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Records management and archives policy

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1. Introduction and purpose

Records Management is a fundamental aspect of good governance for the European Medicines Agency (EMA). Data, information and records form the basis of EMA's operations and thus serve as crucial assets for fulfilling EMA's mandate, preserving institutional memory, facilitating information exchange, providing *evidence*[1] of business activities and decisions, and meeting legal obligations.

To align with the legal, fiscal, and institutional framework governing EMA, all records created or received by the Agency must be systematically and efficiently managed throughout their *lifecycle*, irrespective of their format, location, or the system hosting them. This spans from their *declaration* to their eventual *destruction* or *permanent preservation*. Such uniform record-keeping practices are fundamental to all EMA *organisational entities* to:

- fulfil corporate governance obligations;
- ensure business continuity;
- support auditing and accountability by maintaining a clear and traceable record of actions and decisions;
- facilitate access to corporate knowledge by enabling staff members to find needed information;
- provide accurate and timely information for the decision-making process;
- promote transparency and trust by maintaining clear and accessible records of organisational activities;
- safeguard *sensitive information*, protecting it from unauthorised access, tampering, or theft;
- ensure compliance with any applicable legal and regulatory framework, including the European Union Data Protection Regulation (EUDPR)[2].

EMA has an institutional responsibility to maintain its records, documents and records management system and repositories in accordance with EMA's regulatory environment. The Agency must be able to provide information at any time on any matter for which it is accountable and fulfil transparency obligations by facilitating efficient public access to documents in accordance with the principles, arrangements and limits set out in Regulation (EC) No 1049/2001 of the European Parliament and of the Council[3].

In addition, the Article 6(5) of the agreement between the Kingdom of the Netherlands and the European Medicines Agency on the hosting of the European Medicines Agency[4] establishes that "*The archives of the Agency as well as all documents and data belonging to the Agency or held by it, wherever located, shall be inviolable*".

This policy serves as the foundation for establishing and upholding a uniform and sustainable Records management and archives framework. Alongside the EMA Data strategy[5], the EMA mail management policy, EMA Business Classification Scheme, the Retention List, and the archiving internal rules, this policy forms the overarching framework for any other corporate record-keeping practices detailed for example in specific Standard Operating Procedures (SOPs) such as SOP 1004 on Core Master Files, SOP 0138 on Records disposal, Working Instructions (WIN) or internal records management guidance.

[1] To facilitate the understanding of this document, Records Management-specific terms are written in *italic* and defined under section "3. Definitions"
[2] Regulation (EU) 2018/1725 and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC
[3] Regulation - 1049/2001 - EN - EUR-Lex (europa.eu)
[4] Available at Tractatenblad 2018, 71 | Overheid.nl > Officiële bekendmakingen (officielebekendmakingen.nl)
[5] Section 4.7 Document and Content Management

2. Scope

This policy applies to all *staff* who handle EMA *records* in the course of their duties, regardless of the location or technological environment in which they are stored.

The policy covers all types of records created or received by EMA, no matter their format, age, or medium, including but not limited to paper, digital, optical, audio, photographic, and other media. These records are an integral part of the property, resources and assets of EMA. They shall be identified and retained according to their:

- **Business (operational) value:** these records provide evidence of past decisions, documenting decision-making processes, and demonstrating EMA's fulfilment of its legal obligations. Examples include received applications and submission on marketing authorisation dossiers, Commission decisions, minutes of meetings, communications providing opinions to applicants/sponsors, guidelines, etc.
- **Legal value**: these records are mandated by legislation and demonstrate EMA's compliance with regulatory and statutory requirements. Examples include contracts, legal agreements with vendors, agreements with the host country, etc.
- **Administrative value:** records falling under this category serve administrative purposes and facilitate day-to-day business operations, ensuring consistency and continuity. Examples include part time requests, training and development records, mission reports, inventories, minutes of meetings documenting non-procedural discussions, etc.
- **Financial value:** these records contain documentary evidence of budget acquisition, planning, allocation, control, and expenditure. Examples include bank statements, financial audit reports, accounting journals, tax receipts, annual budget reports, payroll records, etc.
- **Research/Historical Value**[6]: records that provide scientific information on medicinal products and document the history and development of the EMA. These records support future research, preserve institutional memory, and offer insights into the Agency's decisions and operations. Examples include official outcomes of scientific committees, records on the nomination of Executive Directors, official visit summaries, Management Board meeting minutes, adopted budgets, foundational records of EMA, and significant projects such as the Agency's relocation from London to Amsterdam.

