EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Standard operating procedure

Title: Contribution to the 3-yearly JIACRA reports		
Status: **PUBLIC**		Document no.: SOP/V/4161
Lead author	Approver	Effective date: 28-APR-26
Name: on file	Name: on file	Review date: 28-APR-29
Signature: on file	Signature: on file	Supersedes: N/A
Date:	Date:	DREAM no.: EMA/25673/2026

1. Purpose

The purpose of this SOP is to describe the European Medicines Agency's (EMA) contribution to the end-to-end process for the preparation, review, joint endorsement, and publication of the JIACRA report (Joint Interagency Antimicrobial Consumption and Resistance Analysis), produced at least every three years by the EMA, the European Centre for Disease Prevention and Control (ECDC) and the European Food Safety Authority (EFSA).

JIACRA originates from the European Commission's One Health Action Plan against antimicrobial resistance (AMR), which mandates ECDC, EFSA, and EMA to jointly analyse the relationship between antimicrobial consumption (AMC) and AMR in humans and food-producing animals. It is in line with Regulation (EU) 2019/5, which amends Regulation (EC) No 726/2004 and formally establishes the requirement for periodic joint reporting by the three EU agencies.

The data originate from five different surveillance/monitoring networks coordinated by the agencies and cover the European Union (EU) Member States, two European Economic Area (EEA) countries (Iceland and Norway) and Switzerland (only for data on food-producing animals). The data were collected as part of existing clinical and epidemiological surveillance/monitoring systems of AMC and AMR and not specifically for the purposes of this report, specifically:

- **AMC in food-producing animals**, collected by EMA. Until 2022, these data were obtained via the *European Surveillance of Veterinary Antimicrobial Consumption* (ESVAC) voluntary network, which gathered sales data on veterinary antimicrobials. Since the implementation of Regulation (EU) 2019/6 on veterinary medicinal products, the collection of antimicrobial consumption data in animals (covering both sales and use data) is coordinated by the European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) working group.

- **AMC in humans**, collected by ECDC through the European Surveillance of Antimicrobial Consumption Network (ESAC-Net).
- **AMR in humans**, compiled by ECDC using data from two surveillance systems: the European Antimicrobial Resistance Surveillance Network (EARS-Net) and the Food and Waterborne Diseases and Zoonoses Network (FWD-Net).
- **AMR in food-producing animals**, collected by EFSA in accordance with Directive 2003/99/EC.

JIACRA operates under a rolling chairmanship shared among the three Agencies:

- EMA chaired JIACRA I and IV and will next chair JIACRA VII (from 2030)
- ECDC chaired JIACRA III and will next chair JIACRA VI (from 2027)
- EFSA chaired JIACRA II and V and will next chair JIACRA VIII (from 2033).

2. Scope

This SOP applies to the staff in the Veterinary Antimicrobial Monitoring and Resistance (V-SR-AMR) service of the Veterinary Surveillance and Regulatory Support (V-SR) department.

3. Responsibilities

It is the responsibility of the Head of V-SR-AMR to ensure that this procedure is adhered to. The roles responsible for each step are further detailed under section 9.

4. Changes since last revision

New SOP.

5. Documents needed for this SOP

- Joint interagency methodological protocols
- EMA editorial and publication guidance (EMA/39139/2026)

