Pooled Procurement Legal Framework – Assessment

	Brazil
Legal/regulatory frameworks for the purchase of medicines using pooled procurement mechanisms through PAHO.	• Article 1, of Law 10,191/01, establishes the acquisition of products for the implementation of health programs at the Ministry of Health, authorizes the acquisition of drugs through international organizations, such as PAHO. • Although there is legal authorization for the acquisition of drugs through international organizations, such as PAHO, the Ministry of Health is not exempt from observing the other effective rules in the legal system, such as those established in the Law of Industrial Property (Law 9,279/96) or in the Bidding Law (Law 8,666/93). • Therefore, if a particular drug/active ingredient or a technology employed in a drug is covered by a patent in force in Brazil, the product must be purchased from the patent holder or under his/her express authorization, even if the acquisition/importation occurs with the assistance of PAHO, during the term of the patent, under penalty of the infringement of the rights granted to the owner of the patent by article 42, of Law 9,279/96. • When article 1, final part, of Law 10,191/01 establishes that the procedures adopted by the international organizations should be obeyed, this does not mean that there is no legal obligation to choose the most advantageous proposal for the purchases via international organizations, but only that the Ministry of Health is authorized to obey the procedures adopted by these organizations (e.g. PAHO), precisely because the Government can only do that which the law authorizes. This is what prescribes, for instance, article 24, item XIV, of Law 8,666/93, as amended by Law 8,883/94 • The Ministry of Heath has the duty, therefore, to demonstrate that the direct purchase of a particular drug via PAHO will be more advantageous to the Government, in comparison with the acquisition of the same drug via public bid. This is because the manager should justify, for instance, the payment of the service fees and other charges involved in the purchase. The Federal Court of Auditors (TCU), in a process involving the acquisition of drugs by the Ministry of Health through PAHO, decided that, for the purchases made via the terms of cooperation with PAHO, it is appropriate that the manager observes the principles of economy and of efficiency. • This is because there are other legal instruments to achieve this same purpose, thereby seeking the best possible strategic result in the allocation of the financial resources in order to get the best cost-benefit ratio. • The understanding adopted initially by the TCU is correct because otherwise it would Invalidate the control of legality over the purchase of drugs via international organizations. This is not in accordance with the rules that govern the acquisition of goods and services by the Government. • Even the no-bid contracts are submitted, as a rule, to an administrative procedure, taking into account that the absence of a bid is not equivalent to an informal procurement/acquisition. • Because it concerns an administrative procedure of the Government, the formalities established in Law 9,784/99 should be obeyed, as already decided by the TCU, when analyzing the technical cooperation agreements entered into between the Federal Government and PAHO. • Article 50, item IV, and § 1, of Law 9,784/99, establish that the administrative acts that exempt or declare the sole-source contract should give the reasons explicitly, clearly and congruently, within indication of the facts and the legal grounds. • In addition to the formalities required by the law that govern the administrative process within the Federal Government, it is possible to identify other formalities claimed by the legal system for the acquisition of a drug through international organizations, namely: ○ **market approval or authorization from ANVISA**, in compliance with the requirements of safety, quality and effectiveness, for the distribution of the drug in the country;

	○ the Terms of Cooperation and Agreement and their respective amendments should be approved and monitored by the Brazilian Agency of Cooperation (ABC), which is an agency that is attached to the Ministry of Foreign Affairs. This is in view of its role in negotiating, approving, coordinating, implementing and monitoring the Brazilian programs and projects of technical cooperation, performed on the basis of agreements entered into by Brazil with other countries and international organizations (article 41, of Decree 7304/10); ○ the instruments entered into between the Brazilian Government and PAHO should be accompanied by a work plan and a schedule of performance and application (article 116, of Law 8,666/93)"; ○ a budget allocation available for the intended acquisition (article 167, items I and II, of the Constitution.); ○ an estimate of the budgetary and financial impact, accompanied by the assumptions and methodology used in the calculation, as well as a declaration from the authorizing officer of the expenditure that the increase has a budgetary and financial adequacy with the annual budget law and compatibility with the multi-annual plan and with the law of budget guidelines, when it concerns the creation, expansion or improvement of a government program that gives rise to an increase of expenditure (article 16, of Complementary Law 101/00).
Mechanisms (if any), focusing on regulatory standards to ensure quality, safety and effectiveness, are applied to products purchased within the pooled procurement framework of PAHO?	• The exemption of market approval in the situations of importation of drugs via International organizations, such as PAHO, does not signify the exemption of a report by ANVISA or that the rules of health control do not apply to these products. ○ Article 6, of Resolution RDC 203/2017, establishes that it is the responsibility of ANVISA to: ▪ (i) report within 10 (ten) business days from the receipt of the request regarding the Importation, In exceptional circumstances; ▪ **(ii) monitor the profile of the technical complaints and adverse events associated with the use of the products Imported under the terms of this Resolution; and** ▪ (III) publicize the authorization requests for the importation in exceptional circumstances. ▪ Therefore, it is the responsibility of ANVISA to report, either in an administrative proceeding of market approval, or in the request of importation, in exceptional circumstances, regarding the safety, effectiveness and quality of any drugs acquired by international cooperation, via multilateral organizations, such as immunobiological products that are part of the National Immunization Program, acquired via the Revolving Fund for Immunological Acquisitions of PAHO/WHO or donations from multilateral International organizations or official foreign cooperation agencies. ▪ It Is Important to remember that, due to Items VIII and IX, both of article 7, c/c, with article 8, § 1, Item I, of Law 9,782/99, it is a responsibility of ANVISA to consent to the importation and exportation of products and services that Involve a risk to public health, as well as to grant market approval to products, including drugs, in accordance with the rules of its area of participation. ▪ The analysis of the characteristics of a particular product to be imported, even through multilateral international organizations or official foreign cooperation agencies is a measure that is in keeping \with the provisions of article 16, item II, of Law 6,360/76. This establishes that the drugs, medications, pharmaceutical and related inputs should be recognized as safe and effective, by scientific verification and analysis, for the use to which they are proposed. They should also have the necessary identity, activity, quality, purity and innocuousness, under penalty of possibly being acquired and/or distributed as drugs that are harmful to public health. ▪ Furthermore, the provisions of Resolution RDC 81/2008, which establishes the Technical Regulations of Imported Goods and Products for the purposes of Sanitary Surveillance, are also applicable to the acquisition/importation of drugs through international organisms. ▪ It is the exclusive role of ANVISA, and which cannot be delegated to international organizations, to analyze the safety, quality and efficacy

