new incoming data with EMA SPOR compared to legacy data, because, for the legacy data, it is a long process to cleanse, validate, and format, all of which requires significant resources. NCAs are unwilling to expend these resources without first having clear guidance from EMA on both the technical

implementation requirements and the data ownership rights. There is also a lack of regulatory decisions taken at the EU level ensuring that PMS will act as the central European database for product information and whether it will be fully integrated with MAAs. All of these processes and factors will have to be discussed in detail between EMA and NCAs and these discussions are likely to last the next few years, thereby delaying full European implementation of IDMP.

In the case of Portugal, interviewees pointed out that uncertainty around the compatibility of PMS with the existing infrastructure and automation processes represents a major risk. INFARMED is currently working on clarifying whether their native automation processes will continue working once PMS is introduced. They currently have two systems in place, a management system and a medicines' database. The medicines' database would be the one needing alignment with IDMP, which poses a significant challenge due to the amount of legacy data it has. Their initial approach to achieve this is by creating a translation layer that takes their database towards IDMP compatibility in a stepwise manner. Currently, all their systems are developed in INN and using a layered approach in the information and maintenance related aspects of their systems would help them sminimise the risks of introducing IDMP. However, transforming legacy data into IDMP requires very specific expertise and is a time-consuming and expensive process which at the moment, also represents a significant risk.

During their interview, the Croatian NCA, HALMED, pointed out that although the EMA implementation guide has been semi helpful in creating technical architecture for their data modules, implementing the EMA guidelines is still difficult demonstrating a continued risk. The HALMED database, NRL, was based on the RDM 3.0 model (reference data model published by EMA). As their current model is less sophisticated than IDMP models, the present data available is not sufficient for the different processes underlying cross-border ePrescription exchange. Some internal processes underlying the exchange of MPI also face similar difficulties. To deal with this challenge, HALMED analysed all their business processes and the EMA implementation guide to identify possible gaps through dedicated working groups consisting of business users, subject matter experts and business analysts from the IT department. Challenges and risks associated with aligning to EMA timelines were similarly echoed by all other NCAs.

9 Outlook

This deliverable describes the current state of efforts on data collection for the socio-economic impact assessment and cost-benefit analysis within the UNICOM context. It presents the methodological approaches employed and reports on the interim results of desk research, expert interviews, and focus groups on detailing the key domains of expected impact, which are framed as:

- Improved interoperability, data quality and automation
- Enhanced pharmacovigilance and clinical care
- Enriched cross-border ePrescription and eHealth programs
- Capacity building of expertise

The expert interviews were especially important for elucidating the regulators' perspectives and their reported outcomes set a strong foundation for the evaluation of impact indicators, including their societal impacts and scale potential. As the interviews showed, operationalising the impact indicators and their evaluation remains a challenging endeavour when applied to IDMP implementation. Nevertheless, the enumeration of the key domains of impact helps us to focus on the further development of both qualitative and quantitative measures for their continued assessment.

Additionally, the interim results expand upon policy perspectives driving IDMP and foreseen challenges to IDMP implementation, helping contextualise impacts within the wider European medicinal product information network.

The final socio-economic impact assessment and cost-benefit analysis will build upon the work reported in this deliverable and further incorporate results as needed from additional measures including surveys, UNICOM demonstrators, and UNICOM pilots over the course of the project.

10 Appendix

10.1 Questionnaire for Expert Interviews with NCAs

Introduction

This draft questionnaire is a high-level *initial* assembly of issues concerning benefits and costs related to the implementation of the ISO IDMP (IDentification of Medicinal Products) suite of standards. This relates to WP 10 of the UNICOM project "Socio-economic impact assessment", where for selected actor groups an analysis of present data workflows has to be undertaken to compare this in an exploratory mode with how these processes are expected to change, once full IDMP implementation has been achieved.

Further process will be to:

a) test, review and improve these questions with at least two NCAs to identify the most relevant issues and challenges from their point of view and that of their national health system, and to obtain more detail on them
b) collect data and information from NCAs, based, e.g., on concrete accounting data if and where available, otherwise on expert estimates and professional expectations, other data which may be available or derived from publications, reports, etc.
c) analyse and integrate the data and information, hopefully achieving at least high-level (rough) estimates of tangible (e.g., impacts on cash flow) and intangible benefits to both the organisation itself and the healthcare system (patients, professionals, public health…)
d) discuss and validate, perhaps in a workshop, the outcomes obtained.