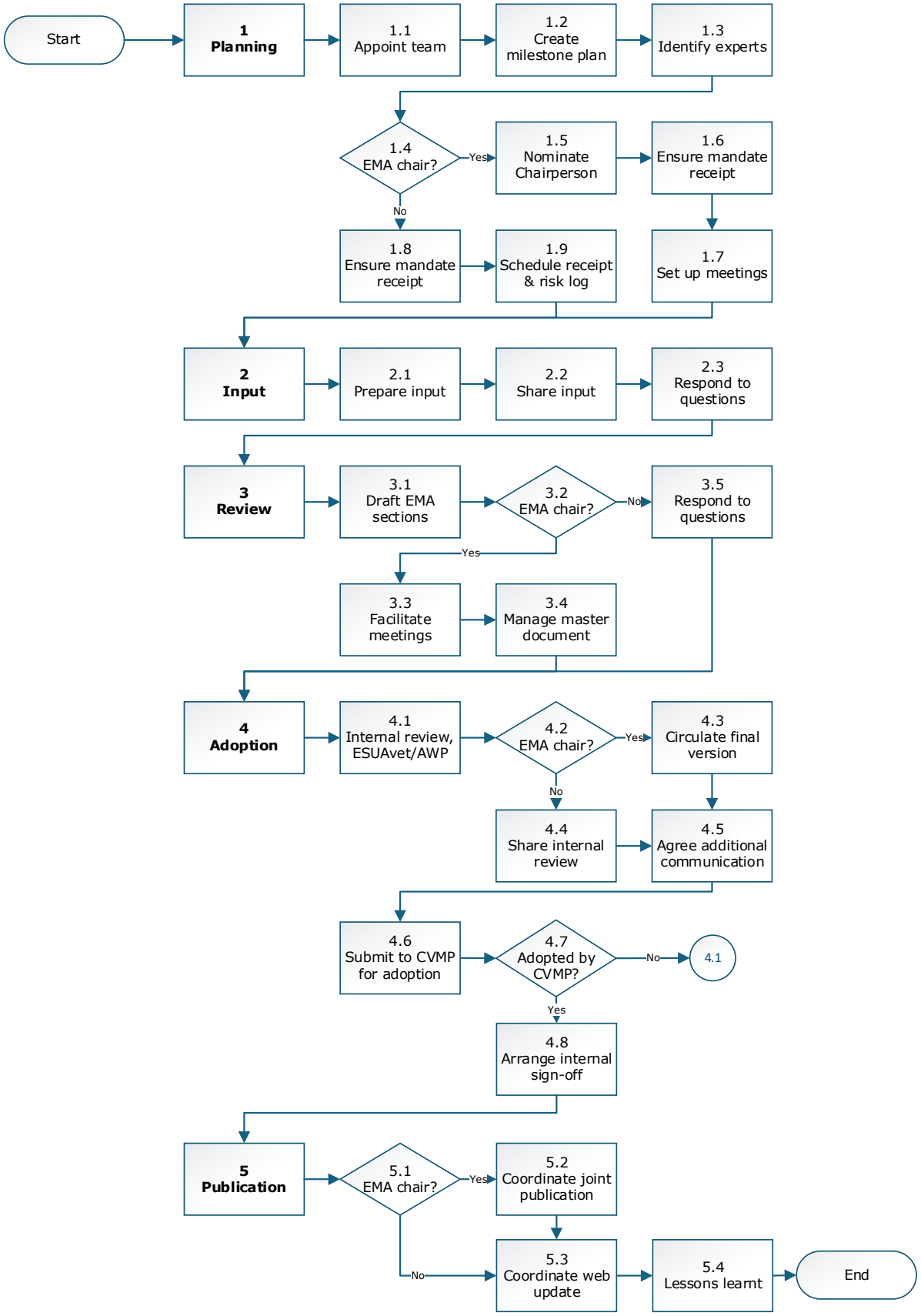
6. Related documents

- ECDC and EFSA procedures for AMR and AMC monitoring
- JIACRA on the EMA corporate website: https://www.ema.europa.eu/en/veterinary-regulatory-overview/antimicrobial-resistance-veterinary-medicine/analysis-antimicrobial-consumption-resistance-jiacra-reports

7. Definitions

Adoption	Formal acceptance of EMA's contribution to the JIACRA report by the CVMP
AMC	Antimicrobial consumption
AMR	Antimicrobial resistance
AWP	CVMP Antimicrobials Working Party
ECDC	European Centre for Disease Prevention and Control
EFSA	European Food Safety Authority
CVMP	Committee for Veterinary Medicinal Products
EMA	European Medicines Agency
ESUAvet	European Sales and Use of Antimicrobials for Veterinary Medicines
ESUAvet WG	CVMP working group supporting the Agency in the scientific preparation and review of ESUAvet outputs. All Member States that collect and report to EMA data under Article 57 of Regulation (EU) 2019/6 have nominated members in the WG.
HDep	Head of Department (in V-SR)
HSer	Head of Service (in V-SR-AMR)
JIACRA	Joint Interagency Antimicrobial Consumption and Resistance Analysis.
SL	EMA Scientific Lead in V-SR-AMR
V-SR	Surveillance and Regulatory Support department in Veterinary Medicines Division
V-SR-AMR	Veterinary Antimicrobial Monitoring and Resistance Service in V-SR