	of drugs for human use and other products that are subject to sanitary surveillance, under the terms of the legislation.
Existing legal/regulatory frameworks waiving local regulatory approval (registration) of the imported product (or if some expedited or exceptional regulatory approval route would be applicable for such registration), and if so, under what circumstances.	• The rule is the requirement of a market approval for the commercialization of a drug for human use in the country. • However, article 5, of Law 9,782/99, establishes an exception, by providing that **ANVISA may exempt from market approval immunobiological products, insecticides, drugs and other strategic inputs when acquired through multilateral international organizations, for use in public health programs by the Ministry of Health and its related entities.** • This **exception is regulated by Resolution RDC 203/2017, which establishes the criteria and procedures for the importation, in exceptional circumstances, of products subject to sanitary surveillance with no market approval granted by ANVISA, which are destined exclusively for use in public health programs by the Ministry of Health and its associated entities, including therein the products purchased through multilateral international organizations**. • Under the terms of article 3, of Resolution RDC 203/2017, the products subject to sanitary surveillance that may be authorized for importation, in **exceptional circumstances**, are those whose drug and/or technology are classified in **at least one of the following situations**: ▪ (i) unavailability in the national market, as well as their therapeutic alternatives or products used for the same purpose are duly registered, if any; • *The unavailability in the national market will be characterized by the temporary or definitive incapacity to meet the demand of the Brazilian Universal Healthcare Program by holders of a duly regularized registration in the country (article 3, § 1, of Resolution RDC 203/2017).* ▪ (ii) public health emergency of national importance, under the terms of Decree 7616/2001 or of international concern (PHEIC), in accordance with the International Health Regulations"; • *The acquisition of products that are subject to sanitary surveillance to comply with the conditions referred to in this second situation (Item II) may be authorized even when they are not performed by the Intermediary of multilateral international organizations.* ▪ (iii) immunobiological products that are part of the National Immunization Program, acquired via the Revolving Fund for Immunobiological Acquisitions of the Pan American Health Organization (PAHO)/World Health Organization (WHO); or ▪ (iv) donations from multilateral International organizations or official foreign cooperation agencies. **RDC 203/2017 was enacted by ANVISA as a response to the importation of products by the MoH without local regulatory approval. However, a RDC can be modified at any time by ANVISA. To secure the legal stability of the contents of RDC 203 would have to be inscribed in law. PL 5994 currently in congress will hopefully close this uncertainty. PL is expected to be approved in congress and move to the senate in mid-February 2019.**
Mechanisms, if any, exist to avoid legal risks (who is responsible for product liability) and security risks (who is responsible for quality and pharmacovigilance tests,	▪ Article 8 of Resolution RDC 203/2017, establishes that the non-compliance with the provisions contained in the Resolution constitutes a health infringement, under the terms of Law 6,437/77, without prejudice to the civil, administrative and criminal liabilities. ▪ However, the implications do not limit the health field, where there could also be the recall of the drugs that represent a risk to human health. ▪ Any non-compliance with the legal rules can generate, to the detriment of the offender, the duty to compensate, for example, (1) the owner of a patent that protects a drug or the technology employed in it, or (ii) the public purse, if the manager fails to select the most advantageous proposal for the Government, remembering that the best proposal is not always the one that is based on the lowest price, even more so

reports of adverse events, withdrawals, etc.) associated with the import of products that do not meet typical regulatory requirements.	when it concerns a drug for human use; or if the rules concerning financial law that govern the participation of the government (e.g. the existence of a budget allocation, etc.) are not observed. ▪ The importation also may not infringe the right to the protection of the test results data contained in the dossier submitted for the consideration of ANVISA for the purpose of market approval, within the time limit of 10 years for medications that use new chemical or biological entities and 5 years for those that do not use them, under penalty of the practice of unfair competition, for the indirect use, by the way of comparison, of this data. ▪ For this reason, the public agents involved in the importation of drugs through multilateral international organizations or official foreign cooperation agencies can be held responsible by Brazilian law, based on article 37, § 4, of the Federal Constitution, and the provisions of Law 1,079/50 (Law of the Crimes of Responsibility) and Law 8,429/92 (Law of Administrative Impropriety).
Identify gaps/risks in terms of non-compliance of imported products through shared procurement with local regulatory standards, which are usually applicable to products submitted for local registration (to monitor quality, safety and efficacy, labeling requirements, post-market surveillance, reports of adverse events, etc.)	