



EUROPEAN DATA PROTECTION SUPERVISOR

Decision 46/2026

of the European Data Protection Supervisor authorising the use of the administrative arrangement between the European Medicines Agency and the Council of Europe - European Directorate for the Quality of Medicines & HealthCare in the context of the Cooperation Agreement on the sampling and testing programme for medicines (Case 2024-0575)

Summary:

This Decision addresses the request from the European Medicines Agency ('EMA') for authorisation by the European Data Protection Supervisor (EDPS) of the administrative arrangement (AA) to be concluded between the European Medicines Agency (EMA) and the Council of Europe - European Directorate for the Quality of Medicines & HealthCare ('CoE-EDQM') pursuant to Article 48(3)(b) of Regulation (EU) 2018/1725¹ (the 'Regulation').

In accordance with Article 57(1)(n) and Article 58(3)(f) of the Regulation, the EDPS authorises the use of the AA as providing appropriate safeguards for the transfer of personal data from the EMA to the CoE-EDQM.

The EDPS authorises the use of the AA considering in particular the Resolution CM/Res(2022)14 on establishing the [Council of Europe Regulations on the Protection of Personal Data, adopted by the Committee of Ministers on 15 June 2022 at the 1437th meeting of the Ministers' Deputies](#) (the 'CoE Data Protection Regulations'). The EDPS considers that the appropriate safeguards included in the AA and in the CoE Data Protection Regulations provide a level of protection for the personal data transferred to the CoE-EDQM, which is essentially equivalent to that which is guaranteed under the Regulation.

¹ Regulation (EU) 2018/1725 of the European Parliament and 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, OJ L 295, 21.11.2018, p. 39.

Table of Contents

1. PROCEEDINGS	3
2. FACTS	5
2.1. EMA's authorisation request	5
2.2. EMA's Transfer Impact Assessment	7
3. LEGAL ANALYSIS	8
3.1. Requirements of Article 48(3)(b) of the Regulation.....	8
3.1.1. Applicability of the Regulation.....	9
3.1.2. Absence of adequacy decision	10
3.1.3. Specific purpose limitation for the EU public administration.....	10
3.1.4. Provision of appropriate safeguards by the controller - Need for EDPS authorisation	11
3.2. Appropriate safeguards requiring EDPS authorisation.....	13
3.2.1. Contractual framework governing the processing of personal data.....	13
3.2.2. Choice of transfer tool: administrative arrangement under Article 48(3)(b) of the Regulation.....	14
3.2.3. Assessment of the data protection safeguards included in the AA	15
3.2.4. Effectiveness of the AA in light of all circumstances of the transfer.....	16
4. CONCLUSION: AUTHORISATION	18
5. JUDICIAL REMEDY	18

1. PROCEEDINGS

1. This Decision concerns the authorisation, under Article 48(3)(b) of the Regulation, of provisions to be inserted into an administrative arrangement ('AA') between the European Medicines Agency ('EMA') and the Council of Europe - European Directorate for the Quality of Medicines & HealthCare ('CoE-EDQM') in the context of the Cooperation Agreement EMA/EDQM/2023 on the sampling and testing programme for medicines entered into between the EMA and the CoE-EDQM ('the Cooperation Agreement').
2. EMA submitted its request for authorisation of contractual clauses to the European Data Protection Supervisor ('EDPS') on 20 June 2024. The request was registered by the EDPS under case number C 2024-0575.
3. According to the request for authorisation, the submitted contractual clauses were based on the [Model Contractual Clauses of the Council of Europe](#)² and intended to provide appropriate safeguards, as well as enforceable data subject rights and effective legal remedies for the concerned data subjects in relation to the transfers of their personal data from EMA to the CoE-EDQM in the context of the sampling and testing programme for medicines, in line with the requirements laid down in Article 48(3)(a) of the Regulation.
4. On 1 July 2024, the EDPS met with EMA representatives and requested clarifications on the applicable legal framework for the processing of personal data by the CoE-EDQM and to provide a transfer impact assessment ('TIA').
5. On 2 July 2024, EMA confirmed that the processing of personal data at the CoE-EDQM is governed by Resolution CM/Res(2022)14 on establishing the [Council of Europe Regulations on the Protection of Personal Data, adopted by the Committee of Ministers on 15 June 2022 at the 1437th meeting of the Ministers' Deputies](#) (the 'CoE Data Protection Regulations'). EMA confirmed also that the [Convention for the protection of individuals with regard to the processing of personal data](#) ('Convention 108+') does not directly apply to the processing of personal data by the CoE-EDQM.
6. On 11 July 2024, the EDPS informed EMA that the draft contractual clauses submitted for authorisation needed to be revised and adapted to meet the requirements of the Regulation and consider also the specific status of EMA and CoE-EDQM as international organisations. As an alternative, the EDPS recommended³ EMA to use the specific EDPS

² Model Contractual Clauses for the Transfer of Personal Data of the Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data Convention 108.

