Group Procurement of Vaccines for Central/Eastern Europe and Newly Independent States:
Feasibility, Issues, and Options

Final Report

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Acronym List

BCG	Bacille Calmette-Guerin vaccine
CCP	Certificate for Pharmaceutical Product
CEE	Central and Eastern Europe
CIF	Cost, insurance and freight (price including shipping and insurance)
CVP	Children's Vaccine Program (of PATH)
DDP	Delivery duty paid (price including shipping, insurance, handling, customs and import duties)
DTP	Diphtheria, tetanus and pertussis vaccine
DTaP	DTP with acellular pertussis
DTwP	DTP with whole-cell pertussis
DT	Diphtheria and tetanus vaccine
ECDS	Eastern Caribbean Drug Service
EMEA	European Medicines Evaluation Agency
EPI	Expanded Program on Immunization
EC	European Commission
EURO	European Region Office of World Health Organization
EU	European Union
FOB	Freight on board (price before shipping, handling, insurance, etc.)
GCC	Gulf Cooperation Council
GMP	Good Manufacturing Practices
GNI	Gross national income
GSK	GlaxoSmithKline Corporation
Hib	*Haemophilus influenzae* type B
IPV	Inactivated polio vaccine
MMR	Measles, mumps and rubella vaccine
MOF	Ministry of Finance
MOH	Ministry of Health
MR	Measles-rubella vaccine
NIP	National immunization program
NIS	Newly Independent States (of former Soviet Union)
NRA	National Regulatory Authority
OECS	Organization of Eastern Caribbean States
OPV	Oral polio vaccine
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PHI	Public Health Institute (Romania)
SSI	Staten Serum Institute (Denmark)
TT	Tetanus toxoid vaccine
UAE	United Arab Emirates
UNICEF	United Nations Children's Fund
USAID	U.S. Agency for International Development
VAT	Value added tax
WHO	World Health Organization

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Executive Summary

A study was conducted to assess the feasibility of countries in Central and Eastern European (CEE) and Newly Independent States (NIS) of the former Soviet Union with a gross national income of $1,000 or more per capita of joining together to procure vaccines for their public-sector immunization programs. Some experts in the field view group procurement as a possible means of addressing several key procurement concerns raised by national immunization programs in the region during regional meetings and country visits. These concerns include: often high vaccine prices and widely varying prices from country to country, insufficient transparency and competition in the vaccine procurement process, limited selection of vaccines, irregular supply of vaccines, and inadequate quality assurance for vaccines (in some countries).

Methods

The study consisted of: a) an in-depth analysis of existing group procurement mechanisms (with a focus on the PAHO EPI Revolving Fund for vaccines and the Gulf Cooperation Council bulk purchasing program for pharmaceuticals and other health commodities among Persian Gulf states); b) brief visits to four countries—Croatia, the Former Yugoslav Republic of Macedonia, Lithuania and Romania—to assess their government's interest in, and the feasibility of their joining a group procurement scheme and to discuss possible options for group procurement with policymakers and other informants; and c) an analysis of the likely impact of accession to the European Union of many countries in the CEE region on the feasibility and design of a regional group procurement mechanism for vaccines. A report on the review of existing group procurement mechanisms is available under a separate cover. [1]

Key Findings and Conclusions

Level of Country Interest and the Feasibility of Group Procurement of Vaccines in the CEE/NIS Region

- Interest in the idea of group procurement for vaccines appears limited to date in the region and was strong at all government levels in only one of the four countries visited—Lithuania. Major reasons informants gave for considering joining such a scheme included: the desire to reduce vaccine prices, improving transparency in the procurement process, improving the regularity and predictability of vaccine supply and reducing protests from firms that lose in competitive bidding.
- The apparent mild interest in the idea of group procurement in the region is due to several significant barriers that would confront countries joining such a scheme. One major barrier is the key role and influence of a few local wholesalers in each country, which some national immunization programs rely on for the central cold storage and internal distribution of vaccines and whose role would likely diminish with group procurement. Another stems from the lack of truly competitive procurement procedures in many countries, as a result of restrictive evaluation criteria and protectionist policies for local producers. A further barrier is countries' fear of losing their power to make decisions concerning evaluation criteria and vaccine selection in a group procurement scheme. Other perceived barriers are: irregular, delayed, or inadequate government funding for vaccines, the limited number of licensed vaccines in many countries—restricting which vaccines they could purchasing through a group scheme until more vaccines are licensed, and the perceived limited cooperation and political ties between countries in this diverse region.
- Accession to the EU, planned for many CEE countries for 2004 or 2007, should significantly facilitate group procurement, as it will lead to reforms that reduce or eliminate many of these barriers. These reforms include: requiring countries to increase the competition and transparency of their public procurement practices and to harmonize their national procurement laws with those of other EU members; ending protectionist practices for local vaccine producers; and

[1] DeRoeck, D. Review of Group Procurement Mechanisms for Pharmaeuticals or Vaccines: The PAHO EPI Revolving Fund for Vaccines and the Gulf Cooperation Council Group Purchasing Program, CVP at PATH, 2003.

adopting EU vaccine licensing standards and procedures, leading to increasing uniformity among candidate states in the vaccines used in their national immunization programs. EU public procurement directives would also allow the practice of international group procurement.

- The strongest candidate countries for a group procurement scheme appear to be those joining the EU, countries with relatively small populations, and countries that are not major vaccine producers. Among these are the three Baltic Republics of Estonia, Latvia and Lithuania.
- An initial, quick analysis of the cost savings that could be realized by group procurement for the newer, more expensive vaccines only (e.g., Hib, IPV, hepatitis B and MMR), based on prices obtained by the GCC program (and increments up to 175 percent of these prices), estimated savings of between €228,000 and €832,000 for the three Baltic Republics per year. Total savings of between €636,000 and €2.4 million were estimated if three additional, larger countries in the region were also included. According to our analysis, cost savings from the group purchase of less expensive, older vaccines, such as DTwP, BCG, OPV and measles, were quite minimal. Additional cost analyses will be required to determine if the creation of a group procurement scheme for the region is justified. These should include further estimates of overall cost savings and savings to individual countries, including reductions in staff time and in other local procurement costs, and estimates of the start-up and operational costs of the mechanism.
- From this initial assessment, we conclude that this project should continue into the next phase to further evaluate the feasibility of group procurement of vaccines in the region. This phase would include the above cost analyses and, if justified, the planning and implementation of a pilot group procurement scheme with three to five countries and a limited number of vaccines. The reasons for this conclusion include: indication of initial interest in enough countries (e.g., three or four) to begin a pilot project (based on initial communications with country officials as well as on the country visits), the future reduction of several barriers to group procurement in many CEE countries as they prepare to join the EU, potentially promising initial estimates of cost savings from potential vaccine price reductions; and the lack of formidable legal barriers to group procurement in several countries visited.

Key Requirements for Group Procurement of Vaccines in the CEE/NIS Region

Based on informant interviews in the four countries visited, a group procurement scheme for vaccines in this region that countries would find attractive would need to:

- Include vaccines that meet countries' requirements for quality, which, for self-procuring countries in the region, increasingly means vaccines licensed and used in Western European countries;
- Allow countries considerable flexibility to join or opt out of the scheme each year and to select which and how many vaccines to purchase. While this flexibility could reduce the viability of the scheme, if, for instance, participating countries buy few vaccines in a given year, it was a strong and clear requirement of most persons interviewed in the four countries;
- Involve country participation in all key decisions of the procurement process, such as determining technical specifications, drafting bidding documents and selecting winning vaccines;
- Involve a procurement process that ensures openness and transparency, efficiency and relative speed and fewer procurement delays and protests than several countries are currently experiencing.

Based on the experience of other group procurement mechanisms, the scheme will likely require a permanent secretariat, strong management, and start-up funding from donor or technical agencies.

Preferred Options for a Group Procurement Scheme in the CEE/NIS Region

According to country informants, especially in the countries with the greatest interest and potential to join a group procurement scheme, the scheme should:

- Be run by a credible international organization, such as WHO, the EU or another UN agency;
- Involve a centralized tender and bid process only, enabling countries to individually contract with and pay suppliers, as with the GCC program;

- Be phased in, perhaps starting with a regional database where countries could share information on suppliers, products, and prices. A pilot group procurement project could follow with three to five countries with the greatest interest and fewest barriers jointly procuring a limited number of vaccines. It may be preferable to include at least one larger country in the pilot to achieve more substantial price reductions, since this will be one measure of its perceived success.

Recommendations

1. As an initial step in regional collaboration in vaccine procurement, a mechanism should be set up to allow countries to share information on vaccines they are using; prices they are paying; their experiences with various suppliers; experience with various vaccines (including reported adverse events; and other useful data). One or more of the countries in the region could manage the database, with technical assistance from WHO or another technical agency.

2. WHO should continue to assess vaccine procurement and quality assurance capabilities and procedures in self-procuring CEE/NIS countries and provide appropriate technical assistance and training, taking into account existing and planned assistance from the EU in these areas.

3. If funding can be secured, the assessment of the feasibility of group procurement of vaccines in the CEE/NIS region should continue into the next phase. Given that the feasibility of and level of interest of countries joining a group procurement scheme will likely increase in the next two or three years as many of them approach EU accession, this interim period provides an excellent opportunity to further assess the feasibility and prepare solid groundwork for starting up such a scheme as a pilot project. The activities of this analysis/preparatory phase, in order, could include:

   a) Conduct visits to a few other countries in the region to assess their level of interest and the feasibility of their participating in the pilot group procurement scheme. Strong candidates for the next country visits are the Baltic republics of Latvia and Estonia, which have at some level indicated initial interest and have collaborated in other immunization activities with Lithuania as a group.

   b) Conduct more comprehensive and refined analyses of the costs and potential cost savings of group procurement. These analyses could include: refined estimates of savings in vaccine costs with additional information and input from countries; estimates of cost savings from reduction of staff time and other costs associated with vaccine procurement at the country level; and estimates of operating costs of a group procurement scheme under various.

   c) Approach potential organizations to manage a regional group procurement scheme to explore their level of interest, capacity to take on such a task, as well as the possibility of their providing financial support for the start-up and/or implementation of the project.

   d) Prepare an options papers that lays out various options for the design and operation of a group procurement mechanism for vaccines, backed up by cost, financing and other analyses described above. The paper would identify and analyze possible options for key aspects and features of the scheme, including: possible functions of the mechanism, staffing, financing of the operation, possible organizations to manage it, degree of and type of country participation in decision-making and implementation, rules for participation and the nature of agreements with countries, and an implementation plan.

   e) Organize a meeting of interested countries to discuss further the feasibility of a group procurement mechanism, each country's anticipated level of participation in the mechanism, and to design the pilot phase of the project. Participants would include appropriate representatives (including policy-makers) from three to five countries most likely to participate in a pilot project, as well as observers from several other countries that could potentially be interested in joining at a later stage. At the meeting, the results of this initial assessment could be presented, the benefits and disadvantages of group procurement discussed in detail, and participants could reach consensus on specific aspects of the design of the scheme, using the options paper.

4. If financing is available and further feasibility analysis for regional group procurement is positive, develop a plan for a pilot scheme involving a small number of countries and a limited number of products. The newer, more expensive vaccines, such as Hib, hepatitis B, MMR, IPV and DTP combinations, may be the most appropriate products to include in the pilot, since they will result in the greatest cost savings. The pilot project will assess the feasibility of implementing such a scheme in the region and provide lessons for its continuation or expansion. Data would also be collected to evaluate the success of the project, and to inform decisions of participating countries on whether or not to continue the scheme as well as other countries on whether or not to join. The data would measure the tangible and intangible benefits and disadvantages of group procurement, including: vaccine cost savings to individual countries and to the group as a whole; total economic savings, including reductions in local staff time spent on procurement; reduction in procurement delays and in protests from losing competitors; increased selection of vaccines; and improved transparency in the vaccine procurement process.

I. Introduction and Background

In the past ten years since the break-up of the Soviet Union and the transition to market economies, most countries in Central and Eastern Europe (CEE) and the Newly Independent States (NIS) with a gross national income (GNI) per capita of $1,000 or more are procuring and/or producing vaccines on their own and have established functional vaccine procurement systems. [2] Most of these countries have achieved considerable success with their immunization programs, including coverage rates that are mostly above 90 percent for childhood vaccines and the introduction of several newer vaccines, such as hepatitis B, Hib, and MMR. However, a number of issues and problems with vaccine procurement in these countries have been raised during several EPI manager meetings organized by WHO/EURO, during a series of vaccine procurement assessment visits conducted by WHO, and from an email survey completed by EPI managers in 15 self-procuring countries. The most prominent issues raised were:

- **Irregular supply of vaccines** resulting from delays in procurement or shipping, leading in one-third of countries surveyed to vaccine shortages;
- **Vaccine procurement procedures** that are not always transparent or in compliance with international procurement standards, or in several cases, do not involve a competitive bidding process;
- **High vaccine prices** in many countries and a huge range of prices among countries in the region. According to a survey conducted by WHO, prices governments paid for recombinant hepatitis B vaccine in 2001 ranged from $0.65 per dose to $8.03—a 12-fold difference. An analysis has shown that in most of these countries vaccine price has not greatly influenced a country's decision to introduce newer vaccines, such as hepatitis B and Hib (WHO, 2002). However, price is a critical factor in a few countries at the low end of this income group, such as the former Yugoslav Republic of Macedonia, which has yet to include hepatitis B in the infant immunization schedule. Price will also affect countries' plans to introduce or switch to more expensive vaccines, such as IPV, acellular DTP and varicella;
- **Limited vaccine selection and competition**. One reason for the relatively high prices paid by immunization programs in many countries is the limited number of vaccines licensed in the country and the limited number of local wholesalers or distributors selling vaccines—in some cases only one or two. Both of these factors lead to limited selection and competition of vaccines available to the immunization program;
- **Inadequate or irregular funding** of vaccines—reported by one-third of countries responding to the email survey;
- **Inadequate quality assurance for vaccines in a few countries**, due to the lack of a fully functional national regulatory system for biologicals or the fact that they are not using the WHO list of pre-qualified vaccines. While WHO has not conducted assessments of national regulatory authorities (NRAs) in all countries in the region with a GNI per capita of $1,000 or more, of those that were assessed, some were found not to be fully functional to regulate and control vaccines, as defined by WHO (WHO, 1999).

