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INTERCOUNTRY MEETING ON VACCINE PROCUREMENT FOR SELF-PROCURING COUNTRIES (CENTRAL AND EASTERN EUROPE, TURKEY AND NIS)

Report on a WHO meeting

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ABSTRACT

During the past decade major progress in vaccine procurement has taken place in the countries of central and eastern Europe (CCEE), Turkey and the newly independent states (NIS) using bidding mechanisms opened up in the global market. However, because of changes in the market, the process has become more complex and countries need to adapt. It is in this context that the Intercountry Meeting on Vaccine Procurement for self-procuring countries was held. The main objective of the meeting was to provide participants with detailed information on vaccine procurement processes and to examine various procurement mechanisms to better respond to country needs. Participating countries shared information and experiences and reviewed the process of procurement and existing mechanisms in order to facilitate improvement in future procurement. Recommendations to countries included the adoption of procurement best practices and to study other procurement options in order to improve efficiency, quality and affordability of vaccines.

Keywords

VACCINES – supply and distribution – economics
IMMUNIZATION PROGRAMS
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Acronyms

AD syringe	Auto-Disable Syringe
AEFI	Adverse Event Following Immunization
BCG	Bacilli Calmet Guerin
CEE	Central and Eastern Europe
CVP/PATH	Children's Vaccine Programme at the Programme for Appropriate Technology for Health
DT	Diphtheria, Tetanus
DTaP	Diphtheria Tetanus acellular Pertussis
DTP	Diphtheria Tetanus Pertussis
EPI	Expanded Programme of Immunization
GAVI	Global Alliance for Vaccines and Immunization
GCC	Gulf Cooperation Council
GMP	Good Manufacturing Practices
Hep B	Hepatitis type B
Hib	Haemophilus Influenza type b
IPV	Inactivated Poliomyelitis Vaccine
MMR	Measles, Mumps, Rubella
NIS	Newly Independent States
NRA	National Regulatory Authority
OPV	Oral Poliomyelitis Vaccine
PAHO	Pan-American Health Organization
Td	Tetanus, diphtheria adult
TT	Tetanus Toxoid

Introduction

Most countries of central and eastern Europe, Turkey and the Newly Independent States (NIS), have succeeded this past decade in setting up their own vaccine procurement system, using bidding mechanisms opened to the global market. Consequently, major progress in securing the provision of vaccines to national immunization programmes has been noticed. The market is now changing with the appearance of more complex and expensive vaccines and lower availability on the global market of production of more traditional vaccines. Countries have to adapt to these changes and find ways to secure the provision of vaccines at an affordable price.

The Intercountry Meeting on Vaccine Procurement for Self-Procuring countries of the central and eastern Europe, Turkey and the Newly Independent States was held on 3–4 September 2002, in Copenhagen, Denmark. The meeting was jointly organized by the World Health Organization Regional Office for Europe and Headquarters, UNICEF Regional Office (Geneva) and Supply Division (Copenhagen) and the Children's Vaccine Programme from the Programme for Appropriate Technology for Health (CVP/PATH).

The aim of the meeting was to provide participants with detailed information on the vaccine procurement process and examine various procurement mechanisms including group (bulk) procurement, in order to better respond to countries' needs.

The main objectives of this meeting were as follows:

- to share information and country experiences in vaccine procurement;
- to review and discuss all components of the vaccine procurement process (vaccine requirement forecasting, budgeting and finance, organization, legal basis and infrastructure, quality assurance, procurement process, delivery, distribution, and cold chain);
- to review and discuss the various existing mechanisms of vaccines procurement with an emphasis on group procurement;
- to facilitate improvement in future procurement in participating countries through the development of plans for action.

Dr Gudjon Magnusson, Director a.i. of the Division of Technical Support 1, Reducing Disease Burden (RDB), WHO Regional Office for Europe, opened the meeting. He welcomed participants and partners on behalf of the WHO Regional Director and briefly reviewed the scope and purpose of the meeting. He underlined that this meeting will be the first in a series of important events to render the vaccine procurement process in Europe more efficient and to ensure the provision of ensured quality vaccines for national immunization programmes, including the newly introduced ones, in all European countries at an affordable price

Twenty-eight participants from 15 countries attended the meeting. The responsibility of chairing was shared between representatives from UNICEF, CVP/PATH and WHO. Dr Nikolai Chaika was the Rapporteur.

During several sessions of the first day, updated information on the best practices for vaccine procurement and how to ensure the quality of vaccines were presented by various experts from UNICEF and WHO and discussed with participants.

Immunization from the child's rights perspective

The perspective of child's rights through universal child immunization was presented by UNICEF Regional Office for CEE, CIS and the Baltic States (Geneva). Childhood immunization is morally and socially indispensable because it saves lives and reduces disabilities. It is one of the essential components of primary health care, one of the key interventions to reduce poverty; it reduces health care costs and increases productivity. Providing immunization is a moral responsibility, even an obligation, for governments, parents and for all caretakers.

The right of the child to be immunized has a legal basis incorporated in several international documents – the Universal Declaration of Human Rights, the European Social Charter, the WHO Constitution, the Declaration of Almaty and the Convention of the Right of the Child. Member States are internationally and publicly accountable for all aspects of child treatments including universal immunization against all vaccine-preventable infections.

The right of every child to be vaccinated is as basic as the right to life, survival and development. Immunizing children is not a matter of charity – any government has a responsibility to provide the vaccination as basic as the responsibility to defend the lives of its citizens. This responsibility was confirmed at the World Summit for Children, the Berlin Conference for Children in Europe, and at the United Nations Special Session on Children.