8. Process map(s)/ flow chart(s)



9. Procedure

Step	Action	Responsibility
1	**Planning**	
1.1	Appoint a responsible V-SR-AMR staff member and project team.	HSer
1.2	Define internal milestone plan (data freeze for ESUAvet inputs, review windows, CVMP adoption window, management sign-off) in agreement with HSer.	SL
1.3	Secure the participation of 2-3 external experts as part of EMA's representation in the JIACRA drafting group and confirm their participation in writing. NB: Ideally, 1-2 external experts should represent the ESUAvet WG and the Antimicrobials Working Party (AWP).	SL
1.4	Is EMA chairing? *If yes, go to 1.5* *If no, go to 1.8*	
1.5	Nominate a chairperson.	HSer
1.6	Verify that all participating agencies have received the Commission Mandate/ToR for the new JIACRA cycle and provide it, if necessary.	SL
1.7	Set up and share a common material repository, ensuring all relevant parties have access. Propose and schedule meetings with partner agencies and coordinate joint timelines. *Proceed to 2*	SL
1.8	Ensure the Commission Mandate/ToR for the new JIACRA cycle is received/recorded; if missing, request the document from the chairing Agency and record the request.	SL
1.9	Ensure that the schedule/materials are received from the chairing Agency and log any risks to EMA deliverables. *Proceed to 2*	SL
2	**Preparation of input**	
2.1	Prepare, quality-control and record ESUAvet AMC datasets for the triennial period and update historic data from previous reporting periods, if required.	SL
2.2	Share JIACRA-ready EMA data via the agreed channel.	SL
2.3	Respond to and record any follow-up requests or questions regarding the shared data. *Proceed to 3*	SL

Step	Action	Responsibility
3	**Preparation of draft report**	
3.1	Attend technical meetings, present or support experts with the presentation of EMA data/analyses, document EMA positions and track EMA action items to closure. Draft EMA-owned sections and prepare figures/tables, or support experts with these activities.	SL
3.2	Is EMA chairing? *If yes, go to 3.3* *If no, go to 3.5*	
3.3	Facilitate meetings, prepare and circulate minutes, and maintain action/decision logs. NB: Most meetings are scheduled online, and one physical meeting could also be organised annually at the EMA premises.	SL
3.4	Circulate harmonisation proposals/updates to partners and consolidate feedback for the next iteration. Manage the master document, integrate partner contributions, issue review versions and compile change logs. Apply agreed editorial standards. *Proceed to 4*	SL
3.5	Respond to requests from the chair. Submit EMA text/figures via the agreed channel, verify incorporation of EMA content and log discrepancies for follow-up. Review harmonisation proposals and submit EMA comments within the agreed timeframe. *Proceed to 4*	SL
4	**Review, adoption & sign off**	
4.1	Run an internal review of EMA's contributions (scientific, legal, editorial) and consolidate comments. Arrange a consultation with the ESUAvet WG and AWP. Consolidate, address and document any comments received.	SL
4.2	Is EMA chairing? *If yes, go to 4.3* *If no, go to 4.4*	

Step	Action	Responsibility
4.3	Incorporate the review outcomes from all three agencies into the master document. Circulate the final version to partners. *Proceed to 4.5*	SL
4.4	Share the outcome of EMA's internal review process with the chairing agency.	SL
4.5	*Approx. 1 month before publication*: discuss and agree on the development of any additional communication materials via the Communication Focal Points.	SL
4.6	Submit the JIACRA draft to CVMP for adoption of EMA's scientific contribution.	SL
4.7	Has CVMP adopted EMA's scientific contribution? *If yes, go to 4.8* *If no, go to 4.1*	
4.8	Record the adoption decision and supporting materials. Arrange internal sign-off by HSer & HDep. Monitor the adoption/endorsement status of other agencies, as needed. *Proceed to 5*	SL
5	**Publication**	
5.1	Is EMA chairing? *If yes, go to 5.2* *If no, go to 5.3*	
5.2	Coordinate the joint publication timeline and circulate the final publication pack, incl. any additional communication materials. *Proceed to 5.3*	SL
5.3	Provide final clearance for EMA contributions Coordinate the update of the EMA web content and align any additional EMA communication with the agreed publication timeline.	SL
5.4	Record lessons learned and potential improvements for future cycles, based on feedback from internal and external stakeholders, as applicable. Update EMA procedures, templates and methodological documentation as needed.	SL
6	**End of procedure**	

10. Records

Documentation and records generated during the preparation and publication of the triennial JIACRA report are maintained in accordance with applicable EMA record-keeping requirements.

Records generated during the reporting cycle may include:

- Governance and planning documents
- Analytical datasets, structured outputs and intermediate materials
- Draft and final versions of the JIACRA report
- Interagency correspondence and meeting records
- WG comment logs and handling documentation
- Presentation prepared jointly with the 2 EU agencies
- CVMP adoption and management sign-off records
- Materials documenting lessons learned and improvement actions

These are saved in the appropriately labelled folder in DREAM: EDMS \ 14. Working areas \ 14.06 V-Division \ 01. V-Division Administration \ 07. V - Other activities \ Knowledge bases \ Antimicrobial resistance \ ESVAC project \ 05 JIACRA agreement and joint reports