This policy does not apply to *non-records.*

3. Definitions

For the purposes of this policy, the following terms and definitions apply:

Accessibility: the characteristic of a record of being easily reached, retrieved, or used by individuals regardless of abilities.

Access to documents: the right of accessing to documents, subject to the procedure established by laws and other regulations.[7]

[6] EMA shall comply with the application of Council Regulation 354/1983 as amended by Council Regulation 1700/2003 and Council Regulation 2015/496 and the related Internal rules. - Non-digital archives, i.e. archives composed of analogue records regardless of the different analogue medium (textual, still and moving images, audio recordings, ephemeral objects, etc.), must be transferred to the Historic Archives of the European Union (HAEU) in Florence after 30 years.

[7] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents.

Accountability: the ability of EMA to acknowledge and take responsibility for its actions, transactions, and decisions, including the creation and execution of policies.

Active records: records needed to perform current operations and that need to be retained and maintained by EMA in accessible locations, whether in staff offices or in electronic systems that support regular and easy digital access. Also known as current records.

Application manager: a person or team responsible for the administration, operation, and maintenance of the electronic document and records management system, an electronic *repository* or database.

Archival value: the ongoing usefulness or significance of records, based on their informational or evidentiary value to EMA, which justifies their retention.

Archives: a set of records that are preserved because of their archival value or as evidence of the functions and responsibilities of their creator.

Archiving: refers to the process of storing and preserving records for long-term retention, typically for historical, legal, or regulatory purposes. It also involves moving data from active systems to more stable, long-term storage solutions, ensuring that the information remains accessible, secure, and intact over time, even after it is no longer actively in use.

Authenticity: records' quality of being genuine and not corrupted or altered.

Author: the individual responsible for the content of a document.

Business Classification Scheme: is an instrument with a hierarchical and logical structure, which enables files (or other aggregations of documents and records) to be organised and linked to the context in which they were drawn up, based on the functions, activities and working processes of the Agency. It provides a common and standard framework across EMA, allowing organisational entities to share and classify the same information for interrelated functions.

Classification: the process of establishing a system for identifying and organising records or documents so they can be filed and retrieved easily.

Creator: the individual that declares records onto an *Electronic Document and Records Management System* (EDRMS) or EMA repositories.

Data: any digital representation of acts, facts or information and any compilation of such acts, facts, or information, including in the form of sound, visual or audio-visual recording[8].

Declaration: the process of registration of a record into an EDRMS[9] or other repositories.

Destruction: the process of eliminating or deleting records, beyond any possible reconstruction.

Digitisation: the process of transforming a paper record or any other traditional medium into an electronic rendition.

Disposal: refers only to the destruction of records that are no longer needed.

Disposition: range of processes associated with implementing records retention, including destruction and transfer decisions.

Document: any content whatever its medium (written on paper or stored in electronic form or as a sound, visual or audiovisual recording) concerning a matter relating to activities and decisions falling within EMA's sphere of responsibility.

[8] Ref: EMA Data Strategy; (Data Act).
[9] For certain business activities, this action may be designed into electronic systems so that the declaration of records is concurrent with the creation of records.

Electronic Document and Records Management System: a software application that uses automated techniques to ensure that information stored in digital formats is properly distributed, used, stored, retrieved, protected, and preserved according to established policies and procedures.

Evidence: proof that an action or activity occurred.

File: aggregation of records/documents organised in line with EMA's activities, for reasons of proof, justification, or information and to guarantee efficiency. The group of records making up the file is organised in such a way as to form a coherent and relevant unit in terms of the activities conducted by the EMA's organisational entities.

