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REGULATORY HARMONIZATION IN CENTRAL AMERICA

HOW HARMONIZATION CAN IMPACT REGIONAL CONTRACEPTIVE PROCUREMENT

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HOW HARMONIZATION CAN IMPACT REGIONAL CONTRACEPTIVE PROCUREMENT

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Abstract
Despite recent efforts to coordinate and standardize laws across countries in Central America, there continue to be a range of prices paid for contraceptives as well as varying procurement options available to public sector entities throughout the subregion. This paper discusses how, in practice, the harmonization of regulatory and procurement functions can facilitate pooled procurement as well as expand the number of contraceptive procurement options available to these countries. The paper concludes with an overview of the current status of harmonization efforts throughout Central America with the objective of providing information regarding the feasibility of a set of options within the current regulatory and legal framework. In addition, the paper presents initial ideas on how potential future changes in regulations could facilitate a broader range of efficient procurement options to public sector health authorities throughout the subregion.

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CONTENTS

ACRONYMS

AAI	Accelerated Access Initiative
ACAME	African Association of Central Medical Stores for Generic Essential Drugs
ART	antiretroviral drug therapy
ARVs	antiretroviral drugs
CIB	coordinated informed buying
DP	direct procurement
CCSS	*Caja Costarricense de Seguridad Social* (Costa Rican Social Security Institute)
CIF	cost, insurance, and freight
ECCB	Eastern Caribbean Central Bank
ECDS	Eastern Caribbean Drug Service
EDL	essential drug list
GCC	Gulf Cooperation Council
GMP	good manufacturing practices
ICB	international competitive bidding
ICH	International Conference on Harmonization
IUD	intrauterine device
LAC	Latin America and the Caribbean
LICB	limited international competitive bidding
MOH	Ministry of Health
NCB	national competitive bidding
NGO	nongovernmental organization
OECS	Organisation of Eastern Caribbean States
PAHO	Pan American Health Organization
SIECA	*Secretaría de Integración Económica Centroamericana* (Central American Economic Integration Secretariat)
STG	standard treatment guidelines
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNICEF	United Nations Children's Fund
UNFPA	United Nations Population Fund
VAT	value-added tax

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[1] Available at http://www.sieca.org.gt/.

GLOSSARY[2]

Branded product	The version of a medicinal product developed and patented by a pharmaceutical company that receives rights to marketing the product in a particular market.
Central contracting	A pooled procurement option whereby member countries jointly conduct tenders and award contracts through an organization that acts on their behalf. A central buying unit manages the purchase on behalf of member countries.
Coordinated informed buying	A pooled procurement option whereby member countries undertake joint market research, share supplier performance information, and monitor prices. Countries conduct procurement individually.
Contraceptive security	Contraceptive security has been achieved when individuals have the ability to choose, obtain, and use quality contraceptives and condoms whenever they need them.
Cost, insurance, and freight	The cost of a commodity, including the cost of insurance and transport to the post of destination or entry.
Group contracting	A pooled procurement option whereby member countries jointly negotiate prices and select suppliers; member countries agree to purchase from selected suppliers. Countries conduct purchasing individually.
Harmonization	As used throughout this paper, the process whereby two or more countries, usually within a given geographical region, choose to standardize (or "harmonize") laws and regulations related to the selection, registration, procurement, and importation of pharmaceuticals and other medical supplies.
Informed buying	A pooled procurement option whereby member countries share information about prices and suppliers. Countries conduct procurement individually.
International competitive bidding	A method for procuring goods and services that requires notification to the international community. Bidders from eligible countries, as defined by the contracting agency or country, are given an equal opportunity to bid.

[2] Definitions come from Abdallah (2005), and Sarley and others (2006).

Limited international competitive bidding	Essentially international competitive bidding by direct invitation without open advertisement. Limited international competitive bidding is normally used when the contract values are small, the number of suppliers is limited, and/or if there are special circumstances.

EXECUTIVE SUMMARY

Despite various efforts to coordinate and standardize procurement policies and regulations across countries in the subregion of Central America, **there continue to be both a range of prices paid for the same contraceptive brands as well as varying and often limited procurement options (suppliers) available to public health authorities in the subregion**. This situation is due to a variety of factors, not least of which is the pressure placed on governments to protect local industries and markets. Additionally, commercial suppliers set prices very differently across countries in the region, based to a large extent on what the suppliers estimate as willingness to pay on the part of commodity purchasers (public government authorities, nongovernmental organizations [NGOs], private corporations, and individuals). To enable countries to obtain the lowest available prices, it is important for public health authorities in the subregion to learn more about the available range of procurement options while working within their existing and often constrained regulatory environments.

Findings from a recent procurement study carried out in 14 Latin American countries suggest that using the United Nations Population Fund (UNFPA) as a procurement agent may be one of the most effective options for obtaining low-priced, quality contraceptives in the short to medium term for many public sector entities in the region (Sarley et al., 2006). Nevertheless, these entities could also consider other possible means of obtaining low-priced, quality contraceptives to guarantee that whatever option they employ is continuously the most effective. For instance, evidence from the same study shows that having a selection of generic products can substantially decrease the cost of procured products, whether countries procure these generics through UNFPA or through their local markets. There are still many questions surrounding the quality of the locally available generic products in the region and a need for product prequalification, but these are options to consider in the long term.

Prices for contraceptives, as for other commodities, depend largely on the competitiveness and transparency of the market. In general, four principal procurement options exist, differing primarily in their degree of competitiveness: (1) international competitive bidding (ICB); (2) limited international competitive bidding (LICB); (3) national competitive bidding (NCB); and (4) direct procurement (DP).[3] In most cases, international competitive bidding results in the lowest prices. This makes sense, as ICB opens the market to all potential bidders, who compete by offering internationally competitive prices.

However, ICB is often not a feasible option in the Latin American and Caribbean (LAC) region for a number of reasons, mainly that countries, in an effort to protect local markets, promote the interests of local suppliers (manufacturers and/or distributors) and therefore shield them from outside competition. In addition, while most countries are technically and legally capable of conducting ICB, suppliers are often required either by law or by regulation to have a local representative in-country to participate in ICB. Therefore, once bids are advertised, international suppliers that have signed exclusivity agreements with local representatives allow these representatives to act as “middlemen” and set prices higher than the international company would have given in a direct response to the bid. In other words, competition is restricted to companies with local representation, which in turn leads to restricted price competition.

[3] See the glossary on p. ix for definitions of these options.

If increased competition through ICB is not a realistic option, how else might countries in the region obtain lower prices? Prices also depend on other factors, including purchase volume, a history of on-time supplier payment and performance, use of generics, and product quality. Many forms of pooled procurement, notably mechanisms established by regional trading blocks, offer opportunities to take advantage of these factors. For instance, regional pooled procurement allows countries to obtain lower prices through high(er)-volume purchasing—higher than if the countries had purchased the supplies on their own—and by combining resources to better ensure product quality and set up efficient systems for gathering market research and monitoring supplier performance.

Increased cooperation among countries as part of pooled procurement can take several forms that vary by degree of complexity, from relatively uncomplicated IB and CIB, to increasingly complex group contracting, to a more complex relationship where countries establish a third-party secretariat to conduct the payment and purchasing function.

Many Latin American countries have actively engaged in informed buying to obtain lower prices for contraceptive commodities. For instance, the Costa Rican Social Security Institute (CCSS) and the Nicaraguan and Honduran Ministries of Health have compared products and prices in order to obtain lower prices for contraceptive commodities. More specifically, Costa Rica, Honduras, and Nicaragua can legally procure from international suppliers and have used this fact to their advantage by alternating between local and international manufacturers to obtain the best prices. However, these public sector entities have not systematically developed a mechanism to assess and compare regulations, products, and prices to guarantee that they are procuring high-quality commodities for the best available price on the market.

In some cases,[4] price information has also been shared within and across countries, often resulting in countries switching from local supplier purchasing to establishing procurement contracts with UNFPA to gain access to better-priced contraceptives. However, this level of information sharing is rarely carried out by contraceptive procurement bodies. Instead, it is often facilitated by the international donor community, whose contractors provide technical assistance in various countries in the region. Nevertheless, despite its nonsystematic and informal methods, coordinated sharing of pricing information in Latin America has allowed countries to identify new sources for competitively priced quality contraceptives that can work within current regulatory constraints, and obtain savings on contraceptive procurement.

There are few examples of the most complex form of pooled procurement—central contracting—whereby member countries establish a third-party secretariat to finance and manage commodity procurement. One such example, the Eastern Caribbean Drug Service (ECDS), established in 1986, manages procurement of pharmaceuticals (including contraceptives) and medical supplies on behalf of member countries of the Organisation of Eastern Caribbean States (OECS).[5] ECDS experience shows how long-term central contracting pooled procurement can lower prices. Since 1986, the average savings achieved for commodities (class A and B essential drugs, including contraceptives) purchased through this mechanism is estimated at 37 percent (Burnett, 2007). Yet for this degree of pooled procurement to occur and operate effectively, countries participating in ECDS needed to harmonize a number of different regulatory functions, including standard treatment guidelines (STGs), essential drug lists (EDLs), product registration, quality standards, policies on the use of generics or brands, intellectual property, and procurement legislation.

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4 Examples include Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Paraguay, and Peru.