To address these issues, WHO/EURO, PATH, and UNICEF organized a meeting in September 2002 in Copenhagen for immunization program managers and vaccine procurement officials from 15 countries. One of the objectives of the meeting was to discuss the possibility of countries in the region joining together to issue a tender or to buy vaccines as a group, as one way to address many of the above problems and especially to reduce vaccine prices. Meeting participants also learned about existing group or bulk procurement mechanisms for vaccines or pharmaceuticals, including UNICEF procurement services, the Pan American Health Organization (PAHO) EPI Revolving Fund for vaccines, and the Gulf Cooperation Council's bulk purchasing system among Persian Gulf states.

[2] These countries consist of: Belarus, Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Kazakhstan, Poland, Romania, Russia, Serbia and Montenegro, Slovakia, Slovenia, the former Yugoslav Republic of Macedonia and Turkey.

This current study was commissioned as a follow-up to the Copenhagen meeting. The objective of the study was to analyze the possibilities for a bulk vaccine procurement mechanism in Central and Eastern Europe/Newly Independent States and Turkey, with a particular focus on the issues, options, and barriers in countries with a GNI/capita of US $1,000 per year or more. [3]

If this initial assessment is sufficiently positive, the next planned step would be to organize another meeting with countries in the region to discuss the study findings, ideas for the design of a group procurement system appropriate for the region, and next steps.

[3] Because of its large size and heavy reliance on local production of vaccines, the Russian Republic was not included in this analysis.

II. Study Design and Methods

The study consisted of:

- A review of existing, successful group procurement mechanisms for vaccines or pharmaceuticals to study the details of how they function, identify factors leading to their success, and determine their appropriateness as a model or identify their most appropriate features for the CEE/NIS region. The study focused on the Pan American Health Organization (PAHO) EPI Revolving Fund for Vaccines and the Gulf Cooperation Council (GCC) Group Purchasing Program in the Persian Gulf region. A report on this review is available under separate cover;[4]
- Visits to four countries in the region to assess the level of interest in and feasibility of participating in a group procurement mechanism for vaccines—including identifying potential facilitating factors and barriers—and to discuss possible options for such a mechanism;
- An analysis of how European Union accession by countries in the region will affect the feasibility and design of a group procurement system, especially regarding quality standards for vaccines and EU procurement directives.

To guide the study, an advisory group of six experts in immunization, vaccine procurement, and pharmaceutical management from WHO, PATH and the private sector, was established. The group provided advice on the study design, selection of countries, and development of the data collection instruments. They also reviewed and commented on drafts of the trip and final reports.

Country Visits

Country Selection

To obtain an overview of the procurement issues in the region and a sense of the feasibility of setting up a group procurement mechanism for vaccines, we decided to choose a mix of countries from different sub-regions and that differed in population size. We especially wanted to include some larger countries, since their larger volume purchases which could be critical to substantially reducing vaccine prices. It was also decided to include both countries that planned to join the EU—and were at different stages in the process—and those that had no current plans for EU accession. In addition, we wanted to select both countries that produce vaccines—since local production could present a formidable challenge to participation in group procurement—and those that do not. Other criteria for selection of countries to visit included:

- GNI per capita of more than $1,000, with a focus on countries at the lower end of the spectrum, that is, those that expressed the greatest need to control vaccine costs;
- Countries that do not appear to have overwhelming barriers to group procurement or would be difficult to visit, including those experiencing political turmoil or economic instability;
- Countries that had not previously expressed a lack of interest in the idea of group procurement of vaccines.

Based on these criteria, letters were sent by the WHO/EURO office to Ministers of Health and/or officials responsible for immunization programs in seven countries (Lithuania, Romania, Former Yugoslav Republic of Macedonia, Croatia, Estonia, Latvia, and Hungary) to determine their interest in a visit to discuss group procurement for vaccines. Positive responses were received from all but one country (Hungary). From the remaining six countries, the following were chosen for a visit: Lithuania, Romania, Macedonia, and Croatia.

As shown in Table 1, the group of countries selected include two that produce vaccines (Croatia and Romania) and two that do not; one country (Lithuania) that is poised to join the EU in 2004, two (Croatia

[4] Roeck, D. Review of Group Procurement Mechanisms for Pharmaeuticals or Vaccines: The PAHO EPI Revolving Fund for Vaccines and the Gulf Cooperation Council Group Purchasing Program , CVP at PATH, 2003.

and Romania) that plan to join in 2007 and one (Macedonia) with no EU accession plans to date. The Baltic republics, Central Europe and Balkans are also represented in the group. No NIS country (other than Lithuania) was selected, as only two (Belarus and Kazakhstan) met the income threshold and neither seemed conducive to such a visit at this time, given political difficulties. The selected countries also present a range of income levels, population sizes (from 2 million to 22.3 million) and the prices their governments are paying for vaccines. While the selected countries may not be totally representative of all those in the region with a GNI per capita of US$1,000 or more, we felt that this sample of countries was adequate to identify key issues, barriers to group procurement, country requirements, and preferred options common to the region (as required for this initial assessment).

Table 1. Key Data on Countries Visited for the Study

Data	Croatia	Lithuania	Macedonia	Romania
Sub region	Western Balkans	Baltics	Balkans	Central Europe
Population size	4.67 million	3.67 million	2.05 million	22.3 million
Birth cohort	54,000	36,000	30,000	202,000
Gross National Income/capita (2001)	$4,500	3,270	$1,690	$1,710
When joining EU?	2007	2004	No plans yet	2007
Local vaccine production?	Yes (private sector producer of MMR and components, DTwP, TT, DT)	No	No	Yes (private sector producer of BCG, DTwP, DT and measles)*
Competitive bidding process?	No (just for 1 EPI vaccine)	Yes	Yes	Yes
*Due to a new requirement as of January 2004 for all pharmaceuticals sold in the country to meet GMP, the local producer will likely have to close its doors by then.				

Data Collection and Analysis

Country visits lasted three to five days. Two-person teams visited three countries and one person visited the fourth country (Macedonia). A series of meetings and interviews were held with key informants, including decision-makers, in each country to discuss:

- Details of the country's current vaccine procurement system;
- The current immunization program and future plans;
- Interest in the idea of group procurement for vaccines and its feasibility (including likely facilitating factors and barriers);
- Required legal and procedural changes to allow country participation in a group procurement system;
- The country's requirements and preferred options for a group procurement scheme; and
- Suggested next steps.

The team began several of the meetings with a presentation that explained the study and objectives of the visits, and provided an overview of the PAHO EPI Revolving Fund and GCC bulk purchasing system. We used a question guide and a spreadsheet to collect detailed information on the procurement systems to guide the discussions. These instruments are shown in Appendix 1.

In each country, the WHO Liaison Officer, EPI manager, or both together identified appropriate informants for the team to meet (with guidance from the team) and arranged the meetings and interviews. We met with the following persons in each country:

- Immunization program manager and staff;
- Supervisors and officials from agency or MOH department responsible for EPI;
- Vaccine procurement officials;
- Senior Ministry of Health officials;
- Officials from the national regulatory authority; and
- Appropriate officials from the country's Public Procurement Office.

The team felt that it was critical to meet with health decision-makers to obtain a true sense of the feasibility of and the government's attitude towards the idea of group procurement. These senior officials included: a Vice Minister and the Head of the Division of Foreign Affairs and European Integration in Lithuania; the State Secretary of Health (the third highest official in the MOH hierarchy) in Macedonia; and an Assistant Minister of Health in Croatia. No senior MOH official was met in Romania. In each country, experts from the Public Procurement Office—which is a separate government agency in Lithuania and an office within the Ministry of Finance in the other three countries—were key informants to discuss whether group procurement was allowed under their current procurement laws and if legal changes would be required.

Other informants met by the teams included officials from the national control laboratory (or laboratories) in Croatia and Macedonia, the newly formed National Immunization Commission in Macedonia, staff of the EU delegation in Croatia, and a representative of the local producer/wholesaler in Croatia. With the exception of Croatia, the teams did not meet with local wholesalers or producers, since these were initial exploratory visits to gauge the interest and viewpoint of the Ministry of Health and the public sector in the idea of group procurement. A complete list of persons who participated in the interviews and meetings can be found in Appendix 2.

In Lithuania and Croatia a wrap-up meeting to discuss the study's findings and to agree upon conclusions, the country's requirements and preferences and next steps was held the last day of the visit with several key officials who had participated in earlier meetings. It was not possible to hold wrap-up meetings in Macedonia or Romania.

Analysis of the Implications of EU Accession on Group Procurement

Several countries in the region are acceding to the European Union in 2004, including Estonia, Latvia, Lithuania, Hungary, Slovenia, Slovakia, the Czech Republic and Poland. A number of others, including Bulgaria, Romania and Croatia, plan to join the EU in 2007 as part of the "second wave". We examined the implications of EU membership on the feasibility and design of a group procurement mechanism for vaccines by focusing on three questions:

Do EU public procurement directives allow for or accommodate group procurement, and if so, what are the conditions and requirements?

1) What are the EU quality standards and licensing requirements and procedures for vaccines, and given these, which vaccines could and could not be included in a group tender involving new EU members from Central and Eastern Europe?
2) What are the efforts and plans of non-European producers to penetrate the EU market and how will these plans affect vaccine choice and competition among vaccine producers in the region in the future?

Internet research, as well as telephone interviews and email exchanges were conducted with a number of experts from the EU and other key informants to answer these questions.

III. Assessment of Feasibility of Group Procurement for Vaccines in the CEE/NIS Region

This section is based largely on the findings from the country visits to Lithuania, Croatia, the Former Yugoslav Republic of Macedonia, and Romania. We also draw upon information on other countries in the region with a GNI/capita of $1,000 or more obtained from country reports and the 15-country email survey conducted prior to the Copenhagen meeting.

Basic Facts about Vaccine Procurement in Four Countries Visited

Table 2 summarizes key data on the vaccine procurement systems of the four countries visited for this study, including tender and bidding laws and procedures, quality control measures, and distribution and payment procedures.

Vaccine Financing

Croatia, Lithuania, and Romania are now self-financing for all vaccines used by their national immunization programs, with funds coming from the Ministry of Health budget in Lithuania and Romania and largely from health insurance contributions by employers and employees in Croatia. Macedonia has received vaccine donations from UNICEF for the last several years, as part of its emergency assistance. UNICEF donated all of the immunization program's needs for BCG, OPV and DTP until 2002 and is still donating BCG and OPV. The government pays for all other vaccines, including MMR, DT, TT, and now DTP. UNICEF support is being phased out, however, with its withdrawal of OPV in 2004 and BCG (the last vaccine) by 2005.

Procurement Laws and Procedures

Procurement Laws and Implementation

All four countries have public procurement laws that have been written in the last decade or so, based upon international models, such as World Bank procedures and European Union guidelines. All are based on the notion of opening up competition and transparency in the procurement process. Countries acceding to the EU in either 2004 or 2007 have been receiving EU assistance in revising these laws to harmonize with EU procurement directives, and thus the laws in several countries will be undergoing further changes in the next few years. Lithuania's procurement laws will need to be aligned closely with EU directives by next year. The laws in Romania and Croatia will also need to undergo further revisions to meet EU requirements by 2007 when they are scheduled to join the EU.

Countries differ considerably, however, in how they implement these laws in procuring vaccines and in the extent to which they follow the spirit as well as the letter of the law. Vaccines are procured through an open tender process (with public announcement of tenders) in Lithuania, Macedonia, and Romania. Croatia, however, bypasses its procurement laws and negotiates directly with companies for the majority of its vaccines. These are vaccines for which only one brand name is included in the Drug Reimbursable List, a drug formulary of all pharmaceuticals covered by national health insurance, which includes the fixed prices for the year. Many of the vaccines on the Drug List are those produced by the local producer, the Immunology Institute, which essentially has a monopoly with the government for all the vaccines that it produces. Only vaccines for which there is more than one brand name or a generic name on the Drug List are procured through an open tender. These include, at present, only two vaccines—Hib and influenza.

Table 2. Key Facts about Vaccine Procurement Systems in Countries Visited

Feature	Croatia	Lithuania	Macedonia	Romania
Tender/Bidding:				
Have public procurement laws that require or encourage open competition and transparency?	Yes	Yes	Yes	Yes
Procurement process used for vaccines	Direct negotiations for most vaccines (those on Reimbursable Drug List); open tender for Hib and flu vaccines only	Open tender, announced internationally	Open tender, announced nationally	Open tender, announced nationally
Entity responsible for vaccine procurement and contracting with suppliers	National Health Insurance Agency (independent from MOH)	State Public Health Service (agency under the MOH that runs the national immunization program)	Ministry of Health	Public Health Institute – Bucharesti (research institute under the MOH)
Source of vaccine funding	Health insurance contributions plus other government funds	MOH budget (funds released by Ministry of Finance)	MOH budget + UNICEF (donates OPV & BCG vaccines)	MOH budget (funds released by Ministry of Finance)
Vaccine procurement separate from drug procurement?	Yes. Drugs purchased by individual patients and health facilities and reimbursed by health insurance	Yes. Drugs procured by different agency (State Health Insurance Agency)	Yes. Drugs purchased by public and private sector pharmacies (and by Health Insurance Agency)	Yes. Drugs procured by State Health Insurance Agency (independent agency)
Vaccine Procurement Commission:				
▪ Nature/length of term	Separate commission for each vaccine tendered (only a few per year). Disbands once award decided.	One commission for all vaccines; term indefinite	One commission for all vaccines; term indefinite	Separate commission for each vaccine. Disbands once award made.
▪ Number of members	N/A	7	6	Around 6
▪ Head of Commission	Health Insurance Institute lawyer	Deputy Director of State Public Health Service (which runs NIP)	MOH lawyer	Director of Public Health Institute-Bucharesti
▪ Includes lawyer?	Yes (president)	Yes (from SPHS)	Yes (president)	Yes (from MOH)
▪ Immunization program manager can participate?	Yes (since 2002)	No	Yes (serves as Deputy President of Commission)	Yes (or head of department running NIP)
Evaluation criteria used in tenders	Lowest price among vaccines meeting technical specifications	Lowest price among vaccines meeting technical specifications	Point system combining price (30 pt.) and quality criteria (70 pt.)	Point system combing price (minimum 60 pt.) and quality criteria (up to 40 pt.)
Who can legally sell/ distribute vaccines and respond to tenders	Local wholesalers or producers (through local agents)	Local wholesalers or producers (through local agents)	Local wholesalers only	Local wholesalers only (producers aren't allowed to sell directly in country)
Preferences for local vaccine producers?	Yes. No tendering for all vaccines produced by Immunology Institute (DTwP, DT, TT, MMR & components)	No local producer	No local producer	Cantacuzino Institute gets 7.5% premium added to evaluation score on bids. Its role is decreasing, however
Usual length of procurement process (tender preparation to contract signing)	As little as 6 weeks if no protests	5-10 months (depending on final approval of budget)	7 or more months, depending on final approval of budget	3-4 months