³ According to the cover note of the submitted draft contractual clauses, the Model Contractual Clauses aim to ensure an appropriate level of protection for the transfer of personal data to countries that are not parties to Convention 108 as amended by the Protocol CETS No. 223 (Convention 108+) and may be subject to transposition and/or approval under the domestic legislation. The EDPS concluded that the submitted contractual clauses needed modifications, in particular references to the applicable legal frameworks had to

model administrative arrangement tailored for transfers of personal data from a Union institution, body, office or agency ('EUI') to an International Organisation ('IO') in accordance with Article 48(3)(b) of the Regulation ('EDPS Model AA'),⁴ to meet the requirements of the Regulation.

7. On 27 August 2024, EMA informed the EDPS that the parties agreed to proceed using the EDPS Model AA. In addition, EMA explained that their collaboration with the CoE requires the exchange of personal data between both entities and that EMA intended to adapt the Model AA to cover such bi-directional data transfers (from EMA to CoE-EDQM and vice-versa).
8. On 11 November 2024, EMA provided the EDPS with a draft AA for transfers of personal data between EMA and the CoE-EDQM based on the EDPS Model AA and the related TIA carried out by the EMA.
9. Since EMA adapted the text of the EDPS Model AA to cover both transfers from EMA to the CoE-EDQM and from the CoE-EDQM to EMA, on 17 and 28 March 2025, the EDPS requested EMA to implement some adaptations to the draft AA and recommended to ensure consistency between the AA and the Cooperation Agreement.
10. On 3 July 2025, EMA provided an up-dated draft AA and a draft amendment to the Cooperation Agreement.
11. In the course of the authorisation process, EMA provided the following documents to the EDPS in support of its authorisation request for transfers of personal data to the CoE pursuant to Article 48(3)(b) of the Regulation:
 - a) the Cooperation Agreement;
 - b) Draft Model Contractual Clauses Transfer of Personal Data on the Sampling and Testing programme for Medicines between the EMA and the CoE-EDQM;
 - c) a TIA;
 - d) a draft AA for transfers of personal data between EMA and the CoE-EDQM based on the EDPS Model AA ('the draft AA');
 - e) a draft Amendment No. 1 to the Cooperation Agreement.
12. The EDPS issues this Decision in accordance with Article 57(1)(n) and Article 58(3)(f) of the Regulation.

be updated and the text had to be aligned with the requirements of the Regulation. Since both parties are international organisations, the EDPS suggested considering using the EDPS Model Administrative Arrangement for transfers to international organisations to address the issues at stake and also to speed up the process.

⁴ This model AA was adopted by [Decision of the EDPS of 31 July 2024](#).

13. This Decision concerns only the appropriate safeguards provided by the draft AA for transfers of personal data from EMA to the CoE-EDQM.
14. This Decision is addressed to EMA.

2. FACTS

2.1. EMA's authorisation request

15. EMA's authorisation request concerns transfers of personal data to the CoE-EDQM in the form of **transmission through electronic means and local storage**. According to the information provided by EMA, the transfer is necessary for EMA's **sampling and testing programme** under Article 57 of Council Regulation (EC) 726/2004 ('EMA Regulation').⁵
16. EMA concluded the Cooperation Agreement on 11 December 2023 to implement the Sampling and Testing Programmes for sampling and testing of centrally authorised medicinal products by the CoE-EDQM. The EMA Regulation stipulates that the agency shall be responsible for coordinating the existing scientific resources put at its disposal by Member States for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products.⁶ In particular, EMA coordinates the **supervision of the quality of medicinal products for human use and of veterinary medicinal products** placed on the market by requesting testing of compliance with their authorised specifications by an Official Medicines Control Laboratory or by a laboratory that a Member State has designated for that purpose.⁷
17. According to the information provided, national authorities of Member States and the CoE-EDQM can support the above-mentioned tasks of EMA. National authorities provide qualified staff with the power to take samples of medicines from the market, while the **CoE-EDQM, is the hosting organisation of the European Network of Official Medicines Control Laboratories** including European Economic Area (EEA) Member States. The CoE-EDQM has an exclusive position to co-ordinate the work of the above-mentioned laboratories as well. In addition, as set out in the recitals of the Cooperation Agreement, the co-ordinating activity carried out by the CoE-EDQM is important in order to avoid duplication of testing in Europe, and to build up mutual confidence on the testing results among the Laboratories of the Network.
18. Article 10 of the Cooperation Agreement establishes that **EMA and the CoE-EDQM are co-controllers** and stipulates provisions for the protection of personal data, including handling of legally binding requests for disclosure of the personal data by national public authorities. The Cooperation Agreement, in its current version, also stipulates that:

⁵ Regulation (EC) No 726/2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (as amended) OJ, L 136, 30.04.2004.

⁶ Article 55 of EMA Regulation.

⁷ Article 57(1)(r) of EMA Regulation.

