**COLLEGIATE BOARD RESOLUTION – RDC NO. 207 OF 3 JANUARY 2018**

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Provides for the organization of health surveillance actions carried out by the Union, States, the Federal District, and Municipalities, regarding Operation Authorization, Licensing, Marketing Authorization, Certification of Good Practices, Monitoring, Inspection, and Standardization, within the scope of the Brazilian Health Surveillance System (SNVS, in Portuguese).

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, combined with Article 7, item I, of Law no. 9,782 of 26 January 1999, and Article 53, item V, paragraphs 1 and 3, of the Internal Regulation approved by Annex I of Collegiate Board Resolution – RDC no. 61 of 3 February 2016, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 10 December 2017, and I, the Director-President, determine its publication.

**CHAPTER I**

**GENERAL PROVISIONS**

Article 1. This Resolution provides for the organization of health surveillance actions carried out by the Union, States, the Federal District, and Municipalities, regarding Operation Authorization, Licensing, Marketing Authorization, Certification of Good Practices, Monitoring, Inspection, and Standardization, within the scope of the Brazilian Health Surveillance System (SNVS, in Portuguese).

Paragraph 1. The actions within the Union's competence, provided for in this Resolution, are carried out by the Brazilian Health Regulatory Agency – Anvisa.

Paragraph 2. This Resolution adopts the Health Risk Level Classification established by Collegiate Board Resolution – RDC no. 153 of 26 April 2017, and its updates.

Article 2. The organization of health surveillance actions is based on the following conditions:

I – the SNVS management must ensure the interaction and integration among the federated entities, in the fulfilment of the competences and duties defined by legislation, and in compliance with the responsibilities defined in this Resolution;

II – the Union is responsible for the national coordination of the SNVS, and States, the Federal District, and Municipalities are responsible for the coordination of state, district, and municipal components, within the scope of their respective territorial boundaries;

III – the principle for the organization of health surveillance actions covered by this Resolution is the health risk level intrinsic to activities and products subject to health surveillance, as well as the compliance with criteria and requirements necessary for their performance;

IV – the health surveillance actions related to high health risk establishments, products, and services must be agreed upon by States and Municipalities, in compliance with the criteria defined in this Resolution, as well as the requirements agreed upon by the respective Bipartite Interagency Commissions – CIBs;

V – the health surveillance actions related to low health risk establishments, products, and services must be carried out by the municipalities;

VI – the Quality Management System implementation is a structuring qualification requirement for the health surveillance actions carried out by the Union, States, the Federal District, and Municipalities;

VII – health surveillance educational activities targeted to the population and the regulated sector constitute health promotion actions carried out within the SNVS, and play an important role in preventing risks and damages from the use of products and services subject to health control; and

VIII – monitoring of health conditions of products and services subject to health surveillance constitutes a strategic action for health control and risk management, and must be systematically developed by the federated entities.

**CHAPTER II**

**DEFINITIONS**

Article 3. For the purposes of this Resolution, the following definitions are adopted:

I – operation authorization: normative document allowing the operation of companies or establishments, institutions, and organisms subject to health surveillance, by compliance with technical and administrative requirements, which are specific to health legal and regulatory frameworks;

II – certification of good manufacturing practices: process aiming to attest the compliance with the good practices established by specific regulations, proven through health inspection and other mechanisms provided for in health legal and regulatory frameworks;

III – health monitoring: set of actions to verify the compliance with the regulations on health protection and risk management, performed through administrative policing power over the production chain, transportation, storage, import, distribution, and commercialization of products and services subject to health surveillance;

IV – health risk management: systemic and continued application of a set of procedures, practices, and resources, aiming at the qualitative and quantitative analysis of potential adverse events that may affect health safety, human health, professional integrity, and the environment, in order to identify, assess, and propose health measures best suited to risk minimization;

V – health inspection: set of technical and administrative procedures aiming at individual and public health protection, through *in loco* verification of compliance with legal and regulatory

frameworks related to the activities carried out by and the sanitary conditions of establishments, processes, and products. Inspection allows the adoption of guidance measures and correction of situations that may cause damage to the population's health;

VI – health licensing: normative document that allows establishments to operate, as long as legal and regulatory requirements are complied with; and

VII – marketing authorization: normative document that acknowledges products comply with health legal and regulatory frameworks. It is prior to commercialization, in order to assess, minimize, and/ or eliminate eventual health risks to the population.