Filing: the process of organising and storing documents/records in a systematic manner within a designated location, such as folders, cabinets, or digital directories, to facilitate easy retrieval and access when needed.

Historical archives: that part of the archives of the EMA which has been selected for permanent preservation, in accordance with the rules set out in the internal rules[10].

Inactive record: a record no longer needed to conduct current business but preserved until it meets the end of its *retention period*. It is rarely accessed.

Integrity: the fact that the record is complete and unaltered.

Lifecycle: See record lifecycle

Migration: process of transferring records from one system, format, or storage medium to another, ensuring that the records remain accessible, readable, and usable over time.

Non-records: documents used and kept for reference and information only or, private and personal documents which were not created or received in pursuance of the Agency's institutional or legal obligations or in the transaction of business[11].

Off-site archives: repository where EMA physical records are kept.

Organisational Entity: a functional unit of EMA, e.g. a division, a task force, an advisory function, a department, a service, an office, etc. as per EMA's organisational structure.

Permanent preservation: the phase of records lifecycle where records are preserved indefinitely because of their ongoing usefulness, significance, or historical value.

Personal data: any information that relates, directly or indirectly, to an identified or identifiable natural person[12].

Record: any information created, received, protected against intentional or accidental alterations and maintained as evidence of EMA activities in pursuance of legal obligations or in the transaction of business regardless its format.[13].

[10] EMA/16533/2024 Internal Rules for the application of Council Regulation (EEC, EURATOM) 354/83 as amended by Council Regulation (EU) 2015/496 of 17 March 2015 at EMA

[11] Examples of non-records include: press articles and books, conference brochures, private documents and personal matters kept at the office for convenience (e.g. documents accumulated by a staff member before working for EMA, presentations or papers of a business nature not representing EMA official opinion) personal notes, duplicates – that is exact copies of official records (correspondence, memos, directives, or any other information kept for personal reference) Drafts with no substantive comments etc).

[12] As defined by Article 3(1) of Regulation (EU) 2018/1725. An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economist, cultural or social identity of that natural person.

[13] Examples of records include: decisions, originals signed contracts and agreements, reports, meeting minutes, final agendas and documents discussed during Scientific Committees or Working Parties meetings, invoices received from vendors, applications files from the pharmaceutical companies, official correspondence (letters, e-mails, faxes, etc.), communications released to or received by third parties, guidelines and guidance documents, scientific assessment reports, architectural plans, photographs, etc. They may be of different media and formats, including paper, sound and video recordings, electronic files and databases.

Record lifecycle: the stages in the life of a record from its creation or receipt to destruction or transfer to permanent archives.

Records management coordinators (RMCs): are –beside their normal duties– the contact point between their organisational entities and the records management function.

Records manager: is responsible for guiding staff on the efficient and systematic control of the creation, receipt, maintenance, use and disposition of records within EMA.

Record's metadata: any information describing the context, content and structure of record and their management over time for the purpose of retrieval, accessibility and reuse.

Reliability: the trustworthiness of a record as a statement of fact.

Repository: a space used to store items of continuing value, particularly records. It is generally used to refer to storage venues holding physical and/or digital records.

Retention list: a document that identifies records or aggregations of records and determines the length of time that they must be kept before they are destroyed or transferred to the archives in accordance with their legal, business and accountability requirements.

Retention period: the length of time records should be kept in a certain location or form for administrative, legal, fiscal, historical, or other purposes.

Sensitive information: encompasses any data that, if compromised, could lead to harm, loss, or unauthorised access. This includes personally identifiable information, financial data, intellectual property, health records, and other confidential information.

Staff: any temporary agent, contract agent, seconded national expert, interim, trainee, contractor, consultant or expert who handles EMA documents and records.

Transfer: the process of moving records as part of their scheduled disposition, especially from an office to an archival repository.

Unique identifier: sequence of letters and/or numbers assigned to a record by a machine or person, by which it is identified in a single and separate manner from any other record.

