ANVISA
Agência Nacional de Vigilância Sanitária

# TECHNICAL NOTE No. 12/2021/SEI/COPEC/GGMED/DIRE2/ANVISA

Case No. 25351.914530/2021-11

Guidance for scheduling hearings with Anvisa's Coordination of Clinical Research on Medicines and Biological Products (COPEC).

## 1. Report

Considering the Ordinance PT No. 54, of January 27, 2021, which provides for the procedures for requesting and granting in-person or virtual hearings to private individuals, through the Parlatory System, and the need to omize technical assistance in meetings, COPEC describes the types of hearings that can be requested, as well as the items required for scheduling each modality.

## 2. Analysis

Pre-submission hearings may be requested to discuss the clinical development of a drug, when the objective is to discuss the development plan or drug research protocols that will have all or part of their clinical development in Brazil for registration purposes. This type of meeting must take place before the submission of the request for Consent in Clinical Research and for scheduling the company may request the presence of the technical area responsible for the registration of the drug in question. The appointment request must contain:

The. complete description of the agenda, containing general information about the investigational drug and purpose of the meeting
B. justification for rare disease, in cases corresponding to experimental drugs that fit the conditions established by RDC No. 205/2017;
ç. presentation or material that will be discussed at a meeting; d. brief synopsis of the proposed study or development plan; and. list of preliminary questions to be addressed during the meeting; f. previous minutes, in case the matter has already been the subject of a hearing.

If the objecve is to deal with matters related to petitions already submitted to Anvisa, hearings can be requested to deal with requirements, but these will only be scheduled if the applicant has contacted one or more service channels and has not had their doubts clarified. . In this case, you must provide the complete description of the agenda, containing at least the following information:

The. Number of the case and file(s) that will be the subject of the hearing; B. Number(s) of the protocol(s) opened in the service channels, accompanied by justification containing the reasons why the response sent was not sufficient to solve the questioning made;

ç. Technical requirement notification number, if applicable; d. For each item of the requirement to be discussed, inform: 1. the item number; 2. the specific questioning regarding this item;

3. if the company has an understanding on the subject, detail this understanding and insert a technical-scientific justification or basis;
4. if the company has a proposal to comply with the item, detail this proposal and insert justification or technical-scientific basis; and. Minutes of

previous hearings, if any.

The requested information may be submitted through the Pre-submission/Discussion of Clinical Drug Development Hearing Request Form (Appendix 1) or through the Hearing Request Form for Discussion of Requests previously submitted to Anvisa (Appendix 2) .

Hearings requested to verify the status of the process or clarify other questions will not be scheduled if the matter can be clarified by the ANVISA Service Center.

Hearings will be scheduled preferably on Thursdays and at least 10 business days after the request date. Scheduling joint meetings that require the presence of other areas of ANVISA may take more than 10 days, as they depend on the availability of other areas and must be requested as soon as possible.

The hearings will have a maximum duration of 1 (one) hour and only one product will be discussed per audience. Items not provided for on the agenda will not be discussed.

It is not necessary to use any other communication channel with Anvisa to deal with hearing schedule. The request will only be evaluated by the Parlatório system.

**Appendix 1**

Pre-Submission Hearing Request Form

Discussion of Clinical Drug Development

| | |
|---|---|
| **Identification of the investigational drug** | Experimental drug code:<br>Business name (if applicable):<br>IFA:<br>Pharmaceutical form:<br>Concentration:<br>Proposed indication: |
| **Purpose of the meeting** | *Describe the moovement of the meeting and what are the company's objecves with holding the meeting.*<br><br>Units to be invited (if applicable): |
| **Prioritized (RDC 204/2017)** | ÿ no ÿ yes |
| **Rare Disease (RDC 205/2017)** | ÿ no ÿ yes<br>If so, submit:<br>*Justified for rare disease, including:*<br>*- National and international epidemiological data on the clinical condition*<br>*- Treatments available in the national and international market* |

**Agenda**

***Description of the meeting agenda with estimated time for each topic.***

| The life of | estimated time |
|---|---|
| | |

| | |
|---|---|
| *Introduction* | *5 minutes* |
| *Product Overview (DDCM) XX minutes* | |
| *Protocol Overview (DEEC) XX minutes* | |
| *Discussion of issues* | *XX minutes* |
| *referrals* | *XX minutes* |

**Discussion history**

***Include the context of regulatory discussion relevant to the hearing, with a brief description of all previous contacts on the topic of the meeting, including the report of contacts made with other areas of Anvisa. The numbers of protocols for attendance by other channels must be cited and minutes of hearings already held on the subject must be presented.***

**Product Development History**

***Brief description of the clinical development project for the product, with a brief summary of the studies already carried out and the schedule of the studies still to be carried out.***

**Protocol Synopsis**

***Summary of studies to be presented in the DDCM consent submission, or***

***Summary of the study to be presented in the DEEC consent submission.***

***List the countries in which the protocol(s) is(are) approved and in which it(are) has already been initiated.***

**list of questions**

***List all the company's doubts that will be discussed at the hearing. Questions related to the agenda not previously described may eventually not be answered at the time of the hearing.***

**Rules for requesting a hearing (Ordinance No. 54, of 01/27/2021)**

1. Hearing requests must be made exclusively by the Parlatory System.
2. Hearings must be requested 10 (ten) business days in advance of the intended date.
3. COPEC will have a maximum period of 5 (five) business days after the request to express its opinion on the scheduling request.
4. The hearings will be recorded.