Table 2 Continued. Key Facts about Vaccine Procurement Systems in Countries Visited

Feature	Croatia	Lithuania	Macedonia	Romania
Quality Assurance and Control:				
Fully functional and independent national regulatory authority (NRA) for vaccines?	Unknown. Has National Institute for Control of Immunobiologicals (separate institute from NRA for drugs), but not yet assessed by WHO.	Yes: State Medicines Control Agency (positively assessed in WHO workshop)	No. National Drug Bureau not competent to evaluate biologicals.	Not completely. National Medicines Agency (merged with Centre for State Control of Biological Products in 2001) found not to be fully functional in all areas in WHO assessment. Is receiving EU assistance.
Vaccine requirements & qualifications for tendering	National license + vaccine must be on Reimbursable Drug List	National license (licensing procedures harmonizing with EU standards)	By law, license is required, but only 2 vaccines licensed to date. License from producing country required in tender	National license
Standards used for licensing	European Pharmacopoeia	European Pharmacopoeia	Few licenses issued to date. Evaluation criteria on tenders include WHO pre-qualification, manufacture by certain "renown" producers and license from producing country.	European Pharmacopoeia (preference), U.S. Pharmacopoeia, other standards from industrialized countries
NRA conducts lot releasing for vaccines?	Yes	Yes, based on review of manufacturer's documents	No. EPI manager reviews documents only	Yes. Lot summary documents and vaccine samples required for products from non-PIC countries*. Only inspection of batch release certification required for products from PIC countries.
Distribution and Payment:				
Entity responsible for storage and internal distribution of vaccines	Since 2003: Immunology Institute (local private sector producer) through a separate contract (for all locally-made and imported vaccines)	Public sector: Division of State Public Health Service that runs NIP	Private wholesalers store and distribute vaccines directly to health facilities	A single public sector company is responsible for central storage of all vaccines. Private wholesalers who win vaccine contracts distribute vaccines to district health authorities.
What's included in offered unit price on bids	CIF price of vaccine (including shipping & insurance). No VAT for vaccines	CIF price of vaccine (including shipping & insurance). No VAT for vaccines	Bundled price: ▪ DDP price of vaccine (with shipping, insurance, customs & import duties) ▪ Central storage ▪ Delivery to health facilities ▪ 18% VAT	Bundled price: ▪ DDP price of vaccine (with shipping, insurance, customs & import duties) ▪ Syringe cost ▪ Delivery to districts. 19% VAT subsequently added to offered price.
Customary payment terms	Within 45 days upon delivery and acceptance of goods in country	Within 30 days upon delivery and acceptance of goods in country	Up to 90 days upon delivery of goods to health facilities	After delivery of goods to districts
Currency of payments	Usually local currency. US$ and Euros also used	Euros or local currency (tied to Euro)	Local currency	Local currency

* PIC = Pharmaceutical Inspections Convention, an agreement among more than 20 countries (including EU members, Canada, Australia, Singapore and several CEE countries), which standardizes GMP inspection procedures and recognizes each country's NRAs.

Entity Responsible for Vaccine Procurement

In all four countries, vaccine procurement is conducted by a separate entity than the procurement of drugs, which in some countries are procured directly by health facilities or pharmacies and reimbursed by national health insurance. In three of the countries (Croatia, Lithuania and Romania) vaccine purchasing and contracting with suppliers is not handled by the Ministry of Health or another huge bureaucracy, but rather by a separate or smaller entity—the National Health Insurance Agency in the case of Croatia, the State Public Health Service in Lithuania, which runs the national immunization program, and a public health research institute in Romania. This presumably results in a more streamlined process than in countries, such as Macedonia, where the Ministry of Health conducts the purchasing and contracting for vaccines. Since drug purchasing is handled elsewhere, these entities mainly procure vaccines (the PHI in Romania also procures contraceptives). In Romania and Croatia the entity that manages the national immunization program is removed from the procurement process—although immunization program staff can participate in procurement commissions—while in Macedonia and Lithuania, the immunization program or its parent agency is also responsible for vaccine procurement.

Vaccine procurement commissions are officially appointed in all four countries to handle the tender and bidding process, including in Croatia for the few vaccines that are bid competitively. In Lithuania and Macedonia, one commission has been set up to handle all vaccines procured for the immunization program, which are tendered through one or more bidding documents for the entire year. In Romania and Croatia, however, a separate tender is prepared for each vaccine and a separate commission is set up for each tender, although several of the same people may participate in the various commissions. These separate vaccine tender commissions are disbanded once vaccine selections have been made. Procurement commissions in each country consist of around six or seven members and all include members with legal expertise. In two countries, in fact, the president of the commission is a lawyer—an MOH lawyer in the case of Macedonia and a lawyer employed by the National Health Insurance Institute in the case of Croatia.

Rules Governing Bidders

All four countries require companies responding to tenders to be registered in the country. Two countries— Romania and Macedonia—lost their public-sector cold chain capabilities when their vaccine storage and/or distribution facilities were privatized during the transition to a free market economy. Both countries are therefore dependent on local private wholesalers for the internal distribution of vaccines and in the case of Macedonia, for central storage of vaccines as well. (Central vaccine storage is Romania is handled by a public sector wholesaler.) Given this situation, as well as drug laws in Romania forbidding producers to sell or distribute pharmaceuticals, only local wholesalers are allowed in both Macedonia and Romania to respond to vaccine tenders, and thus producers can not directly submit bids. In Lithuania and Croatia, on the other hand, the government is not dependent on wholesalers for vaccine cold storage and distribution. These tasks are handled by the public sector in Lithuania and by the local vaccine producer in Croatia through a separate contract since 2003.[5] Consequently, in both countries, either producers (through their local agents) or local wholesalers can respond to vaccine tenders. As discussed below, these rules have obvious implications for the feasibility of a country joining a group procurement scheme, which could reduce or even eliminate the role of local wholesalers in vaccine procurement.

Evaluation Criteria

The procurement laws in all four countries allow two ways to evaluate products that are bid competitively: 1) the lowest price offered among those bidders who meeting all technical specifications and requirements; or 2) the most advantageous offer from the technical and financial point of view, which involves assigning points for price as well as for various technical and quality criteria. Lithuania and Croatia use the first method, limiting accepted bids to those meeting all technical specifications and choosing the lowest price offered among those bids. Romania and Macedonia use the evaluation point method, in which, instead of rejecting bids that do not meet technical specifications or requirements—such as sufficient cold chain capacity of the bidders—these technical requirements are scored. According to informants, this method allows them to receive a sufficient number of bids (to avoid having to repeat

[5] Prior to 2003, cold storage and internal distribution of vaccines in Croatia was the responsibility of the public sector Institute of Public Health for Zagreb, one of 20 regional Institutes of Public Health in the country, and thus the use of the Immunology Institute for the storage and distribution of all locally-made and imported vaccines is relatively new.

the tender process), while still limiting winning vaccines to those meeting their requirements for quality. The scoring in both countries makes it nearly impossible for companies or vaccines not meeting the technical qualifications to win a bid, no matter how low their offered price. In Macedonia the quality and technical criteria are assigned a total of 70 points, while price is worth only up to 30 points. In Romania, price is normally given the lowest score allowed by law (60 points), leaving 40 points for quality/technical criteria. Both countries also depend on a few wholesalers for vaccine storage and distribution. One can argue that this evaluation method, as opposed to choosing the lowest price among bids meeting all technical specifications, can more easily lead to favoritism to certain wholesalers or products by the procurement commissions, who determine the evaluation criteria.

The two countries with local vaccine producers also give preferences to these companies over foreign producers in awarding contracts. As mentioned, all vaccines produced in Croatia by the Immunology Institute are the sole vaccines per type on the Drug List and thus are not bid competitively. Romania's local producer, Cantacuzino Institute, has had to compete with foreign producers (through local wholesalers) since 2001, but still receives a domestic preference of 7.5 percent added to its score in bids. Its role in providing vaccines to the immunization program is diminishing, however, due to limited capacity and investment and to upcoming laws requiring that all pharmaceuticals meet international GMP standards. This is discussed in the next section in more detail.

Quality Assurance and Control

Lithuania, Croatia, and Romania all have national regulatory authorities (NRAs) with experience evaluating vaccines. According to WHO, Lithuania's NRA has been assessed as independent and fully functional in evaluating vaccines, as defined by WHO.[6] Romania's NRA was assessed by WHO as not fully functional for vaccines, but the institution is receiving considerable technical assistance from the EU. Croatia's NRA has not been evaluated by WHO. All three countries require all vaccines sold in the country to have a marketing authorization (license) issued by their NRA and this serves as their principal means of assuring vaccine quality. Macedonia's National Drug Bureau is not competent to evaluate vaccines. Consequently, only two vaccines—a hepatitis B vaccine and a flu vaccine—both used for commercial purposes and not by the immunization program, have been licensed to date. To assure vaccine quality, the immunization program and vaccine procurement commission instead include strict criteria in their bidding documents, as described in Section C below.

Croatia and Lithuania use the European Pharmacopoeia as the standard to evaluate vaccines for licensing, while Romania uses the European, as well as U.S. Pharmacopoeia and other standards from industrialized countries. WHO pre-qualification is mainly used in Macedonia, where it has recently become a criterion on vaccine tenders. Lithuania and Romania have revised (or are in the process of revising) their drug laws to harmonize with EU procedures. This includes following EU "simplified procedures" to streamline the approval of drugs and vaccines that have been licensed in Europe either centrally through the European Agency for the Evaluation of Medicinal Products (EMEA) or through the mutual recognition procedure, in which a product licensed in one member state is quickly approved in all others where the producer has applied for a license.

Lot releasing of vaccines is carried out by the NRAs in Lithuania, Croatia, and Romania, while no official lot releasing takes place in Macedonia.

Distribution and Payment Terms and Practices

In Romania and Macedonia, which both lack public-sector vaccine storage or distribution capacity, local wholesalers are responsible for storing and delivering the vaccines on a semi-annual or quarterly basis, respectively, to the districts. In both countries, the offered unit price is a bundled price that includes the cost of the vaccine and the internal distribution costs. In Macedonia, the bundled price also includes the cost of central storage,[7] while in Romania, the syringe cost is included. In Croatia and Lithuania, on the other hand, suppliers are responsible only for delivery of the vaccines into the country, and thus their

[6] According to WHO, NRAs must be independent and carry out the following control functions for imported vaccines: licensing, post-marketing surveillance, lot releasing, and laboratory access for testing. NRAs in producing countries must also be able to conduct GMP inspections and clinical evaluations (WHO, 1999).

[7] In Romania, vaccine storage is handled by a separate company in Romania through a separate contract.

prices include only the cost of the vaccine, plus shipping and insurance and insurance (CIF). As mentioned, storage and internal delivery of vaccines is carried out by the national immunization program in Lithuania and by the local producer (Immunology Institute) in Croatia, which handles all vaccines under a separate storage and distribution contract. Vaccines are exempt from VAT taxes in Lithuania and Croatia, while VAT taxes of 18 percent and 19 percent are added for vaccines in Macedonia and Romania, respectively.

All four countries pay for vaccines used by the national immunization program after delivery—to the country in the case of Lithuania and Croatia, and to the districts in the case of Romania and Macedonia. Macedonia allows the government to pay suppliers up to 90 days after the receipt of goods, to allow for delays in the release of government funds. All four countries reportedly never pay for vaccines in advance, although the procurement laws in Lithuania and Macedonia allow pre-payment for up to 30 percent of the contract value. The two countries restricting the selling of vaccines to local wholesalers—Romania and Macedonia—always pay in local currency. Lithuania and Croatia pay in both local currency (typically to local wholesalers) and in international currency, such as Euros or U.S. dollars.

Summary of Status and Maturation of Vaccine Procurement in the Four Countries

The four countries visited represent different stages of maturation in their vaccine procurement systems and in compliance with international procurement procedures. The most advanced of the four is Lithuania, which, due to its imminent accession to the EU, has procurement laws and procedures that are relatively open and transparent, as well as an independent and fully functional national regulatory authority for vaccines. Romania is making rapid progress in both its regulatory systems—the development of its NRA and new GMP requirements—and in its procurement laws, which now require local producers to compete with foreign producers. Competition in vaccine procurement is hampered, however, by Romania's reliance on a few wholesalers with cold chain delivery capabilities and by restrictive evaluation criteria (discussed in Section C below). The country will need to further open up its procurement practices, however, as it approaches EU accession in 2007.

Croatia presents a somewhat mixed picture. It has an NRA with considerable expertise in vaccines—although WHO has not yet assessed it. The country also does not restrict competition to local wholesalers. On the other hand, Croatia has a way to go to meet international public procurement standards, given its use of the Reimbursable Drug list and consequent lack of competitive procurement for most vaccines. These procedures will need to change, however, as the country approaches EU accession in 2007. The laws and a structure for competitive procurement for vaccines are already in place and used for a few vaccines.

While Macedonia conducts open tendering for vaccines not provided by UNICEF, competition is quite limited. This is due to the lack of a functional vaccine regulatory system, which has led its vaccine procurement commission to write restrictive evaluation criteria to assure quality. It is also due to the lack of public-sector cold storage and distribution capabilities, which has restricted bidding to a few wholesalers having these capabilities. The country is also still receiving donations from UNICEF for some vaccines, though this support is being phased out. EU accession is not being considered at this point for Macedonia.

Vaccine Use Profile in the Four Countries

Increasingly, vaccine markets are diverging according to a country's wealth and level of development. Wealthier countries are using more expensive vaccines, such as DTP with acellular pertussis; hepatitis B without the mercury-containing preservative, thiomersal; MMR with the Jeryl-Lynn strain of mumps; and inactivated polio vaccine (IPV)—all in response to population concerns about safety and adverse reactions. Many of these countries have also introduced newer, more expensive vaccines, such as Hib, conjugate pneumococcal vaccine, and varicella (chickenpox). Less developed countries, on the other hand, are generally using less expensive, though very effective vaccines, such as DTP with whole-cell pertussis, oral polio vaccine (OPV), MMR with the Urabe strain of mump, and hepatitis B containing thiomersal (in multi-dose vials).

As shown in Table 3, the vaccine-use profile in the four Central/Eastern European countries visited for this study is a mix of industrialized- and developing-country patterns. All four countries have switched to hepatitis B without thiomersal (by including this feature in their technical specifications or in the evaluation criteria on tenders). All three countries using MMR vaccine are using vaccines not containing the Urabe strain of mumps.