4. Policy statement

4.1. Legal and regulatory framework

EMA has legal requirements to implement and keep adequate records of its functions and activities:

Council Regulation (EU) 2015/496 of 17 March 2015 amending Regulation (EEC, Euratom) No 354/83 as regards the deposit of the historical archives of the institutions at the European University Institute in Florence: establishes the obligation of preserving and opening to the public the *historical archives* of the European Union wherever possible after the expiry of a period of 30 years. It is applicable to each of the EU institutions including EMA, under the conditions set out therein.

Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents: promotes openness and accountability in the functioning of the European Union institutions by ensuring transparency and public access to documents. This regulation is applicable to all EU institutions and bodies, including EMA.

Regulation (EC) No 1605/2002 on the Financial Regulation applicable to the general budget of the European Communities applicable to EMA budget: establishes the duty of EU institutions, including the EMA, and recipients of EU funds to fully collaborate with the European Court of Auditors. It ensures the

Court has access to all necessary information and facilities to conduct audits effectively. This includes providing records related to contracts, financial documents, and facilitating on-site inspections. The aim is to promote transparency and accountability in managing EU funds.

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (also known as the "EUDPR"): is a legal instrument that focuses on the protection of personal data processed by the European Union institutions, bodies, and agencies.

Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828: this document has been used as a reference to support definitions on the EMA Data strategy.

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act): while this regulation does not expressly address the use of AI in records management and archival context, key aspects of the Act have applicability to how records are described, classified, managed retained, and accessed by the public.

Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community: it contains provision of HR records, for example the personal file.

Commission Decision (EU) 2021/2121 of 6 July 2020 on records management and archives: establishes the framework to ensure records management practices are up to date and more efficient.

Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use

Article 24 of 'The European code of Good Administrative Behaviour': sets out that organisational entities of institutions shall keep adequate records of their incoming and outgoing mail, of the documents they receive, and of the measures they take.

All the above-mentioned requirements form the basis for EMA's efforts for developing and maintaining record-keeping systems that declare and keep records with appropriate evidential characteristics in accordance with the legal and regulatory framework. In addition, EMA rules and procedures on records management and archives should be reviewed regularly and updated as needed to reflect changes in the applicable legislative and regulatory framework as well as evolution in academic and scientific research, including development and advancements of relevant standards and information and communication technologies.

4.2. Roles and responsibilities

All EMA managers are responsible for:

- endorsing and supporting the application of this policy amongst the staff under their supervision and ensuring that records management system or repositories under their purview adhere to the principles outlined in the policy.

Records manager is responsible for:

- creating and maintaining the Records management and archives policy, in cooperation with EMA's senior policy specialist and relevant internal stakeholders;
- developing other related records management instruments, such as: EMA Business Classification Scheme, Retention List, disposition procedures and assisting with monitoring their implementation in line with professional best practices;
- providing advice, guidance and training to RMCs and staff on the implementation of this policy and records management topics, as needed;
- monitoring EMA's overall compliance with this Records management and archives policy and related procedures.

Archives officer is responsible for:

- managing the retrieval, access and security of records stored in the *off-site archives;*
- promoting and supporting compliance with the archival aspects of the Records management and archives policy for the handling of inactive hardcopy records;
- implementing the archiving rules and preparing EMA's historical records and transferring them to the Historical Archives of the European Union (HAEU):
- providing the HAEU with a digital copy of historical records to make them accessible to the public after 30 years of creation;
- ensuring off-site EMA archives originated or received in hard copy are managed, physically and electronically, in compliance with this policy.

Records management coordinators are responsible for:

- supporting the implementation of Records management and archives policy and related procedures within their organisational entities;
- supporting the Records Manager in drafting and updating the sections of the Business Classification Scheme and Retention List related to their respective organisational entities;
- acting as a point of contact between their organisational entities and the Records Manager or Archives Officer when needed; and, refer to Records Manager with respect to records management related matters.