## CHAPTER III

## ORGANIZATION OF HEALTH SURVEILLANCE ACTION

### Section I

### Operation Authorization

Article 4. The Union is responsible for:

a) the grant and cancellation of the Operation Authorization for Companies (AFE, in Portuguese) subject to health surveillance;

b) the development of ordering regulations, observing the necessary criteria, procedures, flows, and information;

c) the establishment of a database regarding the Operation Authorization for Companies (AFE), available to States, the Federal District, and Municipalities, as well as the provision of technological solutions for data feed; and

d) the development of audit activities aiming at quality and control of the actions related to the Operation Authorization for Companies – AFE.

Article 5. States, the Federal District, and Municipalities are responsible for feeding, on a regular basis, the database referred to in letter c of Article 4 of this Resolution, with information within the scope of their competence.

### Section II

### Licensing

Article 6. States, the Federal District, and Municipalities are responsible for the licensing of establishments that carry out activities subject to health surveillance.

Article 7. Licensing of establishments that carry out activities of high health risk shall be agreed upon among States and Municipalities, within the scope of CIBs.

Sole paragraph. The agreement among States and Municipalities regarding licensing shall observe the health risk inherent to the activities, the requirements established in Chapter IV of this Resolution, and the criteria and procedures defined by the CIBs.

Article 8. Municipalities are responsible for the licensing of establishments that carry out activities of low health risk.

Article 9. States are responsible for monitoring, assessing the performance of, and cooperating with Municipalities in the fulfilment of the requirements and criteria established for the performance of health surveillance responsibilities agreed upon in CIB meetings.

Sole paragraph. Monitoring and assessment shall guide the definition of strategies for cooperation, capacity building, and qualification towards the improvement of health surveillance actions.

**Section III**

**Marketing Authorization**

Article 10. The Union is responsible for the marketing authorization for products subject to health surveillance, as well as for the development of rules and regulations on such process.

Article 11. The Union is responsible for building a database with information on the products authorized and the ones exempt from marketing authorization, which shall be available to States, the Federal District, and Municipalities, as well as for providing technological solutions for data feed.

Sole paragraph. States, the Federal District, and Municipalities are responsible for feeding, on a regular basis, the information referred to in the caption of this article, within the scope of their competence.

**Section IV**

**Good Practices Certification**

Article 12. The Union is responsible for granting and cancelling the certification of good manufacturing, distribution, and/ or storage practices, as well as for the development of rules and regulations on such process.

Article 13. The Union is responsible for verifying the compliance with the good practices by manufacturers of Active Pharmaceutical Ingredients – APIs, Medicinal Products, and Health Products of Risk Classes III and IV.

Paragraph 1. In the cases where the manufacturers referred to in the caption of this article also carry out activities of distribution or storage, the Union is responsible for verifying the compliance with the good practices related to such activities in these establishments.

Paragraph 2. The Union may delegate to States, the Federal District, and Municipalities the responsibilities referred to in the caption and Paragraph 1 of this Article, if the following requirements are met:

a) having a Quality Management System implemented in accordance with the standard operational procedure established within the scope of the SNVS;

b) having health inspection professionals with experience in the inspection of manufacturers of Medicinal Products and Health Products of Risk Classes III and IV, accordingly;

c) having mechanisms to designate administrative competence and policing power to health surveillance professionals to carry out health inspections;

d) having a policy, guide, or regulation implemented, which presents the Institution's Code of Conduct/ Code of Ethics, details scenarios of conflict of interest in the activities related to the health inspection process, and also having a section responsible for investigation into misconduct;

e) having implemented a program of qualification and capacity building of the professionals who carry out health inspections, observing the capacity building requirements established within the scope of the SNVS;

f) having health inspection professionals who are qualified, trained, and in sufficient number for the appropriate coverage of the plants located within the territory;

g) having an updated register of the professionals who carry out health inspections, with information flow and database organized within the scope of the SNVS;

h) having implemented the procedures established in the SNVS, regarding health inspection planning and conduct, classification/ categorization of establishments in accordance with health risk, and elaboration and submission of the inspection report;

i) monitoring parameters and critical stages of the company's manufacturing process;

j) having implemented procedures to verify qualification and validation activities in health inspections;

k) monitoring the corrective actions taken in response to the observations described in the inspection report;

l) taking the appropriate administrative actions against the health infractions identified, and initiating health administrative proceedings in accordance with health legislation;

m) monitoring the quality of medicinal products and health products in the market, based on post-market information; and

n) having safe and controlled management and maintenance of the information related to health inspection process.

