European Medicines Agency
Veterinary Medicines and Inspections

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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE

Involvement of SAGAM in the evaluation of applications for centralised marketing authorisations containing antimicrobial substances

1. Introduction

Article 56.2 of Regulation 726/2004 of 31 March 2004, provides that the scientific committees of the EMEA may establish scientific advisory groups in connection with the evaluation of specific types of veterinary products or treatments to which the Committee concerned may delegate certain tasks associated with the drawing up of the scientific opinions of the Committee. Taking note also of the requirements in Article 57.1.h which requires the CVMP to provide scientific advice on the use of antimicrobials in food-producing species so that the occurrence of antimicrobial resistance is minimised in the European Community, the CVMP has established the Scientific Advisory Group on Antimicrobials (SAGAM) (*See Press Release of the June 2004 CVMP meeting*).

This document lays out the criteria and procedure to involve SAGAM in the evaluation of applications for centralised marketing authorisations containing antimicrobials.

2. Criteria for decision on when to involve SAGAM

2.1. Marketing authorisations to be automatically forwarded to SAGAM

- Any new centralised marketing authorisation application for a veterinary medicinal product containing (an) antimicrobial substance(s), not assessed by the CVMP before and intended for food-producing species will be forwarded to SAGAM.

2.2. Marketing Authorisations to be forwarded to SAGAM after CVMP consideration

For the following products the CVMP will, on a case-by-case basis, decide on the need for SAGAM to be involved in the assessment:

For substances intended for food producing species:

- Any application for a change to an existing centralised marketing authorisation for a veterinary medicinal product containing (an) antimicrobial substance(s) for food producing species that may vary substantially the exposure of the animals to the product.

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For substances that are intended for non-food producing species, the following marketing authorisation applications would be candidates to be forwarded to SAGAM:

- Centralised marketing authorisation applications concerning antimicrobial substances that are of special relevance for human and animal health pending further considerations; this would include at least third generation fluoroquinolones and third and fourth generation cephalosporins;

- Any centralised marketing authorisation application for long acting or other sustained release antimicrobial products;

- Any other centralised new marketing authorisation application for antimicrobials in which claims are made of new antimicrobial properties.

The decision on the need to forward a marketing authorisation application to SAGAM shall take place at the same CVMP meeting when the letter of intent from the applicant is considered by the Committee and a rapporteur and co-rapporteur is appointed.

3. Points to be addressed by SAGAM on antimicrobial resistance

The SAGAM's role is to advise the CVMP regarding the assessment of the centralised marketing authorisation applications containing antimicrobial substances in relation to the data relevant for the evaluation of antimicrobial resistance and related issues. With regard to these SAGAM will address a pre-defined list of points and other related issues.

The summary of product characteristics (SPC), with regard to all centralised marketing authorisation applications containing antimicrobial substances, will be forwarded to SAGAM for information and comments.

The pre-defined list of points will include the following standard questions, which will be sent to SAGAM together with the data to be considered:

- Is the information on antimicrobial resistance adequate? If not, specify which further information should be provided by the applicant;
- Is the proposed dose, dosing frequency and duration of treatment adequate to minimise antimicrobial resistance?
- Are the indications of use proposed justified according to the information provided?

Procedure for the involvement of SAGAM in the evaluation of applications for centralised marketing authorisations containing antimicrobial substances

Step		Action		Responsibility
1.0		**Pre-submission**		
	1.1	Upon receipt of the letter of intent the CVMP confirms the involvement of SAGAM in the evaluation of a MA, or decides on SAGAM's involvement as per criteria under point 2.		CVMP
	1.2	Inform applicant on the involvement of SAGAM in the evaluation procedure with the letter of appointment of rapporteur and co-rapporteur Inform SAGAM on its involvement (or not) following the CVMP decision - If involvement **confirmed** or **agreed**, go to Step 1.3 - If involvement not considered go to step 2.2		EMEA project manager SAGAM secretariat
	1.3	SAGAM members are requested to volunteer as coordinator for the comments to be prepared for CVMP consideration		SAGAM secretariat
	1.4	Members of SAGAM who want to act as coordinator notify secretariat within two weeks.		SAGAM members
	1.5	Nomination of SAGAM coordinator		SAGAM chairperson
2.0		**Initial evaluation**		
	2.1	Following clock start	Send the following information to SAGAM: • Timetable for SAGAM consideration • English SPC • Expert reports, relevant studies, i.e. MIC data, PK/PD data and any other relevant information Pre-defined list of points to be considered	EMEA project manager
	2.2	Following clock start	Send English SPC to SAGAM	EMEA project manager
	2.3	By day 70	Circulated to SAGAM additional/specific points to be addressed as proposed by the rapporteur or SAGAM chairperson (if any)	EMEA Project manager
	2.4	Day 70	Sent rapporteur's assessment report to SAGAM	EMEA project manager
	2.5	Day 85	Send co-rapporteur's critique to SAGAM	EMEA project manager
	2.6	Day 85-100	Send SAGAM members comments to SAGAM coordinator with copy to SAGAM secretariat and EMEA project manager	SAGAM members

Step	Action		Responsibility
2.7	By day 111	SAGAM coordinator to compile comments in liaison with project manager and SAGAM secretariat	SAGAM coordinator; SAGAM secretariat; EMEA project manager
2.8	Day 111	Forward compiled comments to rapporteur, co-rapporteur and SAGAM members, with copy to SAGAM secretariat and EMEA project manager	SAGAM secretariat; EMEA project manager
2.9	Day 115	Rapporteur to take into account SAGAM comments in list of questions	CVMP rapporteur
2.10	After day 120	Circulate to SAGAM the list of questions adopted by CVMP	EMEA Project Manager
3.0	**Evaluation of response to list of questions**		
3.1	Day 121	Circulate timetable for evaluation of list of questions to SAGAM	EMEA project manager
3.2	Day 150	Circulate Joint rapporteur and co-rapporteur assessment report on responses to list of questions and revised English SPC to SAGAM	EMEA project manager
3.3	By day 160	SAGAM members to send comments to SAGAM coordinator with copy to SAGAM secretariat	SAGAM members
3.4	By day 161	SAGAM coordinator to send comments to rapporteur and co-rapporteur with copy to EMEA project manager and SAGAM secretariat	SAGAM coordinator
3.5	By day 180	Rapporteur and co-rapporteur to take into account comments from SAGAM when discussing the need for an Oral Explanation	Rapporteur, co-rapporteur
3.6	Day 180	CVMP to consider the need for involvement of SAGAM in case of Oral Explanation	CVMP
3.7	Post Authorisation:	CVMP to be consider the need for SAGAM members to be involved in post–authorisation follow-up measures, e.g. resistance monitoring	CVMP