Title

Main questions regarding the Analysis Flow of Innovative Synthetic Drugs in Brazil

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☐ Abstract

The objective of this work was to raise the main questions regarding the analysis flow of innovative synthetic drugs according to the legal requirements of ANVISA. This paper presents relevant points that may be doubts of companies around the world and that the information is not always presented clearly in Brazilian legislation.

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1. INTRODUCTION

In order to allow greater technical enhancement by area of knowledge and speed up the technical analysis, since 2014, the Safety and Effectiveness Assessment Management (GESEF) started to exclusively analyze the reports of non-clinical and clinical studies (safety and effectiveness), while the Synthetic Drug Registration Technology Assessment Management (GRMED) started to analyze the production of technical reports and quality of documentation related to new and innovative drug registration requests.

In September 2017, within the administrative structure of GESEF, the Incremental Innovation Coordination (COINC) was created, with the aim of investigating the safety and efficacy data of the innovative drug registration processes. Thus, COINC's attribution is, exclusively, the evaluation of the safety and efficacy of innovative medicines, and COINC is not responsible for assessing the quality of the documentation and technical production reports, which remain under the responsibility of the Synthetic Drug Registration Technology Assessment Management (GRMED).

2. SCOPE

With the restructuring of GESEF, the creation of COINC and the publication of Resolution RDC No. 200 of December 26, 2017, there were several changes in the workflow in the analysis of registration processes for innovative medicines.

The scope of this Q&A is to elucidate the workflow of application analysis for registration of innovative synthetic medicines, specifying the areas involved in the process.

3. QUESTIONS AND ANSWERS

3.1. Subject codes and fields of analysis

3.1.1. What are the subject codes that fall under the category of innovative medicines?

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Code	Description
1455	NEW MEDICATION – Registration of new concentration in the country.
1456	NEW MEDICATION – Registration of new pharmaceutical form in the country.
1457	NEW MEDICATION – Registration of new therapeutic indication in the country.
1460	NEW MEDICATION – Registration of new association in the country.
1461	NEW MEDICATION - Registration of new route of administration in the country.
10559	NEW MEDICATION – Registration of new concentration in the country (Productive Development Partnership).
10560	NEW MEDICATION – Registration of new pharmaceutical form in the country (Productive Development Partnership).
10561	NEW MEDICATION – Registration of new therapeutic indication in the country (Productive Development Partnership).
10563	NEW MEDICATION – Registration of new association in the country (Productive Development Partnership).
10564	NEW MEDICATION - Registration of new route of administration in the country (Productive Development Partnership).
10775	NEW MEDICATION - Registration of same active pharmaceutical ingredient(s) of previously registered new medication.
11116	RDC 73/2016 – NEW – Inclusion of new concentration.
11318	Innovative Medication - Registration of new medication with diverse innovation.

Code 11116 - RDC 73/2016 - NEW - Inclusion of a new concentration, despite it is a post-registration petition, since it is configured as an incremental innovation, it is dealt with the same technical analysis criteria as the registration of innovative drugs and, therefore, binded to the innovators' registration queue.

3.1.2. Which areas are involved in the analysis of petitions for registration of innovative medicines?

An application for an innovative drug registration is necessarily evaluated by at least three areas of GGMED: GRMED, with the evaluation of the documentation related to technology and product quality, COINC, with the evaluation of the safety and efficacy documentation, and CRMEC, with the evaluation of the labeling and commercial name of the product. According to the characteristics of each process, other areas can still be

involved in the analysis, namely:

GESEF - if the proposed limits of impurities are above the qualification limits established by RDC No. 53/2015 and by the ICH Q3A & Q3B guides;

CETER - if the clinical development of the drug involved the conduction of bioequivalence or relative bioavailability studies;

GFARM - if any specific risk is identified or the need for prior assessment for approval of the pharmacovigilance plan or the minimization plan as a condition for granting the registration.

