Pooled Procurement Legal Framework – Assessment

	Argentina
Legal/regulatory frameworks for the purchase of medicines using pooled procurement mechanisms through PAHO.	• The purchase of medicines through pooled procurement mechanisms via PAHO is regulated by the Operating Procedures of the *Regional Revolving Fund for Strategic* Public *Health Supplies* ("Strategic Fund") created by PAHO and updated in June, 2010. • PAHO is the specialized health agency of the Inter-American System and serves as the Regional Office for the Americas of the World Health Organization ("WHO"). Together with WHO, PAHO is a member of the United Nations system. Argentina ratified the PAHO's Constitution in 1947 and has been a member since then. • The Strategic Fund is a regional technical cooperation mechanism for pooled procurement of essential medicines and strategic health supplies that was established in 2000 in order to facilitate the procurement of strategic public health supplies by PAHO Member States at a reduced cost, among other objectives. • Each country member of PAHO needs to sign an agreement with the PAHO Strategic Fund to be allowed to purchase medicines and supplies through the Strategic Fund. Once signed, the Ministries of Health of those countries can participate in a pooled procurement mechanism via PAHO. Government Institutions can also participate upon signature of an Annex to the agreement signed by PAHO, the relevant Ministry of Health and the respective Government Institution. • In parallel to PAHO's pooled procurement mechanism regulated under the Strategic Fund, it is worth mentioning that on June 8, 2015, MERCOSUR and PAHO entered into a Memorandum of Understanding with the purpose of establishing a Cooperation Framework to govern their relationship in connection with specific health related matters of mutual interest ("MoU"). The MoU was approved by MERCOSUR Regulation No. 18/15 and became effective on June 11, 2015. o Pursuant to the procedure established in the MoU, any technical cooperation project that requires the transfer of funds will be governed by a specific agreement to be executed by the parties involved. o The Ad Hoc Committee for negotiation of the price of high cost medicines in Member and Associate States ("Committee") was established by MERCOSUR Agreement No. 05/15 ("Agreement"). Therein, the parties to the Agreement agreed to procure high cost medicines of common interest through PAHO Strategic Fund, waiving the right to carry out parallel procurement procedures for the selected products (except for purposes of provisional supply before the conclusion of an ongoing PAHO procurement procedure). • With respect to the UNASUR, it should be noted that also on September 2015 the South American Health Council ("SAC") held a meeting with MERCOSUR's Health Ministers through which UNASUR (i) adhered to the Agreement and (ii) approved a Memorandum of Understanding between UNASUR and PAHO with the purpose of establishing a Cooperation Framework to govern their relationship in connection with specific health related matters of mutual interest. So far, Argentinean health authorities have not issued regulations setting a regulatory framework for the purchase of medicines using pooled procurement mechanisms via PAHO (or other similar international organization). Please note that on November 23, 2018, the MERCOSUR countries and their associate members announced the joint purchase of "***Tacrolimus"***, an immunosuppressive drug used for treating transplanted patients. The drug was purchased through PAHO's Strategic Fund (*https://www.argentina.gob.ar/noticias/paises-del-mercosur-y-asociados-lograran-rebaja-en-la-compra-de-medicamentos-para*). In accordance with this publication, this initiative would result in substantial savings for the MERCOSUR's countries.
Mechanisms (if any), focusing on regulatory	• As a general rule, supplies procured through the Strategic Fund must meet the criteria set forth in the Operating Principles of the Strategic Fund and must be included in the latest Strategic Fund's Product List, available on its website (www.paho.org/StrategicFund).