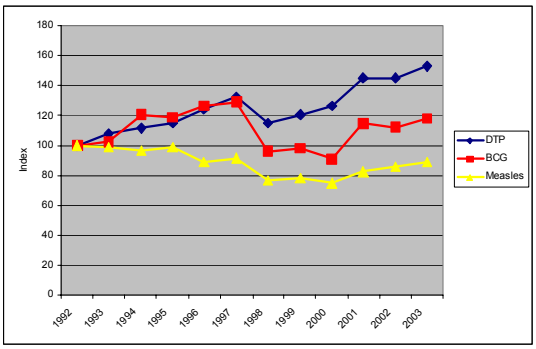
Sustainable vaccine supply is crucial for the implementation of quality immunization programmes and consequently, for the fulfilment of the basic right of every child to health, survival, and development. The realization of all these rights can be guaranteed by national authorities acting in good partnership with international organizations such as the World Health Organization, UNICEF, the Global Alliance for Vaccines and Immunization, and nongovernmental organizations such as CVP/PATH.

Overview of the procurement process and the market

At the subregional meeting of EPI national managers in Vienna (24–26 February 2002) WHO, UNICEF and CVP/PATH representatives already initiated discussions on optimization of vaccine supply to countries of central and eastern Europe. Among several procurement options – direct procurement, pooled procurement, the UNICEF procurement service and vaccine supply through the PAHO revolving fund – direct procurement might be costly while pooled procurement has to be properly managed to be efficient. UNICEF provides major support to countries in vaccine planning and management that is performed in close cooperation with many donors and governments. The value of UNICEF vaccine procurement has been rapidly increasing. In 2001 UNICEF successfully procured around 2.8 billion vaccine doses to more than 100 countries including the poorest countries of the world. EPI vaccines reach over 40% of the world's children through this service, however, it accounts for less than 8% of the global expenditures on vaccines.

The availability of traditional EPI vaccines has been reduced significantly in the last couple of years due to the withdrawal of few manufacturers and the concept of Vaccine Security – i.e. uninterrupted and sustainable supply of vaccine – is now high on UNICEF's agenda.

Vaccine price changes have evolved according to the market situation



In analysing the reasons behind the vaccine shortage, it is important to note that the vaccine market has changed dramatically during these past years. Manufacturers from industrialized countries are diverging intensively from the production of "traditional" vaccines to more complex ones with a larger profit margin. Consequently, there is a significant loss of production capacity related to traditional vaccines such as measles, TT, DTP whole cell pertussis, BCG, and OPV. Low-income countries continue to use these traditional vaccines while middle and high-income countries are progressively switching to combination vaccines such as measles-mumps-rubella (MMR), DTP-HepB, DTP-HepB-Hib vaccines and inactivated poliomyelitis vaccine (IPV). In 2002, 60% of countries from CEE and NIS are using MMR.

Because of the situation outlined above the present market situation is characterized by a great reduction in flexibility for UN purchase of pre-qualified vaccines. By 2001 the volume of vaccines offered by producers to UNICEF dropped as 8 out of 12 manufacturers stopped producing traditional EPI vaccines. At the same time, UNICEF demand for traditional vaccines stabilized in the 1990s with an increasing trend in the last couple of years. The vaccine volume produced is still sufficient to respond to the demand, but the choice of manufacturers has become limited. We can notice that purchase levels are up to 90% of quantities offered by manufacturers. Vaccine price has evolved in accordance with the market situation. After a decrease in the late 1990s, the present trend is in the increase.

The change in the vaccine market calls for a change in the procurement and planning behaviour. During the 1990s there was less focus on precise demand forecast among procurement entities, as there was a significant surplus of vaccines available at the international market. Because today the availability just equals the demand, precise planning is of highest importance to ensure availability when the vaccine is needed. In this respect it should be noted that the standard products procured today typically entered the production 6–12 months ago. If the demand increases and exceeds the production capacity, the construction of a new plant can easily take up to 2–3 years, while introduction of new products can take up to 5 years including regulatory approval.

Therefore, the changing market required a new approach with a shift from buyer/trader relations to strategic partnership in immunization (new guiding procurement principles, new forecasting approach, emphasis on vaccine management at country level, continuous learning/market research). The vaccine requirements forecast depends on programmatic targets including needs for routine and supplementary immunization. Consequently, UNICEF will have to work more closely with countries for better planning and sensitize donors for longer-term commitment.

Vaccine security is determined with several key elements: a) firm future contracting with the industry to ensure affordable vaccines; b) secured future funding; and c) accurate long-term forecasting of demand. The immediate focus of UNICEF is on the support to countries for capacity building in vaccine forecasting and vaccine management. In collaboration with UNICEF local offices, MOHs are requested to establish their requirements for three years. Training MOH staff on vaccine requirement forecasting will be conducted in the next future. In

addition, UNICEF is advocating longer pledges for vaccine funding to donors, which is the pre-condition for long term contracting with the industry.

Assurance of vaccine quality for procurement

In 2001 48 countries continued producing vaccines. Eighty-two countries relied on UN agencies (UNICEF, WHO) for the provision of their routine immunization vaccines and 61 countries practised self-procurement.

National immunization programmes have to achieve very high levels of child protection from infectious diseases. It can be guaranteed only with high vaccination coverage using high quality vaccines. Strong national regulatory authorities (NRA) are instituted to ensure the provision of high quality vaccines.

NRAs have a very important role in all steps of the procurement process – supporting product specification development, qualification of suppliers and their selection, receipt and release of vaccines, surveillance for safety and efficacy of routine and supplementary immunization, continuing quality assessment and resolution of all disputes. The process of regulatory oversight is not finished when a new vaccine is licensed; vaccines are biological products and they have to be released lot by lot.