3.1.3. Why has the analysis process been segmented into so many areas?

The analysis of a registration application requires different areas of knowledge and specialization. Thus, it is unlikely that a single department will be able to develop all knowledge necessary in the same field, and have the same evaluation criteria between different fileds when they all do the same type of analysis, in addition of being counterproductive towards the development of expertise in more than one area.

So, in order to have the same treatment for a given analysis, and standardization in GGMED's manifestations in similar processes, it was decided to segment the analysis according to the major areas of knowledge (pharmaceutical technology, safety and efficacy, therapeutic equivalence, etc.).

Also, when segmenting, GGMED favors celerity when analyzing requests involving the registration of innovative medicines, enabling a simultaneous analysis of the different areas involved.

3.1.4. Which sector is responsible for publishing the conclusion of the analysis of applications for registration of innovative medicines?

After the manifestation of the technical areas involved in the analysis of the process, GRMED is the area responsible for the emission the final decision for publication.

For approval, the publication must necessarily await for the manifestation of all areas involved in the analysis of the process in question.

In the case of rejections, considering the principle of procedural economy, the rejection may be published before the analysis is completed by all areas. It is a consensus in the Agency that, if there is an

insurmountable reason for refusal, there is no reason for the technical analysis to proceed.

For example, if COINC is analyzing a case and GRMED concludes for the rejection, the COINC analysis will halt and the rejection will be published. The company will learn, within the letter of rejection, those analyzes that have been completed; those that have been closed or those that have not been carried out until the date of publication of the rejection. If the appeal is upheld, the unfinished analyzes will be resumed from the point at which they were closed.

3.2. Additions and analysis workflow.

3.2.1. I have filed an innovative medication registration request, do I have to submit any other documents?

Currently, Datavisa, the ANVISA database system, does not allow more than one manifestation to be made concurrent in the same number of files.

For example, if GRMED has started analyzing a case and issued a requirement, until that requirement is met by the company, no other manifestation can be placed in this file. This limitation of the system makes it impossible a concomitant analysis and manifestation of the different areas involved in the analysis of innovative medication registration processes.

To circumvent the limitation of the system and make it possible for the areas to manifest simultaneously in the same process, different additions were created, directed to each area involved in the analysis of the innovations:

11485 - INNOVATIVE MEDICINE - Addendum addressed to COINC, for safety and efficacy assessment, in order to present the safety and efficacy data of the innovative medicine. This addendum must be filed for all requests for registration of innovative medicines.

11487 - INNOVATIVE MEDICINE - Addendum addressed to the Coordination of Therapeutic Equivalence (CETER), of relative bioavailability or Biowaiver study, for cases in which there are studies of relative bioavailability carried out for the purpose of bridging the clinical/biobatch and commercial batch (modifications in formulation, changes in manufacturing locations, etc.) or requests for registration of a new pharmaceutical form, registration of a new concentration and registration of a new route of administration, in cases where phase

2 and 3 clinical studies are replaced by relative bioavailability studies.

11486 - INNOVATIVE MEDICINE - Addendum addressed to the Management of Safety and Efficacy Assessment (GESEF) of impurities qualification study and product degradation for cases where the specifications of impurities / product degradation in the quality control / stability studies exceeds the qualification limit (ICH guides Q3A and Q3B and RDC No. 53/2015).

10474 - NEW MEDICINES - Addendum to the registration request with the Registration Documentation Information Form (FIDR), exclusively electronically, in the case of requests for registration of new and innovative medicines, addressed to the Management of Technology Assessment of Registration of Synthetic Drugs (GRMED).

11213 - NEW - Addendum addressed to the Coordination of Registration of Medicines of Less Complexity, Leaflet and Labeling (CRMEC), of labeling and brand name, exclusively by electronic means, for cases of request for registration of novel and innovative medications.

10717 - Pharmacovigilance Plan / Risk Minimization Plan - New Drug, addressed to the Pharmacovigilance Management (GFARM). This addendum must be submitted for all applications for registration of innovative medicines.