5 Member countries include Antigua and Barbuda, Dominica, Grenada, Montserrat, St. Kitts and Nevis, St. Lucia, and St. Vincent and the Grenadines. The British Virgin Islands and Anguilla are associate members.

Is a similar pooled procurement model currently feasible in Central America? Over the past few years, Central American countries have taken tangible steps toward subregional harmonization—for example, through the creation of a subregional customs union—however, many more functions would have to be harmonized for group or central pooled procurement to become a reality. As part of the process leading toward full customs union, in September 2002, El Salvador, Honduras, and Nicaragua passed a resolution (Resolution 93-2002) that mandated harmonization of the health registries in these three countries. Harmonization, in this case, means that each party to the agreement recognizes and accepts the drug products registered in the other countries. Guatemala became a signatory to the resolution a few months later. Costa Rica is likely to become a signatory in the near future, as certain requirements[6] that Costa Rica had set as preconditions for signing are expected to be met shortly.

Whereas traditionally, manufacturers had to register their product in each of the above-mentioned countries to be able to market and sell it there, this subregional resolution allows suppliers who have gained access to one signatory country's market (by registering the product on that country's health registry) to access the markets of the other signatories. This resolution was retroactive and applied to almost all products registered in the three countries at the time it was passed. However, the agreement covers only products provided or manufactured by local suppliers. International suppliers (and international procurement agents such as UNFPA) must continue to register or ensure registry of each product in each country.

Despite a Central American customs union among El Salvador, Guatemala, Honduras, and Nicaragua (and, most likely, soon to include Costa Rica), the harmonization process is not yet complete; there is no "automatic recognition" of a given product from one country to another. As of April 2007, suppliers must still register each product in each signatory country. Nonetheless, the resolution has expedited the registration process. Local suppliers registering a product that has already been registered in a signatory country now must wait approximately eight days, instead of three to six (or more) months. In addition, local suppliers do not have to pay registration fees or provide any product samples for testing. There is minimal evidence of signatory countries not recognizing products registered in other signatory countries. Yet in spite of these advances, a supplier's legal representative in country must still carry out the burdensome administrative requirement of presenting the required paperwork to demonstrate that each product is registered in one of the other signatory countries.

The Central American subregion has harmonized tariffs for almost all of the 6,383 different product classifications that it intends to standardize in order to enable a regional customs union. Specifically, 94.6 percent (or 6,038) of all product items are harmonized and 5.4 percent (or 345) are not yet harmonized. Thirty-seven product classifications are pharmaceuticals, and it appears that none of these have been harmonized. It is not yet clear whether, following the establishment of a regional customs union, it will be possible for international suppliers to have only one regional representative, rather than one in each of the countries in which the product is sold. This issue is still under negotiation.[7]

As a result of the remaining regulatory constraints, although countries in the subregion have begun to use similar procurement mechanisms and regulations have begun to be harmonized, the options for pooled procurement are limited. In the current regulatory environment, the two

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6 Costa Rica raised the concern that certain WHO Good Manufacturing Practices (GMP) standards were not being met by the signatories of the resolution. Consequently, the resolution is being revised to address these concerns. Once the resolution is revised, it is anticipated that Costa Rica will join the harmonization efforts.

7 Personal communication, Licenciada Patricia de Pontaza (SIECA), March 1, 2007, and http://monedani.terra.com/moneda/noticias/mnd30357.htm.

types of pooled procurement most available in Central America are the least complex: informed buying and coordinated informed buying.

In sum, even though the process for procuring and selling commodities in the subregion has been streamlined, the fact that these harmonization efforts apply only to local suppliers limits the ability of countries in the region to obtain the best prices available for contraceptives worldwide or to pool their procurement. If harmonization efforts were to open the market to international suppliers, LAC countries could see some significantly beneficial results—a broader range of procurement options, increased efficiency, potentially easier access to generic suppliers throughout the world, and an increased opportunity to fully engage in multicountry pooled procurement.

Given the current regulatory framework and status of harmonization efforts, what alternative procurement options exist for countries in the region? In the short term, UNFPA may still be the best option to obtain lower prices for contraceptive commodities. As markets are harmonized and there is more potential for international suppliers to enter these markets, countries may be able to switch from using UNFPA as a procurement agent to procuring or negotiating prices on their own (independently or together). In addition, countries can consider taking advantage of UNFPA's leadership to serve as a prequalifier of condoms and intrauterine device (IUD) suppliers and the World Health Organization's (WHO) lead as prequalifier of oral contraceptives (much as the United Nations Children's Fund [UNICEF] is doing for vaccines and the Pan American Health Organization [PAHO] for antiretroviral drugs [ARVs]), for both generic and branded products, whether they are procuring through UNFPA or on their own.

However, even countries that rely on UNFPA to obtain contraceptives at competitive prices on the international market have occasionally been able to obtain even lower prices than UNFPA by identifying new suppliers. Countries with high contraceptive volume are particularly attractive to any supplier. This fact shows the importance of engaging in informed buying. Countries therefore should be increasingly engaging in CIB to ensure that UNFPA and the public sector are regularly informed of potential new suppliers of high-quality contraceptives.

With Costa Rica expected to join the subregional customs union in the near future, it is even more important that countries continuously explore new supplier options. Costa Rica, for example, presently purchases generic contraceptives (orals and injectables) from a local supplier. If the subregional market were to open and allow the other members of the customs union access to this Costa Rican manufacturer's generic products, the member countries would have one more option for procurement (assuming that these products meet international quality standards). However, to obtain this or similar options, countries would need to be aware of them—illustrating the need to share prices and discuss possible options (such as prequalifying suppliers of generic or branded products) through systematic information sharing and pooling of technical resources.

In addition to the need to identify competitive prices, recent research (Hall et al., 2007) finds that "there are a limited number of companies capable of manufacturing high-quality generic products that can provide a complete registration dossier for use outside their home markets…it is critical that donors and procurement agencies state unequivocally that they will only purchase generic products that have been prequalified by WHO[8] or that are approved by a stringent regulatory authority, defined as a National Drug Authority participating in the International Conference on Harmonization (ICH) and the Pharmaceutical Inspection Convention**.** These

[8] WHO's Supplier Prequalification Program has recently been expanded to include hormonal contraceptives. The program will "provide a list of companies from which governments and procurement agencies could purchase products with a guarantee of appropriate quality" (Hall et al., 2007). See http://mednet3.who.int/prequal/ for more information.

findings further emphasize the need for public sector entities to pool their resources and leverage international prequalification mechanisms to ensure that they are obtaining good-quality commodities, whether they are using UNFPA as a procurement agent or procuring the commodities on their own.

Short- to medium-term steps that countries in the subregion could consider to increase competitiveness in contraceptive procurement include the following:

- Consider the costs and benefits of reducing or eliminating protectionist regulations. Relaxing legislation designed to protect local industries should allow public, private, and NGO family planning supply programs to take full advantage of lower prices on the international market, decrease the prices offered by local suppliers, and help enhance the capacity of procurement programs to conduct more complex, less costly purchases. Additionally, countries should work to get legislation enacted to level the playing field between local and international suppliers to increase the number of available suppliers and lower prices.
- Further explore harmonization within the region—beginning by harmonizing STGs and EDLs for all public sector providers and continuing with establishing quality standards, policies on the use of generics and brands, intellectual property, and procurement legislation. Additionally, countries can consider working toward developing a subregional agreement, at least at the ministerial level, whereby public sector contraceptive purchases are exempt from value-added tax (VAT) and duties (even when procurement does not occur through UNFPA).
- Explore options to increase access to quality generic contraceptives (for example, policies can be implemented that require the public sector to elicit bids under generic names, which can result in considerable cost savings).
- Actively engage in informed buying or coordinated informed buying, for example by implementing a mechanism for systematically sharing reference prices between countries. In the longer term, explore the feasibility of conducting pooled price negotiations at regional or subregional levels, at least at the ministerial level.
- Use UNFPA as a regional procurement agent and take advantage of UNFPA as a prequalifier of condoms and IUD suppliers, as well as WHO's prequalification services.[8]

Additionally, this study reveals that some aspects of harmonization and procurement warrant further research and attention. The following analyses could help identify all of the available efficient contraceptive procurement options in the region:

1. Explore the feasibility and benefits of systematizing the sharing of multicountry pricing and supplier performance data to ensure that countries can capitalize fully on other options and experiences as they move toward procuring their own contraceptives.[9]
2. Determine if there are plans to apply any of the same harmonization efforts that have been revised for local suppliers to international distributors, suppliers, and manufacturers.
3. If there are plans to expand harmonization to international suppliers, identify the potential benefits of those plans.
4. Continue to identify high-quality local (as well as generics) manufacturers who would be able to compete with the prices currently available to the public sector through UNFPA.

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9 Feasibility study under way by USAID | DELIVER PROJECT.