WHO's goal is to ensure that 100% of vaccines used in all national immunization programmes are of assured quality. A standardized process was developed to help NRAs in taking this responsibility. NRAs should be absolutely independent and fully functional, fulfilling six essential regulatory functions. When the source of vaccine is any of the UN agencies, two of six general NRA functions are recommended – licensing of vaccine and surveillance for field performance including efficacy and safety. Procuring countries need to assure an additional two functions, lot release and access to a laboratory when appropriate. When the vaccine is produced in country all six functions should be performed (the four functions mentioned above plus GMP inspection and clinical evaluation).

WHO has developed an assessment tool to help NRAs in identifying gaps and developing plans to address these gaps. To ensure the building up of country capacity, WHO created the Global Training Network consisting of 13 training centres to provide relevant technical expertise and training. During the last four years assessments have been conducted in over 40 countries. Through this process, an additional 60 national experts have been trained in the assessment methodology. As of June 2002 vaccines of assured quality were available to 74% of children in 91% of 191 WHO Member States.

Among the countries from CEE and NIS, nine produce vaccines (Bulgaria, Croatia, Czech Republic, Hungary, Poland, Romania, Russian Federation and Turkey) and others have to import all of them. Many of these countries have had a formal NRA assessment. However, only four of the producing countries and none of the procuring countries has been found to have a fully functional NRA according to the relevant functions needs: Bulgaria, Hungary, Russian Federation, and Ukraine. Clearly more work is needed within the region to increase NRA performance.

Forecasting vaccine requirements

There are two models for vaccine requirement forecasting – historical and new "push and pull" model. The historical model uses data based on programme uptake or real consumption. With this model several biases are possible as a consequence of data incompleteness, inflation of wastage factor and some false assumptions (programme always supply vaccine in sufficient quantities, open vial policy is used uniformly). The second model uses estimated census population data plus a wastage factor. Nevertheless biases are also possible (inaccurate census data, inflated wastage factor, erroneous assumptions – (e.g. "health services can reach 100% of children"). Both models cannot account for special initiatives.

Other variables can influence the results of vaccine requirements forecasting. The most significant factors are as follows: vaccine boosters, special vaccination campaigns, local production of vaccines, competition from local vaccine providers and introduction of new combined vaccines. The analysis of estimated versus actual doses procured by the PAHO EPI Revolving Fund between 1996–2001 gave quite interesting results. The divergence between numbers of actual and estimated doses fluctuated from -40% to +80% for vaccines against poliomyelitis and from -50% to +100% for BCG vaccine. In small countries like El Salvador the difference between estimation and real procurement of vaccine dose can be much greater than in countries with large population size such as in Brazil.

To improve the forecasting in vaccine requirements good planning is critical. All potential factors should be taken into consideration: vaccine boosters, local production of vaccines, introduction of combined vaccines, competition from local vaccine providers and special vaccination campaigns (measles or measles/mumps, tetanus, poliomyelitis etc.).

Shipment and reception of vaccines

Requirements for the shipment of vaccines should be included in any tender or contract. All requirements (packaging, storage volume standards, labelling, standard shipping procedures etc.) have to be described in detail. Temperature ranges for heat-sensitive and freeze-sensitive vaccines are extremely important especially for international shipment. Manufactures should use appropriate monitoring devices and additional equipment. According to storage volume standards the volume of shipment correlates to number of vaccine doses. As to labelling special attention should be paid to the text (appropriate to destination country), indication of expiry date, thermo-sensitivity, and optimal storage temperature.

Direct routes are recommended for any biological products to avoid transshipments at airports. Special messages should be sent in advance: type of vaccine, quantity of vials and number of doses, number of cartons, gross weight and total value of the whole shipment, name of address, flight number, scheduled date and time of arrival, airway bill number and instructions for collection of vaccines.

During the reception of vaccines all related documents (original airway bill, copy of invoice, packing list, release certificate from NRA of producing country and vaccine arrival report) should be verified. Types and quantities of vials with vaccine and diluents as well as the state of cold chain monitors and vaccine vial monitors should be checked. The special "vaccine arrival report" consists of five parts: advance notice, flight details, details of shipment, documents, and cold chain monitors. All stages of vaccine shipment and reception are described in three WHO

guidelines: “Guidelines on the international packaging and shipping of vaccines”[1], “Ensuring the quality of vaccines at country level”[2] and “Equipment performance specifications and test procedures”.[3]

Vaccines prices and factors

During last five years the number of countries using hepatitis B and Hib vaccines (mono- or in combination with other antigens) in their national immunization system has increased greatly, much of it related to use of combine vaccines. These vaccines, when introduced into low-income countries, are generally financed through the GAVI Vaccine Fund. Middle income countries, in contrast, may pay higher prices. At the same time there is no strict correlation between the wealth of the country and the price they pay for hepatitis B and Hib vaccines. Sometimes immunization programmes with limited resources (Ukraine, Uzbekistan) pay bigger prices in comparison with wealthy countries (Malta, Slovakia, Slovenia).