In order to avoid duplication of documents, rationalizing submission to the regulated sector and analysis by technical areas, the amendments have specific documentation to be presented, exclusively provided for in the checklist of each of the aforementioned subject codes, having been removed from the checklists of registration petition. Therefore, the amendments must be filed within 10 days after the submission of the registration petition, and the registration petition that does not contain the amendments may be rejected, due to the absence of documentation provided for in the current registration legislation.

It should be noted that for additions 11487 and 11486, in cases where these are not applicable, that is, in cases where there are no qualifying impurities or there is a need to evaluate studies of relative bioavailability, the protocol of these additions is not necessary. . For all other additions mentioned, the protocol is mandatory in all applications for registration of innovative medicines.

3.2.2. The clinical development of my product was based entirely on studies of relative bioavailability.

Do I have to file the addition of safety and effectiveness to COINC?

Yes. Even in processes whose clinical development has been based on studies of relative bioavailability, there is a need to evaluate the clinical rationale of the proposed product, the advantages that the product will bring over the therapies already available and the package insert text. Such assessment is carried out by COINC, linked to the file of the addition of safety and effectiveness.

It is worth mentioning that, in cases where the main proof of safety and efficacy is bioequivalence or relative bioavailability studies, all the technical requirements provided for in the current legislation for the conduct of these studies must be followed, including the conduct of studies in certified centers, the use of national reference drugs and the confidence intervals for evaluated parameters.

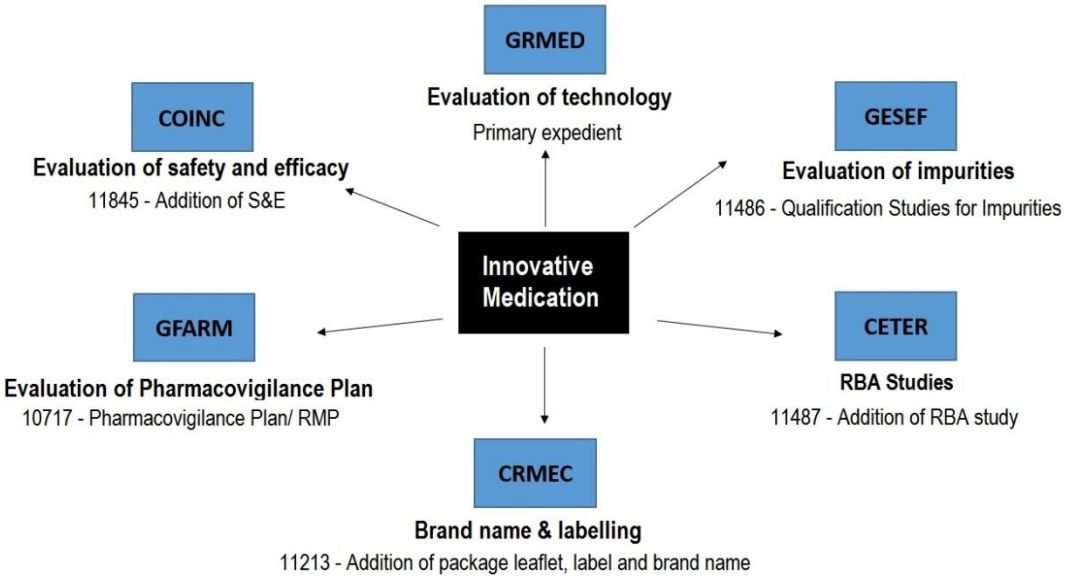
In addition, when opting for the development of the drug by conducting comparability studies, the goal is to extrapolate the safety and efficacy evidence from the reference drug to the new product, so the drug to be registered must have the same conditions reference drug, such as indications, dosage, population and contraindications.

3.2.3. With so many areas involved in the analysis process and so many amendments related to the registration application, how can I monitor the progress of the analysis for each area?

With the exception of GRMED, which will manifest itself in the filing of the registration petition, each area will give its manifestation linked to the file of the amendment intended for it. Thus, the company will be able to monitor the progress of the analysis in a certain area, following the status of the specific amendment. That is, to know the progress of the analysis of a given process at COINC, it is enough to consult the status of analysis of the addendum for the assessment of safety and effectiveness (code 11485) linked to the process in question.