standards to ensure quality, safety and effectiveness, are applied to products purchased within the pooled procurement framework of PAHO?	• The Operating Principles states that the quality of the products supplied through the Strategic Fund is ensured through the prequalification of suppliers (PAHO uses a system to create a basic list of providers and products that meet specific quality criteria). • To ensure the quality of medicines, PAHO requires suppliers to furnish a Certificate of Quality for Pharmaceutical Products Moving in International Trade as well as a certificate of quality for the pharmaceutical product batch. Such documentation is sent to the participating country for each product purchased. Likewise, PAHO reserves the right to select the laboratory of its choice to verify the quality of a product before or after delivery and to obtain samples of the product or its active ingredients, which the manufacturer will supply free of charge (Section 49). • Under the Operating Principles of the Strategic Fund, at the time the product is delivered from the pharmaceutical company, the manufacturer must attach the following: (i) copy of the current public health registration of the medicine recorded in the country of origin or destination (as appropriate); (ii) copy of the current marketing authorization registration of the manufacture batch or batches of the medicine being delivered; (iii) WHO-type certificate of quality; and (iv) any other documentation required by the country under its regulations. • With respect to the registration requirement set forth in (i) above, under Argentine laws and regulations, all medicines must be duly authorized and registered with the health authority before commercialization (Section 2, Decree No. 150/1992 as amended and complemented). • However, Regulation No. 698 and 412 of 2015, issued by the Ministry of Health and Ministry of Economy ("Regulation 698"), respectively, allows (as an exemption to the general rule of local product registration -Decree 150/92) the import of unregistered medicines in connection with National Health Programs, provided certain conditions are met. • In particular, Regulation 698 sets forth that medicines may be imported to Argentina from countries included in Exhibit I or II of Decree No. 150/1992, as amended, in the following circumstances: o When medicinal or pharmaceutical products registered in the Registry of Medicines Specialties (REM, after its acronym in Spanish) are not available in the domestic market; or o When public bids for procurement of medicinal or pharmaceutical products registered in the REM are declared void or unsuccessful, due to an absence of bidders, or when the bids, at the discretion of the Ministry of Health, are inconvenient. • Thus, when procuring medicines through the Strategic Fund, Argentina must still abide the national legal framework and, should the Ministry of Health or authorized Government Institutions request to import unregistered medicines under pooled procurement mechanisms, the requirements set forth in Regulation 698 must be met.
Existing legal/regulatory frameworks waiving local regulatory approval (registration) of the imported product (or if some expedited or exceptional regulatory	• As a rule, any medicine requires being authorized beforehand by the Argentine health authority (ANMAT) for manufacturing or importing purposes and -as an evidence of such authorization- a marketing authorization certificate per product must be issued (Law on Medicines No. 16,463, Decree No. 150/92 as amended and complemented). • Nonetheless, some exceptional regimes exist in the regulatory framework applicable to medicines in Argentina that allow to import non-registered medicines with ANMAT in some cases. • The exceptional regimes for importing non-registered medicines are the following: o National Health Programs. o Travelers for personal use. o Exceptional Regime for Access to Non-Registered Drugs (ANMAT Regulation No. 10,874/17). o Expanded Access Programs (ANMAT Regulation No. 828/17).

approval route would be applicable for such registration), and if so, under what circumstances.	○ Clinical Trials (MoH Regulation No. 1,480/11 and ANMAT Regulations No. 6,677/10, 12,792/16 and 4,008/17). ○ Post-trial Access to Study Drug (ANMAT Regulation No. 12,792/16). • Only for National Health Programs intervenes the Government Authority as importer of records of a non-registered medicine with ANMAT. In the rest of the exceptional regimes listed above, the importation of non-registered medicines with ANMAT is conducted by the patient/treating physician or the pharmaceutical company and, for the purpose of this memorandum, it is not relevant to explore in depth those regimes). • National Health Programs • The importation of non-registered drugs by the Ministry of Health is allowed for National Health Programs. These drugs may be imported only from those countries listed in Annex I of Decree No. 150/92 (e.g., USA, United Kingdom, Japan, Sweden, France, Germany, Canada, Austria, Italy, and Spain, among others) or Annex II (Australia, India, New Zealand, Ireland, Mexico, Brazil, Chile, among others), in the following circumstances: ○ When medicinal or pharmaceutical products registered in the REM (Argentine Registry of Medicines Specialties) are not available in the domestic market; or ○ When public bids for procurement of medicinal or pharmaceutical products registered in the REM are declared void or unsuccessful, due to an absence of bidders, or when the bids, **at the discretion of the Ministry of Health, are not considered convenient.** • Thus, when procuring medicines through the Strategic Fund, Argentina must still abide the national legal framework and, should the Ministry of Health or authorized Government Institutions request to import unregistered medicines under pooled procurement mechanisms, the requirements set forth in Regulation 698 must be met.
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, reports of adverse events, withdrawals, etc.) associated with the	• The Operating Procedures of the Strategic Fund has a specific topic regarding quality assurance of strategic supplies and where the procedure for filing claims in case of quality issues in connection with medicines purchased via PAHO's mechanism is also described (mainly regulated from Section 44 to 53 and in Annex VII). • None of the exceptional regimes referred above allows to avert legal and safety risks associated with the importation of non-registered medicines with ANMAT. The manufacturer of the product will always be held responsible for the quality of the product. • For non-registered drugs imported under National Health Programs regime, ANMAT must verify and supervise without exception and prior to its release for distribution and dispensation through Health Programs of the Ministry of Health, each of the batches of medicinal or pharmaceutical products that enter the country (Section 1 of Annex I of Regulation 698). Besides that, Regulation 698 does not regulate safety risks issues addressing who´s responsible for pharmacovigilance, reporting of adverse events, recalls, etc. • National Health Programs are usually implemented in different jurisdictions (mainly through hospitals and healthcare institutions located in different provinces and municipalities). We assume that in practice ANMAT may delegate the responsibility for pharmacovigilance, safety and quality issues to the healthcare institutions where the programs are being executed (i.e. the relevant healthcare institution would be responsible for ensuring that medicines are being warehoused in accordance with the relevant good manufacturing and distributions practices, reporting adverse events, etc.). However, we did not find any public reference from ANMAT or at the Ministry of Health's website that may give support to such assumption.