Vaccines Dose Price Variation among 15 countries from CEE, NIS and Turkey

Vaccines	Price per dose US $	
	min	max
TT	0.033	0.357
BCG	0.034	1.326
Td	0.046	0.754
HEP B	0.57	11.75
DTP	0.06	3.208
DT	0.08	2.134
OPV	0.082	0.333
Measles	0.102	3.68
MMR	2.367	10.24

There are several factors influencing the price of vaccines: product specification, number of producers, size of the market (at the same time there are small countries that receive vaccines at lower price), number of shipments (more shipments – higher the price), shipping distance, timeline for delivery (“last minute” ordering increases vaccine price), currency of payment (less significant factor during last three years), special labeling and packaging, additional handling requirements and risks (for example, great delays in money transfers after preceding shipments). Other factors influence the final cost of vaccines (shipping, insurance, inspection, testing, custom duties, clearance fees, procurement agent fees, handling fees, licensing and quality control costs, research and development, marketing and other). As a result sometimes production costs are not the main part of vaccine costs. Nevertheless it is true that prices for newer vaccines (acellular pertussis, Hib, varicella, pneumococcal) are 10–50 times higher than prices for the traditional vaccines (DTP, OPV).

However, analysis of price and uptake data of hep B and Hib vaccines among middle income countries in the European Region indicate that price is not the major factor influencing the decision to add one of these vaccines to the immunization programme.

Vaccine procurement assessments

Purchasing vaccines is different from other purchasing because vaccines are biological products. They carry a risk to recipients and can even become a danger for children if they are not stored and handled in a correct manner. The number of pre-qualified vaccine manufacturers is limited but vaccines procured by UNICEF are all pre-qualified by WHO.

[1] Ref. WHO/V&B/01.05
[2] Ref. To be released in the near future
[3] Ref. WHO/EPI/LHIS/97.03

Assessments of vaccine procurement must take into account a number of important factors as follows:

1. The implementation of the critical functions of the NRA is essential to ensure the correctness of vaccine specifications and to control the quality of imported vaccines.
2. Procedures for dealing with adverse events following immunization (AEFI) must be established.
3. Forecasting of future demands and provision of sufficient quantity of vaccine avoiding shortages and programme disruptions.
4. Process of tendering and selection of suppliers have to be stated in advance and reinforced. The vaccine specifications used in the bid documents and the purchase orders must be complete and contain all information necessary to correctly identify the vaccine.
5. The government budget should contain a specific line for vaccine procurement as part of immunization within the overall health budget. Payment mechanisms have to be agreed upon between government and supplier.
6. Ensuring the maintaining of the vaccine quality from arrival in country to the point of use is critical. The checking and recording of vaccine quality all along the chain, including the use of the vaccine arrival report, is of most importance to identify eventual defects of a vaccine or exclude the vaccine as the cause of an adverse event.

Official government purchasing systems are often inflexible and do not distinguish between vaccines and other pharmaceuticals – such practices should be changed to recognize vaccines as unique biological products. National regulatory authorities should establish quality requirements in advance and time-temperature monitors (Vaccine Vial Monitors, when available) should always be required. In addition, a system of lot release should exist and the whole set of specifications should be used for all components – vaccine, vial sizes, packaging, labelling etc. Vaccine arrival reports should be used and records should be maintained by the Ministry of Health at all levels. To have better pricing it might be necessary to use or to establish a multi-country group for the bidding and procurement process.

Vaccine self-procurement

Self-procurement is the direct purchasing of vaccines from the manufacturer or the manufacturer's legal representative. Self-procurement is performed usually through a competitive process such as requested quotations or tender. This method of procurement requires specialized knowledge and specialized approach, well-trained and committed personnel, good infrastructure, appropriate legislation, and sufficient financial resources.

The vaccine procurement process includes many preliminary and subsequent time-consuming and important stages. Countries that do not self-procure vaccines, but sue a procurement agent or other procurement option, are still responsible for implementing the majority of these procurement process stages, such as forecasting, budgeting and financing, pre-qualification and licensing, preparation of specifications, customs clearance, inland transportation, warehousing and distribution to local levels. These activities must be completed by the country regardless of the procurement method being used. Countries that self-procure vaccines, however, must perform the following additional procurement activities: preparation of bidding documents and realisation of the tender, selection of supplier, signing of the contract, financial arrangements and contract monitoring.

For qualified organizations self-procurement has some definite advantages:

- no lump-sum payment to procurement agent or service fees;
- letter of credit can be used instead of cash in advance;
- more flexible procurement and delivery schedules;
- independent selection of supplier;
- individual selection of vial size, packaging, labelling and packing requirements;
- individual selection of shipping mode and route of shipment;
- possibility of pre-shipment inspection and monitoring;
- better access to quality assurance documents;
- direct notification of pending shipments.

Moreover the self-procurement system produces different side benefits:

- builds or enhances procurement and management capacity;
- develops skills transferable to other goods;
- establishes relationships with manufacturers or manufacturer's legal representative;
- builds partnership between procurement entity and NRA.

Self-procurement incurs additional costs to train staff involved in procurement. It requires investment on an infrastructure to support a procurement cell and entail foreign currency exchange. It does not necessarily prevent improper practices.

At the same time, price and quality of vaccines do not correlate with the method of procurement. Under some conditions, for example when a country has large quantity requirements and a strong National Regulatory Authority (NRA), self-procurement can obtain good quality vaccine at competitive prices. Under different conditions, for example low quantity requirements and a weak NRA, other procurement options may offer more benefits.

Country experiences in vaccine procurement

Latvia

Latvia with a population of around 2.4 million people spends €1 million annually for vaccine procurement. Immunization is supported with ten legislative acts (epidemiological safety, state immunization programme, registration of vaccines, safe storage, monitoring of AEFI etc). Levels of vaccination coverage are very high in Latvia (Hib3 – 83.7%, HepB3 – 96.1%, DTP3 – 97.2%, Polio3 – 97.3%, MMR – 97.9%, BCG – 99.9%). The National Immunization Programme had the opportunity to shift from monovalent to polyvalent vaccines as well as introduce acellular pertussis vaccine.