The status of the registration request reflects only the progress of the analysis at GRMED. Therefore, the public queue available on the Anvisa website reflects the GRMED analysis queue.

The following figure summarizes all the areas that may be involved in the analysis of a given process, and in which addition each area will give its expression.



3.2.4. How do I know which processes are awaiting analysis at COINC and what is the position of my process in the analysis queue?

Currently, there is no tool for monitoring the COINC analysis queue, considering that the COINC analysis is linked to the addition of safety and effectiveness. However, the best way is being evaluated so that the analysis status of all files linked to the process are made public.

It should be noted that, although the statement by COINC is linked to the addition of security effectiveness, the distribution for analysis respects the chronological order of entry of the registration petition, and not the date of entry of security and effectiveness amendments.

3.3. Innovative drug safety and efficacy protocol

3.3.1. What about the innovative drug safety and efficacy protocol (code 11305), when should it be presented?

The innovative medicine safety and efficacy protocol (code 11305) was created to clarify doubts from companies regarding the regulatory path or the possibility of analyzing the registration proposal, prior to submission, without evaluating the complete documentation that should make up the Registration Dossier.

The protocol must be submitted in situations where the company has doubts about the regulatory

path for registration of innovative synthetic medicine, or the acceptability of safety and efficacy evidence for registration, without evaluation of the evidence.

The protocol is not a registration request assessment. It is a prior statement about which safety and efficacy documentation must be submitted at the time of registration application. It is like a pre-submission consultation. The company says which product it intends to register and what evidence of safety and effectiveness it intends to present. GESEF assesses whether the proposal is acceptable or not, and whether it will be necessary to provide more evidence than the company has proposed.

The intention of the protocol is not to evaluate the quality of the product, but to analyze case-by-case situations that have not been understood in the reading of RDC nº 200/2017. For example, it can be questioned whether for the registration of a specific product, through a proposed regulatory route, it is possible to present a bioequivalence study, instead of a Phase III clinical study.

Despite being optional in most cases, it is mandatory for the registration of innovative drugs that require prior agreement with Anvisa regarding the safety and efficacy evidence to be presented in the Registration Dossier, namely: Medication with Same (s) IFA (s) of New Medicines already Registered (subject code 10775) and Medicines with Diverse Innovation (subject code 11318), as provided for in article 18 of RDC No. 200/2017. For these cases, the letter received in response to the protocol must be submitted at the time of the registration request.

We emphasize that the code 11305 should only be used to discuss the rationale of the clinical development of the product. Questions related to pharmaceutical technology, the production process and product quality should be discussed with the Synthetic Medicines Registration Technology Assessment Department (GRMED) and will not be answered in the letter sent in response to the protocol.

As already mentioned, the objective of the protocol is to clarify doubts about the framework and to agree in advance a proposal for a cynical development that is sufficient to prove the safety and efficacy to support the registration of innovative medicines. In the analysis of the protocol, exceptionalities will not be evaluated or treatment will be given to situations for which there is no normative predictability of framing. Thus, proposals for clinical development that do not meet the requirements of RDC No. 200/2017 and complementary standards will not be accepted.

The presentation of protocol 11305 should be reserved for the mandatory cases provided for in art. 18 of RDC 200/2017 and in cases where the presentation is requested by Anvisa. For minor clarification of framing doubts and for cases in which the protocol is not mandatory, the questioning must be sent through Anvisa's service channels.

3.3.2. Which documents must be presented in the innovative drug protocol?

The protocol must contain the following information:

• Justification for submission. This justification must bring a summary of the company's proposal to prove the safety and efficacy of the drug in question, with the therapeutic indication to be requested, doses, dosage, route of administration and target population.

• Brief contextualization of the clinical condition for which the product is intended, including therapeutic options available in Brazil, citing information about the use of unregistered treatments for the clinical condition to be treated.

• Benefit proposed by the new drug, compared to the existing therapeutic options.