- the parties must sign contractual clauses for the transfers of personal data in accordance with the Council of Europe's [Model Contractual Clauses for the Transfer of Personal Data from controller to controller](#) (Article 10(12) of the Cooperation Agreement).
 - once approved, the said clauses will constitute a new annex to the Cooperation Agreement which will form an integral part of the Cooperation Agreement, but in case of conflict the terms of the Cooperation Agreement take precedence over those in the annexes (Article 17 of the Cooperation Agreement).
19. The 'draft amendment No. 1' to the Cooperation Agreement (the 'draft Amendment to the Cooperation Agreement') provided by EMA proposes notably the deletion and replacement of these provisions with the following clarifications:
- (As regards Article 10(12) of the Cooperation Agreement): "The CoE-EDQM and EMA have concluded the Administrative Arrangement under Annex V to this Agreement for the transfer of personal data from a Union institution, body, office or agency to an international organisation."⁸
 - (As regards Article 17 of the Cooperation Agreement): "The terms of this [Cooperation] Agreement and its annexes constitute the whole agreement between the parties hereto relating to its subject matter. In the event of any conflict herein, the terms set out in the Agreement shall take precedence over those in the Annexes, with the exception of the data protection obligations where the Administrative Arrangement under Annex V to this Agreement prevails."⁹
20. According to the information provided by EMA, the **purpose** of the processing of personal data is to implement the Cooperation Agreement, holding meetings and exchanging information in the context of the Sampling and Testing programme between EMA and the CoE-EDQM. In particular, the purpose of the processing is to facilitate the communication between Marketing Authorization Holders, the CoE-EDQM and the national competent authorities in the context of performing of EMA's tasks including:
- checking the compliance of products on the market with their authorised specifications by monitoring the quality of the finished products in all parts of the distribution chain throughout the authorised shelf-life;
 - ensuring that control methods are satisfactory.
21. The **categories of data subjects** whose personal data are made available via transmission and local storage are:
- Product contact persons for the Marketing Authorisation Holders for medicinal products (MAH);
 - Rapporteurs and Co-Rapporteurs designated for assessing the safety of the relevant medicinal products;
 - EMA and CoE-EDQM staff members.

⁸ Article 2 of the draft Amendment.

⁹ Article 3 of the draft Amendment.

22. The **categories of personal data** made available via transmission and local storage are:
- Name and last name of the above-mentioned categories of data subjects;
 - Professional email address of the above-mentioned categories of data subjects;
 - Professional telephone number of the above-mentioned categories of data subjects;
 - Job title and place of employment of the above-mentioned categories of data subjects.
23. Based on the information provided by EMA, the transfers of personal data are to take place regularly during the duration of the Cooperation Agreement, including subsequent renewals, and special categories of personal data (Article 10 of the Regulation) are not processed in the context of the authorisation request. Moreover, when signing the administrative arrangement, no onward transfer to other third countries or other international organisations is envisaged in Annex IV of the administrative arrangement. The parties agreed not to exclude the possibility of onward transfers for the duration of the Cooperation Agreement and kept the standard provisions on onward transfers in Article 5 of draft AA in case the data importer needs to share or transfer the received personal data to third parties.

2.2 EMA's Transfer Impact Assessment

24. The EMA provided a TIA concerning the transfers of personal data to CoE-EDQM.

Description of the transfers

25. In the TIA, EMA described the data transfers (see above section 2.1.), assessed the respective legal framework of the CoE-EDQM (data importer), including surveillance practices, identified the transfer tool to be used, assessed its effectiveness in light of the legal framework of the data importer, and identified supplementary measures needed to ensure appropriate safeguards in accordance with Article 48 of the Regulation. In this context, the document listed the technical, organisational and contractual measures to be implemented by the CoE-EDQM.

Transfer tool

26. In the absence of an adequacy decision according to Article 47 of the Regulation, EMA assessed the other possible options to provide for appropriate safeguards under Article 48 of the Regulation.
27. Originally EMA considered two options including appropriate safeguards in the form of contractual clauses pursuant to Article 48(3)(a) of the Regulation or in an administrative arrangement pursuant to Article 48(3)(b) of the Regulation. EMA first opted for the use of contractual clauses based on the Model Contractual Clauses of the Committee of the Convention 108¹⁰ for transborder data flows. After consultation of the EDPS (see above section 1, paragraph 6), EMA and the CoE-EDQM decided to include appropriate safeguards in an administrative arrangement based on the EDPS Model AA.

¹⁰[Consultative Committee of the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data, Convention 108](#)

Assessment of the legal framework applicable to the CoE-EDQM

28. EMA conducted an assessment of the CoE Data Protection Regulations, the data protection legal framework applicable to the CoE-EDQM, and of its effectiveness. The assessment established that there are only slight differences between the applicable regimes, for example under the CoE Data Protection Regulations the rights to erasure and rectification can only be exercised in case of unlawful processing and data protection rights requests shall be handled without excessive delay instead of a month under the Regulation. There are further differences concerning the right to access personal data when it comes to receiving explanations on automated decision making as well.
29. EMA concluded that the data protection regimes of the EU and CoE are similar and the transferred personal data concerns only business to business transactions data, names, job titles, contact details of the product contact for the Marketing Authorisation Holder (MAH), the Rapporteur and Co-Rapporteur for the relevant medicinal products and EMA and CoE-EDQM staff members. Therefore, in view of the above and considering the lack of previous access requests from national authorities, EMA established that the transferred personal data is not of interest to national intelligence authorities.

