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Business Data and Support Department

Data submission of authorised medicines in the European Union

Outlines on Article 57(2) of Regulation (EC) No 726/2004

Contents

Purpose of this document

The collection of data on medicines submitted by Marketing-authorisation holders under the legal requirements introduced by the Article 57(2) of Regulation (EC) 726/2004 is a strategic project performed by the Agency.

This document aims to provide a general overview on the Article 57 data work-flow, data management and governance aspects and future use and evolution of the data.

Specifically, this document has been prepared to address clarifications requested by the EU Regulatory Network within the telematics forum and other Agency's stakeholders.

1. Background information

The submission of data on medicines by Marketing-authorisation holders is a legal requirement introduced in Article 57(2) of Regulation (EC) 726/2004 as amended by the provisions of Regulation (EU) No 1235/2010 and Regulation (EU) No 1027/2012.

This legal provision requires all pharmaceutical companies that hold marketing authorisations for medicinal products for human use in the European Union (EU) and the European Economic Area (EEA) to submit information to the European Medicines Agency (EMA) using the electronic format referred to as *Article 57 format* or *eXtended EudraVigilance Product Report Message (XEVPRM) format.*

Pharmaceutical companies are also obliged to maintain the medicinal product information and notify the Agency of any newly authorised medicine(s) or variations to the terms of the marketing authorisations using the XEVPRM format (so called 'Art.57 data maintenance submission').

2. Scope, benefits and intended use

The Article 57 data aims to support EU National Competent Authorities (NCAs) and the Agency in a number of different ways, for example:

- Improve data analysis and signal management in Europe, specifically by:
  - establishing a central European inventory for all medicinal product and active substance information to support the coding of drug information reported in Individual Case Safety Reports (ICH ICSRs),
  - enhancing signal detection from data analysis activities as a result of medicinal product data available in the EudraVigilance System, via the EudraVigilance Data Analysis System and the electronic Reaction Monitoring Report,
  - provision of access to EudraVigilance data proactively and reactively as outlined in the EudraVigilance Access Policy (e.g. ADR website);
- facilitate medicines regulation to fulfil regulatory actions and legal obligation such as:
  - identifying reliably medicinal products that are falling within the scope of the Periodic Safety Update Report(s) submissions (PSURs) and Referral procedures,
  - supporting literature monitoring activities,
  - collecting pharmacovigilance fees,
  - providing EudraVigilance data to MAHs to enable the performance of signal detection activities in accordance with Article 24(2) of Regulation (EC) No 726/2004,
  - facilitating NCAs' inspections (e.g. sharing information on Pharmacovigilance Master File location),
  - publishing the list of MAH's contact details for *pharmacovigilance enquiries* and medicines under *Intensive Monitoring;*
- communicate efficiently with stakeholders by means of:
  - providing information on medicines in the EU via the European Medicines Web Portal and dedicated business intelligence dashboards,

- supporting EU and International data and information exchange on demand (e.g. Provide information on medicines, supporting in case of medication shortage),

- supporting the Pharmacovigilance Risk Assessment Committee (PRAC) for any communication with its stakeholders (e.g. by means of retrieving the concerned QPPVs to target safety communications),

- supporting communications and actions to facilitate access to medications in case of shortages,

- providing quality controlled structured data on medicines to the EU NCAs that do not maintain medicinal product dictionary.

Overall, the use of common terminologies and format to uniquely identify and exchange information on medicines will:

- reduce costs by decreasing the duplication of encoding and maintenance of the same information on medicines (e.g. by means of implementing a single database and set of terminologies for multiple business cases);

- contribute to the establishment of interoperable systems for the exchange of information on medicines used for the performance of regulatory activities and therefore reducing the operational risks due to lack of common dictionary and terminology on medicine's information (e.g. take prompt precautions and actions to avoid the supply of faulty products);

- strengthen the communication between medicines database and the EU regulatory systems speeding up decisions and actions.