Information management division is responsible for:

- supporting and assisting in the implementation of the records management principles for EDRMS and EMA electronic repositories enabling the adherence to the principles through provision of suitable tools;
- ensuring that business solutions are designed with records management capabilities integrated or that they account for interoperability with records management applications or services that provide these capabilities;
- guaranteeing that records maintained in information systems, including records in databases, always remain secure, authentic, reliable and accessible for the entire period of their retention;
- ensuring that disposal of records is part of routine system operations and not deferred to end of life of a system, except where this has been assessed as appropriate;

- maintaining and upgrading the electronic systems, including system changes, format conversion, migration/transfer to other hardware/software and electronic archiving.

Data protection officer (DPO) is responsible for:

- ensuring the internal application of Regulation (EU) 2018/1725 regarding the protection of personal data.

Information security officer is responsible for:

- implementing access reviews to proactively identify and mitigate data security risks to record management systems and EMA repositories.

All staff are responsible for:

- declaring and managing records they are responsible for within the appropriate EMA document and records management system or EMA repository in accordance with the defined rule;
- ensuring that relevant inactive hardcopy records no longer needed for frequent reference are sent to the off-site archives.

4.3. Principles governing document and records management

A document may be received from external stakeholders or formally drawn up within EMA. It is considered active from its creation date and for as long as its value remains at its highest. During this period, it is frequently used and may undergo multiple versions. Working documents may be removed or replaced by subsequent versions until the file they belong to is closed. However, the final version of a document which is declared in the EDRMS will be considered a record and shall not be altered under any circumstance.

It is crucial to declare final documents as records to ensure their proper preservation. Therefore, when a document acquires the status of a record, it should follow the *records lifecycle* and must be adhered to the following principles:

- the authenticity, reliability, integrity and accessibility of records, along with the accompanying metadata, are maintained over time;
- each record has a *unique identifier*, and associated metadata is generated, enabling effective filing, searchability, and traceability;
- record management adheres to relevant laws and principles;
- the structure of the EMA's document and records management system and repositories, is continuously developed, maintained and updated;
- users are granted only the privileges required for their respective roles to perform their tasks on a need-to-know basis;
- prevent a single individual from having end-to-end control over tasks with potential risks like fraud, abuse or harm;
- the RMCs and employees are trained on best practices as well as the importance and the potential implications of non-compliance;
- record management practices are regularly reviewed and updated to align with changing organisational needs, best practices and external requirements.

Records are created and kept by the EMA to document its business and administrative transactions (i.e. what was communicated or decided, or what action was taken). To ensure its integrity, authenticity, reliability and accessibility, a record is not a stand-alone but rather a compound object which should contain not only the document itself (or content) but also the metadata (or context) and the format (or structure).

Ensuring the precision of metadata is paramount in establishing a robust EDRMS, as accurate metadata facilitates efficient information retrieval and serves as the basis for comprehensive understanding and analysis.

Acknowledging that the nature of records evolves over time, it is vital that metadata adapts dynamically throughout the record's lifecycle, ensuring the continued relevance, coherence and preservation of valuable information.

4.3.1. Electronic Document and Records Management System and other EMA repositories

The administration of EMA records is ensured through the use of trustworthy EDRMS, and other electronic repositories[14] designed to declare, maintain and retrieve records while ensuring their continued *integrity* with appropriate evidential characteristics. They must also ensure the traceability of records and make them available to other users through filing or other means of aggregation of records throughout their lifecycle. Additionally, regular audits should be scheduled to assess the effectiveness of the systems.

The EMA's electronic document and records management system and other repositories must be able to manage the following records management processes:

- the *declaration* and storage of records;
- the protection of record *integrity* and *authenticity*;
- the access and security of records;
- the disposal of records in accordance with the *retention list* including the preservation of those that must become part of the Historical Archives in Florence after 30 years and open to the public.

4.3.2. Creation, digitisation and declaration of records

4.3.2.1. Creation

The *author* of any newly created or received information shall determine where it is to be managed, if it is to be declared and in which repository it is to be kept according to set rules and procedures that should be defined by each system.