The vaccine procurement process includes forecasting and planning (May), evaluation (June), confirmation (July–August), organization of tender and contract signing (September–December), vaccine delivery (January–September), distribution and immunization (during the whole year), and ordering/reporting and monitoring (monthly). The size of the vaccine stockpile depends on

the level: public health institutions – for one month, regional level – for one or two months, and national level – for three months. Recent changes in the vaccine procurement system include the separation of vaccine purchases from vaccine preventable diseases surveillance department, licensing of national and local stocks

Recently a team of WHO experts[4] reviewed the vaccine procurement system in Latvia and made the following conclusions:

- the government has a high level, longstanding commitment to the State Immunization Programme;
- the budget covers 100% of the country's vaccine needs for the public health use including new vaccines (Hib, HepB, IPV, DTaP);
- all national immunization programme vaccines procured by MOH come from sources of assured quality;
- a mandatory licensing and registration process is in place for all vaccines procured for public and private markets;
- there is a well conceived legislation with regard to the public procurement process;
- standard operating procedures and written guidelines are in place for most facets of the vaccine procurement and distribution system;
- a well established documentation system for the receipt and distribution of vaccines was developed and maintained at central and peripheral levels;
- special attention is paid to the cold chain;
- the surveillance system was refined and put in place (including publication of guidelines) to monitor cases of AEFI.

However, the Ministry of Health recognizes that this system could be improved through the institution of a lot release procedure and extending the list of registered vaccines as at present competition is very limited.

Slovenia

All stages of vaccine procurement are regulated by several legislative acts (laws on health, on communicable diseases, on drugs; orders and guidelines of the ministry of public health). Vaccine procurement is realized with the participation of different state institutions: government and Parliament – laws and by-laws; Ministry of Health – registration of vaccines and permission for import; National Institute for Public Health – planning, vaccine import, central storage, distribution to lower levels, immunization register, register of AEFI; Institute of Pharmacy and Drug Research – state quality control. All activities are coordinated by the National Interagency Coordinating Committee and supervised by the National Regulatory Authority.

Quality standards are secured by purchasing from assured sources, use of WHO pre-qualified vaccines, control of relevant documentation, and control vaccine testing. Intensive training of medical and public health personnel on all aspects of rational and safe vaccine use (cold chain, good storage practice, immunization safety, AEFI surveillance, safe waste disposal) is also of

[4] Susan MacKinney, 2001

great importance. Combined vaccines and suitable forms (pre-filled syringes) became more popular in Slovenia during the last years.

Ukraine

High commitment to the immunization programme in Ukraine fostered a stable and high coverage (over 95%) of target groups with the main EPI vaccines. The introduction of HepB is underway with the support of the GAVI vaccine fund.

There are two special laws related to vaccine use in Ukraine – "Assurance of Sanitary and Epidemic Safety of the Population" (article 27) and "Control of Infectious Diseases" (article 12). Routine immunization of children is mandatory and free of charge; over US $4 million were allocated by the state budget for vaccine purchase in 2001.

Ukraine now has a centralized procurement system. The Ministry of Health procures vaccines via a special Department for State Purchase, which supervises all stages of vaccine supply to the country. The overview of the process is ensured by the "State Department for Drug Quality, Safety and Production Control". This entity has the responsibility to register the vaccines to be used in Ukraine. The selection of the supplier is decided upon a scoring system, which gives a high priority on the price. Ukravaccina, a State enterprise, is responsible for the purchasing, storage and distribution to oblasts.

Only diphtheria vaccine is produced in Ukraine, all other vaccines are procured abroad. The main producers of vaccines for the Ukrainian national immunization programme are Aventis Pasteur, Glaxo SmithKline and several Russian, Cuban and Korean companies.

Forecasting and ordering vaccine supply is based on pre-established wastage factors (3.0 for BCG vaccine and 1.3 for all other vaccines). The newly instituted management information system will allow a better estimation of vaccine wastage.

Major efforts are made to render the cold chain as effective as possible to secure safe transportation and storage of vaccine from the national to immunization sites.

In summary, the re-centralization of the procurement system in Ukraine is a major achievement in securing the provision of vaccines. This system needs to be reviewed for more flexibility and increased efficiency.

Self-assessment of vaccine procurement in 15 countries

A specific questionnaire was sent to 15 participating countries – Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Kazakhstan, Latvia, Lithuania, Romania, Slovakia, Slovenia, The former Yugoslav Republic of Macedonia, Turkey, Ukraine and Yugoslavia. Local production of some vaccines (BCG, DTP, DT, TT) is performed in seven countries for local use and to a lesser extent for export. Other vaccines in these countries and all vaccines in eight other countries are purchased in France, United States, Denmark and the Russian Federation. The choice of the source of vaccines was limited for some countries because of prices, quality and specifications.

Most countries (11 of 15) forecast vaccine requirements for at least three years. Nevertheless one in three countries experienced vaccine shortages during the last two years. Stock records were a

problem in only two countries. National Immunization Programmes in five countries consider the government funding for vaccine procurement as inadequate. Public procurement procedures are subject to legislation in 14 of 15 countries, but barriers to international commerce exist in three countries. Due to economic constraints in these three countries, the importation of external goods is restricted by law. Letters of credit and hard currency were not identified as a problem in any of the countries.

Vaccine quality is guaranteed by the NRA in 13 of 15 countries, and seven NRAs were assessed during last two years. Thirteen countries do procurement on the basis of a list of pre-qualified vaccines and 14 of 15 countries have assured sources of vaccines, according to the information provided in response to the questionnaire. Almost all (14 of 15) countries include quality standards and assurance in their technical specifications.

