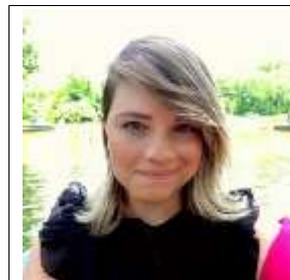


## Title

**ANVISA rules for the transfer of registration**



**Name: Priscilla, Lima Viana Palhano**

**Company Name& Position : Founder of Argo Consulting**

### □ Abstract

This article aims to present the legislation that makes provisions on the procedures for the transfer of registration of products subject to health surveillance, global transfer of responsibility for clinical testing and update of registration data related to the operation and certification of companies as a result of corporate or commercial operations.

### □ Table of Contents

1. INTRODUCTION.....	2
2. THE ANVISA LEGISLATION.....	2
3. CONCLUSION.....	13
4. BIBLIOGRAPHICAL REFERENCES.....	13

## **1. Introduction**

Nowadays, Brazil has the eighth position in the global pharmaceutical market, more and more global companies show interest in develop partnerships with Brazilian companies.

The present work explains the legislation regarding to transfer the registration from one company to another. It may be petitioned exclusively in cases of merger, demerger, incorporation or succession, with or without change of company name, provided that the original technical requirements of the product are unchanged.

## **2. The ANVISA Legislation**

### **Resolution – RDC NO. 102, OF AUGUST 24th, 2016**

The Collegiate Board of Directors of the Brazilian Health Surveillance Agency in the exercise of the powers vested by Article 15, subsections III and IV, combined with the Article 7, subsections III and IV, of Law no. 9,782, of January 26th, 1999; Article 53, subsection V, paragraphs 1 and 3, of the Internal Statutes approved under the terms of Annex I of Collegiate Board of Directors Resolution – RDC no. 61 of February 3rd, 2016, hereby adopts this resolution, as approved by the meeting held on July 12th, 2016, and I, Director-President, determine its publication.

### **CHAPTER I**

#### **General Provisions**

Article 1. This Resolution shall be applied to corporate and commercial operations between companies that perform the activities addressed in the federal health legislation, which result in the need to update the registration data related to the operation and certification of companies, global transfer of responsibility for clinical testing and transfer of registration of products subject to health surveillance.

Sole Paragraph. This Resolution also covers the cases of operations performed abroad that require update under ANVISA.

Article 2. The procedures herein established shall be applied only in cases where the technical and health conditions and characteristics of the companies, products and clinical tests are maintained.

Article 3. The procedures herein established shall not be applied to the changes of company name not related to the operation mentioned in Article 1, which shall be subject to the specific rules in force.

Article 4. For the purposes of this Resolution, the following definitions shall be adopted:

I – Technical and health characteristics: regular conditions of the product, company, or clinical trial at ANVISA, immediately before the corporate or commercial operation;

II – Divestiture: corporate operation in which a legal entity transfers parts of its property to one or more legal entities established for this purpose, or already existent, extinguishing the demerged company if all its assets are transferred, or dividing the capital if the transfer is partial;

III – Succeeded company: legal entity that transfers to the successor company the rights and obligations on the product object of registration transfer, the establishment, or the responsibility for clinical testing as a result of corporate or commercial operations;

IV – Successor company: legal entity that now has the rights and obligations on the product object of registration transfer, the establishment, or the responsibility for clinical testing as a result of corporate or commercial operations;

V – Amalgamation: corporate operation in which two or more legal entities are merged to create a third one, succeeding them in all rights and obligations;

VI – Merger: corporate operation in which one or more legal entities are absorbed by another one, succeeding them in all rights and obligations;

VII – Commercial operation: operation between companies resulting in the sale of assets or group of assets, without the occurrence of any corporate operation between the companies involved;

VIII – Corporate operation: corporate action involving the divestiture, amalgamation or merger under Law no. 10,406, of January 10th, 2002, and, in a subsidiary manner, Law no. 6,404, of December 15th, 1976;

IX – Mercosur representative: company located in the Receiving State Party [Estado Parte Receptor (EPR) in Portuguese], which is contracted to represent a registration holder in the Producing State Party [Estado Parte Produtor (EPP) in Portuguese] and assumes the legal and technical responsibility in the EPR;