By default, the EMA's records shall be created as electronic document and shall be kept in the official EMA's EDRMS or authorised repository for the purpose. However, in the following situations, records may be created in a physical format or kept in a different manner:

- where a provision of Union or national or third country law so requires;
- where protocol requires physical format;
- where practical reasons impede digitisation of the record;

[14] Such as: IRIS, CTIS, EURS/CR, SPO, Exchange, EV, SAP, etc.

- where the preservation of the original physical record has an added value because of its format, the material from which it is made or for historical reasons.

All records created by staff (as defined for the purpose of this policy) carrying out EMA business-related activities are the property of EMA[15] and all received information constituting a record are in the custody of the Agency. Both types of records (those created and those received) are subject to the Agency's overall control. They must therefore be maintained in a systematic manner and compliant with established records management processes.

4.3.2.2. Digitisation

Paper records created or received by the Agency in the pursuit of legal obligations shall be systematically digitised. The resulting electronic renditions, when declared in EMA's electronic records repositories, shall replace the corresponding original physical records, unless any of the exceptions set in section 4.3.2.1 of this policy apply.

Retrospective digitisation of EMA paper records will be assessed case by case and will be described in the archiving internal rules set out by the Archives Services. These internal rules shall also describe the procedural and technical details of digitisation when applicable.

4.3.2.3. Declaration

Records shall be declared into the EMA's official EDRMS to provide evidence of its institutional or legal obligations or in the transaction of its business, unless it is decided that certain types of records must be stored in different institutional repositories due to their sensitivity or for other specific purposes[16]. Records shall no longer be altered, ensuring the integrity and authenticity throughout their entire lifecycle, in compliance with applicable regulations and standards

To ensure that records are complete and accurate and the information they contain is reliable and authentic, records shall:

- contain clear information on their business *context* (e.g. *metadata* such as: date, title, *creator*, type of record, unique identifier, key words, etc.);
- be *declared* in their original format (e.g. the electronic version of an email is the official record while a printed copy is only a convenience copy);
- be filed together with records that relate to the same function / business activity / transaction / project / product, following a uniform and consistent approach across the Agency.

4.3.3. Classification and filing, retention and disposal of records

4.3.3.1. Classification and filing

Each organisational entity shall regularly review the information created or received during its activities to identify which records are declared in the EDRMS and the repositories they use, considering the context in which they were produced, and enabling the management of said records throughout their lifecycle.

The EMA's Business Classification Scheme provides a common and standard framework across EMA, allowing organisational entities to share, classify and file the same information for interrelated functions.

[15] In accordance with article 18 of the Staff Regulations, which states that all rights in any writings or other work done by an official in the performance of his duties shall be the property of the Community which the serves.
[16] e.g., personal files are kept in SAP HR tool, product-related regulatory procedures are stored in IRIS, tickets, security incidents in ServiceNow, etc.

4.3.3.2. Retention and disposal of records

Records shall only be retained for as long as necessary to support EMA's business activities or comply with legal obligations.

The RL is an instrument that defines the statutory or recommended retention periods for each record category. Its consistent application is the most effective approach to preserve EMA's records and to prevent the unnecessary accumulation of outdated records. At the end of the records retention period, a disposition exercise must be conducted to determine which records shall be preserved or destroyed.

To ensure, that records are retained for as long as they are needed and those identified for disposal are destroyed safely and securely, records shall be disposed:

- with the assurance that they are no longer required, no work is outstanding, and no litigation, investigation or access request is current or pending and;
- after written approval and authorisation of the respective manager of the organisational entity responsible for the activity with a possibility to delegate this task.

Finally, a record destruction certificate shall be completed by the records manager to document the destruction exercise, keeping track of the records that have been destroyed. This certificate will ensure EMA can respond to internal queries and requests for access to documents. It will also serve as proof that what records have been eliminated in compliance with established rules and will be crucial for audit purposes.