Table 3. Vaccines Used by National Immunization Programs for Selected Diseases in Four Countries Visited, 2003

Targeted Disease(s)	Croatia	Lithuania	Macedonia	Romania
Diphtheria, tetanus, pertussis	▪ DTaP for first dose only; ▪ DTwP for other doses	▪ DTwP or DTwP-IPV. ▪ Plan to phase in DTaP in future	▪ DTwP	▪ DTwP and DTwP-hepB (at 2, 6 months)
Polio	▪ IPV for first dose only; ▪ OPV for other doses and boosters	▪ IPV or DTwP-IPV for primary series; ▪ OPV for boosters for school children	▪ OPV	▪ OPV
Measles, mumps, rubella	▪ MMR with Edmonston-Zagreb measles strain & L-Zagreb mumps	▪ MMR with Jeryl-Lynn mumps strain	▪ MMR with Jeryl-Lynn mumps strain ▪ Rubella for 14 year old girls	▪ Measles ▪ Rubella for 14 year old girls ▪ Plan to introduce MMR in 2004
Hepatitis B	▪ HepB without thiomersal	▪ HepB without thiomersal	▪ Not in childhood schedule. ▪ Use HepB without thiomersal for some high-risk groups	▪ Monovalent HepB or DTwP/HepB (both without thiomersal)
Haemophilus Influenza type B (Hib)	▪ Act-HIB (Aventis) or Hiberix (GSK)	▪ Not yet in program. Plan to introduce in 2004.	▪ Not in program. Plan to introduce in long-term	▪ No plans to introduce

DTwP = DPT with whole-cell pertussis. DTaP = DPT with acellular pertussis.
OPV = oral polio vaccine. IPV = inactivated polio vaccine (injectable).

Lithuania and Croatia—the two wealthier of the four countries—are approaching the industrialized country pattern of vaccine use. Lithuania has switched to IPV (monovalent or DTwP-IPV) for the primary series of polio vaccination, while Croatia is using IPV for the first dose only,because it costs more than 30 times the price of OPV. Croatia has also switched to the considerably more expensive acellular DTP vaccine for the first dose only, while Lithuania plans to gradually replace DTwP with DTaP in the future. In addition, Croatia has already introduced Hib vaccine into the childhood immunization schedule, while Lithuania plans to introduce the vaccine in 2004.

The vaccines used by the immunization programs in Macedonia and Romania are more similar to those used in developing countries, including DTwP and OPV. Romania continues to use monovalent measles vaccine and has introduced rubella for 14-year-old girls, but plans to introduce MMR in 2004. Neither country has firm plans yet to introduce Hib vaccine.

The switch to vaccines used in Western Europe and the U.S. is due, in part, to the interest within health ministries in minimizing rates of side effects, which can be higher for DTwP than for DTaP and for MMR with Urabe strain than for MMR containing with other mumps strains. It is also in response to pressure from the population (mentioned in Lithuania) or from pediatricians (in Croatia) to use the same "quality" vaccines as in Western Europe. In addition, countries joining the EU feel obligated to switch to vaccines that are licensed in Western Europe. At present, whole-cell DTP, MMR with Urabe mumps strain and hepatitis B with thiomersal are no longer licensed in most EU countries.

Key Issues and Constraints with Vaccine Procurement

The major issues with vaccine procurement in the CEE/NIS region that came to light in the four country visits, in the email survey and the Copenhagen meeting are as follows:

Little Competition in the Vaccine Market and Relatively High Prices

As shown in Table 4, CEE countries rely on a small number of producers for its vaccine supply—mainly local manufacturers for countries producing vaccines, Aventis Pasteur (France) and GlaxoSmithKline (GSK) of Belgium. Limited competition can result in inflated prices. This is most apparent in Croatia where there is no competitive bidding for most vaccines used by the immunization program and where it is paying considerably higher prices for its locally-produced vaccines than other countries in the region are paying for equivalent vaccines.

In examining vaccine prices shown in Table 4, it should be noted that the unit prices across countries include different cost items and thus it is difficult to compare prices directly. This is especially true for Macedonia and Romania, where the prices include storage and/or internal distribution costs, VAT taxes (in Macedonia) and syringe costs (in Romania).

The reasons for this limited competition in the vaccine market in these countries, many already alluded to above, include:

Few Licensed Vaccines

Table 5 compares the list of vaccines currently licensed in Croatia and Lithuania with those pre-qualified by WHO for selected types of vaccines.[8] (Although such a list was not obtained in Romania, the picture appears to be similar.) At most there are three licensed vaccines per type in Croatia and Lithuania.

There is only one licensed vaccine in both of these countries for many types of vaccines, including DT, measles, hepatitis B and DTwP-Hepatitis B. The only competition that can occur for these vaccines in these two countries is if different wholesalers offer different prices for the same vaccine. The number of licenses issued in these countries compares to between three and seven vaccines per type that are WHO pre-qualified. The limited number of licensed vaccines in these countries is, in turn, due to:

- The revoking or non-renewal of licenses for vaccines not licensed in EU countries or those felt to have unacceptably high side effects (e.g., MMR with Urabe mumps, hepatitis B with thiomersal);

- The strong marketing position of GSK and Aventis Pasteur in these countries;

Among other producers there is limited interest in the relatively small markets that many of these countries represent. In Romania, for instance, one producer chose to not apply for the renewal of its OPV license in 2000, leaving the country with only one licensed OPV.

Dominance of a Few Local Wholesalers Dealing with Vaccines

In all countries visited, only a handful of wholesalers or local agents sell vaccines and respond to public tenders. The immunization programs are therefore forced to choose among the products offered by these few distributors. This is especially the case in Macedonia and Romania, which both restrict the selling and distribution of vaccines to local wholesalers and are dependent on the few that have cold chain capabilities for the central storage and internal distribution of vaccines. Up until 2002, only one wholesaler in Macedonia was considered to have adequate cold chain capacity and this firm consequently won all vaccine contracts with the government. More wholesalers have since acquired these capabilities and three won contracts in 2003, thus increasing competition. And while Romania uses an open competitive process to procure vaccines for its immunization program, one local wholesaler has won nearly all vaccine contracts for the past five year.

Restrictive Selection Criteria and Technical Specifications on Vaccine Tenders

Immunization programs or procurement commissions have added technical specification or evaluation criteria on tenders that further restrict vaccine selection and competition, usually in an effort to avoid having to choose vaccines that they consider of lower quality or those not used in Western Europe. Lithuania, for instance, added thiomersal-free to the technical specifications for hepatitis B in its 2003 tender. Macedonia and Romania include evaluation criteria on tenders that clearly limit competition. In

[8] As mentioned above, Macedonia has only licensed two vaccines to date, due to limited capacity in biologicals of its national control authority. The immunization program uses criteria on the tender documents to ensure quality.

Romania, "technical" criteria include additional points for vaccines used in EU countries and those used previously by the Romanian immunization program—criteria that some would consider anti-competitive. Technical criteria on the vaccine tender in Macedonia include vaccines produced by certain "renowned" producers and proof that the vaccine is licensed and used in the country where it is produced. In both countries, the quality criteria are scored in such a way to essentially ensure awards to vaccines meeting these criteria, even if considerably less expensive vaccines also compete. The evaluation criteria and scoring used in vaccine tenders in Romania and Macedonia are shown in Table 6.

The priority of quality—as defined by these programs—over price is clearly demonstrated by the selection of GSK's MMR vaccine (Priorix) in Macedonia in 2002. The Vaccine Procurement Commission wished to select an MMR vaccine without the Urabe mumps strain, due to several adverse events in the previous year attributed to the vaccine. By requiring use of the vaccine in the country of manufacture, the Commission was able to award the contract to the GSK vaccine, which is widely used in Europe and contains the Jeryl-Lynn strain of mumps. This is despite the fact that the competing vaccine—Aventis Pasteur's Trimovax, which contains the Urabe strain and is not licensed in France—was offered at a price 68 percent less than the winning vaccine.

In addition, Macedonia's vaccine budget was insufficient to cover the much higher cost of this MMR vaccine and the Ministry of Health had to find funds from other budgetary sources to cover the additional costs.

Table 4. Vaccines used by National Immunization Programs in Croatia, Lithuania, Macedonia and Romania, including Source and Prices in Euros, 2003

	Croatia		Lithuania		Macedonia (2002)		Romania	
Birth Cohort	**54,000**		**36,000**		**30,000**		**202,000**	
Vaccine (Doses/Vial*)	**Source**	**CIF Price/Dose** (no VAT)**	**Source**	**CIF** Price/Dose (no VAT)**	**Source**	**Price/Dose** including DDP vaccine cost, storage, distribution to health facilities & 18% VAT**	**Source**	**Price/Dose** including DDP vaccine cost, syringe & distribution to districts (Pre-VAT price)**
BCG (10)	SSI/Denmark	0.226	Aventis Pasteur	0.17	Aventis Pasteur	UNICEF provides free	Cantacuzino Institute-Bucharest	N/A (20 dose)
DTwP (10)	Immunology Institute/Zagreb	1.64	Aventis Pasteur	1.20 (1-dose vials)	Aventis Pasteur	0.225	Aventis Pasteur (1 dose) + Cantacuzino (10 dose) (joint contract)	0.38 (blended price)
DTaP (1)	GSK	9.26	----		----		----	
DT (10)	Immunology Institute/Zagreb	0.745	Aventis Pasteur	0.20	Aventis Pasteur	0.225	Aventis Pasteur + Cantacuzino (joint contract)	0.38
OPV (10)	GSK	0.11	Aventis Pasteur	0.16	GSK & Chiron	UNICEF provides free	Aventis Pasteur	0.29
IPV (1)	Aventis Pasteur	3.54	Aventis Pasteur	5.40 (limited quantity purchased)	---		---	
DTwP-IPV (1)	---		Aventis Pasteur	5.50	---		---	
MMR (1)	Immunology Institute/Zagreb	10.11	GSK	5.39	GSK	2.83 (10-dose vials)	---	
Measles	Immunology Institute/Zagreb	3.64 (1-dose) (only 1,500 doses purchased)	---		---		Aventis Pasteur + Cantacuzino (joint contract)	1.10 (1,3,5,9 dose vials)
TT (10)	Immunology Institute/Zagreb	0.35	---		Aventis Pasteur	0.129	---	
Hepatitis B (pediatric dose) (1)	GSK	3.68	GSK	2.66 (2002 price)	No universal immunization		GSK	0.80 (10-dose vials)
Hib (1)	Aventis Pasteur	3.19 (2002 price)	---		---		---	

* Vial size unless otherwise noted.
** CIF = Cost of vaccine, including shipping, handling and insurance. DDP = Delivery duty paid (cost including shipping, insurance, custom and import duties).
N/A = information not available.

Table 5. Vaccines Licensed in Croatia and Lithuania and Pre-Qualified by WHO, for Selected Childhood Vaccines, 2003

Vaccine Type	Producer/Brand Name		
	Croatia	Lithuania	WHO Pre-Qualified
BCG	1. Aventis Pasteur (France) 2. ●SSI (Denmark) 3. Chiron Behring (Germany)	1. Aventis Pasteur (France) 2. ●SSI (Denmark) 3. Chiron Behring (Germany)	1. Japan BCG Laboratory 2. Bulbio NCIPD Ltd. (Bulgaria) 3. SSI (Denmark)
DTwP (whole-cell) (pediatric)	●Immunology Institute/Zagreb	1. Chiron Behring (Germany) 2. Aventis Pasteur (France) (DTCoq)	1. Aventis Pasteur (Canada) 2. Aventis Pasteur (France) 3. BioFarma (Indonesia) 4. Chiron Behring (Germany) 5. Chiron Vaccines (Italy) 6. CSL (Australia) 7. Serum Institute of India
DTaP (acellular) (pediatric)	●GSK (Belgium) (Infanrix)	GSK (Belgium) (Infanrix)	None to date
DT (pediatric)	● Immunology Institute/Zagreb	Aventis Pasteur (France) (DTVAX)	1. Aventis Pasteur (France) 2. Bio Farma (Indonesia) 3. CSL (Australia) 4. Serum Institute of India
OPV	1. ● GSK (Belgium)(Polio Sabin) 2. Chiron Behring (Germany) Oral Virelon T1)	1. GSK (Belgium) (Polio Sabin) 2. Aventis Pasteur (France) (Oral Sabin Vero 1)	1. Aventis Pasteur (France) 2. BioFarma (Indonesia) 3. Chiron Vaccines (Italy) 4. GSK (Belgium)
IPV	1. ●Aventis Pasteur (France) (Imovax) 2. Chiron Behring (Germany) (IPV Virelon)	Aventis Pasteur (France) (Imovax)	None to date
Measles	● Immunology Institute/Zagreb	Aventis Pasteur (France) (Rovax)	1. Biken (Japan) 2. BioFarma (Indonesia) 3. Chiron Vaccines (Italy) 4. GSK (Belgium) 5. Serum Institute of India
MMR	1. ● Immunology Institute/Zagreb (L-Zagreb mumps) 2. GSK (Priorix) (Jeryl-Lynn mumps)	GSK (Belgium) (Priorix) (License of Aventis Pasteur's Trimovax with Urabe mumps strain revoked)	1. Aventis Pasteur (Trimovax) (Urabe mumps) 2. Chiron Vaccines (Italy) 3. GSK (Belgium) (Priorix)
Hepatitis B	●GSK (Belgium) (Engerix B (without thiomersal))	GSK (Belgium) (Engerix B (without thiomersal)) (License for Aventis Pasteur's Euvax-B produced by LG/Korea not renewed)	1. IGB (Cuba) 2. GSK (Belgium) 3. Green Cross Vaccine Corporation (Korea) 4. Lucky Goldstar (Korea) 5. Merck & Co, Inc. (USA) 6. Shantha Biotechnics Private, Ltd (India)
DTwP-HepB	GSK (Belgium) (Tritanrix)	GSK (Belgium) (Tritanrix)	GSK (Belgium) (Tritanrix)
DTaP-HepB	GSK (Belgium) (Infanrix HepB)	GSK (Belgium) (Infanrix HepB)	None
Hib	1. ●Aventis Pasteur (France)(Act-Hib) 2. ●GSK (Belgium) (Hiberix)	1. Aventis Pasteur (France) (Act-Hib) 2. GSK (Belgium) (Hiberix)	1. Aventis Pasteur (Act-Hib) 2. GSK (Hiberix) 3. Merck (liquid Pedvax HIB) 4. Chiron (Italy) 5. Wyeth Lederle (U.S.)

● Vaccines on Croatia's Reimbursable Drug List (only ones which can be used by National Immunization Program)
Note: Only 2 vaccines have been licensed in Macedonia to date (MSD's hepatitis B vaccine (H-B Vax) and Aventis Pasteur's flu vaccine (Vaxigrip). List of licensed vaccines in Romania was not obtained.