Examples of the use of Article 57 data include:

- simplification of adverse reaction reporting for MAHs and implementation of access to EudraVigilance by MAHs to the extent necessary to support their pharmacovigilance activities;

- decision making on the benefit/risk ratio of medicinal products: e.g. correct EudraVigilance data analysis to support referrals, correct information on products impacted by referral decisions;

- efficiency within the EU Regulatory Network: e.g. maintenance of the EURD list to coordinate the submission of PSURs to support the single assessment;

- transparency and sharing of information: e.g. access to all EU medicinal product information on the EU medicinal web portal and publication of correct aggregated ADR information (www.adrreports.eu);

- reporting of ADRs and other structured data: e.g. MAHs/NCAs can incorporate Art 57(2) data in their systems before submitting ADRs, allowing a correct identification of the medicinal product information within the ADR;

- facilitating the cross-border identification and prescription of medicines in Europe.

3. Article 57 at a glance

3.1. Data content

The data on medicines submitted via the XEVPRM format are automatically processed and recorded in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD). The following structured information is electronically submitted and therefore available in the XEVMPD:

1. description of the (invented) name of the medicinal product;

2. details of the marketing authorisation holder (including the name, address and a description of the size of the organisation i.e. SMEs);

3. details of the marketing authorisation such as the status and date (e.g. withdrawal, valid); marketing authorisation procedure and legal basis; marketing authorisation country and related authorisation numbers; Orphan drug designation;

4. description of the pharmacodynamic properties based on the ATC code(s) of the medicinal product;

5. description of the therapeutic indications coded in MedDRA and a declaration that the medicinal product is "authorised for the treatment in children";

6. details of the qualitative and quantitative composition of the medicinal product, including the list of active substance(s), adjuvant(s) and excipients, and the strength (amount) of the active substance(s) (and adjuvants where applicable);

7. description of the medical device(s) for combined advanced therapy medicinal products in accordance with Regulation (EC) No 1394/2007 as applicable;

8. the authorised and administrable pharmaceutical form(s);

9. description of the posology and method of administration (i.e. Route(s) of administration);

10. pharmacovigilance information such as the name and contact details of the Qualified Person Responsible for Pharmacovigilance (QPPV), the location of pharmacovigilance system master file, and the organisation contact e-mail and phone number for pharmacovigilance enquiries;

11. an electronic copy of the latest approved Summary of Product Characteristics (SmPC) including version date, document reference number(s) and document language(s).

Most of the information available in the XEVMPD is encoded based on a set of *controlled terminologies* e.g. XEVMPD substance controlled vocabulary, pharmaceutical form(s) and routes of administration(s). The values of Article 57 controlled terminologies are routinely published and available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b (see Annex 2 - Article 57 useful links).

Additional information on Article 57 controlled terminologies is included in the Article 57 Detailed guidance chapter 3.I available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b.

3.2. Data governance

As regards the Article 57 data governance, the following processes and infrastructures are established:

• pharmaceutical industry is required to register with the EudraVigilance system prior to electronically submitting data on authorised medicines. This is to ensure that proper **privacy** and **security** measures are in place and that the principles of integrity, accountability and availability of data are adhered to;

• once information is submitted to the Agency gateway, each XEVPRM is processed by the EudraVigilance system and undergoes an automatic '**technical validation**' (i.e. by means of an automated check of business rules implemented in the Art57 XSD schema and as described in the Article 57 Detailed guidance chapter 3.I available at

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b). The outcome of the technical validation is automatically and electronically communicated to the sender organisation via an electronic XEVPRM acknowledgment;

- the Agency performs the review of the quality and integrity of the medicinal product information received by means of a systematic '**Business validation**' of the content of each product record against the provided Summary of Product Characteristics (SmPC). The system allows for version control as outlined in section 3.4. (Article 57 data integrity and compliance). Details of the data quality control activities are also outlined in section 3.4. (Article 57 data integrity and compliance);

- the Agency is carrying out substantial **communication** activity in order to support industry in implementing Article 57 requirements and improving the quality of the data submitted. The communication activity includes provision of *face-to-face and e-learning training* as well as publication of a set of *guidance documentations* (See Annex 2 - Article 57 useful links). In addition, the Agency works closely with the European pharmaceutical-industry associations hosting Joint Implementation Working Group (IWG) meetings with representatives from EU industry associations to address technical and practical aspects related to the planning and submission process.