4.3.4. Data management within EMA

Data Owners and Data Stewards[17] shall ensure, in line with their roles and responsibilities, that data is made available and shared as widely as possible within EMA while adhering to the need-to-know principle. This approach supports collaborative work, enhances data findability, accessibility, and reuse, and promotes resource synergies and efficiency. However, access and use may be restricted when required by legal obligations, the protection of sensitive information and personal data, or other clearly defined reasons that necessitate more limited and targeted access.

The EMA Data Strategy is a foundational document for consultation on data management across the Agency.

4.3.5. Storing of inactive records and historical archives

The processing, storage, and retrieval of inactive hardcopy records are the responsibility of the Archives Services, whereas custody of inactive electronic records remains with the originating organisational entity.

Provisions and internal rules shall be in place to guarantee the long-term or permanent preservation of records with *archival value*. Procedures for the preservation of electronic records, their context and structure must also take account of the obsolescence of hardware, software, file format and media formats used for the storage of electronic records and provide for alternate hardware, software, file format and media formats to which the records can be migrated.

EMA shall ensure that records of historical value are preserved and made available to the public wherever possible after thirty years in accordance with Regulation (EU) 2015/496. Article 9 of this Council Regulation provides that each institution shall adopt internal rules for the application of that Regulation. These internal instructions shall include rules for the preservation and opening to the public of historical

[17] EMA/563171/2023 EMA Data roles – Principles and key role descriptions

archives and on the protection of personal data contained therein. The responsibility of developing and maintaining the internal rules on this regard rests with the EMA Archives Services.

The preservation and opening to the public of EMA's archives and the deposit of the EMA's historical archives shall be hosted by Historical Archives of the European Union (HAEU) at the European University Institute (EUI) in Florence.

EMA Archives Services shall provide the HAEU with access to digitised copies of records where possible in order to promote the online consultation of the historical archives and the HAEU shall be the access point to the EMA historical archives that are open to the public, without EMA being excluded from the right to provide direct access to its historical archives.

EMA Archives Services shall provide the description of the archives that are the subject of the deposit to the HAEU. To facilitate the exchange of metadata with the EUI, interoperability shall be used in accordance with international standards.

4.3.6. Access and security of records

In the interest of information sharing, organisational entities shall ensure that their documents and records are as widely accessible as possible within EMA based on the need-to-know principle and to the extent that the sensitivity of their content permits or unless legal obligations necessitate limiting access.

Records shall be managed in accordance with the security rules applicable at EMA to the protection of information, especially sensitive information, and the rules of protection of personal data according to the implementing rules relating to the protection of personal data by the Agency. To this end, records, files, IT systems, networks and means of transmission, and archives shall be protected by adequate security measures for the management of sensitive or restricted information, preservation of certain information (e.g., litigation hold), protection of information systems and protection of personal data.

4.3.7. Records management and personal data

This policy supports the Agency's compliance with Regulation (EU) 2018/1725 with a view to protect personal data and the privacy of individuals. When processing records containing personal data, EMA is required to ensure that they are processed only for the purpose for which they were originally collected, for other compatible purposes including for archiving purposes in the public interest. The personal data contained in such records are to be kept for no longer than is necessary to fulfil these purposes[18].

The rights of the data subjects, including the requirements to provide information and access to the personal data processed concerning them, are set out in Chapter III of the EUDPR.

Certain files may need to be preserved by EMA with a view to their integration in the historical archives of the European Union. Such processing is addressed in EMA's internal rules for the implementation of Council Regulation 354/1983 as amended by Council Regulation 2015/496. As far as data protection rules are concerned, any further processing of personal data for archiving purposes in the public interest needs to comply with Article 13 EUDPR and Recital 33. Restrictions to data subject rights may apply under Article 25(4) EUDPR, in Articles 10(2)(j) EUDPR (exception to the prohibition to process special categories of personal data), 16(5)(b) EUDPR (exemption from the obligation to inform data subjects) and 19(3)(d) EUDPR (exception to the right to erasure).The erasure of personal data contained in such records would undermine the validity, integrity and authenticity of the EMA archives and is therefore likely to seriously impair the achievement of the objectives of archiving in the public interest. Similar

[18] Article 4(1)(e) of EUDPR: EMA, as controller, is responsible under Article 4(1)(e) of the Regulation for adopting a maximum retention period for the personal data undergoing processing in the context of a specific processing operation which is necessary and proportionate to the purpose for which the personal data are processed ("storage limitation").

applies to the rectification of personal data concerned. This is without prejudice to the possibility that EMA, in duly justified cases of inaccurate personal data, may decide to include a supplementary statement or annotation to the relevant record.