import of products that do not meet typical regulatory requirements.	
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.)	• In the event that the Ministry of Health imports non-registered medicines for National Health Programs (under Regulation 698 regime), gaps or differences with local regulatory standards would possibly arise. • Regulation 698 is very concise and does not regulate pharmacovigilance and adverse event reporting duties, recalls, etc. This (two-page) regulation just makes an express reference in regards to ANMAT being the responsible party to verify and supervise the products acquired under regimes prior to their local release but does not provide any other information about other aspects related to the products once they are delivered to patients. • Argentina has not issued specific regulations about packaging and labeling adaptation of products procured via PAHO besides the general packaging and labeling requirements in accordance with Annex II of the Operating Procedures for the Regional Revolving Fund for Strategic Public Health Supplies. • Argentina has no specific regulations that require products imported via PAHO (or under a similar regime) to appoint a local responsible and/or a 0800 phone number for patient complaint reporting. • For a locally registered product with ANMAT, reporting duties for the occurrence of any adverse event are on behalf of the marketing authorization holder of the product. • On the contrary, the marketing authorization holders of locally approved products must comply with several pharmacovigilance and reporting duties to be able to commercialize their products in Argentina (please see below our answer to your last question for a more detailed reference). • For locally approved products, the marketing authorization holder must comply with several duties to commercialize the products in the country. For example: o Technical inspection. Once the marketing authorization certificate for the product is granted, the holder must pass through the first batch technical inspection for being granted with ANMAT's authorization for commercialization. Such technical inspection consists on the verification of control, manufacturing methods, stability tests and operational capacity, either for the local manufacture of pharmaceutical products or for quality control in the case of imported products. o Pharmacovigilance and reporting duties. Pharmaceutical companies must comply with local Good Pharmacovigilance Practices (ANMAT Regulation No. 5,358/12). Likewise, pharmaceutical companies must appoint a professional within its company who assumes reporting duties with the health authority (through its Pharmacovigilance Department) to exchange information regarding adverse effects on medicines marketed by such pharmaceutical company. o Implementation of mandatory traceability system. For tracking in real time every unit during the whole commercialization chain (pharmaceutical companies, distributors, logistic operators, drugstores, pharmacies, healthcare institutions and patients). Local pharmaceutical companies must comply with traceability reporting duties and all the tracking information is uploaded into an online data base controlled by ANMAT. o Implementation of the recall procedures for pharmaceutical products. Mandatory and voluntary recall procedures have specific regulation that must be complied with by marketing authorization holders of locally approved products. • The type of medicines to be imported may also be relevant for the analysis. For example, under local regulations, biologic products' application demands to the local pharmaceutical company to submit a specific risk management plan and to implement a post-marketing evaluation system. Thus, it is not clear in the regulation (legal gap) how ANMAT will manage to comply with these requirements and -therefore- assure quality and safety for these types of products under exceptional regime imports of non-registered medicines with ANMAT. For example, the Strategic Fund's medicine list (updated to September 10, 2018) includes immunobiologic products, blood products and plasma substitutes that may be classified as biological products under the Argentine regulatory framework.

	• It is worth mentioning that ANMAT has lately signed with relevant health authorities in the region -such as INVIMA (Colombia) and COFEPRIS (Mexico)- interagency agreements to facilitate the exchange of inspection minutes within the pharmaceutical industry. The purpose of those agreements is to simplify the cooperation between the agencies (regulatory convergence) for promoting the development of a unified mechanism for the validation of inspections to verify compliance with the Good Manufacturing Practices (GMP) for medicines and to accelerate product regulatory approvals. These agreements were executed to comply with the commitments assumed by the National Regulatory Authorities of Regional Reference (Autoridades Reguladoras Nacionales de Referencia Regional) in the year 2012. • In conclusion, depending on the actual circumstances of the non-registered medicine to be imported into Argentina, some legal gaps and/or risks can be relevant when lack of compliance of products imported via pooled procurement is compared with regards to local regulatory standards applicable to registered medicines with ANMAT. Those circumstances will have a significant impact that must be analyzed on a case-by-case basis; meaning circumstances such as the country from where the product is actually imported and its level of sanitary surveillance, language used on labels, leaflets, type of medicine involved (biologic or synthetic/semi-synthetic), packaging with an unique tracking code, existence of a local affiliate of the pharmaceutical company manufacturer of the product in case ANMAT requests to have their support (for example, for being the intermediary with the manufacturer, assistance on pharmacovigilance, post-marketing surveillance, adverse event reporting etc.).