Explore the advantages and disadvantages of procuring through these suppliers as compared to current practice.[10]

5. Explore the feasibility of passing a regulation whereby a sole source for contraceptives is required to have a transparent procurement process, as in the case of ECDS. Although ECDS administrative transaction costs are 13 percent compared to UNFPA's 5 percent, ECDS obtains products at a far lower price than can be obtained on the open market. Willingness to sole-source with select suppliers, as in the case of ECDS or UNFPA, provides a financial base to fully leverage the buyer power advantage inherent in pooled procurement. In the case of ECDS, sole source was a critical policy commitment; as ministries of health committed to purchasing products exclusively through ECDS, this guaranteed contracted suppliers most of the public sector demand and prevented noncontracted suppliers from undercutting the administrative fee.
6. Monitor the possible creation of a regional quality control laboratory and determine how its establishment might affect contraceptive procurement.

[10] The recent study carried out by Hall and others (2007) found almost no qualified suppliers available in the LAC region. However, the fact that various public health authorities in the region (i.e., Argentina, Brazil, Chile, and Costa Rica) are currently procuring generic products on the local market suggests that further, continuous research on this subject may identify new, qualified sources of supply in the region (Sarley et al., 2006).

INTRODUCTION

BACKGROUND

Despite efforts to coordinate and standardize procurement policies and regulations across countries in the subregion of Central America, there continue to be both a range of prices paid for the same contraceptive brands as well as varying and often limited procurement options, namely suppliers, available to public health authorities in the subregion.[11] This situation is due to a variety of factors, not least of which is the pressure placed on governments to protect local industries and markets. Additionally, commercial suppliers set prices very differently across countries in the region, based to a large extent on what the suppliers estimate as willingness to pay on the part of commodity purchasers (such as public government authorities, nongovernmental organizations [NGOs], and private individuals). To enable countries to obtain the lowest possible prices, it is important for procurement authorities in the subregion to learn more about the available range of procurement options while working within their existing and often constrained regulatory environments. While initial steps recently taken by Central American countries, described in this paper, may begin to relax more protective regulations and streamline the procurement cycle, it is likely that further changes to the regulatory environment and procurement practices need to occur to allow countries access to a broader range of procurement options.

Harmonization

Harmonization is defined as the process whereby two or more countries, usually within a geographical region, choose to standardize (or "harmonize") laws and regulations related to the selection, registration, procurement, and importation of pharmaceuticals and other medical supplies. This process streamlines different drug regulatory and procurement processes across countries. Increased harmonization should allow for expanded procurement options, lower prices, and streamlined and more efficient product registration and importation efforts.

The goals of this paper are (1) to describe how different procurement options[12] can be used to enable public sector access to lower prices for quality contraceptives; (2) to explain how certain regulatory and procurement functions could be harmonized[13] to enable pooled procurement; (3) to provide a "status update" on how far these harmonization efforts have come in Central America (both in theory and in practice); and (4) to explore how these efforts can potentially provide countries with a wider set of options to procure quality, low-priced contraceptives.

Given recent harmonization efforts in Central America—for example, initial steps taken toward the creation of a regional customs union—this paper focuses on the experience of five Central American countries (El Salvador, Guatemala, Honduras, and Nicaragua and, to a lesser degree, Costa Rica, which is not presently part of the regional customs union but is expected to join in the near future), with a

Contraceptive security has been achieved when individuals have the ability to choose, obtain, and use quality contraceptives and condoms whenever they need them.

[11] Even within a particular country, it is not uncommon to find wide disparities in prices between geographical areas and different public and private health service providers.

[12] This paper explores four pooled procurement options that enable access to lower prices, from loosely coordinated informed buying to complete pooled procurement involving central contracting.

few examples from other countries in the wider Latin American and Caribbean (LAC) region. The paper seeks to summarize the state of the practice of harmonization among the Central American countries, highlighting obstacles to harmonization efforts and changes necessary to enable other effective procurement options in the region. The target audiences for this paper are Central American ministries of health (MOH), government and other procurement and funding bodies, the international donor community, and other policymakers working toward achieving contraceptive security in the region.

PROCUREMENT MECHANISMS TO OBTAIN LOWER PRICES

CONTRACEPTIVE PROCUREMENT OPTIONS

How can countries obtain lower contraceptive prices? Findings from a recent procurement study carried out in 14 countries in the Latin American region suggest that using the United Nations Population Fund (UNFPA) as a procurement agent may be one of the most effective options for obtaining low-priced, quality contraceptives in the medium to long term for many countries in the region (Sarley et al., 2006).[14] Nevertheless, these countries could also consider other means of obtaining low-priced, quality contraceptives to guarantee that whatever option they employ is the most effective on a continuous basis. For instance, evidence from the same study shows that having a selection of generic products can substantially decrease the cost of procured products, whether countries procure these generics through UNFPA or through their local markets. There are many questions surrounding the quality of the locally available generic products, but these are still options to consider in the long term.

Even when procuring directly from UNFPA, it is clear that active sharing of pricing information and procurement options between countries can allow them to obtain the best prices and sources for the public procurement of contraceptives. The following section provides a brief overview of the key factors that influence prices and explores a number of procurement mechanisms that countries could explore to diversify their options for obtaining low-priced, quality contraceptives in years to come.

INCREASED COMPETITION DECREASES PRICES

Prices for contraceptives, as for other commodities, depend largely on the competitiveness and transparency of the market. In general terms, four principal procurement options exist, differing primarily in their degree of competitiveness: (1) international competitive bidding (ICB); (2) limited international competitive bidding (LICB); (3) national competitive bidding (NCB); and (4) direct purchasing (DP). In most cases, international competitive bidding results in the lowest prices. This makes sense, as ICB opens the market to all potential bidders, who then compete by offering internationally competitive prices. Table 1 highlights some advantages and disadvantages of these different procurement methods (including pooled procurement).

[14] Although UNFPA will continue to strengthen its work in reproductive health commodity security in the LAC region through a number of mechanisms, it will not work to strengthen local procurement capacity. It is therefore important that countries consider exploring other means of obtaining low-priced, quality contraceptives.

Table 1. Advantages and Disadvantages of Different Procurement Options

Option	Key Element	Advantages	Disadvantages
ICB	Price competition can exist among a wide variety of potential suppliers.	o Potential for low prices through competition. o Requirement under World Bank and donor procurement guidelines. o Increased transparency during the procurement process.	o Requires more substantial human resources and procurement management expertise. o More administratively complex. o Longer lead times.
LICB	Price competition can exist among a more select group of invited potential suppliers.	o Familiar, qualified suppliers. o Potential for low prices through limited competition. o Increased transparency during the procurement process.	o May require prequalification of suppliers.
NCB	Price competition can be restricted to national suppliers and manufacturers.	o More convenient for smaller bids unlikely to interest international suppliers. o Lower delivery costs. o Local suppliers' knowledge of market conditions.	o Higher prices are more likely.
Direct Purchasing through a Procurement Agent	Procurement can be based on limited and often single price quotations.	o Short lead times (when procuring locally). o More efficient and less time-consuming. o Potential for good price and quality (when purchasing through United Nations [UN] and international agencies). o Familiarity with suppliers. o Sometimes only mechanism to access international suppliers due to restrictive regulatory framework. o Guarantees transparency (when purchasing through UN and international agencies).	o Potential for higher prices because of absence of competition. o Depending on supplier, may not qualify for use of World Bank or donor funds. o Requires 100% of payment up front (when procuring through UN organizations).
Pooled Procurement	Bulk purchasing can be done through joint contract negotiations among countries in a region or among subnational purchasers.	o Lower prices through bulk purchasing. o Enhances regional cooperation and information sharing. o Decreases national management burden when conducted through third-party secretariat. o Quality assurance costs divided among participants.	o Often cannot use loan credit or donor funds for central contracting. o Numerous national political and regulatory barriers. o Must maintain fund capitalization.

Source: Adapted from Rao and others (2006).

However, ICB is often not a feasible option in the LAC region for a number of reasons. A main reason is that in an effort to protect local markets, countries will promote the interests of local suppliers (manufacturers and/or distributors) and therefore shield local industries from outside competition. For example, in El Salvador, specific regulations limit the scope of international tendering and require that the government purchase only from local agents (Sarley et al., 2006).

Additionally, even when countries are technically and legally capable of conducting ICB—as in the Dominican Republic, Ecuador, Guatemala, Honduras, and Nicaragua—it is often not carried out. To participate in ICB, suppliers are often required either by law or by regulation to have a local representative in-country. Therefore, once bids are advertised, international suppliers that have signed exclusivity agreements with local representatives allow these representatives to act as "middlemen" and set prices higher than the international company would have given in a direct response to the bid. In other words, competition is restricted to companies with local representation, which leads to restricted price competition. This phenomenon is due to several factors: (1) a local representative typically has invested a large amount of capital to register a product in a country, needs a quick return on investment, and therefore is less likely to offer reduced prices to the public sector; (2) there is a legitimate fear that the product may wind up on the private market and thereby effectively eliminate the supplier's profit margin; and (3) since the administrative costs involved in establishing an office and registering a product are typically high in LAC, competition from other suppliers is often minimal.

Additionally, countries with smaller markets often do not attract enough interested suppliers to guarantee competitive prices. Further, some countries have limited resources to effectively manage the procurement processes necessitated by ICB. For instance, international suppliers often have longer lead times because they are located further from the countries they are supplying and must be regularly held accountable to ensure that they are satisfying their contractual commitments. Countries must possess procurement management capacities—including forecasting skills, distribution capacity, and management information systems to ensure quality—and adequate funding and resources to properly consider these lead times and monitor supplier performance over time. Longer lead times also demand a higher investment from governments, as they need to keep enough buffer stock in the country to avoid stockouts. Finally, countries, multilateral agencies, and the donor community are often deeply concerned with transparency and governance issues associated with the procurement process. As a result, countries often limit procurement to a few prequalified suppliers in order to guarantee transparency and performance. Similarly, donors often believe that purchasing supplies through UN organizations helps to guarantee the integrity of the procurement process.