EMA may be unable or would be required to make a disproportionate effort to notify concerned individuals about the further processing in the historical archives of the EU once files and records are selected for permanent preservation, which constitutes a new processing activity. However, as the individuals should be provided with the information that records containing their personal data may be transferred to the EU historical archives in Florence in accordance with Articles 15 and 16 of Regulation (EU) 2018/1725, for this purpose, a Data Protection Notice[2] has been published on the EMA corporate website to provide the required information prior to the transfer to the historical archives of the EU.

In all instances, provisions on the retention period of records containing personal data should be carefully assessed and reflect how long it is strictly necessary to retain personal data to fulfil the purposes of their processing. Records containing personal data may be retained for a longer period without data protection restrictions where it is anonymised (i.e. kept in a form which no longer permits the identification of the concerned individuals).

EMA may decide, where appropriate and in consultation with the DPO, to reduce retention periods established by the RL to comply with the principle of storage limitation. In particular, EMA may decide to destroy personal data entirely or anonymise it from records to be preserved. However, the retention period for personal data and records can be aligned when duly justified and properly monitored. This justification must be documented by the Records Manager and agreed with the Internal Controller of the respective processing activities. The DPO should be consulted where further advice is needed.

The European Data Protection Supervisor (EDPS) underlines the need to adopt adequate implementing rules to ensure that data protection concerns are effectively addressed in the context of legitimate record keeping including for historical purposes. These rules are set out as part of this policy. To that end, the retention periods established by the EMA-wide retention list shall take into account the retention period of personal data as required for the respective purpose of the processing as set out above.

Appropriate safeguards should be applied to ensure that the principle of data minimisation[19] is adhered to (in accordance with Article 13 of Regulation (EU) 2018/1725). These safeguards may include pseudonymisation provided that those purposes can be fulfilled in that manner. Where the personal data are no longer required, they should be anonymised, unless a duly justified exception applies, as mentioned above.

4.3.8. Monitoring and evaluation

Criteria should be established to monitor and evaluate records management systems, repositories, procedures and processes. Compliance with this records management and archives policy—both by staff and systems—must be regularly assessed. Following established audit procedures, monitoring activities should be carried out through ad-hoc or planned audit procedures.

The creation, declaration, and management of records should be systematically monitored and evaluated with the involvement of relevant stakeholders, including records management experts, IT professionals, legal advisors, auditors, data protection specialists, business managers, and senior management, as appropriate.

[19] Processing of personal data must be adequate, relevant, and limited to what is necessary in relation to the purposes for which they are processed.

Additionally, the Business Classification Scheme, retention list, and related records management guidance must be regularly reviewed and updated to ensure they continue to meet business needs, regulatory requirements, and policy compliance.

5. Related documents

Mail management policy (Policy 0063)

Document classification policy (Policy 0081)

Records disposal procedure (SOP/EMA/0138)

Core master files of medicinal products for human and veterinary use following the centralised and referrals procedures (SOP/PDM/1004)

EMA Retention List

EMA Business Classification Scheme

EMA Data strategy

EMA Internal Rules for the application of Council Regulation (EEC, EURATOM) 354/83 as amended by Council Regulation (EU) 2015/496 of 17 March 2015.

6. Changes since last revision

The policy has been revised to include aspects of archiving in its scope. Definitions have been reviewed for consistency, roles and responsibilities aligned with current EMA organisational structure. The policy also provides further description of the document and record lifecycle at EMA. References to relevant legislation, including on personal data protection have been updated.

Amsterdam,

[Signature on file]

Emer Cooke

Executive Director