• Regulatory proposal for registration, indicating the supposed framework.

• Enumeration of all documentation related to safety and efficacy to be submitted for evaluation by GESEF, to evaluate the regulatory registration route proposed by the company.

• International package insert for the product proposed for registration, when available.

• International regulatory situation, with a list of regulatory authorities in which the proposed product is registered, including: (I) information if the product is already on sale, (II) availability of pharmacovigilance reports to be submitted later, and (III) clarification regarding the possibility of future demonstration of the full / analytical report of approval of such authorities, without borders.

• Brief description of the non-clinical, clinical and literature data that will be filed when registering. Documents must be submitted electronically, in PDF format with the possibility of textual search, copy and printing, accompanied by an index that references the submitted files and pages.

Documents must be submitted electronically, in PDF format with the possibility of textual search, copy and printing, accompanied by an index that references the submitted files and pages.

3.3.3. How is the evaluation of the innovative drug protocol carried out?

The documents sent by the company are evaluated by GESEF, with discussion involving all areas related to safety and effectiveness assessment, the Clinical Research Coordination (COPEC), CETER and COINC.

In response to the protocol, the company will receive an electronic letter with all considerations about product development, the correct regulatory framework and information about the safety and efficacy evidence that must be presented at the time of registration.

The letter is a binding document that, considering that all the premises established in the letter are followed, will ensure that studies not previously agreed upon are not requested, except in cases where new points are found that require clarification for the registration grant.

Likewise, the documents informed in the letter must be presented by the applicant at the time of the application for registration. The absence of documents requested in the letter, without the previous manifestation of Anvisa that justifies the absence of the document, will give rise to the rejection of the request.

During the evaluation of the protocol, there will be no evaluation of the merit of the documents presented.

Documents related to pharmaceutical technology data, the production process or product quality will not be evaluated.

Proposals for clinical study designs or relative bioavailability will not be evaluated. These studies have specific codes to be discussed with COPEC and CETER, respectively (see questions 3.3.5 and 3.3.6).

It should be noted that the acceptance of the development proposal presented does not mean that the registration request will be approved. As highlighted, the objective of the protocol is to evaluate the development proposal, and the merit of the studies will not be evaluated. The assessment of whether the studies were well conducted and whether the data from the studies prove the safety and efficacy of the product or not will be conducted only at the time of the evaluation of the registration application.

3.3.4. How can I follow the analysis queue and what is the deadline for evaluating the innovative drug protocol?

The average time to respond in response to the innovative drug protocol is 30 to 45 days and the company will be able to monitor the progress of the analysis by the status of the file. There is no public queue for this subject code, considering it is not a registration request.

3.3.5. What is the difference between the innovators protocol (11305) and the therapeutic equivalence protocol (10608)?

The innovators protocol (11305) is addressed to GESEF and aims to verify whether the evidence that the company intends to present seems to be sufficient to demonstrate the safety and efficacy of a certain product to be registered through a proposed regulatory route. Therefore, the presence / intention of conducting clinical studies as well as non-clinical and bioequivalence is evaluated.

The therapeutic equivalence protocol (10608) is addressed to CETER and aims to evaluate designs for conducting comparability studies. The protocol for therapeutic equivalence studies extensively assesses the conduct of comparative studies between drugs. In this case, those drugs that are compared according to current regulations or for which specific guides already exist within Anvisa will continue to be evaluated by CETER. If the company has already had a therapeutic equivalence protocol evaluated by CETER, it may present the letter of this assessment under the protocol for the safety and efficacy of an innovative medicine.

In both cases, the company will receive the response from the technical area responsible for the documentation evaluation through an Electronic Official Letter.

3.3.6. What is the difference between the innovators protocol (11305) and the DDCM (Clinical Drug Development Dossier)?

As mentioned, the Innovators Protocol (11305) is addressed to GESEF and aims to give an opinion on which regulatory path and what evidence of safety and effectiveness must be presented at the time of registration. Therefore, it evaluates the intention or proposal to conduct a study, be it clinical, non-clinical or bioequivalence.