3.3. Data submission processes

Marketing-authorisation holders are required to submit to the EMA information on all medicinal products for which they hold a marketing authorisation in the European Economic Area (EEA), i.e.:

- nationally authorised medicinal products;

- centrally authorised medicinal products;

- medicinal products authorised through the mutual recognition;

- medicinal products authorised through the decentralised procedure.

Marketing-authorisation holders are required to submit to the EMA information on new marketing authorisations in the EEA as soon as possible and no later than 15 calendar days from the date of authorisation (i.e. 15 calendar days from the date of notification of the granting of the marketing authorisation by the competent authority): this process refers to '**Article 57 initial submission process**'.

Information on amendments to the terms of marketing authorisations following variation, transfer, renewal, suspension, revocation or withdrawal shall be notified to the EMA no later than 30 calendar days from the date of which the amendments have been authorised): this process refers to '**Article 57 maintenance submission process**'. The Article 57 maintenance submission process includes the following electronic notification:

- extensions of marketing authorisations as defined in paragraph 1 and 2 of Annex I of Regulation (EC) 1234/2008: changes to the active substance(s), strength, pharmaceutical form and route of administration;

- variations to the terms of marketing authorisations as set out in Regulation (EC) 1234/2008 that is affecting the following XEVPRM structured data elements:

  - SmPC Section 1. Name of the medicinal product e.g. change in the (invented) name of the medicinal product,

- SmPC Section 2. Qualitative and quantitative composition e.g.: changes to the active substance of a seasonal, pre-pandemic or pandemic vaccine against human influenza,

- SmPC Section 3. Pharmaceutical Form e.g. change(s) to a pharmaceutical form, which does not result in a "new pharmaceutical form" (the latter requires the submission of an Extension application),

- SmPC Section 4.1 Therapeutic indications e.g. addition of a new therapeutic indication or modification of an existing one,

- SmPC Section 4.2 Posology and method of administration (routes of administration only) e.g. change(s) to route(s) of administration,

- SmPC Section 5.1 Pharmacodynamic properties e.g. change in ATC code,

- SmPC Section 6.1 List of excipients e.g. change or addition of excipient(s),

- SmPC Section 7. Marketing Authorisation Holder *e.g. a change of name and/or address of the MAH;*

- changes to the name and the contact details of the qualified person responsible for pharmacovigilance (QPPV) in accordance with Article 4(4) of Commission Implementing Regulation (EU) no 520/2012;

- changes in the location of the Pharmacovigilance system master file (PSMF) and the contact information for Pharmacovigilance enquiries;

- transfers of marketing authorisations;

- suspension/lifting of the suspension, revocation or withdrawal of a marketing authorisation granted in the Union including the following circumstances:

  - the marketing authorisation was not renewed by the relevant competent authority,

  - an application was not submitted for renewal by the marketing authorisation holder, or

  - the marketing authorisation expired due to sunset clause;

- renewal of the marketing authorisation;

- electronic copy of the latest approved Summary of Product Characteristics (SmPC) where any variations lead to a significant revision of the content of the following sections:

  - section 4.1 Therapeutic indications which do not have a direct impact on the MedDRA coding of the indication,

  - section 4.2 Posology and method of administration (other than route of administration),

  - section 4.3 Contraindications,

  - section 4.4 Special warnings and precautions for use,

  - section 4.5 Interaction with other medicinal products and other forms of interaction,

  - section 4.6 Fertility, Pregnancy and lactation,

  - section 4.8 Undesirable effects,

  - section 4.9 Overdose.