X – global transfer of responsibility for clinical testing: modification characterized by the change of the applicant of clinical trial dossiers, notification of clinical testing, dossiers of clinical development of drugs (DDCM), dossiers of clinical investigation of medical devices (DICD), expanded access programs, compassionate use programs

and supply of post-study drug, in cases of corporate or commercial operations, without any change of technical and health characteristics contained in the Specific Special Communiqué [Comunicado Especial Específico (CEE) in Portuguese], Document for the Import of Product under Investigation or Special Communiqué), object of change;

XI – transfer of registration holder: modification characterized by the change of the registration holder of products subject to health surveillance, in case of corporate or commercial operations, without any change of technical and health characteristics in the registration of product object of transfer.

Article 5. The companies shall perform the application of update of registration data related to the operation and certification of companies, global transfer of responsibility for clinical testing and transfer of registration of products subject to health surveillance, as a result of corporate or commercial operations, under this Resolution.

Sole Paragraph. In case of successive corporate or commercial operations, an application for each operation shall be performed.

Article 6. As of the execution of corporate or commercial operation, the successor company obtains the rights and obligations from the succeeded company, including the compliance with deadlines and rules for adjustment to the health legislation and any restrictive measures applicable to the flow of products.

## **CHAPTER II**

### **Update of Registration Data**

Article 7. Companies shall submit to ANVISA the applications for change, granting and/or cancellation of Company's Operating Permit [Autorização de funcionamento de Empresa (AFE) in Portuguese] and Special Operating Permit [Autorização Especial (AE) in Portuguese], update of the Certificate of Good Manufacturing Practices (CBPF) or Certificate of Good Distribution and Storage Practices (CBPDA), and update of Good Practices of Bioavailability/Bioequivalence of Drugs (CBPBD/BE), whenever there is an corporate or commercial operation.

#### *SECTION I*

##### *Company's Operating Permit (AFE) and Special Operating Permit (AE)*

Article 8. Companies shall request the update of the Operating Permit and Special Operation Permit through the submission of application for change, cancellation, or granting, whenever there is and corporate operation.

Article 9. If the corporate operation results in a new legal entity, or already existing legal entity, not registered at the health surveillance agency, the registration shall be performed by the submission of application for initial grant of Operating Permit and Special Operating Permit.

Article 10. The application for cancellation of Operating Permit and Special Operating Permit shall be submitted by the succeeded company within thirty (30) days as of the publication of the Resolution of cancellation and transfer of registration, if applicable.

Sole Paragraph. The cancellation of Operating Permit and Special Operating Permit of the succeeded company shall be performed only after the transfer of all registrations of the succeeded company to one or more successor companies.

Article 11. The application for update of data in the Operating Permit or Special Operating Permit shall be accompanied by the following documents:

I – Application form duly completed and signed; and

II – Declaration of the corporate or commercial operation performed, as provided in Annex I.

## *SECTION II*

### *CERTIFICATION IN GOOD PRACTICES*

#### *SUBSECTION I*

##### *Certification in Good Manufacturing Practices and Certification in Good Distribution and Storage Practices*

Article 12. The successor company shall request the update of registration data of the establishments involved in the GMP Certificate, or in the Certificate of Good Distribution and Storage Practices, provided that the technical and health characteristics previously examined remain unchanged, whenever there is a corporate or commercial operation.

Paragraph 1. The update addressed in the head of this Article does not lead to a new certification, and the expiration date of the certificate issued prior to the operation remains unchanged.

Paragraph 2. The update of data in the GMP Certificate shall occur per production line and shall be applied only if the corporate and commercial operations involves this entire production line.

Paragraph 3. In case of corporate operations occurred exclusively abroad, the update addressed in the head of this Article shall be submitted by the current company applying for the valid certification.

Article 13. The application for the update of data in the GMP Certificate, or in the GSDP Certificate, shall be accompanied by the following documents:

I – Application form duly completed and signed;

II – Copy of the current GMP or GSDP Certificate, if the same has been issued prior to the operation;

III – Declaration of the corporate or commercial operation performed, as provided in the Annexes;

IV – Copy of the publication of the updated Operating Permit or Special Operating Permit on the Brazilian Official Gazette, if the corporate operation results in the modification or granting of Operating Permit or Special Operating Permit; and

V – Copy of the current GMP Certificate in the name of the successor company, issued by the health authority of the country where the producing establishment is installed or declaration of this authority certifying the operation, in case of corporate operation performed abroad.