INFORMATION SHARING AND INCREASED COORDINATION: POOLED PROCUREMENT OPTIONS CAN LEAD TO PRICE DECREASES

If increased competition through ICB is not a realistic option, how else might countries obtain lower prices? Prices also depend on other factors, including purchase volume, a history of on-time supplier payment and performance, use of generics, and product quality. Many forms of pooled procurement, notably mechanisms established by regional trading blocks, offer opportunities to take advantage of these factors. For instance, regional pooled procurement allows countries to obtain lower prices through high(er)-volume purchasing—higher than if the countries had purchased the supplies on their own—and by combining resources to better ensure product quality and set up efficient systems for gathering market research and monitoring supplier performance.

Increased cooperation among countries as part of pooled procurement can take several forms varying by degree of complexity, from relatively uncomplicated informed buying (IB) and

coordinated informed buying (CIB), to increasingly complex group contracting, to a more complex relationship wherein countries establish a third-party secretariat to conduct the payment and purchasing function. Table 2 summarizes these options.

Table 2. Summary Description of Pooled Procurement Options[15]

Option	Description
Informed Buying	o Member countries share information about prices and suppliers o Countries conduct procurement individually o Examples: Many or most countries; formally or informally
Coordinated Informed Buying	o Member countries undertake joint market research across multiple countries, share supplier performance information, and monitor prices o Countries conduct procurement individually o Examples: Several countries
Group Contracting	o Member countries jointly negotiate prices and select suppliers o Member countries agree to purchase from selected suppliers o Countries conduct purchasing individually o Examples: African Association of Central Medical Stores for Generic Essential Drugs (ACAME) and the Gulf Cooperation Council (GCC) (see Abdallah, 2005)
Central Contracting	o Member countries jointly conduct tenders and award contracts through an organization that acts on their behalf o Central buying unit manages the purchase on behalf of countries o Examples: The Eastern Caribbean Drug Service (ECDS) and Pan American Health Organization's (PAHO) Vaccine Revolving Drug Fund (see Abdallah, 2005)

Source: Adapted from Onyango, 2003.

How extensively are these four degrees of pooled procurement functioning practiced in Central America? What factors seem to facilitate implementation of different pooled procurement options? It is often difficult to even know what prices are being offered and obtained by public (and nonprofit or private) health service providers.[16] For example, in some countries that use competitive bidding, the only price that becomes public is the price of the supplier who won the bid; prices offered by the suppliers who bid but did not win are not publicly available. Without going through an open bidding process, it is very difficult to get current prices from suppliers. So, for instance, a country cannot compare UNFPA prices with local suppliers' prices, because the local suppliers will not share prices unless they enter a bid.

There are few examples of complete pooled procurement, whereby member countries jointly negotiate prices and conduct and award tenders, agreeing to purchase from selected suppliers. Indeed, there is evidence that organizations often do not even pool procurement within a given country. For example, studies of the contraceptive market (such as Sarley et al., 2006) have shown that different public sector agencies involved in contraceptive purchasing and provision

[15] These options also exist within a given country among the different providers of public health services (e.g., MOH, social security).

[16] In some cases, even retail prices are not easy to obtain. For example, while "in several South American countries there are published recommended retail and wholesaler prices for a wide range of pharmaceuticals, including contraceptives," this is not the case for Central America (Sarley et al., 2006).

(e.g., social security institutes and ministries of health) more often than not have procured essential medicines and contraceptives independently rather than in bulk, missing an opportunity to take advantage of volume purchases and price reductions. In the absence of complete pooled procurement, there are still considerable advantages to using other, more informed procurement options.

Throughout Latin America, many countries are actively engaged in more or less systematic product and price comparisons prior to procurement. For instance, the Costa Rican Social Security Institute (CCSS) and the Nicaraguan and Honduran Ministries of Health have compared products and prices to obtain lower prices for contraceptive commodities. More specifically, Costa Rica, Honduras, and Nicaragua can legally procure from international suppliers and have used this ability by alternating between local and international manufacturers to obtain the best prices. However, these public sector entities have not systematically developed a mechanism to assess and compare regulations, products, and prices to guarantee that they are procuring high-quality commodities for the best available price.

Several Latin American countries (Dominican Republic, El Salvador, Guatemala, Mexico, Nicaragua, Paraguay, and Peru) have shared information about obtaining lower prices from UNFPA and thus have switched from procuring from local suppliers to establishing an agreement with UNFPA as a procurement agent. However, this knowledge transfer has rarely been systematic or led by an independent body responsible for sharing pricing data and supplier performance information among countries. Rather, it is facilitated by donors, whose contractors provide technical assistance in various countries at once. Despite the absence of country leadership and the informal nature of these price comparison mechanisms, the sharing of regional pricing information has allowed countries to identify a new source for competitively priced, quality contraceptives—a source that they can use within the current regulatory constraints.

Although there are no examples of group or central contracting in the Central American subregion, the experience of the Eastern Caribbean Drug Service (ECDS), which since 1986 has managed procurement of pharmaceuticals (including contraceptives) and medical supplies on behalf of member countries of the Organisation of Eastern Caribbean States (OECS),[17] illustrates how centrally contracted pooled procurement can help lower prices. Since 1986, the average savings achieved for commodities (class A and B essential drugs) purchased through ECDS is estimated at 37 percent (Burnett, 2007). Box 1 provides an overview of ECDS.

[17] Member countries are Antigua and Barbuda, Dominica, Grenada, Montserrat, St. Kitts and Nevis, St. Lucia, and St. Vincent and the Grenadines. The British Virgin Islands and Anguilla are associate members.

Box 1. Pooled Procurement in the Caribbean

The Experience of ECDS[18]

Description

ECDS was established in 1986 to pool the procurement of class A and B essential drugs for the ministries of health of nine separate islands in the region (three new members have been added to the original six). Through this mechanism, countries have been able to realize substantial savings. The average country savings during the first ECDS tender (1987–88) ranged from 16 to 88 percent, while the average unit price savings over the 1998–2002 period was 37 percent. ECDS's organizational structure includes a policy board (composed of country MOHs assisted by permanent secretaries, the Organisation of Eastern Caribbean States (OECS) director-general, the Eastern Caribbean Central Bank (ECCB) governor, and the ECDS managing director), and two subcommittees: (1) the Technical Advisory Committee and (2) the Tenders Committee. The policy board and the subcommittees meet at least once a year, and the chairmanship rotates. ECDS became self-sufficient by 1989, as a result of charging an administrative fee (originally 15 percent, now reduced to 13 percent) to participating governments. Approximately 85 percent of public sector purchases are procured through ECDS.

How the mechanism works

Each country conducts its own forecasting[19] of required products (a portfolio of approximately 700 products, including contraceptives); this process typically begins more than nine months before the contracts are awarded. ECDS uses restricted tenders, whereby suppliers are screened and prequalified. Tenders are usually made for cost, insurance, and freight (CIF) air and CIF sea prices, especially given the fact that transportation is a major component of purchase costs (delivery of small shipments to nine islands). Instead of operating bulk procurements (purchasing a large volume at one point in time), ECDS requires MOHs to determine their annual needs. These amounts are then pooled and a bid solicitation is put out on behalf of the countries for a year-long contract. If they choose, individual countries can thus order on a more frequent basis (typically two to three orders per year). Strict written guidelines and administrative procedures guide the adjudication process, ensuring transparency. Low price is the major criterion for supplier selection (others include supplier performance, quality standards, and product characteristics). Sole-source commitment is a key feature of the ECDS procurement process; participating MOHs commit to purchasing products tendered by ECDS exclusively through ECDS. This guarantees contracted suppliers most of the public sector demand and prevents noncontracted suppliers from undercutting the administrative fee. Individual countries contribute funds to ECCB, which makes payments for drug purchases. Use of ECCB strengthens the international credibility of ECDS and facilitates foreign exchange; indeed, it is considered one of the key elements contributing to the success of OECS.

What factors have contributed to the success of ECDS? The Organisation of Eastern Caribbean States (OECS) sets precedence for cooperation between Caribbean countries on a variety of topics and areas. It is important to point out that local industry in the region is minimal, so the desire to protect local industry did not impede implementation. Additionally, the fact that the individual supply volumes in many of the Caribbean countries were relatively small was a great motivator to find ways to consolidate need among several countries and lower prices of essential medicines. Finally, it is clear that ECDS went through a "teething process," facing

[18] The following documents were used to develop this box: (1) Abdallah, 2005; (2) MSH/WHO/DAP, 1997; (3) the ECDS/OECS Web site at http://www.oecs.org/units_pps.htm, and (4) a presentation by Francis Burnett on "Group Purchasing in the OECS" at a WHO Expert meeting on Regional Pooled Procurement (Geneva, Switzerland), January 16–17, 2007.

