

Draft
Concept on Pooling of Procurement of Pharmaceuticals and Vaccines

1. At the 1st Session of the Islamic Conference of Health Ministers (Kuala Lumpur, Malaysia, 12-15 June 2007) Member States solemnly committed to expand national immunization services to reach all unvaccinated children with life-saving vaccines of assured quality that will significantly contribute towards MDG4. They considered being self reliant and self sufficient in their immunization programmes by ensuring the reliable supply of good quality, safe, effective and affordable vaccines.
2. The 2nd Session of the Islamic Conference of Health Ministers (Tehran, Islamic Republic of Iran, 1-4 March 2009), adopted resolution No. 4/2-ICHM on Combating communicable Diseases, which, inter alia, encouraged the OIC Member States to cooperate in making available adequate supply of vaccines, diagnostics and medicine through joint research and production to support immunization programmes in the spirit of Islamic Ummah solidarity and dignity to achieve self-sufficiency among Member States.
3. Resolution No. 3/3-ICHM on Self-Reliance in Production of Medicines and Vaccines adopted by the 3rd Session of the Islamic Conference of Health Ministers (Astana, Republic of Kazakhstan, 29th September – 1st October, 2011) inter alia invited the OIC Member States to take additional measures to develop national pharmaceutical industries to ensure adequate supply of essential medicines and vaccines; and encouraged the OIC Member States to further collaborate to ensure self-reliance in the provision of essential medicines and scaling up production of pharmaceuticals including vaccines;

Pooled procurement / joint purchase pharmaceuticals and vaccines:

4. In line with the priority of self-reliance and self-sufficiency in pharmaceuticals and vaccines, identified by the successive Islamic Conferences of Health Ministers, one Thematic Area of the OIC Strategic Health Programme of Action (Thematic Area 4) is devoted to 'Medicines, Vaccines and Medical Technologies'.
5. In order to move towards the objective of self-reliance and self-sufficiency, one of the proposed actions in the implementation of Thematic Area 4 on 'Medicines, Vaccines and Medical Technologies' is the development of regional policy and operational plan for regional pooled procurement/joint purchase of pharmaceuticals and vaccines.
6. Pooled Procurement of Pharmaceuticals and Vaccines could be part of efforts to address issues of accessibility and availability of essential medicines.
7. Pooled procurement, otherwise known as joint purchasing, is increasingly being regarded globally as an efficient strategy to resolve challenges as high pharmaceuticals and vaccines prices, poor quality and other bottlenecks generally associated with Procurement and Supply Chains of Essential Medicines. A number of sub-regional and regional blocs

as well as global initiatives have adopted the pooled procurement mechanisms with success stories to share.

8. The Gulf Cooperation Council (GCC), which is carrying out pooled procurement for about three decades reported that it had reduced costs and made millions of dollars in savings, whilst the East Caribbean Islands reported an average cost savings of 37% for 25 selected items over a five year period. Other successful pooled procurement initiatives, including the WHO Pan American Health Organization (PAHO) Strategic Funds and the WHO Global Drug Facility for TB medicines, have shown significant achievements in lowering medicines prices, improving procurement process and quality of medicines
9. The Organization of Eastern Caribbean States (OECS) has a Pharmaceutical Procurement Service based in the OECS Secretariat that has a centralized tendering and procurement system based on a drug revolving fund for the public sector of its nine member countries. It was established with a USAID grant in 1986 and is financed by members' contributions. The service procures approximately 700 items, 70% of them pharmaceuticals, representing an estimated 80% of the member countries' public sector needs. Between 1997 and 2006, the value of annual purchases increased by more than 100%. The average cost savings for 25 selected items over a five-year period (1998-2002) were reported to be 37%. The OECS system has increased bargaining power, enhanced quality control and led to sharing of information and experiences and measurable increased access to medicines.²

Pooled Procurement Models

10. The WHO has described four different procurement models which form a continuum of increasing cooperation in the procurement process. These are:
 - a. ***Informed buying***: defined as information sharing, in which purchasers or countries share information on prices and suppliers but procurement is done individually;
 - b. ***Coordinated informed buying***: is also defined as information sharing, whereby purchasers or countries conduct joint market research, share information on supplier performance and prices, but procurement is done individually;
 - c. ***Group contracting***: member countries negotiate prices collectively and select suppliers based on the agreement that procurement will be from the selected suppliers, while the actual purchase can be conducted individually;
 - d. ***Central contracting and procurement***: this generally involves a central buying unit established by the member countries to act as their procurement agent in the tendering and award of contracts.
11. The Group Contracting and Central Contracting are similar as they both involve bulk purchasing of pharmaceuticals and vaccines on behalf of a group or countries, with the

main difference being the level of collaboration and integration, the administrative infrastructure required to implement the pooled procurement and therefore the technical and financial resources needed. Thus in Group Contracting countries jointly negotiate prices and agree to purchase through the selected suppliers, but the various member countries conduct the purchasing individually. With Central Contracting, Member countries jointly conduct tenders and award contracts through a centralized procurement unit, which pools the financial resources from the member countries. Apart from reducing cost of pharmaceuticals and vaccines and contributing to a more cost efficient and transparent procurement system, pooled procurement also facilitates harmonization of standard treatment guidelines, medicines registrations and essential medicines lists.

