Pooled Procurement Legal Framework – Assessment

	Mexico

Legal/regulatory frameworks for the purchase of medicines using pooled procurement mechanisms through PAHO.	• Public procurement in Mexico is a constitutional matter whose fundamental dispositions are included in articles 126 and 134
	  ○ Article 126 – determines that no expense can be carried out by the government if it's not inscribed in law, therefore all expenses must be forecasted/inscribed in the official budget
	  ○ Article 134 - determines the legal framework for public procurement in Mexico (principles of public bidding, exceptions etc…)
	• The legal framework for public procurement in Mexico is further defined by:
	  ○ The Procurement Law (*Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público*)
	  ▪ The Procurement Law establishes preferences for nationally produced goods and also established equal treatment for products provided by countries that have treaties with Mexico involving government procurement
	  ○ International Treaties signed by Mexico that include provisions related to government procurement
	• According to the Constitution and to the Procurement Law the Mexican government has the authority and the obligation to conduct public procurement in accordance with the steps and procedures legally established. Procurement via an international organization would violate the existing legal framework in the country.
	• The public procurement process in Mexico is backed by system of judicial appeal and oversight that may take three different forms at the federal level: *Inconformidad; Juicio de Nulidad and Juicio de Amparo.*
	  ○ Under these three cases, the administrative and legal authorities in Mexico would not have the jurisdiction to resolve any dispute resulting from international procurement
	• International treaties specify preferential treatment for certain commercial partners in public procurement in Mexico, purchases conducted by international organizations would likely violate such preferences, or at least it is unclear how they would be respected.
	• Intellectual property rights are recognized in Mexico by the constitution and several auxiliary regulations and international treaties, therefore any purchase conducted for Mexico by international organizations would need to ensure respect to such laws.
	
	Conclusion: Currently there is no legal framework sustaining pooled and international procurement conducted by an international organization in Mexico and international procurement by international organization would violate the Constitution and potentially other lower-level laws as well as international treaties.

Mechanisms (if any), focusing on regulatory standards to ensure quality, safety and effectiveness, are applied to products	**none**

purchased within the pooled procurement framework of PAHO?	
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 Mexican legal framework regarding health products requires the need to obtain a marketing authorization issue by the Mexican Health Care Authority for Medicines. The Regulation of Supplies for Health establishes some exceptions in which the Ministry of Health can grant a special permit for the importation of medicines that do not have the registration, following we describe the same: I. When a contingency arises; II. When required by health policy; III. For purposes of scientific research, registration or personal use, or IV. For laboratory tests.
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 import of products that	The Mexican legal framework on health products requires the importer of medicines to have adequate facilities for the safe handling of them, to ensure control of their quality and pharmacovigilance, in accordance with the requirements established in the corresponding Official Standard.

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.)	**none**