Assessment of the transfer tool

30. EMA concluded that in accordance with its assessment of the applicable laws and practices the transfer tool including specific technical, organisational and contractual measures is effective to ensure an essentially equivalent level of protection to what is guaranteed under EU law. Taking into account the limited scope of personal data categories, the Data Protection Officer of EMA considered that the technical and organisational measures applied are adequate. The transfer impact assessment has shown that the provisions set out in the data protection regulations governing the CoE-EDQM are fundamentally equivalent to those outlined in the Regulation. Additionally, the draft AA has established clear obligations for both parties to safeguard the rights and freedoms of the data subjects involved.
31. EMA established that considering the specific circumstances of the transfer, in particular the categories of personal data transferred and the legal framework applicable to the CoE-EDQM, specific technical, contractual and organisational measures need to be implemented as listed in Annex III and Annex V of the administrative arrangement to constitute appropriate safeguards in the sense of Article 48 of the Regulation.

3. LEGAL ANALYSIS

3.1. Requirements of Article 48(3)(b) of the Regulation

32. In order for the EDPS to grant the authorisation pursuant to Article 48(3)(b) of the Regulation, the following requirements need to be cumulatively fulfilled:

- the Regulation must apply to the transfer in question,
- no Commission adequacy decision exists in relation to the Council of Europe,
- the specific purpose limitation for the EU public administration¹¹ is complied with,
- the controller provided appropriate safeguards with enforceable data subject rights and effective legal remedies for data subjects,
- an EDPS authorisation is required.

3.1.1. Applicability of the Regulation

33. The Regulation is applicable to the transfers in question.
34. EMA is a Union institution or body (EUI), as defined in Article 3(10) of the Regulation. It has been established as a Union agency by Article 55 of the EMA Regulation on the basis of the Treaties.¹²
35. Personal data (Article 3(1) of the Regulation) such as names, contact details, job titles and places of employment of the above-mentioned data subjects involved in the implementation of the Sampling and Testing Programme, are processed (in the meaning of Article 3(3) of the Regulation) by EMA and the CoE-EDQM. The processing is carried out by EMA as a controller, in the meaning of Article 3(8) of the Regulation, as they determine the purposes and the means of the processing of personal data.
36. There is also a transfer of personal data.
37. While the Regulation does not provide a definition of international transfers, the European Data Protection Board (EDPB) has identified three cumulative criteria to identify an international transfer:
- i. the controller or processor transferring the personal data is subject to EU data protection law for the given processing,
 - ii. it makes personal data available to another data controller or processor by means of disclosure or transmission, and
 - iii. the receiving data controller or processor is in a country outside the European Economic Area (EEA) or is an international organisation.
38. When it comes to the second condition, a transfer of personal data entails the communication, transmission, disclosure or otherwise making available personal data to a third party, conducted with the knowledge or intention of the sender that the recipient(s) have access to it. It includes "deliberate transfer" of personal data and "permitted access" to personal data but excludes cases of access happened in the context of illegal actions.

¹¹ Article 47(1) of the Regulation.

¹² Articles 114 and 168(4)(b) of the Treaty on the Functioning of the European Union (former Articles 95 and 152(4)(b) of the Treaty establishing the European Community).

39. The present request concerns the transmission of personal data by a controller subject to EU data protection law to a receiving data controller which is an international organisation, as well as the local storage of personal data by these two controllers. This transmission of personal data and the local storage of personal data are transfers of personal data falling under Chapter V of the Regulation.

3.1.2. Absence of adequacy decision

40. In line with Article 47(1) of the Regulation, personal data may be transferred to a third country or an international organisation where the Commission has decided pursuant to Article 45 of Regulation 2016/679, the General Data Protection Regulation (GDPR),¹³ or Article 36 of Directive 2016/680, the Law Enforcement Directive (LED),¹⁴ that the third country or an international organisation provides a standard with regard to data protection that is essentially equivalent to that within the EU, and the personal data may be transferred ‘solely to allow tasks within the competence of the controller to be carried out’.
41. This is not the case here: as regards the Council of Europe, the Commission has not adopted an adequacy decision under Article 45(3) of the GDPR, or Article 36(3) of the Law Enforcement Directive.

3.1.3. Specific purpose limitation for the EU public administration

42. The EDPS takes the view that the specific purpose limitation referred to in Article 47(1) of the Regulation equally applies in this context.¹⁵ This reading is supported by the Schrems II judgment,¹⁶ which makes clear that a transfer subject to appropriate safeguards must benefit from the same level of protection as a transfer under an adequacy decision. For EUs, that level of protection includes the purpose limitation under Article 47(1) of the Regulation,¹⁷ otherwise personal data transferred on the basis of appropriate safeguards could be subject to a lesser level of protection than personal data transferred under an adequacy decision. Therefore, even a transfer subject to appropriate safeguards should take place ‘solely to allow tasks within the competence

¹³ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1.

