Pooled Procurement Legal Framework – Assessment

	Colombia
Legal/regulatory frameworks for the purchase of medicines using pooled procurement mechanisms through PAHO.	• Colombian Ministry of Health and Social Protection –MHSP-, and PAHO executed the Agreement 093 of 2010, for purposes of establishing the general conditions of the participation of Colombia in the PAHO Fund. Decree 249 of 2013 is the regulatory framework of pharmaceutical products imported into Colombia in the form of purchase through the Pan American Health Organization (PAHO). This provision states is not mandatory to obtain a regulatory approval in order to import pharmaceutical products purchased by PAHO. Thus, the Ministry of Health in the import process only must certify the products are in compliance with the WHO´s guidelines for quality in pharmaceuticals products. Also, the Decree 249 of 2013 states that labels of pharmaceutical products will be accepted as they come from abroad. Law 1753 of 2015 allowed the MHSP to set forth the mechanisms to perform centralized negotiations for medical supplies. Furthermore, the referred regulation established that the prices resulting of the centralized negotiations are mandatory for the providers and buyers of the medicines, health devices, and consequently nor the buyers or the providers are allowed for the commercialization of the products using a higher price. • According to the Colombian case law the provision in connection with the establishment of maximum prices as consequence of the centralized negotiations would be applicable not only to the governmental entities but to the private ones, however this provision has not been regulated by the Colombian government, therefore, at this point is not possible to determine their scope. • In connection with the governmental entities, the Colombian Procurement Agency Colombia Compra Eficiente, has tried to centralize the purchases of medical products for municipalities, military forces and local hospitals, avoiding the inefficiencies and transaction costs caused by the performance of having a lot of minor procedures in each municipality or governmental hospitals, through the Framework Agreements (Acuerdos Marco de Precios), therefore, given the advantages of the aggregation of the demand, the Colombian Government has used the Framework Agreements as an instrument of rationalization of the acquisition of goods and services through public contracts coordinating the needs of several entities. • The Framework Agreements are a tool that allows the governmental entities to consolidate market information and identify opportunities for cooperation between governmental entities. The Framework Agreements offer an agile process to acquire goods and services of uniform technical characteristics, including those related to the health sector. • Law 1150 of 2007 sets forth that the governmental entities may use an abbreviated process to acquire goods and services of uniform technical characteristics1, and after the referred procedure, execute the corresponding Framework Agreement. • According to Decree 1082 of 2015 Colombia Compra Eficiente is the entity in charge of “Designing, organizing and executing the Framework Agreements and other mechanisms for the aggregation of demand”. The municipalities, the military forces, the national police, or the governmental hospitals may adhere to the Framework Agreements, and obtaining the prices offered during the procedure. • In that way in despite of the interest of Colombia Compra Eficiente of aggregating the demand, it is important to bear in mind that their scope is limited to the public entities which are not the greatest part of the of the purchasers. • In fact, considering that the EPS are competing with each other, would not be allowed to centralize the purchase of products as per the competition regulations, unless the government expressly intervene in the market of medical products. • Therefore, in Colombia the private entities –that are the greatest part of the purchasers of medical products- are not obliged to participate in a pooled or centralized procurement, but also in accordance with the competition protection regime, they would be forbidden to enter in any agreement for the aggregation of the demand.

[1] Lit. (b) of item 2 of article 2 of Law 1150 of 2007.

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?	• In the Colombian regulatory framework there are not mechanisms in order to ensure quality, safety and effectiveness in products purchased within the pooled procurement framework of PAHO. However, the Ministry of Health requires a document from PAHO stating that the products purchased are in compliance with WHO´s guidelines for quality in pharmaceutical products.
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.	• Decree 249 of 2013 is the regulatory framework of pharmaceutical products imported into Colombia in the form of purchase through the PAHO. This provision states is not mandatory to obtain a regulatory approval or a Marketing Authorization in order to import pharmaceutical products purchased by PAHO. Thus, the Ministry of Health in the import process only requires a document from PAHO stating that the products purchased are in compliance with WHO´s guidelines for quality in pharmaceutical products. . Also, the Decree 249 of 2013 states that labels of pharmaceutical products will be accepted as they come from abroad.
Mechanisms, if any, exist to avoid legal risks (who is responsible for product liability) and security risks (who is responsible for quality	• It should be noted that on this matters there is no specific regulation in the Colombian framework. In this way, the entity responsible of products imported through the purchase of PAHO is Ministry of Health. The Ministry of Health being the importer of the product is the entity in charge of any product liability. Additionally, the Ministry of Health is responsible for reports of adverse events, pharmacovigilance reports and recalls. However, the regulatory authority INVIMA could request information from the manufacturer or the local entity of the manufacturer about the quality of the product, or international adverse events related with the product.

and pharmacovigilance tests, reports of adverse events, withdrawals, etc.) associated with the 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.)	• The main risk/gap is that a medicine purchased through PAHO would have an adverse event and the regulatory authorities establish that the responsibility is the manufacturer of the product or the local entity that represents the manufacturer in Colombia, and not the Ministry of Health who is the importer of the product. The previous case has occurred when the medicine has a Marketing Authorization previously granted to the manufacturer or the local entity before the purchase to PAHO. • In this way, it is possible that the local authorities could be confused and request information to the manufacturer or the local entity. In the case of any review on issues of quality, safety, efficacy, label requirement, reports of adverse events, the local authority may initially call the manufacturer or to the local entity of the manufacturer, to respond on these matters. However, the Ministry of Health has indicated that the medicines to be imported through PAHO are the direct responsibility of the Ministry of Health. • Finally, if the product purchased by PAHO does not have Marketing Authorization in Colombia, this situation does not impact the Marketing Authorization procedure in the future