Table 6. Evaluation Criteria on Vaccine Tenders in Macedonia and Romania, 2003

Macedonia		Romania (hepatitis B tender)	
Criteria	**Maximum Points**	**Criteria**	**Maximum Points**
Technical characteristics: a. Vaccines produced by Aventis Pasteur, SmithKline Beecham, Behring and other renowned producers of vaccines b. Quality ▪ Original certificates for pharmaceutical product (CPP) issued by an authorized institution from the country of origin ▪ WHO pre-qualification c. Packaging (10 dose vials and monitoring cards) d. Expiry date no shorter than 2/3 total validity period at date of delivery	40	**Technical and function characteristics:** ▪ Past use by Romanian national immunization program (3 pt. per year – max. 15 pts.) ▪ Used in EU countries (1 pt. per country – max. 10 pts.) ▪ Free of (or low in) thiomersal – max. 10 pts. ▪ Minimum heat stability for 2 years of +2/+8 Celsius – max. 5 pts.	40
Qualifications for storage, transport and handling of vaccines (various details provided)	30		
Price	30	**Tender price:** (lowest price among tenders/price on this tender) x maximum allocated score	60
TOTAL	100	**TOTAL**	100

Preferential Treatment for Local Vaccine Producers

Most local vaccine producers, which exist in several of the CEE/NIS countries, including Bulgaria, Croatia, the Czech Republic, Romania, Slovakia, Ukraine and Serbia and Montenegro, are either granted special "domestic preferences" in competition with foreign producers or do not have to compete at all for the vaccines that they produce. Most of them produce a limited range of traditional EPI vaccines, such as DTwP and related vaccines (DT, TT), BCG and MMR or its components. Few of these locally produced vaccines have been licensed in Western Europe or are currently WHO pre-qualified.

The local producer in Romania, Cantacuzino Institute, used to negotiate directly and contract with the immunization program to supply 100 percent of its needs for the vaccines that it produced—BCG, DTwP, DT and measles. In 2001, as part of the country's movement toward EU accession, the public procurement law was revised to require all local producers to compete with foreign producers for all public procurement. The law still allows local firms to receive a "domestic preference"—in the case of Cantacuzino Institute, 7.5 percent extra points are added to the score on bids from wholesalers offering its vaccines. The producer is still supplying the immunization program with all the vaccines that it manufactures, but due to increasing production and financial problems, it has been less able to meet the immunization program's needs in recent years, and a foreign producer has been used to fill in the gap. Aventis Pasteur now produces two-thirds of the DTwP vaccine used by the immunization program and Cantacuzino produces only one-third. The provision of DT and measles vaccines is also now shared between Aventis and the local producer, whereas these vaccines used to be supplied entirely by Cantacuzino.

As a result of a new drug law recently passed as part of the reforms required for EU accession, Cantacuzino's role in supplying vaccines in Romania will further diminish, if not be eliminated altogether. The new law requires that all pharmaceuticals sold in the country meet international GMP standards, starting in January 2004. Cantacuzino does not meet GMP and is unlikely to be purchased in time by an international company meeting these standards. Therefore, it will likely have to close its doors in 2004 and the immunization program will have to rely 100 percent on imported vaccines. Thus, in the case of Romania, preparation for EU accession has meant the likely elimination of the local producer as a supplier of vaccines to the immunization program.

The local Croatian producer, Immunology Institute, on the other hand, is still the sole supplier to the immunization program of all of the vaccines that it produces (DTwP, DT, TT, MMR and its components). This is because, for each of these types of vaccines, only its vaccines are on the Reimbursable Drug List and thus can be used by the program. This situation bypasses the need for these vaccines to be procured through a competitive process and the government simply negotiates the terms and price with the Immunology Institute each year for these vaccines. As Croatia approaches EU accession, however, the country will have to open up competition, eventually remove domestic preferences, and perhaps require international GMP standards. These reforms may significantly impact the Immunology Institute's role in the provision of vaccines within the country, as has been the case in Romania.

Other Reasons for Limited Competition

These include:

- The lack of a competitive bidding process for most vaccines in Croatia (as mentioned above), due to the fact that only one vaccine brand is on the Reimbursable Drug List for most types of vaccines. At this time, the only EPI vaccine bid competitively is Hib vaccine. The lack of competitive bidding for vaccines also appears to be the case in neighboring Slovenia.

- The limited interest among producers in submitting bids due to the relatively small markets involved. The Lithuania immunization program, for instance, sent letters to 17 producers and wholesalers inviting them to submit bids (as well as advertised internationally), but only received one to three bids per vaccine from a small number of firms.

- The insistence in Croatia in continuing to use certain strains for selected vaccines (MMR, BCG, DTP) and their reluctance to introduce new strains into the population for safety reasons. Since the specific strains they are using for these vaccines (e.g., Edmonston-Zagreb measles and L-Zagreb mumps in MMR) are often produced by one or few manufacturers, this requirement greatly limits their vaccine selection. This is not an issue for vaccines containing the same or similar strains across brand names, including hepatitis B, Hib, IPV and flu vaccines.

Protests among Competing Firms

Several countries in the region have been plagued with protests from losing firms since they began to procure vaccines competitively. In 2002, the government halted all vaccine procurement in Bulgaria in response to a court case by a producer when the producer lost most of its bids that year. In Lithuania, the contract for hepatitis B vaccine for 2003 still had not been signed by April 2003 as a result of a protest from a firm that offered a vaccine containing thiomersal. The company claimed that the new technical specification requiring thiomersal-free vaccine limited the award to a single licensed vaccine and was therefore too restrictive. Croatia has experienced numerous protests for the few vaccines it has put out on open tender, including both times Hib has been tendered. The 2003 Hib contract is still under protest, on the grounds that the winning firm—Immunology Institute, playing the role of wholesaler for a foreign-made vaccine—is majority owned by the purchasing agency, the National Health Insurance Institute, thus resulting in a conflict of interest. The numerous protests that Croatia has experienced in the competitive bidding process have given the immunization program a negative view towards competitive bidding and a preference for direct negotiations. Protests are also a major reason for the interest among some stakeholders in group procurement for selected vaccines, which they believe would result in fewer protests.

Inadequate, Irregular or Delayed Funding

This was an issue reported by one-third of respondents to the email survey (5 out of 15 countries) and by three of the four countries visited for this study. In Lithuania, both reductions in their proposed budget and irregular and unpredictable release of funds by the government have led to delays in vaccine procurement, including hepatitis B in 2000, which could not be procured until well into 2001. Only good management strategies, including keeping a six-month reserve, have prevented vaccine shortages. Fund flow problems in Romania have also caused delays in vaccine procurement, although the total amount of

funds allocated is reportedly always eventually released. In Macedonia severe budget constraints have delayed the introduction of hepatitis B vaccine for the past three or so years. The vaccine budget for 2003 has more than doubled to allow for the purchase of DTP (previously donated by UNICEF) as well as for hepatitis B, but there are concerns among informants about whether this and future budgets will be adequate to sustain hepatitis B introduction. Delays in final government approval of the budget, reported especially in Lithuania and Macedonia, have also resulted in delays in vaccine procurement.

Funding problems appear to be less of an issue in Croatia, the wealthiest of the four countries visited and the only one in which vaccines are largely funded by health insurance contributions instead of from general government revenues. Nonetheless, the country's vaccine budget is not limitless, which is why the program has limited the use of inactivated polio vaccine (IPV) to the first dose only, while it would like to provide it for all three primary doses of polio. IPV, however, costs more than 30 times the price of OPV.

Delays in Vaccine Procurement

Vaccine shortages were reported by one-third (5 out of 15) of the countries responding to the email survey and could be a result of funding problems as well as problems with procurement procedures. Delays in the procurement of imported vaccines have become an important concern in Croatia. Immunization program staff were uncertain of the reasons for these delays.

Lack of Public-Sector Vaccine Storage and Distribution Capabilities

Both Romania and Macedonia lack public-sector cold chain capabilities, as the central warehouse and distribution facilities became private-sector wholesalers as part of the countries' market reforms. This consequent dependence on local private wholesalers for the central storage and internal distribution of vaccines not only severely restricts competition for the public-sector vaccine market, but also limits the government's ability to control or improve local cold chain capabilities. While not considered a significant problem by PHI and immunization program staff in Romania, this dependence on the private sector for cold storage and program staff in Macedonia cited distribution as a growing issue. Since the number of local wholesalers winning vaccine contracts has increased in the past few years from one to three, vaccine storage and distribution is no longer centralized and may be further dispersed in the future, as more wholesalers submit tenders and win bids. With the fragmentation of the vaccine storage and distribution system in Macedonia, some government officials have begun to think about the idea of the government once again acquiring cold chain capabilities and taking over this responsibility. The need for wholesalers to handle vaccine storage and delivery in both Romania and Macedonia presents a significant barrier to group procurement *(see Section below titled Country Participation in Decision-Making and Operations of the Scheme)*.

Croatia also has limited vaccine storage and internal distribution capacity in the public sector and now contracts out to the local private sector producer, the Immunology Institute, to carry out these tasks. However, unlike in Romania and Macedonia—where wholesalers are responsible for procuring, storing and distributing vaccines and offer a bundled unit price that includes all of these tasks—the storage and distribution services provided by the Immunology Institute are conducted through a separate contract and cover imported, as well as their own locally produced vaccines. Since the firm is already storing and delivering vaccines of its competitors, it could conceivably continue to play this role if Croatia joined a group procurement scheme for selected imported vaccines.

Level of Expressed Interest in Group Procurement in the CEE/NIS Region

The level of interest in group procurement of vaccines among countries in the region with a GNI per capita of US$1,000 or more was ascertained in three ways:

1) during discussions at meetings, including the Copenhagen meeting in September 2002;

2) from responses by MOH officials (Health Ministers or those with overall responsibility for the national immunization program) to letters sent by WHO/EURO to determine interest in a visit by the team; and

3) through interviews and meetings in the four countries selected, including high-level MOH decision-makers (Vice Ministers or State Secretary of Health) in three of the four countries.

During previous discussions at meetings, representatives from some countries expressed a lack of interest in the idea of group procurement of vaccines. At the Copenhagen meeting, it was difficult to gauge countries' interest level, since participants were mainly mid-level officials, such as NIP managers, and were hesitant to speak for their governments. Several participants of the meeting, however, expressed interest, including those from the three Baltic republics (Lithuania, Latvia and Estonia). Responses to the WHO letters showed interest in at least exploring the idea of group procurement at the Health Minister level (in Macedonia, Croatia, Latvia and Estonia) or at the level of the agency responsible for EPI (Lithuania). Hungary responded negatively to the letter requesting a visit. Some NIP officials in Bulgaria have recently expressed some interest in exploring the idea. It was difficult, in any event, to determine the true level of interest among key decision-makers, including senior officials in charge of the immunization program and public procurement officials, without a country visit. However, we were able to obtain a good sense of the interest level among key players and some policymakers in the four countries visited, as summarized in Table 7.

As shown in the table, the level of interest in group procurement for vaccines was highest in Lithuania, which had explored the idea with the two other Baltic republics in the past. The idea had not gone beyond initial discussions, however, and Lithuanian informants believed that an external catalyst was needed to advance the idea. There was a high degree of consensus among those interviewed in the country, although higher-level officials were the most cautious and non-committal. Major reasons given for their interest in group procurement were the potential reduction in vaccine costs and potential increase in the vaccine selection and competition.

Officials in Croatia at all levels—from the Minister of Health (through intermediaries) to those in the institute responsible for the immunization program—expressed some interest. They would, however, limit their participation in a group procurement scheme to vaccines not being produced in the country. Their interest relates more to their concern in improving the regularity of vaccine supply and in reducing protests than in reducing prices, although this is also a consideration. They are also reluctant to change strains for several vaccines (e.g., BCG and MMR) and thus would be interested in group procurement for only a limited number of vaccines, such as Hib, hepatitis B, flu and IPV.

Table 7. Level of Expressed Interest in Group Procurement of Vaccines among Officials Interviewed in Croatia, Lithuania, Macedonia and Romania

Country	Level of Interest and Degree of Consensus	Reasons Given
Lithuania	Moderately high	▪ Potential reduction in vaccine costs ▪ Increased competition and selection of vaccines ▪ Could reduce tendency of suppliers to push unwanted products on the immunization program
Croatia	Moderate to mixed (for vaccines currently importing only)	Reasons in favor: ▪ Potential improvement in regularity and timeliness of provision of imported vaccines ▪ Could reduce or eliminate problem of protests from losing competitors ▪ Reduction in prices of imported vaccines Reasons not in favor: ▪ Reluctance to change strains for certain vaccines (e.g., MMR, BCG) ▪ Reducing vaccine costs is a relatively low priority, given the relatively small budget (~€4 million per year)
Macedonia	Low to mixed (interest expressed by mid-level personnel, including NIP manager and Health Minister, but not by other senior MOH officials)	Reasons in favor: ▪ Potential reduction in cost of hepatitis B and other expensive vaccines ▪ Could provide adequate quality control Reasons not in favor: ▪ The need to keep wholesalers for cold chain storage and distribution services ▪ The potential difficulty in collaborating with other countries in the region ▪ Concern about switching to vaccines they haven't had long experience with, even if WHO pre-qualified ▪ Belief that they can obtain reasonable hepatitis B prices once they purchase enough for universal immunization, reducing the benefit of group procurement ▪ Potential decrease in the country's decision-making in vaccine selection ▪ Travel costs from frequent meetings and communications for tender and bid process (per the GCC model) may offset savings in vaccine costs. ▪
Romania	Low (interest mainly from Ministry of Finance official)	Reasons in favor (MOF): ▪ Will increase transparency and openness of competition Reasons not in favor: ▪ Need to use local wholesalers for cold chain storage and distribution ▪ Cost benefits may be low, since Romania is already obtaining reasonable prices (lower than GCC prices) ▪ Reducing vaccine costs is a relatively low priority, since they represent only around 1% of the MOH's pharmaceutical expenditures ▪ Fear that a group procurement scheme will result in vaccines with lower quality standards

In Macedonia, some, but limited, interest was expressed in the idea of joint procurement of vaccines, mainly among mid-level program implementers, as well as the Health Minister who agreed to the visit. The main reason cited for their interest was to reduce vaccine costs, due to their budget constraints and their interest in introducing hepatitis B into the childhood schedule in a sustainable manner. Savings in time required by personnel in the procurement of vaccines was also mentioned as a benefit of an international procurement mechanism. Opposition or disinterest in the idea was significant, however, especially among some senior ministry officials, who believed that they could obtain reasonable prices for hepatitis B and other newer vaccines, once they bought sufficient quantities for nationwide introduction. These officials were also hesitant to switch to products they weren't familiar with and were reluctant to reduce the country's ability to select vaccine entirely on their own. The need to use local wholesalers for vaccine storage and distribution was also a major reason for their relative lack of interest in the idea.