The procurement process is based on written policy and procedures, and competitive procurement with bid evaluation is used in 14 of 15 countries. Thirteen countries include terms for packaging, labelling, handling and shipping in their contracts, and contracts in 11 countries include terms for the quality assurance provision. As to vaccine delivery two third of countries perform systematic inspection at entry and use vaccine arrival reports. Cold chain monitors are routinely used in 11 countries.

Major problems and issues perceived by programme managers and related to the procurement procedures stated in the questionnaire were as follows:

- procurement process not always transparent, human resources not adequate, and non-perfect selection of vaccines – 11 countries;
- high prices – 8 countries;
- inconsistent or incorrect use of temperature monitors – 7 countries;
- delivery time and quantity – 4 countries;
- inadequate budget and financing – 3 countries.

Group procurement options

Country self-procurement has been the traditional method of vaccine supply to national immunization programmes during many decades. However several other possible mechanisms of coordinated (group) vaccine procurement were used by countries in different WHO regions.

UNICEF Procurement Services

UNICEF is dedicated to the protection of children's rights by helping meet their basic needs and expanding their opportunities so they can reach their full potential. Access to essential supplies is a fundamental part of a child's rights.

Through Procurement Services UNICEF leverages additional resources for children by using its global expertise and operations to purchase strategic supplies on behalf of partners. The main principle is that any project should be consistent with UNICEF’s national and international programme priorities. UNICEF through Procurement Services acts as a procurement agent for other partners, including governments, nongovernmental organizations, other United Nations

agencies and international funding agencies. UNICEF does not procure for individuals or for profit-making entities.

The standard process in UNICEF Procurement Services includes the signing of a memorandum of understanding, issuance of cost estimate (including pricing, quantity and delivery details) for the specific supplies, depositing of funds to UNICEF (prior to procurement) and proceeding with procurement according to agreement. All charges taken by UNICEF are not for profit but on a cost recovery basis only (6–8% handling fee, freight and insurance at cost price); 10% buffer deposit is required until completion of transaction.

Vaccines procured through Procurement Services are subject to the same quality standards as the normal UNICEF tender-based procurement for humanitarian services, including WHO pre-qualification of vaccines, meeting established WHO standards for transportation and shipment, and support for post-marketing surveillance by WHO. Longer-term agreements ensure uninterrupted supply and facilitate budgeting. Vaccine arrival reports are routinely used as feedback system for elimination of any possible irregularity in deliveries.

Engaging the mechanism of UNICEF Procurement Services for vaccine supply can allow governments to move stepwise. For example, while ensuring uninterrupted quality vaccine supply through Procurement Services, governments can build capacity and implement systems such as creating budget line for immunization supplies, building NRA capacity for licensing of vaccines, building procurement capacity. UNICEF Procurement Services can gradually replace self-procurement not compromising vaccine security in the transition phase.

In conclusion, UNICEF Procurement Services is one of several procurement mechanisms that could be considered. Advantages and disadvantages for the use of UNICEF Procurement Services and self-procurement vary within each country situation and should be closely evaluated on a case-by-case basis. Although UNICEF's intent is to work with developing countries, it will openly consider all country proposals and suggestions.

PAHO Revolving Fund

The Directing Council of the Pan-American Health Organization (PAHO) established the Revolving Fund in 1977. It capitalized US $1 million in 1978 and began operations in 1979 with 19 countries and with a total of US $2.6 million in orders placed. The first contracts included DPT, TT, OPV, measles and BCG vaccines plus syringes. After 12 years the capitalization approached US $16 million and 34 countries placed a total of US $110 million in vaccine orders. Eleven vaccines (DTP, TT, DT, Td, BCG, OPV, measles, MMR, hepatitis B, Hib and pentavalent DTP/HepB/Hib) and syringes were on contract.

The PAHO Revolving Fund does not buy or sell vaccines – it procures vaccines for governments via defined procurement arrangements between vaccine suppliers and purchasers. The Fund offers bids of separate countries to pre-qualified suppliers only and selects two suppliers for each vial size to keep options for supplementary emergency orders. The Fund enhances the Pan-American approach and establishes the annual vaccine contracts on behalf of the member governments. Depending on the country situation the Fund allows the use of local currency in certain circumstances. The Fund provides countries with a continuous source of funds for ordering vaccines and syringes, helps to avoid interruptions in supplies and thus maintain immunization programme activities.

All countries have to accept the conditions of the Fund:

- standardized selection of basic products including labelling, vial size and packaging;
- standardized planning to providing estimates of required vaccines using PAHO Form 173, responding to PAHO confirmation fax, pre-fixed ordering and delivery dates;
- selected suppliers pre-qualified by WHO;
- established contracts with suppliers based on price, history of contract performance, terms of delivery, estimated freight costs, presentation and price for each vaccine for a one year period for all members;
- developed financial guidelines with invoice payment within 60 days, loss of right to place orders if there are outstanding invoices, and payment of 3% administration service charge.

The ordering cycle starts in August when all participating members present their yearly requirements for the following year; these national orders are consolidated by PAHO for bulk purchase and tenders are solicited in September. Bids are opened in October and contracts are established for the following year. Orders are placed for delivery during the last month of each quarter (December, March, June and September).

The financial cycle includes preparation of invoices for each country and their dispatching after the vaccine has arrived. Each country has 60 days to repay the Fund. The 3% capitalization fee is added to cover losses for currency exchange and the cost of lost vaccine shipments. This fund is kept in a reserve account and excesses over US $100 000 are transferred to the working capital.