Article 14. The update of data in GMP or GSDP Certificate is not applicable to applications for initial certification that are waiting for analysis, or with uncompleted analysis.

Paragraph 1. For the cases provided in the caput, the succeeded company shall perform the amendment of the application to update the documentation, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company shall submit the documents specified in Article 13 of this Resolution.

## *SUBSECTION II*

### *Certification in Good Practices of Bioavailability/Bioequivalence of Drugs*

Article 15. The successor company shall request the update of registration data of the establishments involved in the GPBA/BE Certificate, provided that the technical and health characteristics previously examined remain unchanged, whenever there is a corporate operation.

Paragraph 1. The update addressed in the head of this Article does not lead to a new certification, and the expiration date of the certificate issued prior to the operation remains unchanged.

Paragraph 2. In case of corporate operations occurred exclusively abroad, the update addressed in the head of this Article shall be submitted by the current company applying for the valid certification.

Article 16. The application for the update of data in the GPBA/BE Certificate shall be accompanied by the following documents:

I – Application form duly completed and signed;

II – Copy of the current GPBA/BE Certificate; and

III – Declaration of the corporate operation performed, as provided in Annex I.

Article 17. The application for the update of data in GPBA/BE Certificate is not applicable to applications for initial certification that are waiting for analysis, or with uncompleted analysis.

Paragraph 1. For the cases provided in the caput, the succeeded company shall perform the amendment of the application to update the documentation, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company shall submit the documents specified in Article 16 of this Resolution.

### **CHAPTER III**

#### **Registration Transfer**

#### **SECTION I**

##### *Pesticides, their Components and Suchlike*

Article 18. The successor company shall report to ANVISA the transfer of registration of pesticides, their components and suchlike in the federal registering body, in accordance with the established by Decree no. 4,074, of January 4th, 2002, within sixty (60) days by the submission of application for the notification of change of registration, whenever there is a corporate or commercial operation.

Article 19. The application for the notification of change of registration shall be accompanied by the following documents:

I – Application form duly completed and signed; and

II – Copy of the Brazilian Official Gazette proving the transfer of registration in the federal registering body.

## *SECTION II*

### *Smoking Products Derived or Not from Tobacco*

Article 20. Companies shall update the data related to the registration of smoking products at ANVISA through the submission of application for transfer of registration and cancellation of registration, whenever there is a corporate or commercial operation leading to the change of registration.

Article 21. Applications for transfer of registration and cancellation of registration shall be submitted simultaneously to ANVISA by the successor and succeeded companies within sixty (60) days.

Paragraph 1. Applications submitted after the deadline established in the head of this Article shall be rejected by ANVISA.

Paragraph 2. The deadline addressed in the head of this Article shall be counted as of the date of filing the corporate action registered in the competent commercial registry, or signing the contractual instrument of transfer of assets or group of assets, as appropriate.

Paragraph 3. In case of Mercosur representative, the deadline established in the head of this Article shall be counted as of the date that the contractual relation is formally interrupted between the domestic Mercosur representative company and registration holder in Brazil and the represented company, registration holder in another Mercosur State Party.

Article 22. The transfer of registration of smoking products entails the simultaneous publication of the new registration and cancellation of the old registration on the Brazilian Official Gazette. The technical and health characteristics of the product and expiration date of the registration object of transfer shall remain unchanged.

Article 23. The application for the transfer of registration shall be accompanied by the following documents:

I – Application form duly completed and signed;

II – Declaration of the corporate or commercial operation performed, as provided in Annex I;

III – Proof of registration and registration situation at the Department of Federal Revenue of Brazil – Brazilian Registry of Legal Entities (CNPJ); and

IV – Copy of the Executive Declaratory Act (ADE) that grants the Special Registration of Manufacturer or

Importer, in case of cigarette or cigar, issued by the Department of Federal Revenue of Brazil, already related to the successor company.

Article 24. Corporate or commercial operations involving the transfer of rights and obligations related to applications for registration that are waiting for analysis, or with uncompleted analysis, do not characterize transfer of title.

