

INFORMATION NOTE No. 1/2026/SEI/GGBIO/DIRE2/ANVISA

Case No. 25351.902941/2026-78

Subject: **Evaluation of comparative pharmacokinetic studies of biosimilars submitted as supporting documentation for the registration and approval of DDCMs.**

1. Considering the Collegiate Board Resolution – RDC Anvisa No. 875/2024, which provides supplementary information on the registration of Biosimilars, notably article 8, which stipulates that clinical studies and/or parameters of comparative clinical evaluation may be waived upon compliance with the conditions described in said regulation, and with the aim of streamlining and integrating the evaluation of the technical elements contained in the dossiers, the comparative Pharmacokinetic (PK) Studies presented as supporting documentation for the registration of Biosimilars and for the approval of the Clinical Development Dossiers for Biosimilar Medicines (DDCMs) are now evaluated by the Biological Products Evaluation Management (GPBIO/GGBIO/DIRE2).

2. The petitioning topics listed below should continue to be used, as indicated below.

- 10846 – BIOLOGICAL PRODUCT – Pharmacokinetic study; and
- 10900 – CLINICAL TRIALS – Comparative pharmacokinetic studies for investigational drugs – Biosimilars – submitted as DDCM

3. When submitting the registration dossier for a Biosimilar drug, PK studies must be filed in conjunction with the main petition (registration process) using the subject code “10846 – BIOLOGICAL PRODUCT – Pharmacokinetic study”. If more than one PK study is related to the main petition, all studies must be included in the same file corresponding to subject 10846.

4. For clinical developments of biosimilars for which the submission of a DDCM (Detailed Clinical Development Plan) is foreseen in the Collegiate Board Resolution – RDC Anvisa No. 945/2024, and whose DDCMs contain completed comparative PK (Pharmacokinetic) trials used as a basis for the proposed subsequent phases, a secondary petition with the subject code “10900 – CLINICAL TRIALS – Comparative pharmacokinetic studies for investigational medicines – Biosimilars – submitted as DDCM” must be submitted to Anvisa at the time of DDCM submission, linked to the DDCM petition. If the clinical development is limited to comparative PK studies (relative bioavailability), the submission of a DDCM is not necessary.

In addition to the submission via subject 10900, described above (which will be evaluated by GPBIO), the comparative PK study must be included in the Investigational Drug Development Plan in the main DDCM documentation, and the corresponding data must be presented in the Investigator's Brochure for evaluation by COPEC. Therefore, PK studies linked to a DDCM will be evaluated by COPEC and GPBIO in a complementary manner, observing the specific competencies of each area, and both areas may issue requirements regarding relative bioavailability studies.

6. In the event of prioritization of DDCM analysis, pursuant to Resolution RDC No. 1001/2025, which is linked to petition subject 10900, the COPEC and areas

GPBIO must respond within 45 days of the prioritization approval. If the applicant has not filed a petition regarding matter 10900 by the time the prioritization is approved, the deadline for GPBIO's first response will begin to be counted from the date the document with matter code 10900 was filed.

7. The applicant for DDCM approval should be aware that the analysis cannot be completed without the final opinion of GPBIO on the comparative PK study, and must submit matter 10900 in a timely manner.
8. When the PK study is evaluated by GPBIO during clinical development, it will not be necessary to submit the same documentation via subject 10846 at the time of registration; it is sufficient to indicate, via subject 10846, the file number of subject 10900 that was previously approved.
9. The documentation related to PK studies submitted through subjects 10846 and 10900 must follow the respective checklist available at <https://consultas.anvisa.gov.br/#/consultadeassuntos/>.
10. In addition to other relevant standards, PK studies must comply with the following regulations and their updates:
 - RESOLUTION - RDC No. 55, OF DECEMBER 16, 2010 (Provides for the registration of new biological products and biological products and takes other measures); RESOLUTION OF THE BOARD OF DIRECTORS
 - - RDC No. 875, OF MAY 28, 2024 (Provides additionally for the registration of Biosimilars through the comparability development pathway); RESOLUTION - RDC No. 742, OF AUGUST 10, 2022 (Provides for the criteria for conducting relative bioavailability/bioequivalence (BD/BE)
 - studies and pharmacokinetic studies); RESOLUTION - RDC No. 941, OF NOVEMBER 18, 2024 (Provides for the validation of bioanalytical methods and analysis of study samples for regulatory submissions of manufactured medicines for human use); and
 - Guideline No. 72, dated April 1, 2024 (Guideline for validation of bioanalytical methods and analysis of study samples for regulatory submissions of manufactured medicines for human use).
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11. The following documents are hereby revoked:
 - CLARIFICATION NOTE No. 002/2015/GPBIO/GGPBS/SUMED/ANVISA (Comparative Pharmacokinetic Studies of Biological Products); TECHNICAL NOTE No. 118/2016/GGMED/ANVISA-
 - MS (Comparative Pharmacokinetic Studies of Biological Products (Biosimilars)); Questions and Answers document of March 3, 2017, issued by the THERAPEUTIC EQUIVALENCE
 - COORDINATION of the GENERAL MANAGEMENT OF MEDICINES AND BIOLOGICAL PRODUCTS (Validation of Binding Assays for Bioequivalence and Pharmacokinetic Comparability Studies); and the Questions and Answers document of March 14, 2019, issued by the THERAPEUTIC EQUIVALENCE COORDINATION of the GENERAL MANAGEMENT OF MEDICINES AND BIOLOGICAL PRODUCTS (Documents for the analysis of
 - comparative pharmacokinetic studies of biological products).



This document was electronically signed by **Anderson Vezali Montai, Acting General Manager of Biological Products, Radiopharmaceuticals, Blood, Tissues, Cells, Organs and Advanced Therapy Products**, on June 26, 2026, at 9:59 AM, Brasília time, pursuant to § 3 of Article 4 of Decree No. 10,543, of November 13, 2020 http://www.planalto.gov.br/ccivil_03/_ato2019-2022/2020/decreto/D10543.htm.



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