[19] According to Abdallah (2005), forecasting has been "an area of chronic problem for ECDS…factors include inadequate stock control at county level, sudden changes in prescribing patterns, marketing of new products by suppliers, partial shipments from previous tender cycles, extended lead time and formulary changes." As a result, there were "multiple negative consequences: understocking or overstocking, reducing supplier confidence in submitting tender offers …also meant that ECDS had difficulty guaranteeing supplies with multiple countries participating, meaning that (the) opportunity to maximize cost saving are not (being) fully leveraged."

some initial challenges[20] early on. Most of these challenges have been overcome through successful harmonization and standardization efforts across countries in the region.

For pooled procurement to operate effectively, countries participating in ECDS needed to harmonize a number of regulatory functions. For example, the ECDS countries had to develop a *Regional Formulary and Therapeutics Manual* from which the ECDS Tenders Subcommittee could select drug items to be procured. To develop the manual, "choices had to be standardized for items on the tender list, including specific drug products, package sizes, dosage forms and strength; indeed the process for standardizing these elements took varying amounts of time and effort" (Abdallah, 2005). Policy regarding drug donations was also harmonized (Burnett, 2007).

Other factors have been identified as possible contributors to successful pooled procurement in OECS. These factors include a certain level of development (whereby most or all of the countries involved are no longer dependent on donors) and the channeling of funds through a single source (in the case of OECS, this is ECCB) to streamline the payment process and provide a bank guarantee to strengthen creditworthiness. Finally, countries participating in ECDS are bound by a sole-source commitment, which requires them to commit to purchase products tendered by ECDS exclusively through ECDS. This commitment might not be possible in a country where there is a strong local industry or a regulatory preference for local suppliers or representatives.

One important issue to keep in mind is that donors have historically been important clients for international manufacturers. As a result, there has been little incentive for suppliers to sell small amounts to a country or group of countries. Keeping donors, rather than individual countries, as main clients has also helped suppliers keep down their marketing and distribution costs. In the recent past, this constraint had been a large incentive for suppliers in the LAC region. However, because donation levels are decreasing precipitously in the LAC region, suppliers may have an incentive to reconsider their approach to contracting with a country or group of countries.

[20] Forecasting, for example, was an initial ECDS challenge, as it often is in pooled procurement arrangements (R. Raja, personal communication). Countries considering pooled procurement should seek to use forecasting tools, such as PipeLine (DELIVER, 2006). Another ongoing ECDS challenge is late payment by countries; however, ECDS keeps a reserve fund to ensure that this does not result in late payment to suppliers (and thus poor credit standings). In some cases OECS has had to borrow from its own operating funds, but it has managed to maintain good credit with suppliers and continues to obtain good prices (Burnett, 2007).

REGULATORY HARMONIZATION: WHAT IS IT AND HOW CAN IT ENABLE COUNTRIES TO OBTAIN BETTER PRICES?

Given the current regulatory framework in Central America, it is useful to explore how countries in the subregion can benefit from harmonization efforts similar to those of ECDS. The following section defines regulatory harmonization and provides an overview of how it can facilitate different pooled procurement options.

WHAT DO WE MEAN BY HARMONIZATION?

This paper defines "harmonization" as the process whereby two or more countries, usually within a geographical region, choose to standardize (or "harmonize") laws and regulations related to the selection, registration, procurement, and importation of pharmaceuticals and other medical supplies. This process streamlines different drug regulatory and procurement processes across countries. Increased harmonization should allow for expanded procurement options, lower prices, and streamlined and more efficient product registration and importation efforts.

HOW DOES HARMONIZATION FACILITATE THE DIFFERENT POOLED PROCUREMENT OPTIONS?

As can be seen from Table 3, each pooled procurement option requires an increasing degree of coordination and collaboration.

For **informed buying** and **coordinated informed buying**, there are very few harmonization requirements: Countries must have laws stating that information can be shared or, conversely, not have laws that prohibit information sharing. As part of IB and CIB, countries systematically share information (for example, on a quarterly basis) through a central authority. If laws in one country somehow hamper this information exchange, then neither IB nor CIB can function optimally.

For **group contracting** or **central contracting**, many more functions of the drug registration and procurement process should be harmonized, from essential drug lists (EDLs) and standard treatment guidelines (STGs) to the list of contraceptive commodity suppliers that the group will prequalify and/or negotiate with for contracts. Drug registration processes also must be harmonized, including clarifying and standardizing dosage forms, treatment regimens, and policies regarding drug donations across all participating countries.

In regions where group or central contracting models of pooled procurement are being considered for purchasing second-line antiretroviral drugs (ARVs), efforts are also under way to

harmonize intellectual property legislation. For example, if one country in a pooled procurement arrangement seeks to invoke a Trade-Related Aspects of Intellectual Property Rights (TRIPS) clause and use compulsory licensing to purchase second-line ARVs at lower cost, the implication is that the other countries participating in the pooled procurement will have to do the same.

What are some implications of the Central American Free Trade Agreement (CAFTA) on the regional integration and customs harmonization?

An example of the harmonization efforts specific to Central America is the Central American Free Trade Agreement (CAFTA), which is part of a widespread international trend to promote more global and productive economies. From a regional perspective, there are several advantages that Central America can gain from both the CAFTA and the harmonization process:

Common strengths are enhanced by a larger common market, as it promotes economies of scale in terms of negotiations in and out of the region, strengthens complementary strengths, and it generates a common dynamic to become a more competitive commercial partner in the global market.

It also creates regional market spaces for financing emerging markets, reducing logistics costs because of the unified customs scheme, joint export activities in agriculture, textile and manufacture industries. In addition, the signing of CAFTA has speed up the harmonization process, due to the deadlines of the accord to gradually implement the agreement. In this regard, in areas where the harmonization process alone would naturally take longer, the CAFTA agreement has influenced to speed up the negotiations amongst the Central American countries to move on the customs union and the harmonization processes.

Table 3. Critical Requirements for Pooled Procurement Options (Rao et al., 2006)

	Informed Buying	Coordinated Informed Buying	Group Contracting	Pooled Finance/ Central Contracting
Supportive Policies and Legal Mechanisms				
• Legal/policy mechanism for information sharing	✓	✓	✓	✓
• Independent representative secretariat for the procurement			✓	✓
• Clear understanding of the costs, benefits, and obligations for each country and possible need for a transfer mechanism			✓	✓
• Good governance and accountability for funds flow			✓	✓
• Supportive policies and a legal mechanism for jointly negotiating (outsourcing negotiation) of prices and selection of suppliers			✓	✓
Reliable forecasting, procurement, and distribution systems				
• In-country capacity to computerize/standardize supplier and price information	✓	✓		
• Reliable supply chain management including forecasts of national commodity needs and national distribution systems			✓	✓
• Similarity and transparency of procurement policies and procedures			✓	✓
• Ensure supply chain does not lengthen with central contracting				✓
Reliable financial support				
• Financial commitment by participating countries and funding partners			✓	✓
• Evidence of reliable payment of suppliers by countries				✓
Commitment to sole source				
• Political will including willingness to sole source				✓
Common language and currency				
• Common language			✓	✓
• Convertible currencies among participating countries			✓	✓
Harmonizing drug registration, essential drug list, suppliers, and standard treatment guidelines				
• Establish a unique regional drug registration standard policy and procedure			✓	✓
• Existence of similar EDLs and STGs			✓	✓
• Adequate in-country QA capacity			✓	✓

Another example of successful regional coordination resulting in significant price reductions is that of ARVs in Central America (see Box 2). It is important to mention, however, that this regional negotiation benefited from considerable pressure (especially from Brazil, which, claiming a national emergency, decided to produce ARVs without respecting patent protection) and efforts to reduce ARV prices globally, as well as from the successful experience of other areas of the world in obtaining lower prices. Nonetheless, the Central American countries accomplished a number of regional collaborative efforts necessary to make the price reductions and greater intercountry cooperation a reality (such as passing specially coordinated HIV/AIDS laws).

Box 2. Regional Coordination Efforts to Achieve ARV Price Reductions in Central America

Bringing Down ARV Prices in Central America

Regional[21] Central American coordination was essential to achieving considerable price reductions for antiretroviral drug therapy (ART) for HIV/AIDS. As part of the Accelerated Access Initiative (AAI), a global mechanism created by the Central American countries, five pharmaceutical companies,[22] and five principal UN agencies[23] to provide increased access to those in need, regional efforts resulted in an average reduction of 55 percent (PAHO, 2003) for brand name antiretrovirals. For Central American countries that have expressed interest in using WHO-certified generic ARVs, the annual price of first-line therapy has dropped further to U.S.$800–$1,200 per patient.

Regional negotiations were led by the Central American Secretary of Social Integration (SIECA). Negotiations began in August 2002. Important precursors to the regional agreement included (1) "creation and bolstering of national responses through the national HIV/AIDS control programs, including regulations on comprehensive care for people living with HIV/AIDS;" (2) "negotiation, preparation, passage, and implementation of special national HIV/AIDS laws that guarantee access to comprehensive care for people living with HIV/AIDS;" and (3) "development and implementation of National Strategic Plans to fight AIDS, which include comprehensive care as one of the main interventions" (PAHO, 2006).

Other crucial steps were (1) recommendations to explore the option of regional pooled procurement for ARVs and (2) regional discussions on establishing mechanisms for joint registration of ARVs and for determining initial treatment regimens and calculating ARV requirements at national and regional levels.