There was also relatively little interest in group procurement expressed among health officials in Romania, who felt that they are already obtaining very reasonable vaccine prices. Their close relationship with and dependence on one or two local wholesalers for vaccine distribution and storage was another factor, as was their fear that vaccines purchased through a group mechanism would be of lesser quality than the vaccines they were currently using.[9] In Romania, a Ministry of Finance official dealing with public procurement, expressed the greatest interest in group procurement as a way to increase transparency, open competition and reduce the role of local contracting authorities. Public procurement officials were, in fact, generally in favor of the idea in all four countries.

Enabling Factors for Group Procurement of Vaccines in the Region

There are a number of factors that are conducive to the joint procurement of vaccines among several of the countries in the region. Among the most prominent are:

The Separation of Vaccine from Drug Procurement

In many countries in the region, including all four countries visited, procurement of vaccines is carried out by a separate entity (or group within the entity) than the procurement of drugs or medical supplies. Drug procurement is, in fact, decentralized to the level of individual pharmacies (much like in the U.S.) in several countries with national health insurance. This separation of vaccine from drug procurement facilitates the establishment of a new scheme exclusively for vaccines and perhaps injection supplies.

The Lack of Overwhelming Legal Barriers to Group Procurement

In all four countries visited the public procurement laws contain provisions that could facilitate or accommodate their joining a group procurement scheme with other countries. Croatia, Romania, and Macedonia allow the establishment of "joint procurement bodies" or "contracting associations," while Lithuania's law allows a contracting authority to delegate procurement to another "authorized entity." These provisions were written with only domestic entities in mind, according to public procurement experts interviewed in all countries. However, in both Romania and Croatia procurement experts believed that international group procurement would be allowed under these provisions without having to revise the law. Legal experts in Lithuania were unsure whether the "authorized entity" to which procurement could be delegated could be an international organization. However, the country is revising its laws further to harmonize with EU procurement directives, which have provisions that would allow international group procurement (see next bullet). The Croatian law has two other provisions that would accommodate such a scheme, according to a MOF procurement expert. One allows exemption from procurement laws for international agreements and another allows direct dealing with one tenderer to take advantage of favorable circumstances and lower prices. While the law seems least accommodating in Macedonia, an MOF official interviewed believed that any international agreement signed by the government would supercede national law, as long as the group procurement scheme follows international procurement standards, including a competitive and transparent process.

[9] It should be noted that no high-level health officials were interviewed in Romania.

Europe Union Accession of Many CEE Countries

The upcoming accession to the EU of a number of countries in the region may be the greatest facilitating factor for the establishment of a group procurement scheme for the following reasons:

1) EU accession leads to *harmonization of national public procurement laws* among candidate states, requiring countries to open up competition and increase transparency in procurement procedures. The growing similarity between national procurement laws and the movement towards increased competition and transparency should both facilitate the development of an international agreement to establish group procurement, as long as the procurement process meets international standards. This harmonization should eliminate the potential barrier of different national procurement rules and procedures making group procurement difficult. The fact that several countries in the region have also joined the World Trade Organization, which also requires open competition and the elimination of protectionist policies, further facilitates the establishment of a group procurement scheme.

2) Accession to the EU also requires *elimination of trade policies that protect local producers* and that give them an advantage in securing contracts. Local producers can be powerful opponents of group procurement, as was the case with local pharmaceutical producers in Morocco, which pressured the country to withdraw from a drug purchasing scheme among Magrebian countries. With EU accession, however, local producers can no longer enjoy monopoly status or even preferential treatment in competitive bidding procedures. The Romanian vaccine producer, Cantacuzino Institute, must meet the newly required GMP standards, like its foreign competitors, likely leading to the closure of the company in 2004. As EU candidate countries increasingly require local producers to compete on the same basis as everyone else, the power of these companies to block or otherwise influence government decisions concerning a group procurement scheme will likely diminish significantly.

3) EU *procurement directives do not exclude the possibility of international group procurement*, according to communications with EU procurement experts and a review of EU documents. Several provisions in the EU directives revised in March 2003 would accommodate group procurement between countries. These include: articles allowing public authorities to delegate procurement to a separate entity, an article allowing them to purchase through a "central purchasing body", and an article allowing exemptions from public procurement directives for contract governed by the procurement rules of an international organization.

4) *Harmonization of vaccine licensing standards and growing compatibility of vaccines* among countries is another outcome of EU accession that will facilitate group procurement. Countries joining the EU are obligated (with certain exceptions) to follow the "simplified procedures" of granting national licenses for vaccines registered centrally or those licensed in one member state (through mutual recognition agreements). As discussed above, many of the EU candidate countries are already switching to a similar set of vaccines used in Western Europe, such as hepatitis B without thiomersal and MMR without Urabe mumps. While these new standards can reduce vaccine selection and thus competition, they, along with the simplified procedures speeding up national licensing, should make it easier for a group of countries to develop a common list of licensed vaccines to procure through a joint tender.

Ability to Bypass Local Wholesalers and Buy Directly from Producers in Several Countries

Several countries in the region, including Lithuania and Croatia, are not bound by law or logistics to purchase vaccines through local wholesalers, who are often few in number and can be quite influential. In Lithuania, for instance, vaccines are purchase about half the time through local wholesalers and the half the time directly from producers (through local agents). Since group procurement could reduce or even eliminate the role of local wholesalers, countries that allow direct purchase of vaccines from producers will not be faced with as great a barrier as countries, such as Romania and Macedonia, that must purchase through local wholesalers and depend on them for vaccine storage and internal distribution. Further work

on group procurement in the region would require determining how many and which countries permit direct purchasing from producers.

Penetration of Some Non-European Made Vaccines into the Western European Market

While the switch to vaccines used in Western Europe by several countries in the region, especially EU candidate states, is further reducing their vaccine selection, several non-European producers are making efforts to penetrate the European market. During the course of this study, we learned that Serum Institute of India is currently conducting a clinical trial in Germany of its MMR vaccine (made with the L-Zagreb strain of mumps), as a first step in obtaining a market authorization in that country. Through mutual recognition, the granting of a marketing authorization in Germany should lead national licenses for the vaccine throughout the European Union. Serum Institute also has plans to apply for licensing of its hepatitis B vaccine through the EMEA (as required for all recombinant vaccines). In addition, GreenCross Vaccine in Korea, which recently merged with Berna Biotech of Switzerland, plans to complete development of a thiomersal-free hepatitis B vaccine by the end of 2003. The firm plans to conduct a large clinical trial of the vaccine in Eastern Europe and then apply for market authorization through the EMEA. If these efforts are successful, at least two more hepatitis B vaccines and an additional MMR vaccine will be available on the European market, expanding the selection of vaccines for a group tender and likely leading to a reduction in price. Informants in Lithuania, including policymakers, claimed that Indian or Korean vaccines would be acceptable to them as long as they are licensed in the EU. Some informants in other countries, however, were more wary of using Asian products and wondered if Europeans will really use vaccines made in Asia.

Ability to Pay in International Currency

A group procurement scheme will likely require countries to pay in international currency, such as Euros or U.S. dollars. Most countries responding to the email survey claimed that access to international currency was not a problem and several, including Lithuania and Croatia, already pay some foreign suppliers in hard currency. While it may be difficult for some poorer countries to pay with Euros or dollars, it should not be a problem for countries most likely to join a group procurement scheme, including EU candidate countries.

Flexibility in Procurement and Payment Schedule

Informants in Lithuania believed that changes in the timing of vaccine procurement and payments, as likely required in joining a group procurement scheme, would be possible. Romania appears to have a rather flexible procurement schedule, since tenders are issued at different times during the year, and funding is provided for vaccine procurement by the MOH on a monthly basis. We do not yet know to what extent other countries could be flexible in their procurement and payment schedules.

Potential Barriers to Group Procurement of Vaccines

The following potential barriers to countries in the region joining a group procurement scheme for vaccines were identified:

Limited Interest in the Idea of Joint Procurement in Many Countries

As mentioned above, there appears thus far to be a limited number of countries that either have expressed strong interest in group procurement of vaccines or whose interest level is unknown. In some countries we visited (Romania and Macedonia) there was at least some interest expressed in exploring the idea at the highest level of the Ministry of Health (i.e., the Health Minister) and among program implementers, such as immunization program managers, but not among critical decision-makers between these two levels. However, the degree of interest in group procurement has not been ascertained in most countries in the region and in addition, countries' interest could grow once a group procurement scheme is successfully implemented.

Dominant Role of Local Wholesalers in Several Countries

While the power of local vaccine producers is waning in several countries, including Romania, and will do so in other countries as they approach EU accession, local wholesalers continue to exert considerable

influence and power in many of the countries in the region. This is because there are only a few of them who handle vaccines in many of the countries, and in some, they have developed quite close relationships with those procuring vaccines for the immunization program. Their potential opposition to group procurement, which would likely reduce their role as vaccine sellers to the public sector, could present an important barrier to several countries joining such a scheme. The dominance of local wholesalers is greatest in countries that either require by law that all pharmaceutical sales be conducted through wholesalers (as opposed to producers), or that depend on them to store and distribute vaccines within the country. While laws restricting sales by local wholesalers may change over time with EU accession, the lack of public sector cold chain storage and distribution capacity in several countries in the region makes it more difficult for them to purchase their vaccines elsewhere. These countries, including Macedonia and Romania, would therefore not likely be strong candidates for a group procurement scheme for vaccines at this time.

Influence of Large International Vaccine Producers in the Region

A few large multi-national vaccine producers dominate the public sector market for imported vaccines in many countries in the region, including all four visited for this study. These few producers have a strong presence in these countries and may be influential in convincing governments to oppose joining a group procurement scheme as a means of reducing vaccine prices.

Dramatic Change in Current Procurement Practices that Group Procurement Would Entail

Several countries in the region are either not procuring vaccines on a competitive basis (e.g., Croatia and Slovenia) or are not following the spirit of competitive procurement by having restrictive criteria on tenders that limit competition (e.g., Macedonia and Romania). A group procurement scheme would therefore represent a dramatic change in the way many of these countries currently procure vaccines, since it would involve a competitive and transparent process. Equally important, a group procurement system would reduce the role of those currently responsible for vaccine procurement, including vaccine procurement commissions, potentially leading to their resistance in joining such a scheme. This was not seen as a potential issue in some countries, but not in others, including Lithuania and Croatia.

Fear of Losing Power in Selecting Vaccines for the Immunization Program

Much of the initial opposition to the idea of group procurement in the countries visited was due to the reduced role that each country would have in determining technical specifications or requirements on tenders and in selecting winning vaccines. Countries were especially concerned that group procurement would lead to their being forced to use "lower quality" vaccines, such as those not used in Western Europe. In every country, informants raised suspicions about vaccines produced in, but not licensed or used in Western Europe—that is, those destined for the developing-country market. The priority that immunization programs in the region place on quality (as they define it) over price was mentioned frequently in every country. This priority was demonstrated by Macedonia's selection of a high priced MMR vaccine, despite the lack of sufficient funding in the budget. Any group procurement scheme established for this region would therefore have to include technical requirements that satisfy these countries (such as MMR without Urabe mumps), as well as the involvement of country representatives in the tender preparation and award selection process.

Limited Vaccine Selection

As countries in the CEE region look towards EU countries in deciding which vaccines to license and to use for their immunization programs, this restricts them to a rather limited choice of vaccines, since few vaccines produced outside of Western Europe or the U.S. have been licensed in Western European countries. Some non-European producers are making efforts to get their vaccines licensed in Europe, as mentioned above, but this process requires that vaccine trials be conducted in Europe. All hepatitis B vaccines must also undergo an elaborate review process by the EMEA, since they are derived from biotechnology. Despite the streamlining of the national licensing process in countries following the "simplified procedures" once a product is licensed in one country or by the EMEA, the time and expense involved in obtaining the first license will likely limit the number of vaccines from these emerging producers that enter the European market for some time to come. Thus, the selection of vaccines offered

through a CEE group procurement scheme will likely be quite narrow, reducing the potential cost savings and expanded choice that such a scheme can provide.

Inadequate and/or Irregular Funding for Vaccines

The delays and inconsistencies in the release of funds for vaccines that were reported in three of the four countries visited and in other countries responding to the email survey could seriously jeopardize their continued participation in a group procurement scheme. If payments are not received in a timely manner, this could discourage suppliers from responding to joint tenders and otherwise undermine the operation of the mechanism. However, some informants, especially in Lithuania, believed that the government funding situation would improve if an international organization and international agreements were involved, as would be the case with a group procurement scheme.

Limited Cooperation and Relationships Among Countries in the Region

Informants in three of the four countries visited mentioned the lack of close political ties with other countries in the diverse CEE/NIS region and their lack of experience collaborating together as a potential barrier to establishing a regional group procurement scheme for vaccines. Some informants in one country expressed resistance to collaborating with certain countries, one declaring that it was "premature to talk about many of these countries working together on such an initiative." Informants cited differences in culture, language, and level of economic development between countries and sub-regions as reasons for the perceived difficulty of these countries joining together on such an effort. However, other informants, especially in Lithuania and Croatia, didn't believe that this was an overwhelming barrier. Given the limited regional cohesiveness or cooperation, and the fact that many of these countries look mainly towards Western Europe for alliances, informants in all four countries visited viewed an international organization outside of the region, such as WHO or the EU, as the most appropriate vehicle for a group procurement scheme (see below).

IV. Requirements and Preferred Options for Group Procurement of Vaccines

During the country visits, informants were asked about their requirements and preferred options for a group procurement scheme for vaccines in the region, after seeing a brief presentation on the PAHO EPI Revolving Fund and GCC mechanism. Due to very limited discussions in Romania and Macedonia, the information below comes mainly from Lithuania and Croatia, the two countries with the greater potential and interest in participating in group procurement among the four countries visited.

Vaccines to Purchase through a Group Tender

All four countries, with the exception of Macedonia, would require that all vaccines offered through a group tender be licensed in their country. Since Lithuania is about to join the EU, it would limit selection to vaccines licensed in EU countries, while Romania would require vaccines that meet "European standards". Croatia would consider purchasing only vaccines they are currently importing and ones in which the strain is similar across producers, given their reluctance to introduce new strains into the population. They listed only four vaccines they would currently consider purchasing through a group procurement scheme: Hib, hepatitis B, IPV, and flu vaccine.[10] This list could be expanded if specific strains could be included in a group tender, but it's unlikely at this time that Croatia would purchase vaccines through a group mechanism that are being produced locally (e.g., MMR, DTwP, DT).

