Brazilian Health Regulatory Agency

TECHNICAL NOTE No. 5/2023/SEI/CETER/GGMED/DIRE2/ANVISA

Case No. 25351.910775/2020-98

Revocation of Technical Notes No. 23/2020/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 33/2021/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 10/2022/SEI/COPEC/GGMED/DIRE2/ANVISA, and No. 24/2022/SEI/CETER/GGMED/DIRE2/ANVISA, which provide for guidance to sponsors, study sites, and investigators involved in conducting clinical trials and bioequivalence studies during the Covid-19 pandemic.

1. Report

This document presents the revocation of Technical Notes No. 23/2020/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 33/2021/SEI/COPEC/GGMED/DIRE2/ANVISA No. 10/2022/SEI/COPEC/DIRE2/ANVISA, and No. 24/2022/SEI/CETER/GGMED/DIRE2/ANVISA, which provide for guidance to sponsors, study sites, and investigators involved in conducting clinical trials authorized by Anvisa and bioequivalence studies during the Covid-19 pandemic.

2. Analysis

The current epidemiological situation of SARS-COV-2 infection in Brazil has shown a significant decrease in the number of cases and deaths from Covid-19, as well as a considerable level of vaccination of the general population. The pandemic has also cooled down worldwide, which led the World Health Organization to declare the end of the international emergency caused by Covid-19.

Considering the aforementioned facts, it is concluded that there is no longer any reason to maintain the differentiated treatments related to the performance of clinical trials and bioequivalence studies linked to the registration and post-registration of drugs and health products. Therefore, it is concluded that Technical Notes No. 23/2020/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 33/2021/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 10/2022/SEI/COPEC/GGMED/DIRE2/ANVISA, and No. 24/2022/SEI/CETER/GGMED/DIRE2/ANVISA, currently in force and which describe the differentiated procedures due to the Covid-19 pandemic, should be revoked. By revoking the aforementioned Technical Notes, the subject of clinical trial on drugs and health products and bioequivalence studies will be regulated only by the applicable resolutions and other regulatory instruments in force.

3. Conclusion

Based on the reasons described above, it is concluded that Technical Notes No. 23/2020/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 33/2021/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 10/2022/SEI/COPEC/GGMED/DIRE2/ANVISA, and No. 24/2022/SEI/CETER/GGMED/DIRE2/ANVISA should be revoked, and the subject of clinical trial on drugs and health products and bioequivalence studies should be regulated by the applicable resolutions and other regulatory instruments in force.

4. Change history

- 23/Mar/2020 (NT No. 03/2020): Technical note with guidance to sponsors, sites, and investigators involved in conducting clinical trials authorized by Anvisa and bioequivalence studies, during the Covid-19 pandemic, in order to discuss proposals for new clinical trials as a priority and provide support for those that were already underway.
- 22/Apr/2020 (NT No. 13/2020): Inclusion of the items “Specific information for clinical trials with drugs for COVID-19”; “Specific information for clinical trials with medical devices for COVID-19”; details on remote source document verification; telemedicine; change of terminology throughout the text to align with current regulations and references.
- 22/Apr/2020 (NT No. 14/2020): Inclusion of the item “Clinical trials of COVID-19”; - “Specific information for clinical trials with medical devices intended to combat COVID-19”; details on remote source document verification; telemedicine; change of terminology throughout the text to be aligned with current regulations; and update of references.
- 15/Jun/2020 (NT No. 22/2020): Update on remote verification of source document; change of terminology in some parts of the text to be aligned with current regulations, inclusion of special procedures for return of bioequivalence centers in locations where there are no restrictions

from state and municipal authorities to conduct their activities, and update of references.

- 13/Jul/2020 (NT No. 23/2020): Inclusion of the need for training for telemedicine visits; remote endpoint assessment; withdrawal of the need for documentation of agreement of the parties in case of remote verification of source documents; inclusion of the protection of blinding and the adopted flow for accelerated assessment of COVID-19 studies; considerations related to the time between collection of biological material and obtaining of the test result for bioequivalence studies; update of references.
- 29/Dec/2020 (NT No. 37/2020): It describes guidelines for sponsors, CROs (Contract Research Organizations), study sites, and investigators involved in conducting clinical trials authorized by Anvisa for the clinical development of vaccines against Covid-19, in order to qualify and promote agility in reporting serious and unexpected adverse events to Anvisa.
- 07/Jan/2021 (NT No. 01/2021): Update of Technical Note No. 37/2020/SEI/COPEC/GGMED/DIRE2/ANVISA, which describes guidance to sponsors, CROs (Contract Research Organizations), study sites, and investigators involved in conducting clinical trials authorized by Anvisa for the clinical development of vaccines against Covid-19, in order to qualify and promote agility in reporting serious and unexpected adverse events to Anvisa.
- 23/Nov/2021 (NT No. 33/2021): Complementary information to the guidance contained in Technical Note No. 23/2020/SEI/COPEC/GGMED/DIRE2/ANVISA, regarding the evaluation time of clinical trial dossiers with drugs and vaccines for COVID-19.
- 24/Nov/2021 (NT No. 34/2021): Update of Technical Note No. 1/2021/SEI/COPEC/GGMED/DIRE2/ANVISA describing guidance issued to sponsors, CROs, study sites, and investigators involved in conducting clinical trials authorized by Anvisa for the clinical development of vaccines against Covid-19, regarding the reporting of serious and unexpected adverse events occurring in these studies in the country.
- 30/Jun/2022 (NT No. 08/2022): End of Public Health Emergency of National Concern - PHENC.
- 18/Jul/2022 (NT No. 10/2022): Update of Technical Note No. 33/2021/SEI/COPEC/GGMED/DIRE2/ANVISA and revocation of Technical Notes No. 1/2021/SEI/COPEC/GGMED/DIRE2/ANVISA and No. 34/2021/SEI/COPEC/GGMED/DIRE2/ANVISA regarding the end of Public Health Emergency of National Concern (PHENC) due to Human Infection by the new Coronavirus (2019-nCov), referred to in GM/MS Ordinance No. 188, of February 3, 2020.
- 26/Sep/2022 (NT No. 24/2022): guidelines to sponsors, study sites, and investigators involved in conducting clinical trials authorized by Anvisa and bioequivalence studies, in order to enable the conduct of clinical trials in Brazil with the speed that the moment requires and ensuring the safety of participants. Possibility of not testing for SARS-COV-2 for individuals with complete vaccination, as well as the possibility of using antigen immunochromatographic diagnostic kits that target asymptomatic individuals.
- 11/May/2023 (NT No. 05/2023): Revocation of Technical Notes No. 23/2020/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 33/2021/SEI/COPEC/GGMED/DIRE2/ANVISA, No. 10/2022/SEI/COPEC/GGMED/DIRE2/ANVISA, and No. 24/2022/SEI/CETER/GGMED/DIRE2/ANVISA that allowed differentiated treatments due to the Covid-19 pandemic.