Pooled Procurement Legal Framework – Assessment

	Chile
Legal/regulatory frameworks for the purchase of medicines using pooled procurement mechanisms through PAHO.	• The main public authority involved in pool procurement of pharmaceutical products in Chile is the Central de Abastecimiento del Sistema Nacional de Servicios de Salud (CENABAST). This is a decentralized State Institution that depends upon the Ministry of Health and which manages the purchasing operations mandated by the Ministry of Health, the Undersecretary of Health Care Networks, the Undersecretary of Public Health, National Health Fund, Health Services, Municipalities and Municipal Corporations, and in general by all entities forming the National Health Services System for the exercise of health actions. • As with every other State institution CENABAST is to adjust its purchasing operations in conformity with Law N° 19.886 of Administrative Contracts for Supply and Provision of Services, which establishes the general rules entitling these institutions to execute purchases and acquisitions. • According to article 7 of this Law, purchases can be executed by either public or private tenders, or through direct contracts. The general rule is to purchase through public tenders, with private tenders and direct contracts being available only under certain special conditions defined in the Law. • Article 8 of this Law establishes the conditions allowing purchases by private tenders and direct contracts which are permitted, among others, in the following cases: "…c) In cases of emergency, urgency or unforeseen situations, qualified by founded resolution of the head of the contracting State institution, without prejudice to the special provisions for cases of earthquakes and catastrophes contained in the relevant legislation….; d) If there is only one supplier of the product or service; e) In the case of agreements for the provision of services to be entered into with foreign legal entities that must be executed outside the national territory…". This article also indicates that a minimum of three previous quotations shall be required in private tender and direct contract acquisitions, however, negotiations under the conditions c) and d) above are exempted from this obligation. • There is no specific law in Chile expressly regulating the manner in which the government is to purchase pharmaceutical products through the PAHO Strategic Fund, accordingly the general rules described before should also apply in these negotiations. It is important to note that for purchases through PAHO, it is not regulated who is responsible for management of Product Quality Complaints nor Adverse Events, but could be implicitly expected that the local License Holder assumes this responsibility.
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?	
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 general rule is that prior to importation and distribution every pharmaceutical product must secure licensure through registration with the National Health Institute, which will grant this registration only once the applicant has evidenced the safety, quality and efficacy of its product. Conversely, pharmaceutical products that have not secured this registration cannot be commercialized in Chile. • This general rule is established both in article 97 of the Sanitary Code and in article 20 of Health Decree N° 3, in similarly strict terms: "… No pharmaceutical products can be distributed in Chile without sanitary registration…" and "…Every pharmaceutical product to be entitled for distribution in Chile must previously hold a sanitary registration…". • Notwithstanding the above, the legislation and regulation in place already establish several exceptions to this general rule. Justification for these exceptions can be grouped in two broad categories: scientific and research needs, and, urgent needs derived from situations of lack of supply or lack of access to medicines. • In this manner, Article 99 of the Sanitary Code allows provisional authorizations for distribution, commercialization and use of pharmaceutical products destined to clinical trials or other scientific investigation, as well as to cope with situations of **lack of access to medicines**. • Likewise, in addition to those two motives, Article 21 of Health Decree N°3 allows commercialization of pharmaceutical products without sanitary registration, to cope with **emergency, urgent and catastrophic situations** which endanger the life or health of the population. • On its part projected legislation contained in the Medicines II Bill, currently being discussed in the lower house of Congress, includes a rule that would allow the Ministry of Health to exclude some pharmaceutical products from complying with certain marketing authorization requirements if the medicine already has a marketing authorization from a "High Vigilance" foreign Health Service. • In practice a rule of this nature entirely obviates the need of a local regulatory agency. • Also, the Medicines Bill II, according to the text that was approved by Senate, modifies Article 99 of the Sanitary Code including a new paragraph which expressly indicates that from a health perspective it would be understood that a product is inaccessible whenever economic, financial, opportunity or geographic obstacles impede its access. • The legal implications of linking inaccessibility to economic and financial considerations are manifold, with most prominent examples in the regulation of patent compulsory licenses, which theoretically could be justified only upon high prices of the patented medicine; and also, in the ability of CENABAST to import, acquire and distribute unlicensed medicines. It should be noted, that this past January, the Health Commission of the Lower House of Congress in the debate of the Medicines II Law Bill approved articles relating to the possibility of issuing compulsory licenses on the grounds of economic unavailability. The Law Bill is still pending further legislative steps before final approval. • Finally, in this respect it is worth mentioning that Governmental Authorities have already advanced a clear disposition to incorporate financial and economic considerations as a basis for a finding of inaccessibility of pharmaceutical products, thus anticipating in their rulings a principle still awaiting formal legal sanction. • Examples of the above criteria are reflected in the Oficio 9889 of the General Comptroller resolving that the National Health Service is entitled to authorize the importation and distribution of a medicine by CENABAST in a situation of economic inaccessibility; and Resolution 399 of the Ministry