Paragraph 1. For the cases provided in the caput, the succeeded company shall perform the amendment of the application to update the documentation, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company shall submit the documents specified in Article 23 of this Resolution.

### *SECTION III*

#### *Drugs, Active Pharmaceutical Supplies, Cosmetics, Sanitizing Products, Health Products and Food*

Article 25. Companies shall update the data related to the registration of products subject to health surveillance through the submission of application for transfer of title and cancellation of registration, whenever there is a corporate or commercial operation leading to the change of registration of products.

Article 26. Applications for transfer of registration and cancellation of registration shall be submitted simultaneously to ANVISA by the successor and succeeded companies within one-hundred and eighty (180) days.

Paragraph 1. Applications submitted after the deadline established in the head of this Article shall be rejected by ANVISA.

Paragraph 2. The deadline addressed in the head of this Article shall be counted as of the date of filing the corporate action registered in the competent commercial registry, or signing the contractual instrument of transfer of assets or group of assets, as appropriate.

Paragraph 3. In case of Mercosur representative, the deadline established in the head of this Article shall be counted as of the date that the contractual relation is formally interrupted between the domestic Mercosur representative company and registration holder in Brazil and the represented company, registration holder in another Mercosur State Party.

Article 27. Products subject to cadastro are equivalent to those subject to registro for the purposes of transfer of registration.

Article 28. Products subject to notification and those exempt from registration shall not be object of transfer of title, and the company shall perform a new notification or new registration procedure, as appropriate.

Article 29. The transfer of registration entails the simultaneous publication of the new registration number and cancellation of the old registration number on the Brazilian Official Gazette. The characteristics of the product and expiration date of the registration object of transfer shall remain unchanged.

Article 30. The application for transfer of registration shall be accompanied by the following documents:

I – Application form duly completed and signed;

II - Payment proof of the Health Surveillance Inspection Fee (TFVS in Portuguese) through the corresponding Brazilian Federal Tax Collection Form (GRU), or a fee exemption voucher;

III – Declaration of the corporate or commercial operation performed, as provided in Annex I; and

IV – Copy of the Operating Permit or Health Permit issued by the competent body, properly updated after the corporate or commercial operation.

Article 31. Corporate or commercial operations involving the transfer of rights and obligations related to applications for registration that are waiting for analysis, or with uncompleted analysis, do not characterize transfer of title.

Paragraph 1. For the cases provided in the caput, the succeeded company shall perform the amendment of the application to update the documentation, in order to record and continue the analysis of the application in progress.

Paragraph 2. The succeeded company shall submit the documents specified in Article 30 of this Resolution.

Article 32. Post-registration applications already submitted by the succeeded company that are waiting for analysis, or with uncompleted analysis, may be transferred to the successor company, through the submission of the declaration of interest provided in Annex I.

Sole Paragraph. Post-registration applications that do not have the declaration provided in Annex I shall characterize withdrawal by the successor company and those applications shall be closed by ANVISA.

Article 33. Adjustments in the texts of instructions for use, package inserts and labeling, as a result of transfer of title, may be implemented after the approval of the application for transfer of title by ANVISA.

Paragraph 1. Adjustments in the texts of instructions for use, package inserts and labeling addressed in the head of this Article shall be restricted to the update of registration holder data.

Paragraph 2. In case of drugs, the successor company will have thirty (30) days to submit the Notification of change of the text of package inserts and Notification of change of labeling related to the characteristic of the new registration holder, after the entry into force of Resolutions of cancellation and transfer of registration.

Article 34. The maintenance of different or distinct names for drugs with the same active ingredient(s) shall be permitted as a result of the transfer of title.

## **CHAPTER IV**

### **Global Transfer of Responsibility for Clinical Testing**

Article 35. The succeeded company shall update the data of clinical testing through the submission of application for global transfer of responsibility for clinical testing, whenever there is a corporate or commercial operation.

Article 36. The application for global transfer of responsibility for clinical testing shall be accompanied by the following documents:

I – Application form duly completed and signed; and

II – Declaration of the corporate and commercial operation performed, as provided in Annex I.