The Clinical Drug Development Dossier (DDCM) is sent to COPEC and is intended to assess whether a clinical study with a certain drug can be conducted in Brazil. Therefore, DDCM assesses the quality of the drug,

safety and efficacy information obtained previously, the clinical study protocol extensively discussed, among other data.

If the company has already had a DDCM evaluated, it can present the special announcement of this evaluation under the protocol for the safety and efficacy of an innovative medicine.

The answer to the innovative drug protocol is given through the electronic letter, while the answer to the DDCM is given by the issuance of the special communiqué and the agreement to conduct the clinical study.

3.4. Diverse innovation and IFA already registered

3.4.1. Which products can fall into the category of diverse innovation (code 11318)?

As provided for in art. 41 of RDC No. 200/2017, products that cannot be classified in other regulatory categories (new association, new pharmaceutical form, new concentration, new route of administration, new indication, medication with the same) fall under the category of diverse innovation (s) new drug IFA (s) already registered).

This category also includes drugs that have new salts, isomers, esters or ethers of molecules already registered as IFA.

Unpublished molecules, that is, not registered in Brazil, are not eligible for the category of diverse innovation, and should be treated as a new drug registration.

3.4.2. Which products can be classified as a medicine with the same IFA (s) of a new medicine already registered (code 10775)?

As described in art. 39 of RDC No. 200/2017, the product that has the same characteristics as a new medicine already registered with this IFA falls into the category of medicine with an already registered IFA.

Some examples of products that can be classified in this category are the cases of synthetic peptides comparable to products registered as biological medicines, contrasts with IFA already registered, new administration devices and medicines with IFA that have already been registered with Anvisa, but whose registration does not is more active. In the latter case, it is necessary that the previous registration has all the safety and efficacy tests evaluated by Anvisa, and it will be evaluated through the innovative drug protocol which

the safety and efficacy tests the new product being proposed for registration must present .

This category does not include drugs classified as generic and similar for which there is technical feasibility to perform pharmaceutical equivalence and study of relative bioavailability (bioequivalence) to prove the efficacy and safety of the drug.

The unavailability of the reference drug for conducting bioequivalence or relative bioavailability studies is not interpreted as infeasibility for the conduct of the study, and does not characterize a condition for qualifying the product in the drug category with the same IFA (s) of new medicine already registered.

As for the category of diverse innovation, unpublished molecules, that is, not registered in Brazil, are not eligible for inclusion in the category of IFA already registered, and should be treated as a new drug registration.

3.4.3. What documentation must be submitted to prove the safety and effectiveness of products falling under the categories of diverse innovation and IFA already registered?

According to articles 40 and 42 of RDC nº 200/2017, both for products classified as diverse innovation, and for products classified in the category of IFA already registered, in addition to the administrative and quality documentation provided for in Sections IV and V of Chapter III of RDC No. 200/2017, registration petitions must be accompanied by:

"I - technical justification;

II - clinical rationale for drug development;

III - Safety and Effectiveness report according to a specific guide, containing:

a) scientific literature data obtained from indexed international journals with presentation of the full article, if applicable;

b) report of non-clinical trials, if applicable; and

c) report of phase I, II and III clinical trials, if applicable.

IV - Pharmacovigilance plan, in accordance with the specific legislation in force.

§ 1st In specific situations related to safety, a Risk Minimization Plan may be required in addition to the Pharmacovigilance Plan.

§ 2nd In the case of drugs sold in other countries, updated Pharmacovigilance Report on the drug. "

As provided for in art. 18 of RDC nº 200/2017, for products falling under the category of diverse innovation and IFA already registered, it is mandatory to previously evaluate the rationale of clinical development of the product, at which time the safety and efficacy tests must be evaluated and defined. be presented at the time of registration.

Thus, for products falling under the category of diverse innovation and IFA already registered, the documentation for safety verification will be defined on a case-by-case basis, during the evaluation of the innovative drug protocol.

More details on the safety and efficacy protocol of an innovative medicine are described in subitem 3.3.