Benefits and challenges of pooled procurement

12. Both price and non-price benefits have been identified in existing pooled procurement initiatives. Price benefits result not only from economies of scale but also from reduced administrative costs (such as market research) and the sharing of information on prices paid by other procurement agencies and on reference prices. Lower prices can also be made possible by more stable supply arrangements that reduce variance in demand.
13. The likelihood that at least some OIC member states are procuring the same pharmaceuticals at times – even from the same manufacturers – creates the opportunity for those member states to cooperate in order to obtain lower prices for greater volumes.
14. Some small size OIC member states, coupled with the large size of others, makes it likely that greater volumes could be achieved through pooling. However, greater volumes require participation of large countries on a regular basis and incentives are required to ensure the participation of at least some of them, as they can negotiate price reductions on their own. At the same time, greater volumes do not require the participation of all OIC member states.
15. The number and diversity of OIC member states also militate against any approach that would subject an initiative to mandatory participation by all member states. Price benefits also arise from the opportunity to create a more cost-efficient and transparent system of purchasing as well as to reduce administrative costs due to shared price information.
16. Some higher costs are caused by poor supplier performance or anti-competitive collusive behaviour which can also be addressed through information-sharing. However, there will be no reduction in administrative costs caused by national capacity constraints until there is political will to move toward centralized contracting.
17. Information-sharing mechanisms can not only gather information but also generate systematic methods of assessing prices or developing reference prices to permit comparisons and evaluate savings. For example, they can collate data on previous local tender prices and specific regional or international benchmarks.

18. Participants could also devise key division-wide performance indicators to monitor various stages of the supply chain and set targets for each, gradually raising them. For example, they could set target percentages for rapid response orders shipped within 48 hours of sales order release, international procurement orders delivered at port of entry at or within agreed upon time; international supplier deliveries on time; shipments inspected upon arrival. They could also develop lists of approved suppliers and harmonize bidding documents and evaluation of tenders.
19. Procurement of pharmaceuticals within some OIC member states is often financed by donors or outside funding organizations that have their own requirements which may not be suitable for inclusion in a pooled procurement mechanism. Regional pooled procurement would not be a substitute for global pooled procurement mechanisms, although it could at times complement them by combining recipients of a single donor into one procurement plan.
20. Non-price (or value-added) benefits also accrue. Pooled procurement exposes the factors that prevent participants procuring different products for the same therapeutic use and creates pressure toward harmonization of quality assurance standards, standard treatment guidelines, and pre-qualification requirements.
21. Pooled procurement also builds confidence between purchasers and suppliers, rationalizes the procurement process and facilitates forecasting of demand. All of these non-price benefits promote the creation of a single market which encourages regional trade.
22. At the same time, lack of harmonization in these areas is an obstacle to pooled procurement as they effectively create different ranges of suppliers available to different procurement agencies. This suggests that any pooled procurement mechanism should, at least initially, begin with those products that different member states already procure separately.
23. The products selected for any pilot project should be those where there is a demonstrable price advantage in pooling procurement, based on the difference between prices currently paid and reference prices or benchmarks. A quantitative study to identify these products would be essential to promote participation in the pilot project.
24. A successful pooled procurement initiative could attract more manufacturers, both brand name and generic, to register their products with the drug regulatory authorities of different member states. Under the right conditions, it could also serve as one incentive for manufacturers to invest in production capacity within the region.
25. Participants in a pooled procurement initiative could promote the development of the regional industry by negotiating with patent holders to grant licenses to manufacturers in the region, to license technology and to provide technical assistance in the pharmaceutical manufacturing processes.

26. A pooled procurement initiative could be enhanced by cooperation among different member states in the use of **Trade Related Aspects of Intellectual Property Rights (TRIPS)** flexibilities to obtain better access to patented pharmaceuticals. Availability of the TRIPS flexibilities in each member state would increase the leverage of participants in negotiations with patent holders. Participants could also have actual recourse to the TRIPS flexibilities. For example, they could submit joint notifications to use the importation mechanism under the Waiver Decision and, where manufacturing capacity within the region is sufficient, trade products under the regional trade mechanism in the same Decision. These strategies are conditional not only upon close cooperation among the procurement authorities but also upon compulsory licensing in each member state where there is a patent and drug registration in each importing country (discussed above).
27. Common guidelines on the procedures for compulsory licensing, such as the period for prior attempts to negotiate a voluntary license, assessment of applications and the amount of compensation would facilitate these efforts.
28. The primary monetary advantage of pooled procurement is that unit prices can be reduced by purchasing higher volumes. As a sub-regional bloc, the opportunity to negotiate for lower prices does exist, with monetary savings identified as one of the potential benefits of pooled procurement.
29. The amount of financing necessary to support the procurement of the range of essential pharmaceuticals and vaccines is quite substantial. There is no question that the support of international donors in partnership and ministries of health will be a vital component in ensuring adequate quantities of pharmaceuticals and vaccines can be procured. This scale, however, also provides opportunities for significant savings over current prices.

