# Stakeholder's submission form[1]

Union Interest referral (Article 82 of Regulation (EU) 2019/6)

## Product name or active substance

Procaine benzylpenicillin

## Note on requirements

Within the framework of the Union Interest referral introduced by Regulation (EU) 2019/6, interested parties (e.g. veterinary healthcare professionals, farmers, academia) have the opportunity to submit to the European Medicines Agency information relevant to the procedure (in line with Article 83(1) of Regulation (EU) 2019/6).

The following requirements shall apply for information to be considered:

1. Submissions must be accompanied by a duly completed submission form (available below), with all fields filled in.

2. Information submitted should make reference to the specific Committee for Veterinary Medicinal Products (CVMP) questions being addressed:

   List of questions to Stakeholders

3. The submission of all information should take place before the deadline specified at the time of the announcement of the start of the procedure:

   **09/09/2022**

4. Stakeholders' submissions of information relevant to the procedure should be sent electronically only; the name of the veterinary medicinal product/active substance concerned should be specified. Information relevant to the assessment should be submitted to the Agency by means of the following dedicated e-mail address:

   Vet.referrals@ema.europa.eu

The size of the submission file should not exceed 25MB. If your attempt to send your data package to the dedicated e-mail address is unsuccessful, please use alternative submission means.

In order to facilitate the review, it is of the utmost importance that information is provided promptly and in English.

[1] Not to be used by marketing authorisation holders/applicants.

## Note on data privacy

It should be noted that in any contribution made by external stakeholders, personal data submitted are subject to data protection rules as established by Regulation (EC) 45/2001 and will be treated in accordance with the EMA's privacy statement for public and targeted consultation (EMA/472380/2019).

Information submitted will be received and recorded by the Agency. The Agency will prepare a list of all submissions received which will be published for transparency purposes and public awareness.

## Note on commercially confidential information

Please note that all information submitted in the context of this procedure may be shared and disclosed in the public domain.

# Stakeholder's submission form

| | |
|---|---|
| **Product name or active substance:** | Procaine benzylpenicillin |
| **CVMP list of question(s) to be addressed by stakeholders:** | List of questions to Stakeholders |
| **Deadline for submission:** | **09/09/2022** |
| **Submission inbox:** | Vet.referrals@ema.europa.eu |

***To be completed by the stakeholder***

All information submitted should be accompanied by a summary of the content and make reference to the specific CVMP question(s) being addressed (as per the numbering of the published CVMP list of questions).

| | | |
|---|---|---|
| **Title:** | <Select> | |
| **Name:** | | |
| **Surname:** | | |
| **E-mail address:** | | |
| **Country of residence:** | | |
| **Submission in capacity of:** | <Select> | |
| **Summary of contents** [Constrained to 400 words] | | |
| **<Please enter question>** | | |
| **Summary of answer:** [Constrained to 250 words] | | |
| **Number of attachments:** | | |
| **Titles of attachments:** | | |
| **Have bibliographic references been attached:** | Yes ◉ | No ○ |
| **Submission date:** | | |

Personal data in this form are processed in accordance with Regulation (EC) 45/2001 and the EMA's privacy statement for public and targeted consultation (EMA/472380/2019).

The size of the submission file should not exceed 25MB. If your attempt to send your information package to the dedicated e-mail address is unsuccessful, please use alternative submission means.

**Submit by e-mail** Ready form for publishing