3.4. Article 57 data integrity and compliance

Since the Article 57 database relies on the electronic submission of information from pharmaceutical industry, the Agency established strategic processes and activities to ensure adequate level of data quality and to monitor the industry compliance on the electronic submission. The following paragraphs aim to outline the activities performed by the Agency concerning data quality control and to determine the level of completeness of the Article 57 database.

### 3.4.1. Controlled terminologies quality control

Prior to the start of the Article 57 data maintenance submission, the Agency carried out extensive activities to improve the quality of the following Article 57 Controlled Terminologies:

- organisations (MAHs): where the Agency enabled the Marketing-authorisation holders to maintain and improve the quality of their own terms and details within the Article 57 Organisation controlled terminology as in the context of the medicinal product data maintenance submission[2];

- pharmaceutical Dose Forms and Routes of administration: where, in liaison with EDQM, the Agency merged duplicated terms received and re-mapped provisional terms against existing EDQM standard terms where available;
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/11/WC500153999.pdf

- substance names: where the Agency merged all duplicated substance names (in English and any translations where the medicinal product is authorised) as submitted in the Article 57 database since 2012 to unique EudraVigilance identifier (Substance EVCode). The substance controlled terminology cover any substance submitted in the Article 57 medicinal product (i.e. active ingredient, excipients and adjuvant). As outcome of this Substance Name de-duplication activity, guidance on *EMA Substance names best practice* has been published for stakeholders' use (http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/06/WC500168582.pdf).

The Article 57 controlled terminologies are routinely published and available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac05804d8b2b (see Annex 2 - Article 57 useful links).

3.4.2. Medicinal Product data quality control

Data quality in Article 57 database is a key aspect that is built incrementally within the various phases within the overall business process as described in the following graph:

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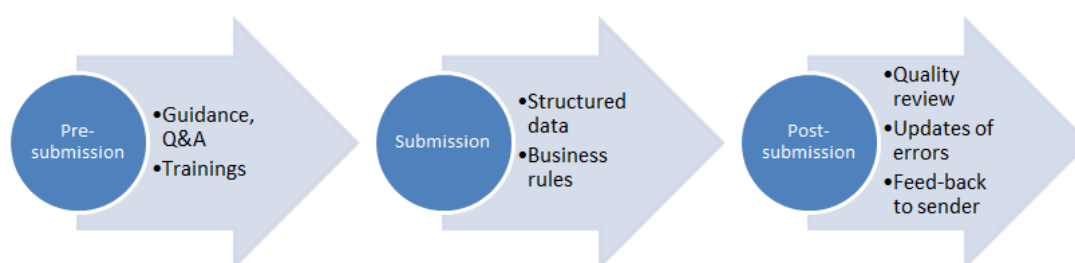
[2] The Agency product data quality control activity ensures that the MAH name referenced in the Article 57 product is in line with the information provided in the Summary of Product Characteristic, Section 7 *Marketing Authorisation Holder;* it is responsibility of MAH to ensure the quality and accuracy of organisation details. The Agency does not validate the addresses provided for the organisation beyond format validation (e.g. spelling out 'ltd').

The following steps summarise the Article 57 data quality activities:

Pre-submission phase: documentation, guidance and trainings material are developed collaboratively with industry. These documents are routinely updated by the Agency to ensure clarity of the data requirements and to support industry in the submission of the data with an adequate level of quality of information.

Submission phase: as outlines in paragraph 3.2. , a 'technical validation' is automatically performed by the system against the XEVPRM Schema business rules. The technical validation allows for the automatic rejection of messages containing erroneous data (e.g. system will not allow entering of non-EU countries with EU authorisation procedures) ensuring consistency and better quality of medicinal product information recorded in the database. These rules have been introduced and improved over years of experience in handling product data submission and data analysis related to identification of preventable errors (last update of the schema business rules was released on 16 June 2014).