¹⁴ Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA, OJ L 119, 4.5.2016, p. 89 (also called "the Law Enforcement Directive" - LED).

¹⁵ See [EDPS Decision of 8 March 2024 on its investigation into use of Microsoft 365 by the European Commission](#), in particular paragraphs 241-243 and 247.

¹⁶ See paragraphs 92 to 94 and 96 of the judgment of the Court of Justice of 16 July 2020 in case [C-311/18](#), Data Protection Commissioner v Facebook Ireland Limited and Maximilian Schrems (“Schrems II”), ECLI:EU:C:2020:559.

¹⁷ This reading is also supported by Article 94(1) of the Regulation which clearly imposes a similar purpose limitation condition for transfers of operational data under an adequacy decision (point a) of Article 94(1)) and for transfers of operational data under appropriate safeguards transfer tools (points b) and c) of Article 94(1)).

of the controller to be carried out.’ It is therefore incumbent on the EUI to limit the purposes for which it or its (sub-)processors transfer data out of the EEA to purposes without which the EUI cannot carry out its tasks.

43. In the present case, the transfers at stake in the form of transmission and local storage, are carried out to implement the Cooperation Agreement between the parties for the Sampling and Testing programmes concerning sampling and testing of centrally authorised medicinal products by the CoE-EDQM. Pursuant to Article 57 of the EMA Regulation, EMA is responsible for the evaluation, supervision and pharmacovigilance of medicinal products for human use and of veterinary medicinal products,¹⁸ in particular by requesting testing of compliance with the authorised specifications by an Official Medicines Control Laboratory or by a laboratory that a Member State has designated for that purpose.¹⁹ According to the information provided, the CoE-EDQM is the hosting organisation of the European Network of Official Medicines Control Laboratories and has an exclusive position to co-ordinate the work of the laboratories as well to avoid duplication of testing in Europe.
44. Based on the above, the EDPS considers that the transfers at stake are carried out by the EMA solely to allow EMA to fulfil its tasks under the EMA Regulation and the conditions set by Article 47(1) of the Regulation are therefore met.

3.1.4. Provision of appropriate safeguards by the controller - Need for EDPS authorisation

Provision of appropriate safeguards by the controller

45. In the absence of an adequacy decision, controllers and processors may transfer personal data to a third country only if appropriate safeguards are provided, and on condition that enforceable data subject rights and effective legal remedies for data subjects are available.²⁰
46. Standard data protection clauses adopted by the Commission or by the EDPS and approved by the Commission may provide for such appropriate safeguards.²¹ Such safeguards may also be provided, subject to the authorisation from the EDPS, by contractual clauses between the controller or processor and the controller, processor or the recipient of the personal data in the third country or international organisation ("contractual clauses") or in administrative arrangements between public authorities.²²
47. The transfer tool relied on must ensure that data subjects, whose personal data are transferred to a third country or an international organisation pursuant to that transfer tool, are afforded a level of protection in that third country or international organisation

¹⁸ Article 55 of the EMA Regulation.

¹⁹ Article 57(1)(r) of the EMA Regulation.

²⁰ Article 48(1) of the Regulation.

²¹ Article 48(2) of the Regulation.

²² Article 48(3) of the Regulation.

that is essentially equivalent to that guaranteed within the EU by EU data protection law, read in the light of the Charter of Fundamental Rights of the European Union.

48. In accordance with the interpretation provided in the Schrems II judgment of the Court of Justice of the European Union (the 'Court of Justice'), where the transfer by the EUI or on its behalf relies on transfer tools under Article 48 of the Regulation or Article 46 of the GDPR, supplementary measures may be necessary to ensure an essentially equivalent level of protection, depending on the third country law or practices.
49. EUIs must therefore carry out an individual case-by-case assessment in accordance with the Schrems II judgment, to determine whether, in the context of the specific transfer, the third country or international organisation of destination affords an essentially equivalent level of protection to that guaranteed in the EU. The EUI, where appropriate in collaboration with the data importer in the third country or international organisation, must carry out this assessment of the effectiveness of the proposed safeguards before any transfer is made or a suspended transfer is resumed.
50. The assessment by the EUI should take into consideration the specific circumstances of the transfer (e.g. categories of transferred data, purposes for which they are transferred and processed in the third country or international organisation and how) and all the actors participating in the transfer (e.g. controllers, processors and sub-processors processing data in the third country or international organisation), as identified in the mapping of the transfers. The EUI will also need to factor into this assessment any envisaged onward transfers.²³
51. Where the required essentially equivalent level of protection for the transferred data is not effectively ensured, because the law or practice of the third country or international organisation impinges on the effectiveness of the appropriate safeguards contained in the transfer tool, the EUI must implement contractual, technical and organisational measures to effectively supplement the safeguards in the transfer tool, where necessary together with the data importer.
52. This process of assessing the level of protection in the third country or international organisation and whether supplementary measures are needed, and then identifying effective supplementary measures, is commonly called a 'transfer impact assessment'. The methodology to be used is available in the EDPB Recommendations 01/2020²⁴ and, as regards the assessment of access by public authorities for surveillance purposes, in the EDPB Recommendations 02/2020 on European Essential Guarantees.²⁵

Need for EDPS authorisation

²³ Onward transfers are subsequent transfers of personal data from controllers, processors or other recipients in the third country or international organisation to other controllers, processors or recipients in another third country or international organisation or in the same third country or international organisation.