Participating Countries

Informants often mentioned neighboring countries as appropriate to include in a group procurement scheme. Those interviewed in Lithuania and Romania felt that the scheme would be most viable with a group of countries that are similar in terms of their vaccine requirements, economic level, and future membership in the EU, in order to develop a common list of vaccines to be tendered. Informants in Croatia expressed no opinions about participating countries, while Lithuanian informants suggested the other two Baltic republics as possible candidates for a CEE group procurement scheme.

Entity to Manage the Scheme

Several possibilities were discussed during the country visits concerning the type of organization that could manage a CEE group procurement scheme for vaccines. These included a regional trade or cooperative group, an international organization such as WHO or the EU, a new organization created for the scheme, or a private procurement agent. Also discussed was the possibility of having PAHO procure vaccines at its listed prices on behalf of interested CEE countries, as the organization has offered to do. This option would not allow CEE countries to use the common fund and would require prepayment.

Informants in the four countries were, in general, interested in an international organization with strong credibility and longevity, such as the EU, WHO, or another UN agency, as opposed to a new organization or a regional group. While some informants in Croatia were favorably disposed to joining the PAHO EPI Revolving Fund, others felt that the EU would be the best choice. Lithuanian policymakers felt that PAHO would not be appropriate, since they are joining the EU and would want a European-based alliance.

Terms Regarding Participation and Choice

The findings from the country visits indicate that great flexibility in countries' ability to participate in the scheme from year to year and the extent of their participation would be a key requirement of many prospective countries. As with the PAHO Revolving Fund, informants in both Croatia and Macedonia would require 100 percent flexibility in choosing which vaccines to procure through a group scheme each year, to avoid being forced to purchase products they do not want or that do not meet their quality standards. The GCC requirement that countries buy 60 percent of their vaccine needs through the group

[10] While flu is not an EPI vaccine, the Croatian government purchases a large quantity of the vaccine as compared to children's vaccines and has experienced problems with the availability of supply.

scheme (and 20 percent for producing countries) may therefore be too restrictive to attract many countries in the CEE region.

Preferred Model/Functions of a Group Procurement Scheme

There was a consensus among informants in Lithuania that the GCC model, in which individual countries contract with and pay suppliers, would be a more appropriate model for the CEE region than the PAHO EPI Revolving Fund, in which the organization handles nearly all aspects of the procurement process. Opinions were split between the GCC and the PAHO model among informants in Croatia. In Macedonia, there was a preference for the PAHO model among the few persons who discussed the issue, in part because of the presumed high cost and inconvenience of the frequent meetings and communications required with the GCC tendering process.

Country Participation in Decision-Making and Operations of the Scheme

This issue was mainly discussed in Lithuania, where informants felt that the government would require that a country representative participate in the tender and bid process to ensure transparency and compliance with international public procurement standards, since government funds would be involved.

Other Requirements

Public procurement experts in all countries stressed that, to be allowed under their national procurement laws, a group procurement scheme would need to follow EU or other international standards of openness and transparency in the tender and bid process. According to some officials, such a scheme should also be as quick and efficient as their current national procurement system and should allow for emergency procurements during disease outbreaks or natural disasters.

Required Changes and Actions

According to local public procurement experts, no changes in the procurement laws would be required to join a group procurement scheme in Croatia, Macedonia, and Romania. Either provisions in their current laws allow group procurement, or an international agreement would take precedent over national law. In Lithuania, however, it may be necessary to amend the public procurement laws to allow the "authorized entity" procuring on behalf of a Contracting Authority to be an international organization. The governments in all countries would require international agreements before they could participate in such a scheme. Other changes in current regulations, for example, to allow advance payment or a letter of credit for vaccine purchases, may be required for some countries, if such payment terms were required by the group procurement scheme.

V. Summary and Conclusions

Feasibility of Group Procurement in the CEE/NIS Region

Success of Group Procurement Schemes

Several group procurement schemes for drugs or vaccines, including the PAHO EPI Revolving Fund and the Gulf Cooperation Council Group Purchasing Program, have proven to be successful in improving the regular supply of commodities, reducing prices significantly and assuring quality. They have also proven to be extremely popular with countries, leading to the impressive growth in the number of participating countries and the number and volume of commodities purchased in the past two decades. Key ingredients required for their success appear to be: political will from participating countries, strong central leadership and management, sustainable financing of the operation, flexibility in country participation, and designing agreements and procedures that minimize contractual risk to the mechanism.

Level of Expressed Interest and Motivating Factors

The interest in joining a group procurement scheme for vaccines among self-procuring countries in the CEE region—and thus the political will—appears to be limited at this time, judging from the country visits, from discussions with country representatives at WHO meetings, and their correspondence with WHO/EURO. Among the four countries visited, interest in the idea was strongest—at all administrative levels—in Lithuania; was moderate in Croatia, but only for a few vaccines; and was quite low in both Romania and Macedonia. While the interest level among policymakers is still unknown in several countries in the region, the findings of the country visits, as well as initial discussions with country officials in the region, indicate that it is strongest in small countries without local vaccine production capacity, such as the three Baltic republics (Lithuania, Latvia and Estonia). Although reducing vaccine prices is a strong motivating factor, other important incentives in some countries are: improving transparency in the selection process, improving the regularity and predictability of supply, and reducing delays in procurement caused by protests from losing competitors. CEE countries also place a higher priority on being able to select products that meet their definition of high-quality—which increasingly means products used in Western European and other industrialized countries—than in buying the least expensive vaccines, even if these vaccines are WHO pre-qualified. This is exemplified by Macedonia's selection of an MMR vaccine not containing the Urabe strain, despite insufficient funding in the government budget.

Barriers to the Establishment of a Group Procurement Scheme

Besides the apparent limited interest, there are a number of significant barriers to joining a group procurement scheme in many of the countries in the CEE region. These barriers include: 1) the dominant role and influence of a few local wholesalers, on whom some countries are totally dependent for the cold storage and internal distribution of vaccines; 2) the lack of truly competitive procurement procedures in many countries, due to policies protecting local producers, overly restrictive evaluation criteria, and in some countries, the practice of direct negotiations with suppliers; 3) the limited number of licensed vaccines in many countries, which could limit which vaccines they could purchase through a group scheme; 4) countries' fear of losing their ability to make decisions concerning evaluation criteria and vaccine selection; 5) limited cooperation and political ties between countries in this rather diverse region; and 6) often irregular and inadequate vaccine funding.

Facilitating Factors Related to EU Accession

Many of these barriers are being reduced or even eliminated as countries accede into the European Union. Joining the EU requires countries to: 1) revise their procurement laws to increase competition and transparency and to harmonize with the laws of other member states, 2) end protectionist practices that have allowed monopolies for local vaccine producers in several countries; and 3) adopt European quality control standards for vaccines. The harmonization of public procurement laws with those of the EU and among candidate countries in the region will remove the potential barrier of trying to reconcile vastly different procurement laws and practices between the various countries. The adoption of European

quality control standards, while leading to a reduction in vaccine selection in some cases (as they drop vaccines not licensed in Europe), should result in increased compatibility between countries in their vaccine requirements, facilitating the development of a common vaccine list. It may also mean requiring local producers to meet EU GMP standards.

Countries preparing to join the EU are thus stronger candidates for joining a group procurement scheme for vaccines than are countries where EU accession is further away or unlikely. These latter countries are more likely to have significant barriers to group procurement, such as non-transparent or non-competitive procurement procedures, laws requiring the use of local wholesalers, overly restrictive evaluation criteria and economic or political instability. Revised EU procurement directives also appear to accommodate the practice of member countries conducting joint procurement, as long as the procedure is open, transparent and otherwise follows EU directives. Since EU candidature or membership is conducive to the establishment of a group procurement scheme, it may be sensible to wait two or three years to launch such a scheme—once the first wave of countries has already joined the EU (in 2004) and the second wave, scheduled to join in 2007, begins to enact the reforms required for EU membership.

Estimated Cost Savings from and Viability of Group Procurement

As a first step in determining the viability of a group procurement scheme and whether the potential cost savings justify the cost and effort required to plan and implement such a project, we conducted estimates of cost savings under two scenarios. The first scenario involves group procurement for the three Baltic republics only, based on the interest of Lithuania and reported initial interest of the other two republics. Cost savings were estimated only for the newer, more expensive vaccines—MMR, Hib, hepatitis B (adult and pediatric) and IPV—depending on which each country is using. Other basic EPI vaccines were dropped from the analysis, since they resulted in relatively little savings. To estimate prices that a group procurement scheme could obtain, we used the GCC prices as a base and added to them in increments of 25 percent, up to 75 percent above the GCC prices. These prices were compared to the prices the countries paid in 2002 or 2003, as reported in the email survey (WHO/EURO, 2002) or obtained during a country visit, in order to estimate potential cost savings.[11] One could argue that using GCC prices is not appropriate for these small Eastern European countries, given that the GCC states have a birth cohort of around one million as compared to only 63,000 for the three Baltic republics. On the other hand, producers practice tiered pricing and the Gulf States in the GCC are considerably wealthier than the Baltic republics, which should result in the GCC states generally being offered higher prices. In any event, we present a range of estimated savings, assuming that the group scheme obtains up to 175 percent of the GCC prices.

In the second scenario, we add three larger countries to the three Baltic republics. These are countries that either have expressed interest in the idea of group procurement or where interest in unknown. Only vaccines that the countries are not producing locally are included in the calculations.

In both scenarios, the total cost savings for each country reflect only the savings from vaccines that would be cheaper if countries purchased them through the scheme than on their own. If the estimates show that a vaccine would be more expensive through the scheme, the resulting negative savings is not included in the total. Therefore, we assume that countries could pick and chose which vaccines to purchase through the scheme and would not choose those that would not result in cost savings.

The results on the two cost savings scenarios are shown in Tables 8 and 9. Details on the estimates, including assumed vial sizes and vaccine specifications, are shown in Appendix 3.

[11] All vaccine prices, including GCC prices, are CIF and do not include value-added taxes.

Table 8. Scenario 1: Estimated Cost Savings (in Euros) from Group Purchasing of Selected Vaccines Involving Three Baltic Republics, Based on GCC Prices

Country	Birth Cohort	Assuming GCC Prices	Assuming GCC + 25%	Assuming GCC + 50%	Assuming GCC + 75%
Lithuania (MMR, Hep B (paed.), IPV, Hib*)	32,000	486,998	313,079	202,421	103,963
Latvia (MMR, HepB (paed.), Hib)**	19,000	117,412	44,864	20,182	2,402
Estonia (MMR, hepB (paed.), hepB (adult)	12,000	228,047	185,368	142,689	122,108
Total	**63,000**	**832,457**	**543,311**	**365,292**	**228,473**

* Hib vaccine is being introduced in Lithuania in 2004. The price Latvia is paying was used as an estimate of the price Lithuania could obtain on its own.

** Latvia is using several combination vaccines, such as DPT-HepB-Hib-IPV, which we were not able to include in the cost savings estimates, since GCC prices for these vaccines are not available. This explains much of the relatively small estimated savings for Latvia. If such combination vaccines were included in a group procurement scheme and used by more countries, Latvia's cost savings would be considerably larger.

Prices used in the estimates assume the use of MMR with Jeryl-Lynn mumps strain in single dose vials and single-dose vials of hepatitis B (without thiomersal).

Table 9. Scenario 2: Estimated Cost Savings (in Euros) from Group Purchasing of Selected Vaccines Involving Six Central/Eastern European Countries, Based on GCC Prices

	Birth Cohort	Assuming GCC Prices	Assuming GCC + 25%	Assuming GCC + 50%	Assuming GCC + 75%
Lithuania (MMR, Hep B (paed.), IPV, Hib)	32,000	486,998	313,079	202,421	103,963
Latvia (MMR, HepB (paed.), Hib)	19,000	117,412	44,864	20,182	2,402
Estonia (MMR, hepB (paed.), hepB (adult)	12,000	228,047	185,368	142,689	122,108
Country X (MMR,, Hep B (paed.), Hib)	55,000	815,308	578,043	340,777	150,087
Country Y (MMR, HepB (paed.)	61,000	213,377	61,080	-	-
Country Z (HepB paed., IP, Hib)	54,000	582,156	418,545	315,774	258,003
Total	**233,000**	**2,443,298**	**1,600,979**	**1,021,843**	**636,563**

See notes in Table 8.

These estimates show that a scheme with the three Baltic republics alone Table 8 (Scenario 1) could result in cost savings ranging from around €228,000 to €832,000 for a few relatively expensive vaccines, assuming prices range from the GCC prices to 175 percent of these prices. As shown in Table 9 (Scenario 2), adding a few larger countries to increase the birth cohort from 63,000 to 233,000 significantly increases the overall cost savings, even for the few vaccines included in the assumptions. These cost saving estimates range from around €636,000, assuming 75 percent above GCC prices, to €2.4 million, if prices similar to those of the GCC could be obtained. Thus, by adding a few larger countries, the total estimated cost saving realized are around three times greater than for the three Baltic Republics alone. While adding these countries to the scheme does not necessarily increase the cost savings for each of the Baltic republics, it is likely that increasing the volume of purchases overall would result in lower unit prices and thus greater cost savings per country.

To determine if these estimated cost savings justify establishing a group procurement scheme, it will be necessary to: a) refine and improve the cost savings estimates with addition country input; b) obtain

feedback from the target countries on whether they perceive these estimated savings to be worth establishing such a mechanism; c) estimate the costs of operating a group procurement mechanism; and d) estimate the total economic savings, including savings in staff time spent on procurement.

Potential Impact on Vaccine Selection and Competition

While adoption of vaccines used in Europe is further restricting vaccine selection in many CEE countries, a group procurement scheme may actually increase the choice of vaccines for some countries. This is especially true for small countries where producers have not bothered to obtain licenses for their vaccines or have not responded to tenders. Producers may be more reluctant to pass up the opportunity of responding to a tender from a block of countries and applying for vaccine licenses, due to the fear that their competitors would win this market. The entry onto the European market of some vaccines from lower-cost producers in Asia, including thiomersal-free hepatitis B in the next few years and MMR with non-Urabe mumps strains, may also increase competition in the not too distant future.