Post-submission phase: at the end of July 2014, the Agency started the review of the quality of the medicinal product information submitted; involving an external contractor in the context of the wider EudraVigilance data cleaning project.

The quality control (QC) activity consists of a manual check of structured product information against the document attached in the Article 57 product record (e.g. SmPC, PIL) and the methodology largely follows the principles outlined in the Article 57 QC methodology guidance document available at http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/04/WC500165468.pdf .

When errors are found and the correct information is available, a new version of the medicinal product record is created by the Agency where corrections are made. A quality control report is provided to the Qualified Person for PharmacoVigilance (QPPV) of the sender organisation, outlining the data quality findings and the required actions to be taken by the concerned Marketing Authorisation Holder.

Once the product version has been quality controlled, it becomes available for use within the EudraVigilance System to support the pharmacovigilance activities as described in section 2. (Scope, benefits and intended use).

The Article 57 data quality review is currently performed by the external contractor team of 60 people (soon becoming 70) with scientific background and in-depth knowledge of both the database and the management of product information. The work performed by the team is reviewed independently by two quality assurance teams and their error rates targets are under 0.5%. All data related to this activity is tracked in a tool specific for this activity (data management tracking tool), and monthly breakdown of figures is as follows:

Month	Error rate
August	0.42%
September	0.35%
October	0.10%
November	0.32%
December	0.08 %

According to the current data quality review plan, the Agency expects that 100% of the medicinal product records in the Article 57 database will be quality reviewed by the end of August 2015 (i.e. current contract with the external contractor is due to expire).

3.4.3. Data compliance and completeness

Since the implementation of the Article 57 database, the Agency has invested significant efforts to ensure efficient communication in notifying pharmaceutical industries in various EU countries about their legal obligations on the electronic submission of medicinal product information (e.g. the *Article 57 fact sheet* in national languages has been published on the [Article 57 webpage](#)). It is however not possible to control compliance and therefore not possible to know how many companies still have to comply and how many products are missing in the Article 57 database.

In order to determine the level of compliance of industry to submit data, the EU Network Data Board (EUNDB) agreed to conduct a pilot to compare the data available in the Article 57 database against the data available in the databases of a number of National Competent Authorities[3] (NCAs).

Following the assessment of the level of completeness of the Article 57 database, the Agency will take corrective measures that will include communication to non-compliant Marketing-authorisation holders, copying the relevant National Competent Authorities for information.

The pilot will be conducted by means of mapping of the Article 57 data against the data received by four NCAs. The result of the first pilot is expected to be available within Q2 of 2015 and the modus operandi and methodology is currently being agreed by the EUNDB. Following this pilot with four NCAs, the EUNDB may consider extending this activity to involve additional NCAs.

3.5. Data publication

The Agency intends to make public Article 57 data to its stakeholders by establishing the European medicines web portal.

In addition, the Agency is defining the requirements to develop reports and dashboards as part of the 'EudraVigilance Auditable Requirements' project set-up to implement the EudraVigilance functionalities to be audited and endorsed by the EMA Management Board. The aim is to proactively grant access to information and data on medicinal products as submitted in the Article 57 database to the Agency stakeholders (e.g. MAH) and partners (e.g. National Competent Authorities) by means of dedicated webpage and the EudraVigilance Data Analysis System (EVDAS) by means of ad-hoc queries (e.g. including listing of QPPVs for each MAH).

4. Article 57 database current status

Marketing-authorisation holders were initially required to submit information on medicinal products for human use by 2 July 2012. Since July 2012, MAHs were required to submit information on new marketing authorisations granted after 2 July 2012 within 15 calendar days from the date of notification of the granting of the marketing authorisation by the NCA. Since the initial implementation of the electronic submission (i.e. July 2012) and up to February 2014, around 460.000 medicinal product records have been received in the Article 57 database (i.e. XEVMPD).