²⁴ [Recommendations 01/2020 on measures that supplement transfer tools to ensure compliance with the EU level of protection of personal data](#), adopted on 10 November 2020.

²⁵ [Recommendations 02/2020 on the European Essential Guarantees for surveillance measures, adopted on 10 November 2020](#).

53. In the present case, there is a need for the authorisation by the EDPS under Article 48(3) of the Regulation since none of the appropriate safeguards listed in Article 48(2) of the Regulation are available to the EMA.
54. In this context, it should be underlined that standard data protection clauses for transfer of personal data were adopted by the Commission pursuant to Article 46(2)(c) of the GDPR ('GDPR SCCs'). However, so far, no standard data protection clauses for transfers of personal data have been adopted under Article 48(2)(b) or (c) of the Regulation. Therefore, these provisions could not be relied on directly by EMA for transfers of personal data to third countries under Chapter V of the Regulation.

3.2. Appropriate safeguards requiring EDPS authorisation

3.2.1. Contractual framework governing the processing of personal data

55. EMA concluded the Cooperation Agreement²⁶ with the CoE-EDQM on 11 December 2023 to implement the Sampling and Testing Programmes for sampling and testing of centrally authorised medicinal products by the CoE-EDQM.
56. Article 10 of the Cooperation Agreement establishes that EMA and the CoE-EDQM are co-controllers, defines the duration of the processing, the applicable legal framework for the parties, and lists some data protection principles as well as rights and obligation of the controllers to assist each other in fulfilling their respective obligations, notify data breaches, ensure confidentiality and adopt appropriate technical and organisational security measures. The co-controllers shall notify each other without delay of any legally binding request for disclosure of the personal data exchanged under the Cooperation Agreement made by any national public authority, including an authority from a third country. A co-controller may not give such access without the prior written authorisation of the other co-controller.
57. The Cooperation Agreement provides that the parties must sign contractual clauses for the transfers of personal data in accordance with the Council of Europe's [Model Contractual Clauses for the Transfer of Personal Data from controller to controller](#). The clauses must be annexed to the Cooperation Agreement and will form an integral part of the Cooperation Agreement,²⁷ but in case of conflict the terms of the Cooperation Agreement would take precedence over those in the Annexes.²⁸
58. However, according to the draft Amendment to the Cooperation Agreement provided to the EDPS in the context of EMA's request for authorisation, EMA and the CoE-EDQM must conclude an administrative arrangement for the transfer of personal data from an EUI to an international organisation which will become an integral part of the Cooperation Agreement as Annex V to this agreement.²⁹ The draft Amendment also establishes that the administrative arrangement forms an integral part of the amended

²⁶ Cooperation Agreement No. EMA/EDQM/2023.

²⁷ Article 10(12) of the Cooperation Agreement.

²⁸ Article 17 of the Cooperation Agreement.

²⁹ Article 2 of the draft Amendment deleting and replacing Article 10(12) of the Cooperation Agreement.

Cooperation Agreement and, in case of conflict, it takes precedence over the provisions of the amended Cooperation Agreement and the other annexes.³⁰

59. The EDPS welcomes the above clarifications introduced by the draft Amendment to the Cooperation Agreement.

3.2.2. Choice of transfer tool: administrative arrangement under Article 48(3)(b) of the Regulation

60. As established in section 3.1.3 the transfer of personal data from EMA to the CoE-EDQM in line with Chapter V of the Regulation is necessary to fulfil EMA's tasks under the EMA Regulation.
61. In the absence of an adequacy decision,³¹ an administrative arrangement based on the provisions of Article 48(3)(b) of the Regulation, was identified by EMA as the tool providing for appropriate safeguards and ensuring compliance with Chapter V of the Regulation.
62. EMA decided to base the administrative arrangement (AA) on the [EDPS Model AA](#) for transfers from EUIs to international organisations adopted on 31 July 2024. The administrative arrangement will be annexed to the amended Cooperation Agreement concluded between the parties. Since the Cooperation Agreement covers exchanges between EMA and the CoE-EDQM, the EDPS notes that the EDPS Model AA was adapted to cover transfers both from the EMA to the CoE-EDQM and from the CoE-EDQM to EMA as well.
63. EMA concluded in its TIA (see section 2.2. thereto) that considering the specific circumstances of the transfer and the legal framework applicable to the CoE-EDQM, the AA should include specific technical, contractual and organisational measures to be implemented (as listed in Annexes III and V of the administrative arrangement) to provide appropriate safeguards in the sense of Article 48 of the Regulation.
64. The EDPS observes that both EMA and the Council of Europe are public authorities, therefore the parties can include appropriate safeguards in administrative arrangements pursuant to Article 48(3)(b) of the Regulation.
65. The EDPS notes that the CoE-EDQM is also an international organisation pursuant to Article 3(21) of the Regulation and welcomes that EMA used the EDPS Model AA for transfer from EUIs to international organisations, taking into account specificities of international organisations.
66. The EDPS reiterates that based on the above-mentioned EU standards for transfers of personal data (see section 3.1.), administrative arrangements should include a series of guarantees, safeguards and commitments by the EUI and the recipient to take actions and measures.