ARV price reductions are in effect for one year from the date of negotiation and are available only to government institutions in the region. (NGOs and for-profit health care providers cannot obtain reduced prices, while social security institutes and armed forces health services can.) Regionally agreed price reductions constitute a ceiling; each Central American country can choose to further negotiate lower prices directly with a given manufacturer.

See Appendix 1 for an overview of a handful of ARV prices in the region prior to and following regional price negotiations.

The above example highlights the fact that while harmonization efforts often require global and national efforts and (often considerable) time for negotiation and pressure to ensure that they are put into practice, when actually implemented, harmonization can lead to significant efficiencies and price reductions through an increase in procurement options. These price reductions stem not only from full group or central pooled procurement, but also from informed buying and coordinated informed buying.

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21 In this case, "regional" refers to Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and Panama.

22 Boehringer-Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Merck Sharp and Dohme, and F. Hoffman-LaRoche.

23 WHO, UNAIDS, UNICEF, UNFPA, and the World Bank.

For example, in Costa Rica, the CCSS currently purchases from a contraceptive manufacturer at a very low price. If the regional market were to open, allowing Central American countries to efficiently access this manufacturer's products (assuming that the laboratory used by the manufacturer meets quality standards acceptable to the new purchasers and regulations established by the funding source), the public sector would have one more option for procurement. However, to access this or similar options, countries would need to be aware of them—illustrating the need to share prices and discuss possible options (such as prequalifying suppliers of generic or branded products) through systematic information sharing and pooling of technical resources.

In addition to the need to identify competitive prices, recent research (Hall et al., 2007) finds that "there [are] a limited number of companies capable of manufacturing high-quality generic products that can provide a complete registration dossier for use outside their home markets…it is critical that donors and procurement agencies state unequivocally that they will only purchase generic products that have been prequalified by WHO[24] or that are approved by a stringent regulatory authority, defined as a National Drug Authority participating in the International Conference on Harmonization (ICH) and the Pharmaceutical Inspection Convention." This finding further emphasizes the need for public sector entities to pool their resources and leverage international prequalification mechanisms to ensure that they are obtaining good-quality commodities, whether they are using UNFPA as a procurement agent, procuring commodities individually, or engaging in group contracting.

[24] WHO's Supplier Prequalification Program has recently been expanded to include hormonal contraceptives. The program will "provide a list of companies from which governments and procurement agencies could purchase products with a guarantee of appropriate quality" (Hall et al., 2007). See http://mednet3.who.int/prequal/ for more information.

CURRENT STATUS OF HARMONIZATION EFFORTS IN CENTRAL AMERICA

PUBLIC TENDERING FOR CONTRACEPTIVES IN CENTRAL AMERICA

What is the current contraceptive procurement "reality" in Central America? How do procurement policies and systems differ among countries in the subregion and, given this reality, how feasible would it be to introduce any of the four pooled procurement options? Is an ECDS-like procurement model a feasible option? What is the status of harmonization efforts in the region, and what are the regulatory and legal functions that have already been harmonized (or will be in the near future) that could facilitate increased pooling of procurement and/or a broader range of effective procurement options to achieve better prices?

WHAT HAS BEEN HARMONIZED ACROSS THE REGION? IN PRACTICE? IN THEORY?[25]

Central American regional harmonization efforts began as far back as 1960.[26] However, the past decade has brought considerable momentum to these efforts, and many substantive steps have been taken to "break down borders"—for example, through the creation of a regional customs union. With regard to harmonization efforts that affect pharmaceuticals (and contraceptive commodities in particular) and other medical supplies, two key points should be highlighted: (1) the passage of Resolution 93-2002 though which regional harmonization of *registros sanitarios* (health registries) began and (2) the current status of regional tariff harmonization efforts as part of overall regional customs union.

RESOLUTION 93-2002 AND HARMONIZATION OF HEALTH REGISTRIES

On September 27, 2002, El Salvador, Honduras, and Nicaragua passed a resolution that mandated harmonization of health registries in these three countries. Harmonization in this case means that each party recognizes and accepts the drug products registered in the other countries. Whereas traditionally, manufacturers had to register their product in each country to be able to sell it there, now, suppliers who have accessed one signatory country's market (by including its product on the given health registry) can access the markets of the other signatories without having to register with them. This resolution was retroactive, and applied to almost all products registered in the three countries at the time it was passed. However, the resolution covers only products from local suppliers. International suppliers (and international

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25 This section draws heavily from discussions held with Licenciada Patricia de Pontaza from the *Secretaría de Integración Económica Centroamericana* (SIECA) between February and April 2007 and from SIECA's Web site, consulted during the same period. See www.sieca.org.gt/SIECA.

26 In late 1960, the *Tratado General de Integración Económica Centroamericana* (General Agreement for Central American Economic Integration) established the *Mercado Común Centroamerico* (Central American Common Market).

procurement agents, such as UNFPA) must continue to register or ensure registry of each product in each country.

Guatemala became a signatory a few months later. Costa Rica is likely to become a signatory in the near future, as certain requirements[27] it had set as preconditions are expected to be met soon. One key aspect of Resolution 93-2002 is that individual countries or groups of countries are given the authority to move forward with harmonization efforts as they become ready to do so; that is, not all signatory countries need to be ready to implement a new strategy or law; instead, each can proceed at its own pace.

Resolution 93-2002 set out a number of legally binding resolutions, emphasizing the need for increased coordination and standardization across signatory countries to facilitate health registry harmonization and move further toward a regional customs union. Examples include establishing a *Formato Unico de Certificado de Producto Farmacéutico,* single format for pharmaceutical products applying the good manufacturing practice (GMP) standards highlighted within an Annex to the resolution, establishing alphanumerical codes for the health registries, and determining the number of samples required to evaluate product quality for the health registry. The resolution gave countries 30 days to implement these harmonization processes. In theory, therefore, all changes have been implemented for quite a while now; in practice, however, this is not yet the case.

The harmonization process is not yet complete. There is no "automatic recognition" of a given product from one country to another, and as of April 2007, suppliers must still register each product in each signatory country. Nonetheless, the resolution has expedited the registration process. Instead of waiting approximately three to six (or more) months, suppliers registering a product that has already been registered in a signatory country wait approximately eight days.[28] In addition, suppliers do not have to pay registration fees or provide any product samples for quality testing and verification of chemical composition. However, the burdensome administrative requirement for the supplier's legal representative in country to present the required paperwork to show that each product is registered in one of the other signatory countries is still in place.

There is minimal evidence of signatory countries not recognizing products registered in other signatory countries. SIECA maintains a publicly accessible electronic database of conflicts among signatory countries, although it has no formal conflict resolution role. (Conflicts, when they arise, are usually handled bilaterally.) As of February 5, 2007, one pharmaceutical-related dispute was alluded to in the database: Nicaragua did not accept the product ALUSOR, produced by Laboratorios ARSAL in El Salvador and included on El Salvador's health registry. Nicaragua justifies its nonrecognition by concerns about the efficacy and security of the product.[29]

Several categories require harmonization for effective pooled procurement. These categories have been mentioned throughout the paper but have not been systematically examined. They include STGs, EDLs, product registration, quality standards, policies on the use of generics and

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[27] Costa Rica raised the concern that the signatories of Resolution 93-2002 were not meeting certain WHO GMP standards. Consequently, the resolution is being revised to address these concerns. Once the resolution is revised, it is anticipated that Costa Rica will join the harmonization efforts.

[28] A similar example of regional harmonization of health registries is the case of the Andean Community countries (Bolivia, Colombia, Ecuador, and Peru—Chile is in the process of joining and Venezuela left in 2006). These countries have agreed to recognize each others' health registries. While this still means that companies must register their product in each country of the Community, the registration process is considerably sped up—from an average of 8–12 months in the case of Ecuador or 6–12 months in the case of Colombia to 1–2 months total (Juan Agudelo, personal communication).

[29] See www.sieca.org/gt/SIECA.htm—go to "*Integración Económico Centroamericano*," then to "*libre comercio*," then to "*obstáculos*," and then scroll down to #3.

brands, intellectual property, and procurement legislation (e.g., ability to conduct international tenders, or preference for local suppliers and industry). To the authors' knowledge, no category apart from registration has been harmonized in the Central American region. As a result, the more "sophisticated" pooled procurement mechanisms (group contracting and central contracting) are presently not feasible options in the region.

CURRENT STATUS OF REGIONAL TARIFF HARMONIZATION EFFORTS AS PART OF AN OVERALL REGIONAL CUSTOMS UNION

As of early March 2007, the region had harmonized tariffs for almost all of the 6,383 products that it intends to standardize. Specifically, 94.6 percent (or 6,038) of all product items were already harmonized and 5.4 percent (or 345) were still unharmonized. Thirty-seven product items concern medicines. It is not yet clear whether, following the establishment of a regional customs union, it will be possible for international suppliers to have only one regional representative rather than a representative in each country where the product is sold. This issue is still under discussion.[30]

Box 3 provides a brief overview of tariff harmonization that impacts contraceptive procurement in the Andean region.