From 16 June 2014, the Agency requires Marketing-authorisation holders to start with the maintenance of the information on authorised medicines. This includes completing previously submitted information with additional information (new format has been released to support new regulatory obligations placed on the Agency), bringing information up–to-date, and improving the data quality. Companies were required to complete this major resubmission by the end of 2014.

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[3] The current pilot involves Sweden, Netherlands, Croatia and Italy.

Up to 26 January 2015, around 385.400 products have been received and recorded in the Article 57 database with the new format by pharmaceutical industry by 1450 MAHs.

As of January 2015, the Agency enforces the Article 57 data maintenance submission 'full process' that requires MAHs to electronically notify to the Agency of amendments to the terms of marketing authorisations following variation, transfer, renewal, suspension, revocation or withdrawal no later than 30 calendar days.

In addition, MAHs are still required to submit information on new marketing authorisations within 15 calendar days from the date of notification of the granting of the marketing authorisation by the NCA.

In view of the timelines for the Article 57 data maintenance submission the Agency intends to start using Article 57 data as the business data quality review is progressing: from the end of Q1 2015 the Article 57 database is expected to support some of the core activities at the Agency (e.g. calculation of the pharmacovigilance fees for the advice note and codification of medicines' information referenced in Individual Case Safety Reports reported in the EudraVigilance system); it is foreseen that by the end of Q2 2015 the Article 57 database will be fully operational to support the business cases as outlined in paragraph 2. (Scope and intended use).

5. Article 57 planned evolution

Article 25 and 26 of Commission Implementing Regulation (EU) No 520/2012 requires the use of common standards, formats and terminologies in the EU for the identification and exchange of information on medicines. Specific reference is made to the ISO Identification of Medicinal Product (IDMP) standards that were finalised in 2012 and implementation guides are currently under development at international level.

The Agency will replace the current Art57/XEVPRM format with the formats, terminologies and standards as defined by the ISO IDMP standards and as agreed within the EU Regulatory Network. The implementation of the ISO IDMP terminology in the EU is expected to take place in July 2016.

The Agency is currently developing an EMA roadmap to implement Substance, Products, Organisations and Referentials (SPOR) master data management services, which will also support the implementation of the ISO IDMP standards in consultation with the EU regulatory network and European pharmaceutical-industry associations. The roadmap will cover aspects related to the implementation of a SPOR Master Data Management system (MDM) and a suite of services around it. The SPOR master data implementation will include activities around business processes, data, and governance aspects around these processes as well as the technology to be used as the enabler for the desired MDM services. The EMA roadmap will provide a high level strategy of integrating non ISO IDMP compliant data from the existing core EMA systems into an ISO IDMP compliant MDM system and related processes considering the legal deadlines set in the implementing regulation.

The following general activities will have to be performed regarding Article 57 database: a full gap analysis to compare the current XEVPRM and the ISO IDMP format, data migration from the current Article 57 database into the future MDM system, optimisation of current processes to capture and manage the SPOR master data and implementation of a new data governance to mention some.

The legal obligations as described in the Article 57 will continue to apply, however the Agency is discussing with the EUNDB an operating model for the exchange of medicinal product information within the EU Network based on the ISO IDMP format, where information may be obtained from different sources (i.e. industry and NCAs) instead of only MAHs and is cleaned, consolidated and stored in a single repository. The EU data operating model will be defined cooperatively, taking into account

international initiatives such as GInAS for the identification of Substance in compliance with the ISO IDMP 11238 standard.

The EMA roadmap is planned to be consolidated by end of Q1 2015 in consultation with the EU regulatory network partners. Starting from Q1 2015, the industry will be involved in the discussion of the roadmap and in the aspects related to the ISO IDMP implementation.

NOTE: The scope of the ISO IDMP standards covers human medicines only, however there is an ongoing discussion assessing the possibility to adopt/adapt the standards for the identification of veterinary medicines. A summary of the realisations planned for the Article 57 project is summarised in Annex 1 - Article 57 summary of next deliverables.