³⁰ Article 3 of the draft Amendment to the Cooperation Agreement.

³¹ *In line with Article 47(1) of the Regulation adopted on the basis of Article 45 of the GDPR.*

3.2.3. Assessment of the data protection safeguards included in the AA

67. The EMA based the administrative arrangement (AA) providing data protection safeguards on the EDPS Model AA. The draft AA has been adapted to describe the retention period of the personal data transferred,³² as well as the redress³³ and the oversight³⁴ mechanisms in place. The EMA also duly filled out Annex I.I. describing the specific circumstances of the transfers of personal data from the EMA to the CoE-EDQM, Annex II describing the applicable legal frameworks, including their privileges and immunities, and provided a list of technical and organizational measures to ensure the security of the personal data in Annex III.
68. As the collaboration between the CoE-EDQM and the EMA requires the exchange of personal data between the parties, they agreed to adapt the EDPS Model AA to cover all data transfers (from EMA to the CoE-EDQM and vice-versa). In this context the definitions of the transferring³⁵ and receiving sides³⁶ and Article 1(1) guaranteeing the effective implementation of the data protection safeguards under the respective legal frameworks have been adapted. Two new annexes have been added, Annex I.II describing the specific circumstances of the transfers of personal data from the CoE-EDQM to EMA and Annex V on the CoE-EDQM security notice listing specific security measures implemented by the CoE-EDQM for the envisaged transfers. The EDPS reiterates that the transfers from the CoE-EDQM to EMA fall outside of the scope of this Decision.
69. In addition, the parties adapted the text to reinforce their mutual obligations concerning notifications and handling of data breaches³⁷ and introduced stricter provisions for the handling of requests for access to personal data by national authorities requiring prior written authorisation of the transferring side before disclosure.³⁸
70. The EDPS Model AA provides for a template for appropriate safeguards pursuant to Article 48(3)(b) of the Regulation, which shall be adapted considering the specific circumstances of the transfer to ensure an essentially equivalent level of protection for the data transferred outside of the EEA to what is guaranteed under EU law. In this context, the EDPS welcomes that EMA made only minor modifications to the text of the Model AA and provided a draft administrative arrangement duly completed with the necessary details describing the specific circumstances of the transfers of personal data from EMA to the CoE-EDQM.
71. In view of the above and in light of all the applicable legal framework to the CoE-EDQM as well as the specific circumstances of the transfer³⁹ and the applicable technical and organisational measures listed in Annex III and Annex V of the AA **the EDPS is of the**

³² Article 3(3) of the draft administrative arrangement.

³³ Article 8(3) of the draft administrative arrangement.

³⁴ Article 9(2) and (3) of the draft administrative arrangement.

³⁵ Article 2(4) of the draft administrative arrangement.

³⁶ Article 2(5) of the draft administrative arrangement.

³⁷ Article 3(4)(2) of the draft administrative arrangement.

³⁸ Article 6(1) of the draft administrative arrangement.

³⁹ Paragraph 113 of the judgment of the Court of Justice of 16 July 2020 in case C-311/18, *Data Protection Commissioner v. Facebook Ireland LTD and Maximilian Schrems ("Schrems II")*, ECLI:EU:C:2020:559.

opinion that EMA provides appropriate safeguards for transfers of personal data to the CoE-EDQM in the context of the Cooperation Agreement, once modified by the draft Amendment, on the sampling and testing programme for medicines concluded between EMA and the CoE-EDQM.