Overall Conclusions

While this initial assessment found limited interest among self-procuring countries in the CEE region, we conclude that there are sufficient reasons to justify continuing this project to the next phase. These reasons include:

1. Initial discussions with country representatives and the country visits indicate initial interest in pursuing the idea of group procurement in enough countries (e.g., three or four) to begin a pilot project;

2. The prospect of further reduction or elimination of barriers, such as divergent and/or non-transparent procurement procedures and divergent vaccine requirements, as many CEE countries prepare to join the EU in the next one to four years;

3. Initial estimates of cost savings from vaccine price reductions that are potentially promising; and,

4. The lack of formidable legal barriers to group procurement in several countries and the fact that EU public procurement directives would allow group procurement arrangements between member states.

The next phase should consist of further activities to assess and test the feasibility of group procurement of vaccines in the region, including additional cost savings analyses; country visits to additional, potentially interested countries; analysis of possible financing options; and the planning and implementation of a pilot group procurement project with a small number of countries and products.

Specific Design Features of a Viable CEE/NIS Group Procurement Scheme

Vaccines to Include in Group Purchasing Scheme

Technical specifications in a group tender will have to be written in such a way as to ensure that individual countries will be able to buy vaccines that meet their national quality requirements, such as hepatitis B without thiomersal (1-dose vials) and MMR with mumps strains other than Urabe. Countries joining the EU also feel obliged to procure only vaccines that are licensed in EU countries, including these types of hepatitis B and MMR vaccines. Since countries in the region are increasing switching to or adding newer, more expensive vaccines, other vaccines that may be appropriate for group purchasing include IPV, Hib, DTP with acellular pertussis, DTP combinations and perhaps flu vaccines. In any event, the greatest potential cost savings should be realized from these more expensive vaccines, as our estimates indicate. Other older or less expensive vaccines, such as OPV, DTP with whole-cell pertussis, and MMR containing Urabe, could also be included, depending on how many and which countries decide to participate in the scheme.

Degree of Flexibility in Participation

In order to attract countries in the region, the scheme will have to allow countries considerable flexibility in whether or not to participate each year, to what degree, and for which vaccines. Flexibility in participation will counter countries' fear of being forced to buy products they do not want and which they had limited involvement in selecting—a fear that we found to be a barrier to their interest in joining a group procurement scheme. Some countries, including Croatia, made it clear that they would be interested in procuring only a limited number of vaccines through the scheme—mainly ones they are not producing themselves. As one informant said, "such a system should assist countries, not restrict them." While this flexibility could jeopardize the viability of the scheme—if, for instance, countries buy very few vaccines through the mechanism in a given year—it was a very strong and clear requirement of nearly all those interviewed in the four countries.

Managing Entity

Informants in the countries visited believed that the viability of a group procurement mechanism for the region as well as countries' interest in participating would be enhanced if it is run by a credible, international organization, such as the EU, WHO, or another UN agency, as opposed to a regional or a brand new organization. Identifying an appropriate organization with sufficient interest and capability will be a critical next step in designing a group procurement mechanism for the region.

Preferred Group Procurement Model and Country Participation

While several informants were attracted to the PAHO Revolving Fund model, it is likely that the GCC model, based on a centralized tender and bid process and individual country contracting, is likely to be more politically feasible for this region, especially given its level of economic development. The option of countries procuring their vaccines through the PAHO Revolving Fund also seems politically unlikely, given their strong identity and interest in forming alliances with Europe. A politically viable scheme will require considerable country participation in all phases of decision-making—from determining technical specifications to drafting bidding documents and awarding bids.

Procurement Process

The procurement process in a group mechanism will need to conform with international standards of openness in competition and transparency in order to comply with national procurement laws and EU directives. The process should be as quick and efficient as those currently taking place in individual countries and should result in fewer procurement delays and fewer protests.

Operation and Financing of the Scheme

As with other successful joint procurement schemes, such a mechanism in the CEE region will likely require a permanent secretariat, strong management and procedures, and considerable expertise in vaccine procurement. Start-up funding from donors or from the organization chosen to manage it will also likely be required. Options for financing the operation on a continual basis will need to be explored. These can include analyses to determine the feasibility of using administrative fees added to each purchase to finance the operation and the optimal level of fees that would generate sufficient revenues while still resulting in significant cost savings to participating countries. While the Eastern Caribbean Drug Service (ECDS) program in the Eastern Caribbean successfully uses such a fee (15 percent) to finance operations, both the PAHO Revolving Fund and the GCC program use other methods of financing—general budgetary funds, and a combination of membership dues and revenues from the sale of tender documents, respectively. A number of different financing options should therefore be investigated.

Information Sharing as a First Step towards Group Procurement

Since it appears likely that only a limited number of countries would join a group procurement scheme in the near term, one very feasible option is to begin by having countries share data on the vaccines they are using, suppliers, prices, adverse events, and other useful information. Sharing such information through a database or other means of communication (e.g., list serve) could be the first step towards regional collaboration in vaccine procurement. To be most effective, one country could take the lead in organizing this, with WHO, the EU, or other technical agencies providing technical assistance, as necessary, so that ownership rests with the countries themselves.

Phase in of Scheme

Other successful group procurement schemes started small—with a limited number of countries or a limited number of products—and grew as they gained experience and learned lessons. It may therefore be best to begin the scheme as a pilot project with three or four countries—those with the greatest political will and the fewest barriers. Since countries and other observers will at least partly judge success of the pilot scheme on the price reductions and overall cost savings achieved, it may be preferable to include at least one larger country in the pilot phase in order to achieve more substantial price reductions. Including one larger country (e.g., with a birth cohort of 50,000 - 60,000) in the pilot project for the purchase of a limited number of products could likely be carried out while still keeping the pilot relatively small and manageable.

We conclude that for the pilot and any subsequent group procurement scheme to be successful, the program will need to be designed with the heavy input of participating countries, run by a credible international organization, benefit from on-going participation of countries in all major areas of decision-making, and allow for considerable flexibility in country participation from year to year.

VI. Recommendations

1. As an initial step in regional collaboration in vaccine procurement, a mechanism should be set up to allow countries to share information on vaccines they are using; prices they are paying; their experiences with various suppliers; experience with various vaccines, including reported adverse events; and other useful data. One or more countries in the region could manage the database, with technical assistance from WHO or other technical agency.

2. WHO should continue to assess vaccine procurement and quality assurance capabilities and procedures in self-procuring CEE/NIS countries and provide appropriate technical assistance and training, taking into account existing and planned assistance from the EU in these areas.

3. If funding can be secured, the assessment of the feasibility of group procurement of vaccines in the CEE/NIS region should continue into the next phase. As many of these countries move closer to EU accession in the next two to three years, it is likely that the feasibility of and interest in group procurement of vaccines will increase significantly. The interim period provides an excellent opportunity to further assess the feasibility and prepare solid groundwork for starting up such a scheme as a pilot project. The activities of this analysis/preparatory phase, in order, could include:

    a) Conduct visits to a few other countries in the region to assess their level of interest and the feasibility of their participating in the pilot group procurement scheme. Strong candidates for the next country visits are the Baltic republics of Latvia and Estonia, which have at some level indicated initial interest and have collaborated in other immunization activities with Lithuania as a group.

    b) Conduct more comprehensive and refined analyses of the costs and potential cost savings of group procurement. These analyses, which could be conducted simultaneously with the additional country visits, could include:

        - Refined estimates of savings in vaccine costs with additional information and input from countries;

        - Estimates of cost savings from reduction of staff time and other costs associated with vaccine procurement at the country level;

        - Estimates of operating costs of a group procurement scheme under various scenarios (varying in the number of participating countries, volume of purchases, degrees of country participation in the operation, etc.).

    c) Approach potential organizations to manage a regional group procurement scheme to explore their level of interest, capacity to take on such a task, as well as the possibility of their providing financial support for the start-up and/or implementation of the project.

    d) Prepare an options papers that lays out various options for the design and operation of a group procurement mechanism for vaccines, backed up by cost, financing and other analyses described in (b) above. The paper would identify and dissect possible options for key aspects and features of the scheme, including:

        - Functions of the mechanism (e.g., centralized tendering only, centralized contracting with suppliers; quality control functions, etc.);

        - Staffing (types and numbers of personnel) for varying degrees of country participation;
        - Financing of the operation, based on estimates of staffing requirements and operating costs. Financing options to explore could include: charging administrative fees with each

order, membership dues, donor support, and income-generating activities, such as the sale of bidding documents;

- Entities to manage and operate the scheme;
- Level and types of country participation in decision-making and in implementing the mechanism;
- Rules for participation, nature of agreements with countries, etc.;
- Implementation plan, including a pilot project and possible later expansion of the scheme.

This options paper would be prepared for an initial meeting of countries that have expressed interest in further exploring the idea of group procurement for vaccines.

e) Organize a meeting of interested countries to discuss further the feasibility of a group procurement mechanism, each country's anticipated level of participation in the mechanism, and to design the pilot phase of the project. Participants would include appropriate representatives (including policy-makers) from three to five countries most likely to participate in a pilot project, as well as observers from several other countries that could potentially be interested in joining at a later stage. At the meeting, the results of this initial assessment could be presented, the benefits and disadvantages of group procurement discussed in detail, and participants could reach consensus on specific aspects of the design of the scheme, using the options paper.

4. If financing is available and further feasibility analysis for regional group procurement is positive, develop a plan for a pilot scheme involving a small number of countries and a limited number of products. The newer, more expensive vaccines, such as Hib, hepatitis B, MMR, IPV and DTP combinations, may be the most appropriate products to include in the pilot, since they will result in the greatest cost savings. The pilot project will assess the feasibility of implementing such a scheme in the region and provide lessons for its continuation or expansion. Data would also be collected to evaluate the success of the project, and to inform decisions of participating countries on whether or not to continue the scheme as well as other countries on whether or not to join. The data would measure the tangible and intangible benefits and disadvantages of group procurement, including: vaccine cost savings to individual countries and to the group as a whole; total economic savings, including reductions in local staff time spent on procurement; reduction in procurement delays and in protests from losing competitors; increased selection of vaccines; and improved transparency in the vaccine procurement process.

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Appendix 1. List of Persons Participating in Interviews and Meetings during the Country Assessments

Croatia

WHO:
Dr. Antoinette Kaić-Rak, WHO Liaison Officer

Croatian National Institute of Public Health:
Dr. Marijan Erceg, Director
Dr. Ira Gjenero-Margan, Head of Department of Infectious Disease Epidemiology
Dr. Bernard Kaić, National EPI Manager
Dr. Vlasta Hrabac-Žerjavić, Head of Department of Epidemiology

Institute of Immunology:
Dr. Sabina Rabatić

National Institute for the Control of Immunobiologicals:
Dr. Tatjana Sindik-Miloševič, Head of Biological Testing Department

Ministry of Health:
Dr. Siniša Varga, Assistant Minister of Health
Dr. Csaba Dohoczky, Head of Drugs and Medical Devices Department and Pharmaceutical Inspection
Dr. Valerija Stamenič, Head of Health Inspection

Ministry of Finance:
Ivica Balogovič, Senior Counselor

Croatian Institute for Health Insurance:
Dr. Lidija Hrastič-Novak, Assistant Director for Health Care

EU Office:
Ms. Friederike Wunschmann, Project Manager
Ms. Ritva Heikkinen, Sector Manager for Public Administration, Public Finance
Ms. Laura Garagnani, First Secretary

Lithuania

State Public Health Service:
Dr. Vytautas Bakasenas, National Immunization Programme Manager
Dr. Vytautas Kriauza, Director of the SPHS
Dr. Algis Sasnauskas, Deputy Director, SPHS and chair of the Public Procurement Commission
Dr. B. Morkunas, Director of the CCDPC
Mr. P. Celkis, head of the legal division of SPHS
Dr. N. Kupreviciene, epidemiologist, National Immunization Programme

Public Procurement Office:
V. Jakstas, head of Methodological Division

Ministry of Health:
Gediminas Cerniauskas, Vice Minister of Health
V. Meizis, Head of the Division of Foreign Affairs and European Integration

State Medicines Control Agency:
Dr. Myukolas Mauricas, Chairman, Commission on Bioproducts and Diagnostic Test Systems

WHO:
Dr. Robertas Petkevicius, WHO Liaison Officer

Macedonia

WHO/Macedonia:
Dr. Marija Kisman, Liaison Officer
Dr. Boris Rebac, Public Health Officer, WHO Disaster Preparedness and Response Office
Dr. Jukka Pukkila, Head of WHO Disaster Preparedness and Response Office
Dr. Marija Gulija, Program Officer dealing with pharmaceuticals, WHO Disaster Preparedness and Response Office (by phone)

Ministry of Health:
Dr. Jovanka Kostovska, EPI manager and WHO National Counterpart on EPI and Deputy President of the Procurement Commission for Vaccines

Dr. Avzilativ Xhemaiki, State Secretary of Health and member of the Procurement Commission for Vaccines

Mrs. Angelina Bacanovia, Head of the Normative and Legislation Issues Department and President of the Procurement Commission for Vaccines

Dr. Borislav Josifovski, Head of the Primary and Preventive Health Care Department and member of the Procurement Commission

National Drug Bureau:
Mr. Romil Sandzakovsi, Director
Tatiana Petrusevska, Head of Department for Supply of Medicines, Narcotics and Remedial Medicine

National Immunization Commission (members not listed above):
Dr. Stojance Stefanovski, Director of the Mother and Child Institute
Head of Epidemiology and Microbiology, Republic Institute of Health Protection
Director, Health Inspection Department, Ministry of Health
Pediatrician from the Clinic for Children's Diseases

Department of Drug Control, Republic Institute for Health Protection:
Dr. Donka Nesova, Director
Other laboratory staff

Faculty of Pharmacy, Ss. Cyril and Methodius:
Prof. Ljubica Suturkova, Dean
Dr. Aleksandar Dimovski, Head of Institute of Pharmaceutical Chemistry

Ministry of Finance:
Mr. Ljubomir Jordanov, State Advisor, Legal and Administrative Affairs Department

Romania

WHO/Romania:
Dr. Victor Olsavszky, Liaison Officer

Ministry of Health:
Dr. Alexandru Rafila, Director, Department of Public Health
Dr. Daniela Pitigoi, former Manager of National Immunization Program
Dr. Adriana Pistol, Head of the Communicable Disease Surveillance Unit
Ms. Eugenia Erhan, Director, Budget Department

Institute of Public Health-Bucharest:
Mr. Octavian Mihalcea-Eliade, Director

Ministry of Finance:
Ms. Carmen Apostol, Deputy Director for Regulation of Public Procurement

National Medicines Agency:
Rodica Badescu, Vice President

Appendix 2: Detailed Cost Savings Analyses

Appendix 3. Data Collection Instruments for Country Visits