The EMA will foster the creation of a dedicated ISO IDMP Implementation Task Force with NCAs and MAHs.

6. Annex 1 - Article 57 summary of next deliverables

	Will have by Jan'15	May have by Jan '15	Will have by Mid'16	Should have by Mid'16	May have by Mid'16	Will not have – out of scope of Art57
Data	• Information on each medicinal product received via Art57 as described in chapter 3 of the Art57 Legal Notice • By Jan 2015, all MAHs have to have resubmitted all their Medicinal Product data: EMA monitors the resubmission rate on a bi-weekly basis. • Almost all the fields that are not coded with CVs are in the national language of the MS where the product is authorised. The substance dictionary contains the translation of the substance names in most of the EU languages	Not applicable	ISO IDMP Technical Specifications, Technical report on maintenance and HL7 Messages published	• Art57 current data structure migrated to the ISO IDMP data structure as per IR520/2012 • Availability on the Market	Not applicable	Additional data elements not ISO IDMP compliant but required by MSs
Identification of Medicinal Products	• Each Medicinal product entry and each substance entry in the Art57 database has a unique EU identifier (e.g. EVCODE)	Not applicable	A global ISO IDMP system in place capable to generate unique global IDs	Not applicable	Not applicable	Not applicable
Data Quality Management	• MAHs are responsible for maintaining the Art57 data[*] and to ensure that data of the highest quality possible[**] are provided. • EMA implements a data quality assurance process[***].	Not applicable	To be defined	To be defined	To be defined	Not Applicable

	Will have by Jan'15	May have by Jan '15	Will have by Mid'16	Should have by Mid'16	May have by Mid'16	Will not have – out of scope of Art57
Access to Data	• Each MAH has the permission (controlled by specific rules embedded in the Art57 IT System) to modify only the entries which they have sent.	Art57 data is published on the EMA website in the form of Excel files which allow the data to be consulted/used /integrated by external parties/systems. (Foreseen by Aug 2015, upon completion of Art57 data validation by EMA)	To be defined	• European Medicinal Product Web Portal implemented integrating Art57 data with the latest information on the product published by the MSs where it is authorised (subject to resources availability). • Tool to allow public/HCPs/MAHs to query Art57 data (substance, country, dose, product brand name, authorisation status, indication, etc.)	Availability of "web services" (or similar technology) to support the interoperability with national systems without downloading and importing offline exports from Art57.	

* MAHs are required to comply with the published guidelines: substance names best practice, splitting of the full presentation name of the medicinal product best practice, Data quality control methodology for data submitted under Article 57(2) of Regulation (EC) No.726/2004

** MAHs are responsible for the maintenance of information on medicinal product in Art57 database as defined in chapter 5 of the Art57 Legal Notice

*** In addition, from Aug 2014, the EMA starts validating the data submitted by MAHs. EMA will provide reports on the quality of the data on the basis of quantitative metrics

7. Annex 2 - Article 57 useful links

- Article 57 Guidance Documents webpage - is the main portal, which provides Article 57 legal requirements (Legal Notice), technical specifications and guidance (Detailed guidance on the electronic submission of information on medicinal products), Data Quality control activities, FAQ document and controlled terminologies lists.

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000336.jsp&mid=WC0b01ac058079126c

- Data submission for authorised medicines webpage – outlines the main reporting requirements and provides updates on Article 57 activities as regard data quality and system enhancements.

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000496.jsp&mid=WC0b01ac058078fbe0

- Reporting and submission plan requirements for marketing-authorisation holders webpage – outlines the data maintenance submission plan up to ISO IDMP implementation.

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000594.jsp&mid=WC0b01ac058078fbe1

- Registration to XEVMPD webpage – provides information on how to access the XEVMPD in order to submit data.

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000522.jsp&mid=WC0b01ac058079126d

- Training and e-learning webpage – provides information on face-to-face training and the links to the e-learning and training documents (including EVWEB user manual).

  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000596.jsp&mid=WC0b01ac058079126e