Due to consolidated requirements, quality vaccines at lower prices are obtained and (one of key principles) a single price for each vaccine and vial size for a one-year period for all members could be guaranteed. Hence, prices were kept quite stable during many years or increased very slowly. For example the cost of BCG vaccine, ten doses in a vial, fluctuated from seven to twelve cents per dose but the overall increase during ten years was 10% only from ten to eleven cents. During five years the cost of pentavalent vaccine increased from US $3.5 in 1998 to US $3.65 in 2002. The immunization coverage in the Americas increased from 30% of all newborns in 1988 to 91% in 2002, and in Latin America from 34% to 89% respectively. Low prices allowed the introduction of Hib vaccine (1.5–3.2 times lower when compared to prices of the same vaccine acquired by countries outside the revolving fund) in almost all countries of the WHO Region of the Americas. The same comparison between revolving fund and country direct procurement with DTP and OPV correspond to a cost savings of more than 300% for DTP and 450% for OPV.

In conclusion, the benefits for countries procuring vaccines though the PAHO Revolving Fund and vaccine producers can be summarized as follows:

- reduced cost of vaccines;
- stability of prices provided over years;
- possibility to use local currencies;
- better scheduling of vaccines production by suppliers;
- obtaining requirements in orderly and continuous manner;
- use of vaccines pre-qualified by WHO and approved by PAHO;

- possibility for urgent vaccine orders on short notice;
- affordability for introduction of new vaccines at a common low price.

The bulk purchasing system in GCC states

The Gulf Cooperation Council unites 25 million people in six countries – Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and United Arab Emirates. The Gulf Cooperation Council is a cooperation organ in different domains including health. The GCC executive office for health ministers has many functions including procurement of safe and efficient pharmaceutical products and vaccines. This office has an executive board with an executive director, a full-time Secretariat permanently based in Riyadh, Saudi Arabia, technical departments and committees. The personnel of the office prepares technical and administrative documents for tenders, communicates with bidders and ministries of health, and performs the bulk purchasing of vaccines and drugs.

The system for bulk purchasing started in 1978 with one tender for 32 products for a total value of US $1.1 million and nine selected suppliers. This system has several objectives:

- securing financial surplus through purchasing large amounts for a smaller price;
- qualifying companies that follow Good Manufacturing Practices;
- ensuring use of the same drugs manufactured by the same company by all GCC states;
- rapid processing and awarding of presented tenders;
- ensuring a continuously flowing supply of drugs and vaccines;
- encouraging other health sectors to secure their needs through group purchasing;
- supporting the local industry.

The tender procedure is organized by the special committee composed of two representatives of the pharmaceutical sector and a delegate of the executive bureau. The committee has a president on a rotational basis and meets at all three decisive stages of the tendering process – the preparation of the tender, the opening of the tender, and the tender award. The GCC only invites registered suppliers to the tender and supplied vaccines should be registered in at least two of six countries of GCC. Ten samples are generally required to accompany the submitted bids – one sample for each of the six Member States, two samples for the award meeting and two samples for the reference archives.

The Secretariat makes a list of tender awards, including costing, of the previous year available for Ministries of Health in order to allow countries to make estimations of budget and to prepare their requisitions. On the basis of the compiled data the complete tender document is then prepared by the Secretariat and is sold to pre-qualified supplies. The tender is opened, Secretariat reviews records and makes corrections, and the committee takes decision on the award. Countries will have four weeks to confirm or to reconsider their initial requirements included in the tender. The quantities may be increased or decreased before the signing of the supply contract and variations up to 20% can be authorized after the contract is signed.

The contract is conducted directly between the individual country and selected supplier. A bid security of 1% of the submission value is required from participants of the tender and 5% of the contract value is required from the selected suppliers. The Secretariat collects 0.5% of the total

awarded items as fee for each state to support Medical Research Fund. When the Executive Office announces the results of bidding all companies can submit their complaints within two weeks and final decisions will be taken by the Committee.

The main positive results of the vaccine bulk tendering system in GCC states are cost reduction, high quality of vaccines, information sharing, enhancement of purchase operations, ensuring the use of the same vaccines in all GCC states. The tender of year 2001 included 43 vaccines and sera from eight producers for the total cost of US $19.5 million.

* * *

After all presentations the participants were divided into three working groups (Group 1 – Belarus, Bulgaria, Russian Federation, The former Yugoslav Republic of Macedonia and Ukraine; Group 2 – Estonia, Hungary, Latvia, Lithuania and Slovakia; Group 3 – Croatia, Romania, Slovenia, Turkey, and Yugoslavia) for detailed discussion on optimal mechanisms for group procurement in this WHO Region, major country priorities and possible obstacles during the implementation of different forms of group procurement in Europe. During the group work recommendations for countries and expectations for WHO and UNICEF were formulated. At the plenary session participants of the meeting approved the list of conclusions and recommendations.

Conclusions and recommendations

Conclusions

These past years, major progress has been noticed in securing the provision of vaccines to national programmes of the 15 countries represented in the meeting. However, countries are now facing some new challenges due to the changes of the market situation. Self-assessments as well as assessments conducted by external experts have highlighted some of these issues. The various presentations gave countries the opportunity to explore some alternatives to be considered for the strengthening of their procurement system. The experience of group procurement through three different mechanisms was shared with participants. It led to the conclusion that group procurement would be beneficial to several countries in the region in improving the efficiency of their procurement system. This meeting was a first step towards the concretisation of such a new approach to the procurement of vaccines.

Recommendations

Countries are recommended to:

1. Inform national health authorities on the results of the meeting on vaccine procurement in the context of National Immunization Programmes, and to provide feedback to the WHO Regional Office for Europe on possible approaches for group vaccine procurement in the future.
2. Discuss at the highest possible governmental level the possibility to separate vaccine procurement from procurement of other goods and to initiate the revision of their legislation accordingly.