3.5. Concomitant innovations

3.5.1. My product has more than one innovation when compared to products that are already registered with Anvisa. How will it be categorized?

In the case of multiple innovations, eg a new pharmaceutical form that is also characterized as a new concentration, it is necessary to pay attention to the linkages provided for in each section of RDC No. 200/2017, and the product must be placed in the most specific category. characteristics of the proposed products.

Art. 31 does not provide for any link to the registration of a new pharmaceutical form, it is described only as a new pharmaceutical form for an already registered drug. In this case, the registration of a new pharmaceutical form may bring with it a new route of administration or a new concentration.

As for the registration of a new concentration, art. 33 defines it as a new concentration, considering the same pharmaceutical form.

For the registration of a new route of administration, the product must present the same pharmaceutical form, the same concentration and the same therapeutic indication of the product already registered with Anvisa, as described in art. 35 of RDC No. 200/2017.

Art. 37 shows that for the registration of a new therapeutic indication, the product must have the same

pharmaceutical form and the same concentration of the drug already registered.

In case of doubts about the framework of the drug to be registered, the company must send a question through the public service channels or, when instructed, present the innovative drug protocol, so that the correct framework and evidence of safety and effectiveness to be presented.

3.6. Special flows

3.6.1. Can the registration of innovative medicines be requested through the special procedure for new medicines for the treatment, diagnosis or prevention of rare diseases, provided for by Resolution RDC No. 205 of December 28, 2017?

No. According to art. 2 of RDC No. 205/2017, the special procedure applies only to new drugs for rare diseases, which are defined as those with an active pharmaceutical ingredient unprecedented in the country.

3.6.2. Can analysis prioritization be requested for the registration of innovative drugs?

Yes, in some cases it is possible. Resolution RDC No. 204 of December 27, 2017 defines the criteria for framing petitions for registration, post-registration and prior consent in clinical research in the priority category.

The company requesting the registration must assess whether the proposed product meets any of the prioritization criteria provided for in the resolution, and must follow the current flow for the prioritization request.

It is worth mentioning that, as provided for in the sole paragraph of art.11, if the inclusion in the priority category is not confirmed during the technical analysis, the registration or post-registration petition will be rejected.

4. REFERENCES

Resolution-RDC No. 53, of December 4, 2015. Establishes parameters for the notification, identification and qualification of degradation products in medicines with synthetic and semi-synthetic active substances, classified as new, generic and similar, and other measures. Federal Official Gazette, December 8, 2015.

Resolution-RDC No. 73, of April 7, 2016. Provides for post-registration changes, cancellation of registration of drugs with synthetic and semi-synthetic active ingredients and other measures. Federal Official Gazette, April 8, 2016.

Resolution-RDC No. 200, of December 26, 2017. Provides for the criteria for granting and renewing the registration of drugs with synthetic and semi-synthetic active ingredients, classified as new, generic and similar, and other measures. Official Gazette of the Union, January 29, 2018.

Resolution-RDC No. 204, of December 27, 2017. Provides for the inclusion in the priority category, of registration petitions, post-registration and prior consent in clinical drug research. Federal Official Gazette, December 28, 2017.

Resolution-RDC No. 205, of December 28, 2017. Establishes a special procedure for the approval of clinical trials, certification of good manufacturing practices and registration of new drugs for the treatment, diagnosis or prevention of rare diseases. Federal Official Gazette, December 29, 2017.

☐ Profile

Priscilla Viana Palhano Lima was Manager of Regulatory Affairs and Special Projects of the Brazilian public laboratory. He was directly in charge of the legal compliance of technology transfers with foreign companies from France, Poland, the United States and South Korea. He has experience in dossier analysis and elaboration of Partnership for Productive Development projects for the Ministry of Health. She is currently a consultant in Regulatory Affairs and Project Management of Partnership Projects for Productive Development for the Ministry of Health. Priscilla is the founder of the Argo Consulting company that promotes consulting in the areas of regulatory affairs, business development, project management international partnerships and technology transfers.