3.2.4. Effectiveness of the AA in light of all circumstances of the transfer

72. As regards the effective implementation of the AA, EMA established in the TIA that there are only slight differences between the applicable legal frameworks, concerning for example the rights to erasure and rectification, the timelines for handling data subject rights requests or to receive explanations on automated decision making in the context of the right to access personal data.
73. Therefore, considering the categories of personal data transferred⁴⁰ as well as the lack of previous access requests from national authorities, EMA established that the transferred personal data is not of interest to national intelligence authorities. EMA concluded that the transfer tool including specific technical, organisational and contractual measures listed in Annexes III and V to the AA is effective to ensure an essentially equivalent level of protection to what is guaranteed under EU law.
74. In view of the above, the EDPS notes that the Regulation and the CoE Data Protection Regulations follow the same data protection principles, the definitions and core provisions are aligned to a great extent.
75. Applying the structured assessment developed by the EDPB in its Recommendations 02/2020 on European Essential Guarantees, the EDPS reaches the following conclusions as regards the relevant essential guarantees:
 - (A) The CoE Data Protection Regulations, adopted by Resolution CM/Res(2022)14 on 15 June 2022, lay down clear, precise and publicly accessible rules governing the processing of personal data at the CoE-EDQM, including a defined set of data subject rights.
 - (B) The CoE Data Protection Regulations establish an independent Data Protection Commissioner for the Council of Europe, endowed with investigatory and corrective powers including the power to order limitations on processing and erasure of data, acting with full independence, thereby satisfying the requirement of independent oversight.
 - (C) As regards effective legal remedies, data subjects may lodge complaints with the CoE Data Protection Commissioner, whose decisions are final and binding. For data subjects who are not eligible to bring proceedings before the Administrative Tribunal of the Council of Europe – in particular, the MAH product contact persons, Rapporteurs and Co-Rapporteurs covered by this transfer – further recourse is available through binding arbitration under the Permanent Court of Arbitration Optional Rules for Arbitration between International Organisations and Private Parties. The EDPS considers that these remedy paths, taken together, satisfy the requirement of effective legal remedies within the meaning of Article 48(1) of the

⁴⁰ Business to business transactions data, contact details.

Regulation, read in the light of Article 47 of the Charter of Fundamental Rights of the European Union, as interpreted by the Court of Justice in the Schrems II judgment.

76. Concerning requests to access personal data by national authorities, the EDPS observes that the Council of Europe is subject to the General Agreement on Privileges and Immunities of the Council of Europe.⁴¹ This Agreement, concluded in accordance with the provisions of the Statute of the Council of Europe, provides for the immunities and privileges necessary for the fulfilment of the function of the Representatives of the member States to the Committee of Ministers and the Parliamentary Assembly, as well as of the Secretariat. Among these immunities and privileges, the immunity of jurisdiction, the inviolability of the buildings and premises of the Council of Europe are included. Therefore, the EDPS considers that the privileges and immunities accorded to the CoE-EDQM and the reinforced provisions of Article 6(1) of the AA ensure effective implementation of the safeguards in case of access requests from national authorities.
77. According to the AA, the CoE-EDQM shall implement appropriate technical and organisational measures to ensure the security of the data, protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access to that data. Annexes III and Annex V of the AA list technical and organisational measures to ensure the security of the personal data at stake.⁴²
78. As regards joint controllership, Article 10 of the Cooperation Agreement, as amended by the draft Amendment, and the AA together allocate data protection responsibilities between EMA and CoE-EDQM as co-controllers, including obligations to notify each other of data breaches, to assist each other in fulfilling data subject rights requests, and to designate a point of contact for data subjects. The EDPS notes that the arrangement requires the essence of the co-controller arrangement to be made accessible to data subjects, consistent with Article 28 of the Regulation and the EDPS Guidelines on the concepts of controller, processor and joint controllership.
79. In view of the specific circumstances of the transfer, the legal framework applicable to the CoE-EDQM and the assessment carried out by EMA, the EDPS agrees that the AA and its annexes provide appropriate safeguards to ensure an essentially equivalent level of protection to what is guaranteed by EU law, taking into account the technical and organisational measures committed to by the parties in Annexes III and V of the AA.

⁴¹ *General Agreement on Privileges and Immunities of the Council of Europe (ETS No. 002), signed in Paris on 2 September 1949.*

⁴² *Annexes III and Annex V of the AA list technical and organisational measures to ensure the security of the personal data covering the following categories: technical controls implemented by the CoE-EDQM, information security policies, organization of information security, Human resource security, asset management, access control, cryptograph, physical and environmental security, operations security, communications security, system acquisition, development, and maintenance, supplier relationships, information security incident management, information security aspects of business continuity management and compliance.*

4. CONCLUSION: AUTHORISATION

80. In light of the safeguards provided by the CoE Data Protection Regulations and the TIA conducted by EMA, the EDPS considers that the AA and its annexes provide appropriate safeguards, including enforceable data subject rights and effective legal remedies for data subjects, for the purposes of the transfer of personal data by the EMA to the CoE-EDQM.
81. Therefore, considering the CoE Data Protection Regulations adopted on 15 June 2022, pursuant to Article 57(1)(n) and Article 58(3)(f) of the Regulation, the EDPS **authorises the use of the AA as a means for providing appropriate safeguards under Article 48(3)(b) of the Regulation.**

5. JUDICIAL REMEDY

82. Pursuant to Article 64 of the Regulation, any action against a decision of the EDPS shall be brought before the Court of Justice of the European Union within two months from the adoption of the present Decision and according to the conditions laid down in Article 263 TFEU.

Brussels, 5 May 2026

(e-signed)

Wojciech Rafał WIEWIÓROWSKI