Article 14. Within the scope of the CIBs, States and Municipalities shall agree upon the verification of compliance with the good manufacturing, distribution, and/ or storage practices by the establishments carrying out high risk activities, except those referred to in the caption of Article 13, observing the responsibilities of the federated entities regarding licensing and monitoring of such establishments.

**Section V**

**Monitoring**

Article 15. The Union, States, the Federal District, and Municipalities are responsible for monitoring activities, in the performance of health surveillance actions, observing the specific cases provided for in the legislation in force.

Article 16. Within the scope of the CIBs, States and Municipalities shall agree upon the responsibility for monitoring establishments, products, substances, vehicles intended for transportation of products, and services of high health risk.

Sole paragraph. The agreement referred to in the caption of this Article shall observe the health risk inherent to the activities, the compliance with the requirements established in Chapter IV of this Resolution, the criteria and procedures defined by the CIBs, and the responsibility for service management, in the case of public health services.

Article 17. Municipalities are responsible for monitoring establishments, products, substances, vehicles intended for transportation of products, and services of low health risk.

Article 18. The Union may advise, complement, or supplement the monitoring activities which States, the Federal District, and Municipalities are responsible for.

Article 19. States may advise, complement, or supplement the monitoring activities which Municipalities are responsible for.

**Section VI**

**Inspection**

Article 20. The Union, States, the Federal District, and Municipalities are responsible for carrying out inspections that support health surveillance activities, in accordance with the legislation and the provisions in this Resolution.

Paragraph 1. The inspection shall follow the standard operational procedure and the criteria established in the scope of the SNVS.

Paragraph 2. The inspection report shall be available to the Union, States, the Federal District, and Municipalities, accordingly, and the Union shall be responsible for establishing conditions, procedures, and flows.

Paragraph 3. Specific cases, which may demand joint inspection activities, shall be agreed upon among SNVS entities.

**Section VII**

**Regulation**

Article 21. The Union is responsible for establishing health surveillance regulations.

Article 22. The States, the Federal District, and Municipalities are responsible for establishing health surveillance regulations in addition to the regulations established by Anvisa, regarding the specificities in the respective territories.

Sole paragraph. The regulatory initiative provided for in the caption of this Article shall be informed to Anvisa, which shall have a period of up to 30 (thirty) days, from receipt of the notification, to inform if there is regulation on the matter, and a potential conflict between regulations.

Article 23. The regulatory initiatives on the SNVS national coordination shall be discussed by Anvisa's Collegiate Board of Directors and agreed upon by the three spheres of government.

Article 24. Anvisa shall promote the participation of States and Municipalities in the discussion of regulatory initiatives that have an impact on the provision of health services.

**CHAPTER IV**

**REQUIREMENTS FOR AGREEMENT ON HEALTH SURVEILLANCE ACTIVITIES**

Article 25. The agreement on health surveillance activities shall observe the health risk classification for the purposes of licensing and compliance with cognitive, structuring, and operational requirements to qualify the activity at issue.

Paragraph 1. Cognitive requirements are: professional formation, theoretical and practical capacitation, and experience from previous inspections in the object of activities.

Paragraph 2. Structuring requirements are: the health surveillance team, the adoption of standard operational procedures established in the scope of the SNVS, the appointment of health monitoring professionals, and the absence of conflicts of interest.

Paragraph 3. Operational requirements are: monitoring of corrective actions, in response to the demands made by the inspection team, and the adoption of pertinent administrative actions.

Article 26. The definition of parameters for high health risk actions, to be established in the scope of the SNVS through a specific Anvisa regulation, shall be a tripartite work.

Article 27. Anvisa shall develop a program of cooperation and support to States, the Federal District, and Municipalities, with the objective of strengthening health surveillance actions, and the Quality Management System shall be deemed as the main focus thereof.

Article 28. Anvisa shall establish a Normative Instruction on procedures, flows, instruments, and timetable regarding monitoring of the compliance with the provisions in Paragraph 2 of Article 13 of this Resolution by States, the Federal District, and Municipalities.

Article 29. This Resolution enters into force three hundred and sixty-five days from the date of its publication.

**JARBAS BARBOSA DA SILVA JR.**