Box 3. Tariff Harmonization for Contraceptives in the Andean Community

The experience of Bolivia, Colombia, Ecuador, and Peru[31]
In addition to recognizing the health registries of other community countries, the Andean Community has harmonized the tariff regulations that impact contraceptives. Community countries no longer pay tariffs on contraceptives imported from another Community country. Contraceptives that come from outside the Andean Community remain subject to tariffs, which usually range from 1 to 10 percent of the product's price.

There are four product items (corresponding to three codes, in parentheses) within the SIECA classification system that pertain to contraceptives:

- Oral hormonal contraceptives (3004.39.10)
- Injectable hormonal contraceptives (3004.39.10)
- Latex condoms (4014.10.00)
- Copper IUDs (9021.90.00)

Product importation tariffs differ: A 5 percent tariff is applied to product code 3004.39.10 in El Salvador and Guatemala. Costa Rica, Honduras, and Nicaragua do not apply a tariff to this code. There are no tariffs for the other product codes in any of the countries in the region.

It should be pointed out that a common regional tariff policy on pharmaceuticals might not be a requirement for more sophisticated and complex pooled procurement. Once the purchase is made and products are shipped to their destinations (in different countries), the various tariff charges simply affect the final destination price for a particular customer, not the procurement price or the management of the actual procurement. Nonetheless, it would be useful to have a common external tariff (zero percent would be preferable for all contraceptives, whether from

[30] Personal communication, Licenciada Patricia de Pontaza (SIECA), March 1, 2007, and http://monedani.terra.com/moneda/noticias/mnd30357.htm.

[31] Information to develop this box comes from personal communications with Juan Agudelo.

public or private sources), as lowering the final destination costs to warehouse (post customs clearance) theoretically would lower the retail price.

OTHER EFFORTS TO STREAMLINE REGIONAL PROCESSES

In late March 2007, the Nicaraguan government and the U.S. government held discussions which, among many other topics, centered on creation of a quality control laboratory based in Central America for evaluating the quality of generic medicines entering the region.[32] At present, it is unclear whether this will occur, but if it did, it could have a significant impact on procurement in the region; it could potentially serve as a more independent and autonomous regional quality control laboratory, separate from the interests of any single country.

CURRENT PRICES FOR CONTRACEPTIVES IN THE REGION

Given that evidence suggests that an absence of harmonization may lead to price variance for similar products, it is important to get some sense of how contraceptive prices compare across the Central American region. Table 4 presents a price comparison for a number of contraceptive commodities in the region. Examples clearly show how suppliers presently set prices very differently across countries in the region, based to a large extent on what they estimate as willingness to pay, and illustrate the potential for increased coordination and price information sharing among countries to lower prices.

Table 4. CIF and Retail Price Comparison for Selected Contraceptive Commodities in Central America (in U.S.$)

	Costa Rica	El Salvador	Guatemala	Honduras	Nicaragua
Oral contraceptives (public sector CIF price)	0.25	0.31	0.33	0.39	0.34
Injectable contraceptives (public sector CIF price)	1.12	0.89	0.78	Data unavailable	0.78
Copper T-380A IUD (CIF price)	Data unavailable	Data unavailable	1.49	Data unavailable	1.63
Oral contraceptive: Microgynon (average retail price)	5.85	6.47	9.92	5.69	5.00
Injectable contraceptive: Depo-Provera (average retail price)	9.04	13.84	23.57	6.82	3.37
Injectable contraceptive: Mesigyna (retail price)	7.66	7.03	9.93	5.89	4.64

Source: Compiled from information contained in Sarley and others (2006). Costa Rica data are from Cisek and Olson (2006).

[32] http://www.agenda-latina.de/index2.html

CONCLUSIONS

Although countries in the subregion have begun to procure contraceptives on their own and have a number of procurement regulations in place, the options for international pooled procurement in the Central American subregion are limited. In the current regulatory environment, the more complex forms of pooled procurement (group contracting and central contracting) are not feasible—numerous functions would need to be harmonized to make them realistic options. What might be possible is some more structured and systematic coordinated informed buying mechanism.

Countries have engaged in international informed buying and have shared information about various options with one another to identify more efficient sources for contraceptives in the region (i.e., UNFPA). However, efforts to systematically share pricing and supplier performance information have not yet been made. There may be some benefit to systematizing the sharing of multicountry pricing and supplier information to ensure that countries are fully aware of options in the subregion and capitalize on these options as they move toward increasingly procuring their own contraceptives.

Countries will not be able to engage in multicountry procurement of contraceptives until further regulatory reform takes place. Current harmonization efforts apply only to local suppliers in the subregion. Thus, the option to pool procurement from international suppliers is not feasible without some major regulatory reforms. If countries were to systematically identify a local Central American manufacturer that provides quality contraceptives at competitive prices, the current regulatory environment could facilitate coordinating buying or even central or group contracting from such a source (i.e., by a Central American body from a Central American supplier). However, issues about monopoly need to be examined to guarantee transparency in the process. The ideal scenario would involve a pool of suppliers who can provide low-cost contraceptives based on annual competitive bids, thereby avoiding any possible practice of ring-fencing.[33]

In sum, although the process for procuring and selling commodities in the subregion has been streamlined, the fact that these harmonization efforts apply only to local suppliers limits the ability of countries to obtain the most competitive prices available for contraceptives worldwide or pool their procurement. If harmonization efforts were to open up markets to international suppliers, there could be some significantly beneficial results—increased efficiency, more competition, a broader range of procurement options, and easier access to generic suppliers throughout the world. Nevertheless, even if regulations that apply to both local and international suppliers were harmonized, there are still many factors dictated by suppliers and pharmaceutical manufacturers (i.e., how they set their prices and gauge the markets) that no amount of harmonization or opening of the market will resolve. These factors would be resolved only through advocacy efforts and coordination with the commercial sector—as was the case with ARVs—as well as by encouraging or creating incentives for the commercial sector to make a broader range of contraceptive prices available to the subregion.

[33] The practice of isolating a designated pot of money from outside risk.

In the short term, given the current regulatory environment, it appears that using UNFPA as a procurement agent may be the most efficient manner of ensuring access to high-quality, low-cost contraceptives in Central America.

OPTIONS AND RECOMMENDATIONS

What has been learned from this rapid review of contraceptive procurement options and current harmonization efforts in Central America? This section seeks first to highlight a few key lessons learned, and second to provide an overview of possible options and recommendations to increase procurement options in the Central American subregion.

KEY LESSONS

- The effect of protectionist policies and consequent limitation of competitive procurement mechanisms in support of local industry should not be underestimated.
- Increasingly complex forms of pooled procurement (from informed buying to group and central financing and contracting) can be beneficial to countries, even though the investments are high and regulatory requirements complex.
- Collection, systematization, and use of key procurement data are key to effective harmonization in the subregion; future harmonization will require further collection of data and their use for advocacy purposes.

What realistic options exist in the near future for Central American contraceptive procurement? The following section presents a brief overview of possible options. It is suggested that countries consider all of these options, especially as several could be implemented simultaneously.

OPTION/RECOMMENDATION #1

CONSIDER BOTH THE COSTS AND BENEFITS OF REDUCING OR ELIMINATING PROTECTIONIST REGULATIONS

Legislation and regulations designed to protect local industry and pharmaceutical suppliers should be reduced. Doing so will allow public, private, and NGO family planning supply programs to take full advantage of the lower prices offered in the international market and enhance the capacity of procurement programs to conduct more complex, but less costly, international purchases. There are, however, a series of both costs and benefits to countries taking over the procurement process once restrictions have been lifted. On the cost side, countries will need to assume the procurement functions that UNFPA presently undertakes, implying a possible increase in staff and capacity building as well as an increase in concomitant costs at the local level. In addition, there are issues around ensuring financial commitment, transparency, and good governance as countries manage the procurement process from solicitation to payment and distribution. For example, if funds are not disbursed and payments made up front, as required by UNFPA, there is a much higher risk that the procurement of adequate amounts of contraceptives will suffer due to competing priorities. When procuring directly from international suppliers who have no representation in country, the products most likely will be delivered from door to port. As a result, the MOH will have to pick up the cost of customs clearance, warehousing at the central level, and distribution to service delivery points. Finally, prices may be higher than those obtained by UNFPA; unless countries pool procurement, volumes are likely to be low, resulting in higher prices (at a minimum, countries

should ensure that they pool across public sector bodies such as ministries of health and social security). However, these costs are countered by a number of benefits, namely that countries would not necessarily have to disburse payments up front (as they presently are required to do through UNFPA). Further, contracts could specify that suppliers must deliver products to any given point(s) in the country, which may make it easier for countries to reach service delivery points. (This is not the case with UNFPA, which delivers to one central point and places the distribution responsibility on the country's authorities.)

OPTION/RECOMMENDATION #2

FURTHER EXPLORE HARMONIZATION WITHIN THE REGION

Central American harmonization of drug registries is a solid beginning to pooled procurement. In addition, countries need to harmonize their EDLs, contraceptive commodity suppliers, and STGs to facilitate full pooled procurement. Also, within a country, all public sector providers (including international suppliers) should harmonize drug lists to guarantee access to a wider range of low-priced, quality contraceptives (as was done in Paraguay). A mechanism for sharing reference prices among countries would be needed to guarantee all countries the most up-to-date information on available options in the subregion. Finally, if all these harmonization efforts were to take place, countries could begin to consider pooled price negotiations at a regional or subregional level.