Article 37. In case of applications for global transfer of responsibility for clinical testing, even those under the responsibility of the Representative Organization of Clinical Research [Organização Representativa de Pesquisa Clínica (ORPC)], the Special Communiqué, Specific Special Communiqué or Document for the Import of Product under Investigation must be issued under the name of the new responsible for the application.

## **CHAPTER V**

### **Final and Transitional Provisions**

Article 38. Imports carried out by the succeeded company, based on the Operating Permit of the successor company, must be permitted until the decision of ANVISA on the regularization of the company, provided that the deadlines for submission established by this Resolution are observed.

Sole Paragraph. The importing company shall present a certified copy of the declaration of operation performed to the health authority at the disembarkation point, such as documentary evidence of the corporate or commercial operation, as provided in Annex I.

Article 39. The successor company shall be responsible for the product and any remaining stock of finished products, including for importation purposes, in cases of transfer of registration.

Paragraph 1. Imports performed by the successor company shall be accompanied by the declaration of the succeeded company, signatory of the application for registration of product at ANVISA, authorizing the import until the transfer of product registration in ANVISA.

Paragraph 2. The provisions of the head of this Article do not exempt the joint and several liability of the company for actions performed prior to the corporate or commercial operation before the health surveillance bodies and entities.

Article 40. The remaining stock of finished products object of registration transfer may be regularly imported or commercialized by the new registration holder, provided that these products have been manufactured before the entry into force of Resolutions of cancellation and transfer of registration.

Sole Paragraph. Companies will have a maximum of one-hundred and eighty (180) days to sell out the remaining stock of finished products after the entry into force of Resolutions of cancellation and transfer of registration.

Article 41. The use and depletion of any remaining stock of packaging with outdated labeling wording or information shall not be allowed for new batches produced after the entry into force of Resolutions of cancellation and transfer of registration.

Article 42. The provisions of Articles 39, 40 and 41 shall not apply to pesticides, their components and suchlike, given that the same are subject to the rules established by the federal registering body.

Article 43. Applications for transfer of registration as a result of corporate operations, submitted before the effective date of this Resolution, shall be analyzed in accordance with the Resolution in force at the time of submission.

Article 44. Submission deadlines established by this Resolution will not be imposed on the applications for transfer of registration as a result of commercial operations performed before the entry into force of this Resolution.

Sole Paragraph. In the cases covered in the head of this Article, companies may submit the corresponding applications for transfer of title and cancellation of product registration to ANVISA within one-hundred and eighty (180) days as of the entry into force of this Resolution, as appropriate.

Article 45. Companies involved in corporate or commercial operations shall provide information and submit additional documents, whenever required by ANVISA.

Article 46. ANVISA may request at any time the copy of the certificate of filing of corporate action registered in the competent commercial registry, in case of corporate operation, or the contractual instrument of transfer of assets or group of assets, in case of commercial operation.

Article 47. Except as otherwise provided herein, Resolutions of cancellation and transfer of registration of products subject to health surveillance addressed in this Resolution shall come into force ninety (90) days after its publication.

Article 48. The delay, omission or provision of false or misleading information in disagreement with the provisions of this Resolution shall constitute a health violation, subjecting the offender to penalties provided in Law no. 6,437, of August 20th, 1977, without prejudice of civil and criminal liabilities provided in the current applicable rules.

Article 49. The Collegiate Board of Directors Resolution – RDC no. 22, of June 17th, 2010, Normative Instruction no. 03, of May 3rd, 2012, and the item 4, chapter III of Annex of RDC no. 323, of November 10th, 2003 shall be revoked.

Article 50. This Resolution shall come into force one-hundred and twenty (120) days after its publication.

### **3. Conclusion**

Due the dynamics of global pharmaceutical market, all the movements in business partnerships needs to attend the legislation described in this article. Many companies has to change theirs marketing positioning for good interest of its brands and strategy prosperity.

### **4. Reference**

1. BRASIL. ANVISA. Agência Nacional de Vigilância Sanitária. RESOLUÇÃO RDC número 13 de 27 de janeiro de 2004.

[BRAZIL, ANVISA - Brazilian Health Surveillance Agency. RESOLUTION RDC no. 102, AUGUST 24TH, 2016].

## **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 in partnership with MM Assessoria Industrial company.