Mapping the Current Dataflow

1) How are incoming marketing authorisation applications (MAA) processed by your agency?
2) Is there a data flow diagram available? What are the major steps in this process?
3) Is it mostly based on paper or electronic documents (PDF)?
4) What are the major challenges with the current workflow?
5) Where do you see the most urgent problems to be dealt with?
6) What are the differences in processing workflows between applications for new products and those for renewals or variations?
7) Are you also responsible for pharmacovigilance in your country? Are these workflows separate or are they related to the MAA workflows?
8) Are continuous application workflows envisioned in the future for your organisation? e.g., as seen with Covid-19 vaccines.
9) Which organisations are linked to or have access to your national MP databases? e.g., national ePrescription systems, providers for medicinal product dictionaries, or private healthcare providers. How do these organisations access your data?
10) For what purposes and how is data exchanged with NCAs of other member states and/or EMA?
11) How do you ensure the quality of MP data in your database?

Changes due to IDMP Implementation

1) What benefits do you expect from implementing IDMP for your organisation?
2) What are the major risks involved?
3) Where do you foresee IDMP implementation leading to changes in your workflow?
4) To what extent will IDMP implementation change pharmacovigilance-related adverse event reporting in your organisation?
5) What improvements are foreseen to the medicinal product shortage, falsification, and recall systems in your organisation?
6) To what extent are response times and organisational efficiency a concern for your organisation? Is increased automation in application processing of value to your organisation?
7) What are the operational risks associated with your current medicinal product information systems? Does IDMP mitigate these risks?
8) Would a standardised format for medicinal product information improve your organisation´s assessment and scientific evaluation of that medicinal product?
9) To what extent are you already involved in the implementation of cross-border and e-prescription programs?

Operationalising Costs

1) How long does a MAA currently take to process from end to end?
2) What are the estimates of current costs per application and of the different stages of medicinal product information management at your organisation?
3) Can you provide us with an estimate of the investment costs to change towards IDMP? e.g., including technical and training costs.
4) How will costs of operations change?

Expected benefits

1) Do you expect IDMP implementation to reduce long-term operational costs? Which in particular?
2) What other benefits do you expect for your organisation?
3) Do you see intangible benefits for your organisation?
4) Will IDMP implementation offer the opportunity for new business activities?

Looking beyond institutional boundaries: Policy perspective

1) What is guiding your investment perspective for spending funding on IDMP implementation? Is it primarily benefits for your organisation, or to improve national and European data flows, or higher-level benefits for the health system?
2) Will this improve the competitive position of European pharmaceutical companies, e.g., because of faster marketing authorisation processing?
3) Will this increase patient safety through better pharmacovigilance?
4) Will this speed up and improve data flows across European agencies?

5) What other higher-level benefits do you foresee?
6) Are these or other arguments (which ones) of relevance when discussing internal distribution of investment and operational funding with your organisation´s leadership?
7) Do you or others discuss such issues at the national health policy level? What impact does this have?

10.2 UNICOM WP10: Cost-Benefit Analysis Survey for Regulators

This survey collects data to operationalise the benefits and costs of the implementation of the ISO IDMP (IDentification of Medicinal Products) suite of standards from the regulatory perspective. It relates to the final socio-economic impact assessment and cost-benefit analysis being conducted by WP10 of the UNICOM project.

1. Please provide your name and organisation:

2. How long does a marketing sauthorisation application (MAA) currently take to process from end to end at your organisation?

3. What are the current costs or cost estimates per marketing sauthorisation application?

4. How many Marketing sAuthorisation Applications were processed by your organisation over the last 5 years? Please provide any available data for 2018, 2019, 2020, 2021, and 2022.

5. If your organisation is responsible for maintaining a medicinal product database, please provide the associated yearly IT and maintenance costs.

6. Are these yearly costs (referred to in question 5) confidential data?

7. Can you provide us with an estimate of the investment costs to change your organisation towards IDMP? e.g., including technical, training, and business costs?

8. In your estimate, in which year will your organisation's technical architecture be IDMP-compliant? i.e., 2024, 2025, 2030 etc.