	of Health declaring the existence of a public health situation meriting the grant of a compulsory license because of the price of the patented medicine being too high.
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 do not meet typical regulatory requirements.	• In order to distribute pharmaceutical products in Chile, as a general rule, one must first secure a sanitary registration or marketing licensure from the National Health Institute. However, Health Decree N°3 (which contains the sanitary regulation), also contemplates that under given special circumstances or for special purposes, some pharmaceutical products can be distributed without the need of a registration licensure from the National Health Institute. • the rules that govern the eventual liabilities arising out of the distribution of pharmaceutical products, are the same for both i.e. products distributed under the general rule, this is, with registration licensure, or without said registration licensure, under the special circumstances or purposes defined in Health Decree N°3. This is, products distributed without registration licensure are not subject to diferent liability rules than the ones applicable to products holding said registration licensure. • The general rule concerning responsibility for imports and distribution of pharmaceutical products is set forth in articles 173- 177 of Health Decree N° 3. These rules generally establish that every subject involved in the manufacturing, importation, distribution, sales or possession at any title of pharmaceutical products, will be responsible to the corresponding degree, about the quality of said merchandise. • Likewise, these rules impose analogous obligations of guarantying quality to every holder of a sanitary registration, and to those natural or juristic persons that have been authorized to import and distribute unlicensed pharmaceutical products. • Additionally, Article 111 i) of the Sanitary Code establishes that every damage caused by the use of a defective sanitary product will result in civil and criminal liabilities, as may be appropriate. Likewise, it also confirms that owners of sanitary registrations shall be jointly liable for these damages along with the manufacturers and the importers, as appropriate. • This same article also establishes that CENABAST can be responsible for damages. In this sense, it should be noted that the Government Country (Fisco) in Chile does not enjoy sovereign immunity unlike other jurisdictions and thus is commonly the defendant in tort and responsibility cases. • Finally the law establishes a statute of limitations of 5 years to file the corresponding lawsuit by the injured party (and can be counted from when the patient has suffered the damage and not only when the product was purchased). The procedure itself is of standard civil damages, but it can have a previous mediation process. • No special rules exist in Chile concerning responsibility for distribution of pharmaceutical products either if these are imported or distributed with the corresponding registration licensure issued by the National Health Institute, or without said registration under any one of the exceptional regimes sanctioned in the referenced pharmaceutical legislation and regulations. • Likewise there are no special rules for the determination of responsibility in the case of pharmaceutical products imported from PAHO, either alone or jointly with other countries. • Accordingly, from the responsibility perspective, the importation and distribution of pharmaceutical products without the corresponding sanitary registration will not necessarily imply a stricter standard for the determination of liabilities in case said products turn out to be defective. • The above provided of course that said unlicensed importations and distributions had been duly authorized in conformity with the laws and regulations in place.
Identify gaps/risks in terms of non-compliance of imported products through shared	• No identified Laws or Regulations that regulate packaging and labeling only of products procured via PAHO. • The general rule regarding product packaging is in article 72 and following of the Health Decree N° 3 which establishes a considerable number of mandatory mentions that the product package must include and characteristics of the type of letter and the minimum size of the letter.

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 current Medicines II Law Bill being legislated does include new regulations regarding the size of the INN and of the trademark in the product packaging. • No identified specific Laws or Regulations establishing special rules for products imported via PAHO regarding the reporting of adverse events. Therefore, we consider that the general rules established in the Sanitary Code, Health Decree N° 3 (articles 216 and following), Resolution 1287 and Technical Norm 140 apply. • In Chile informing about suspicions of adverse reactions is an obligation for all health professionals (including doctors, pharmaceutical chemists, nurses, etc…), Technical Directors of centers of assistance, Technical Directors of the pharmacies as well as the holders of the sanitary registration (Technical Director or a person in charge of adverse events whose name and contact information must be provided to the national center of adverse events). In the case of the holder of a sanitary registration, adverse effects must be informed immediately and in any event within a maximum deadline of 15 calendar days since they took knowledge of the event. In the case of non-compliance, the penalty is to be determined in an administrative procedure before the National Health Institute.