Pooled procurements requirements

30. **Political will and commitment** supported by the implementation of required policies and reforms **at the operational level;**
31. **The harmonization of current procurement legislations** and **institutional framework in the OIC member states**, providing the basis for Good Pharmaceutical Procurement Practice for the adoption of regional pooled procurement.
32. **Harmonization of regulatory procedures, including common Essential Medicines Lists Standard Treatment Guidelines** and medicines registration procedures;
33. Adequate and predictable **financial resources for the** regular and timely allocation of funds and manage payments;
34. Opportunities to achieve **greater pricing efficiencies** through bulk purchasing as main justification basis;
35. Robust **supply systems** to deliver products to the end user;
36. **Adequate Logistics Management Information System**, which impacts on the accuracy and availability of information, has a substantial negative impact of quantification of needs and further limits information sharing.
37. We need to consider how to utilize the capacities of **the local manufacturers** and create opportunities for them to participate in the pooled procurement arrangements.

38. The regulatory legislations, institutional framework and capacities to **regulate the movement of quality** assured pharmaceuticals and vaccines within the member countries are relatively diverse. It is important to note that the National Medicines Regulatory Authorities are meeting regularly and working towards harmonization of standards and practices for Quality Assurance.
39. **System of mutual recognition** of OIC member states National Medicines Regulatory Authorities (NMRA) decisions on registration of medicines. The harmonization of medicines registration procedures and process needs to be prioritized for regional pooled procurement.
40. The **level of awareness** on pooled procurement at national level thus needs for advocacy and further consultations.

Recommendations

41. It is propose for the OIC region to adopt and embark on regional pooled procurement of pharmaceuticals and vaccines, with an initial limited list of essential medicines. With adequate technical and financial assistance, the existing capacity in the OIC member states will be able to implement regional pooled procurement of pharmaceuticals and vaccines.
42. The Group Contracting could be more feasible than the central contracting model.
43. The rationale for the selection of Group Contracting model included the following:
 - Individual member states have resources and the technical capacity to assist in conducting tenders and negotiating prices.
 - It allows member states to retain a degree of autonomy in the procurement process.
 - The current degree of harmonization of essential medicines lists and medicines regulations is adequate to initiate the Group Contracting.
 - Group contracting requires less investment, financial and human resources for efficient management and coordination of the process and requires less cumbersome payment mechanisms.
 - Establish a Regional Pooled Procurement Taskforce that will be responsible to develop, implement and monitor regional operational plan and coordinate activities within countries and other stakeholders.
 - Develop with the support of partners, the budgeted regional operational plan for the implementation of the pooled procurement programme, including timeframe.
 - Mobilize resources for initial capital expenditures and on-going external financing for medicine procurement.
 - Design a pilot phase of the pooled procurement and define the initial list of medicines to be used.
 - Identify relevant structures at country level for coordinating pooled procurement activities (e.g., forecasting/quantification, financing, and price monitoring)
 - Ensure that all member states are actively involved and take **ownership** of the regional pooled procurement programme.
 - A contractual, binding, and funded agreement should be signed among the OIC member states for the implementation of pooled procurement.

44. However as part of the consensus process, both models Group Contracting and Central Contracting Model are proposed for consideration by the OIC Member States and its development partners.

References:

1. Pooled Procurement, Implementation of the WTO Decisions on TRIPS and Public Health COMESA Member States – Seminar Series Papers; 31 January 2011;
2. Pooled Procurement of Medicines & Allied Commodities; Joint WHO, WIPO, WTO Technical Symposium Access to Medicines: Pricing nad Procurement Practices - Zafar Mirza, Secretariat Public Health, Innovation and Intelctual Property; Geneva 16 – 20 July 2010;
3. Regional Pooled Procurement of Essential Medicines in the Western Pacific Region: An Asset or Liability? - O’neal M. Mendoza, Working Paper 1, August 2010;
4. Final Report: A situational analysis and feasibility study on Regional Pooled Bulk Procurement of essential medicines and other health supplies in the East African Community Partners States; September 2007
5. Meeting Report: Multi-country Regional Pooled Procurement of Medicines, Geneva, 15 – 16 January 2007;
6. GCC Drug Central Registration “Update” – Mohammed Al-Haidari, Head of Drug Central Registration Department, Executive Board of Health Ministers Council of GCC States.