3. The department of finance or equivalent should set separate budget line for procurement of vaccines distinct from other essential drugs and biological substances.
4. Secure complete and stable financing for vaccines from the national budget and/or external donors in order to ensure a smooth procurement process in the framework of National Immunization Programmes. This includes instituting a long-term requirements forecasting.
5. Assess the national process of vaccine procurement and analyse it against the recommended best practices. Examine the various possibilities to optimise its efficiency.
6. Weigh up other vaccine procurement options that would maximize the provision of vaccines in sufficient quantity and of assured quality at an affordable price. If relevant, consider the possibility of joining a system for vaccine group procurement – especially for countries with limited population size, implying a small volume of vaccines to be purchased.
7. Revise tender procedures for vaccine procurement if these do not comply with WHO recommendations.
8. Analyse the role of local distributors against vaccine price practiced as well as the regularity of the deliveries.
9. Assess the perspectives of group procurement for implementation of new vaccines and replacement of monovalent antigens with combined vaccines in the routine immunization programme.
10. Introduce auto-disable syringes and safe disposal boxes to ensure safe administration and collection.
11. Review and assess the cold chain system and maintain regular inventories to identify requirements at different levels.

Partners (WHO, UNICEF, CVP/PATH) in coordination and close collaboration are expected to:

1. Upon request by Ministries of Health, provide technical, organizational and methodological support on aspects related to vaccine procurement to countries in the region, including assistance for training implementation.
2. Provide technical support for improvement of tender and bidding process in relation to vaccines specifications for routine child immunization.
3. Assist countries in establishing communications with vaccine producers and suppliers.
4. Upon request, perform detailed analysis of vaccine procurement systems in countries of central and eastern Europe in the context of their National Immunization Programmes paying special attention to countries most in need and give country-specific recommendations to health ministries for improving procurement systems efficiency.
5. Develop and distribute a clear and detailed description of the bulk tendering process that can be suitable to several countries in obtaining high quality vaccines at an affordable price.
6. Upon request, assist countries in establishing specific budget lines for vaccine procurement.

7. Organize a special meeting on group vaccine procurement for managers of National Immunization Programmes and deputy-ministers of Health Ministries for countries of central and eastern Europe in the second half of 2003.

8. Intensify communications between WHO Regional Office for Europe and governments and Health Ministries of Member States to obtain stronger political commitment for improvement of immunization programmes and vaccine procurement.

9. Actively influence governments and Health Ministries to secure sufficient budget for vaccines and implementation of full-scale National Immunization Programmes.

10. Supply countries with the results of cost-effectiveness assessments of new and combined vaccines.

11. Continue assisting countries in strengthening their National Regulatory Authorities through performing detailed assessments of their functions, and involvement in the global training network.

12. Address requests for emergency vaccine orders in some specific situations and conditions.

13. Maintain the efforts in conducting comprehensive assessments of the safety of immunization including, cold chain, logistics and safety of injections.

Annex 1

PROGRAMME OF THE MEETING

Tuesday, 3 September – Information on Vaccine Procurement

09.00–09.30 **Opening Session**
Welcome remarks – *Dr Gudjon Magnusson*, *WHO Regional Office for Europe*
Nomination of chairperson and Rapporteur
Adoption of agenda and programme

09.30–09.50 **Immunization from the Child's Rights Perspective**
Dr Dragoslav Popovic, UNICEF, Geneva

09.50–10.10 **Overview of the Procurement Process and the Market**
Mr Thomas Sorensen, UNICEF, Supply Division, Copenhagen

10.10–10.30 **Assurance of Vaccine Quality for Procurement**
Dr Julie Milstien, WHO Headquarters

10.30–11.00 Coffee break

11.00–11.20 **Forecasting Vaccine Requirements**
Mr Peter Carrasco, WHO-PAHO

11.20–11.40 **Shipment and Reception of Vaccine**
Mr Denis Maire, WHO Regional Office for Europe

11.40–12.00 **Price Spread and Its Determinants**
Dr Julie Milstien, WHO Headquarters

12.00–12.30 **Discussion**

12.30–13.30 Lunch break

13.30–13.50 **Vaccine Procurement Assessments**
Mr David Halliday, WHO Consultant

13.50–15.30 **Reports from Countries on Activities/Accomplishments on Issues in the above Five Areas**
Latvia, Slovenia, Ukraine

15.30–16.00 Coffee break

16.00-16.20 **Summary of Status and Issues from Country Self-Assessment Forms**
Mr Denis Maire, WHO Regional Office for Europe

16.20–17.30 **Discussion**

Wednesday, 4 September – Procurement options

08.30–09.00	**Countries' Self-Procurement** *Dr Todd Dickens, PATH, Seattle*
09.00–09.30	**UNICEF Procurement Services** *Mr Thomas Sorensen, UNICEF, Supply Division, Copenhagen*
09.30–10.00	**PAHO Revolving Fund** *Mr Peter Carrasco, WHO–PAHO*
10.00–10.30	**Discussion**
10.30–11.00	Coffee break
11.00–11.20	**Gulf Cooperation Council** *Dr Saleh Bawazir, Ministry of Health, Saudi Arabia*
11.20–11.40	**Discussion**
11.40–12.00	**Financing Mechanisms** *Chairperson and facilitators*
12.00–12.30	**Group Work**
12.30–13.30	Lunch break
13.30–15.30	**Group Work** *Chairperson and facilitators*
15.30–16.00	Coffee break
16.00–17.00	**Panel Discussion** *Chairperson and facilitators*
17.00–17.15	**Closing Remarks** *Chairperson*

Annex 2

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