**General information**

1. The day for COPEC's consultation in the parlor is **Thursday.** Requests for other days of the week, the unless previously agreed, will be refused.
2. In case of unavailability of the COPEC agenda for the proposed date, the request will be scheduled with change of date and/or time proposed by the individual.
3. If the questions sent in this form can be answered in writing, COPEC will forward responses to the applicant's e-mail address described in the form, and the request will be refused. If there are still doubts, the company may send a new request for a hearing, with a new form explaining what has not been clarified.
4. Requests without the detailed agenda description as requested in the form will be refused.

5. The presentation that will be discussed at the meeting as well as the previous minutes, in case the matter has already been object of any hearing must be forwarded as an attachment to this form.
6. The hearings will have a maximum duration of 1 (one) hour and only one product will be discussed per audience. No unforeseen items on the agenda will be discussed.

**Appendix 2**

Hearing Request Form for

Discussion of Requests Submitted to Anvisa

| | |
|---|---|
| **Identification of the investigational drug** | Process number:<br>Number of the file under review:<br>Requirement file number:<br>Experimental drug code:<br>Business name (if applicable):<br>IFA:<br>Pharmaceutical form:<br>Concentration:<br>Proposed indication:<br>Prioritized request (RDC 204/2017): ÿ no ÿ yes Rare<br>Disease (RDC 205/2017): ÿ no ÿ yes *Describe the* |
| **Purpose of the meeting** | *movement of the meeting and the company's objecves with holding the meeting .*<br><br>Units to be invited (if applicable): |

**Agenda**

***Description of the meeting agenda with estimated time for each topic:***

| **The life of** | **estimated time** |
|---|---|
| *Introduction* | *5 minutes* |
| *Discussion of questions X* | *X minutes* |
| *referrals* | *XX minutes* |

**Discussion history**

***Include the context of regulatory discussion relevant to the hearing, with a brief description of all previous contacts on the topic of the meeting, including the report of contacts made with other areas of Anvisa. The numbers of protocols of attendance by other channels must be cited with justification containing the reasons why the answer sent was not sufficient to solve the question made and minutes of hearings already held on the subject must be presented.***

**list of questions**

***List all questions the company wants to discuss.***

***If applicable, list all the items of the requirement that raised doubts and the company's questions about each item that will be discussed at the hearing.***

***For each item of the requirement to be discussed, inform:***

***1. the item number;***

***2. the specific questioning regarding this item;***

***3. if the company has an understanding on the subject, detail this understanding and insert a technical-scientific justification or basis;***

***4. if the company has a proposal for compliance with the item, detail this proposal and insert justification or technical-scientific basis;***

***Items not listed will not be discussed.***

***Example:***

***Item 1 – The company did not understand what information is being requested, if it is the presentation of a new study or if a literature review can provide the requested information.***

***Item 10 – The company's proposal to fulfill the aforementioned item is the presentation of a study conducted to evaluate the interaction of X with Y. Is the proposal plausible?***

**Rules for requesting a hearing (Ordinance No. 54, of 01/27/2021)**

1. Hearing requests must be made exclusively by the Parlatory System.
2. Hearings must be requested 10 (ten) business days in advance of the intended date.
3. COPEC will have a maximum period of 5 (five) business days after the request to express its opinion on the scheduling request.
4. The hearings will be recorded.

**General information**

1. The day for COPEC's consultation in the parlor is **Thursday.** Requests for other days of the week, the unless previously agreed, will be refused.
2. In case of unavailability of the COPEC agenda for the proposed date, the request will be scheduled with change of date and/or time proposed by the individual.
3. If the questions sent in this form can be answered in writing, COPEC will forward responses to the applicant's e-mail address described in the form, and the request will be refused. If there are still doubts, the company may send a new request for a hearing, with a new form explaining what has not been clarified.
4. Requests without the detailed agenda description as requested in the form will be refused.
5. Support material may be requested for the meeting to be held.
6. The hearings will have a maximum duration of 1 (one) hour and only one product will be discussed per audience. Items not provided for on the agenda will not be discussed.

**3. Conclusion**

The holding of pre-submission hearings does not replace the technical evaluation and is not enough to exhaust all the possibilities of requirements.

COPEC reinforces that the intention of adopting this procedure is to make the meetings more objective and productive techniques, optimizing the service provided.

Furthermore, COPEC emphasizes that requests for hearings that do not comply with Ordinance PT No. 54, of January 27, 2021, and the provisions of this note will be refused.

Document signed electronically by **Claudiosvam Marns Alves de Sousa, Coordinator of Clinical Research in Drugs and Substitute Biological Products,** on 05/18/2021, at 19:37, according to Brasília official time, based on art. 6, § 1, of Decree No. 8.539, of October 8, 2015 hp:// www.planalto.gov.br/ccivil_03/_Ato2015-2018/2015/Decreto/D8539.htm.

Document signed electronically by **Gustavo Mendes Lima Santos, General Manager of Medicines and Biological Products,** on 05/19/2021, at 10:00 am, according to Brasília official time, based on art. 6, § 1, of Decree No. 8.539, of October 8, 2015 hp://www.planalto.gov.br/ccivil_03/ _Ato2015-2018/2015/Decreto/D8539.htm.

The authenticity of this document can be checked on the website hps://sei.anvisa.gov.br/autencidade, informing the verifier code **1456413** and the CRC code **8B38E10E.**

**Reference:** Case No. 25351.914530/2021-11 YOU ARE No. 1456413