OPTION/RECOMMENDATION #3

EXPLORE OPTIONS TO INCREASE ACCESS TO QUALITY GENERIC CONTRACEPTIVES

A recent article (Hall et al., 2007) argues that "one approach to improve access to and provide an adequate supply of hormonal contraceptives (in developing countries) would be to use existing market forces and expand supply from generic manufacturers" and that, instead of establishing "new facilities to meet the demand for supplies of hormonal contraceptives…attention should focus on the feasibility of developing a network of existing generic pharmaceutical manufacturers in lower- and middle-income countries that could supply their products to people in the developing world provided that those products are of appropriate quality and are affordable and accessible." The authors describe two feasibility studies (one quantitative, one qualitative) and conclude, "[given that] there are a limited number of companies that are capable of manufacturing high-quality generic products that can provide a complete registration dossier for use outside their home markets…it is critical that donors and procurement agencies state unequivocally that they will only purchase generic products that have been prequalified by WHO[34] or which are approved by a stringent regulatory authority, defined as a National Drug Authority participating in the International Conference on Harmonization (ICH) and the Pharmaceutical Inspection Convention." This finding emphasizes the need for public sector entities to pool their resources and leverage international prequalification mechanisms to ensure that they are obtaining good-quality commodities, regardless of the procurement mechanism.

Although the study by Hall and others (2007) found that there are few qualified suppliers available in the LAC region, the fact that various public health authorities in the region (Argentina, Brazil, Chile, and Costa Rica) are currently procuring generic products on the local

[34] WHO's Supplier Prequalification Program has recently been expanded to include hormonal contraceptives. The program will "provide a list of companies from which governments and procurement agencies could purchase products with a guarantee of appropriate quality" (Hall et al., 2007). See http://mednet3.who.int/prequal/ for more information.

market suggests that further research on this subject may identify new qualified sources of supply in the region (Sarley et al., 2006).

For example, Costa Rica presently purchases generic contraceptives from a local supplier. Once Costa Rica joins the Central American regional customs union (which is expected to occur in the near future), other countries of the union should be able to obtain these generic products at equally advantageous prices more efficiently than they could have previously. However, sufficient quality assurance mechanisms must be in place to prevent product quality from being compromised if countries decide to procure independently of UNFPA mechanisms.

Additionally, new policies could legally require the public sector to continue soliciting bids for generic products. In Argentina, both generic companies and brand companies respond to the solicitations, but because solicitations are made by naming specific generics, the process serves to drive down prices naturally. Brand name manufacturers would present bids at prices closer to cost (as has been the case in Argentina) to compete with generic manufacturers. Again, mechanisms must be in place to ensure the quality of generic products.

Finally, if a Central American regional quality control laboratory becomes a reality, all countries in the region could probably obtain approved products. Though initial capital costs may be high, this laboratory would provide necessary quality control. Another option is to ask WHO to assist with the prequalification of manufacturers, suppliers, and contraceptive generic products in the region and to guarantee quality and bioequivalence of products. Assistance from WHO would avoid the need for a quality control laboratory in the region.

OPTION/RECOMMENDATION #4

INCREASE SYSTEMATIC PRICE SHARING TO AUGMENT INFORMED BUYING OF CONTRACEPTIVES

Even where countries rely on UNFPA for information on the best pricing options in the global market, on some occasions countries (such as Costa Rica and Chile, which procure from local generic manufacturers [Sarley et al., 2006]) have been able to obtain even lower prices than UNFPA. Certain countries, especially those with high contraceptive volume, are able to identify and attract new suppliers. This fact shows the importance of engaging in informed buying. Countries therefore should be increasingly engaging in coordinated informed buying to ensure that UNFPA and the public sector are aware of potential new suppliers of high-quality contraceptives.

However, the authors are not aware of any systematic long-term price sharing arrangements. These arrangements have the potential to significantly lower costs and guarantee consistent access to qualified suppliers. Instead, countries have learned of better prices almost by chance, often by word of mouth from independent consultants who work in a handful of countries. It would be beneficial to explore establishing more systematic and regular cross-country (and cross-institutional) price comparisons, along with the most appropriate platform to facilitate this exchange. A feasibility study to explore this option is under way with USAID funding.[35]

OPTION/RECOMMENDATION #5

USE UNFPA AS A REGIONAL PROCUREMENT AGENT

For the time being, UNFPA may still be the best option for efficiently obtaining low-cost, quality contraceptives. Countries are increasingly engaging in CIB to regularly inform UNFPA of

[35] Feasibility study results report by USAID | DELIVER PROJECT should be available by October 2007.

potential new quality suppliers, and vice versa. Countries also can consider taking advantage of UNFPA as a prequalifier of condoms and IUD suppliers, as well as WHO's prequalification services. WHO's Supplier Prequalification Program has recently been expanded to include hormonal contraceptives. The program will "provide a list of companies from which governments and procurement agencies could purchase products with a guarantee of appropriate quality" that can help public sector health authorities to select or preselect optimal suppliers.[36] Further, as more harmonization takes place in Central America and there is increased potential for international suppliers to enter these markets, countries might be able to switch from using UNFPA to procuring or negotiating prices on their own (independently or in groups). If regulations throughout the Central American subregion are truly harmonized for all suppliers, UNFPA's role, as part of the United Nations system, might be even further strengthened. UNFPA could focus its efforts even more on technical assistance and expert consultation as a prequalifier of contraceptive manufacturers, suppliers, and products, in addition to or instead of acting as a procurement agent on behalf of international donors or Central American countries. However, given the current regulatory environment, it is unlikely that countries will soon be able to procure as efficiently on their own as they currently do through UNFPA.

[36] Hall et al., 2007. See http://mednet3.who.int/prequal/ for more information.

NEXT STEPS

Although options for central or group contracting are limited in Central America, this analysis reveals that some aspects of harmonization and procurement warrant further research and attention. Further analysis could help identify all of the available efficient contraceptive procurement options in the region:

1. Explore the feasibility and benefits of systematizing the sharing of multicountry pricing and supplier performance data to ensure that countries are fully aware of and capitalize on one another's options and experiences as they move toward increasingly procuring their own contraceptives.
2. Determine if there are plans to expand any of the same harmonization efforts that have been applied to local suppliers to international distributors, suppliers, and manufacturers.
3. If there are plans to expand harmonization to international suppliers, identify the potential benefits of those plans.
4. Continue to identify high-quality local (also generics) manufacturers who would be able to compete with the prices currently available to the public sector through UNFPA. Explore the advantages and disadvantages of procuring through these suppliers as compared to current practice.
5. Explore the feasibility of passing a regulation whereby a sole source for contraceptives is required to have a transparent procurement process, as in the case of ECDS. Although administrative transaction costs are 13 percent compared to UNFPA's administrative cost of 5 percent, ECDS obtains products at a far lower price than can be obtained on the open market. Willingness to sole-source with select suppliers, as in the case of ECDS or UNFPA, provides a financial base to fully leverage the buyer power advantage inherent in pooled procurement. In the case of ECDS, sole-source purchasing was a critical policy commitment: As ministries of health committed to purchasing products exclusively through ECDS, this commitment guaranteed contracted suppliers most of the public sector demand and prevented noncontracted suppliers from undercutting the administrative fee.
6. Monitor the possible creation of a regional quality control laboratory and determine how its establishment might affect contraceptive procurement.

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APPENDIX

ARV Price Comparisons Regionally and Pre.Post Price Negotiation

ARV Generic Name	Doses	Present-ation	Company Name	Cost prior to negotiation in U.S.$ (October 2002)					Price post negotiation (January 2003)
				CR	*ES*	*GUA*	*HO*	*Panama*	
Zidovudine (AZT)	100 mg	Capsule	GSK	0.10 (generic)	0.93 (MOH) and 0.65 (SS[37])	0.28 (MOH, generic)		0.99 (SS)	0.25 (brand) *Generic by CIPLA costs 0.10*
Zidovudine (AZT)	300 mg	Capsule	GSK					2.58 (SS)	0.70 *Generic by CIPLA costs 0.27*
Lamivudine (3TC)	150 mg	Tablet	GSK	0.13 (generic)	1.26 (SS)	2.00 (MOH) and 2.05 (SS)		1.70 (MOH and SS)	0.29 *Generic by CIPLA/RAMBAXY costs 0.17*
Lamivudine (3TC)	10 mg/ml (sol 240 ml)	Solution	GSK			81.17 (SS)	25.96		10.93 *Generic by CIPLA/RAMBAXY costs 4.80*
AZT and 3TC	300 mg and 150 mg	Tablet	GSK				1.15	3.09 (MOH) and 3.11 (SS)	0.94 *Generic by Rambaxy costs 0.40*
Didanosine (ddI)	100 mg	Capsule	BMS	1.33	2.49 (MOH and SS)	3.34 (SS)		1.33 (MOH) and 1.88 (SS)	0.21 approximately
Stavudine (d4T)	40 mg	Capsule	BMS	0.10 (generic)	2.37 (SS)	7.22 (MOH) and 9.28 (SS)		2.33 (MOH) and 3.33 (SS)	0.37 approximately

Source: PAHO, 2006.

[37] "SS" in this case means *Seguro Social* (social security) of the country in question.

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