Concept Paper

06/2006

Review of Quality Assurance (QA) Mechanisms for Medicines and Medical Supplies in Humanitarian Aid

EUROPEAN COMMISSION

Humanitarian Aid

EUROPEAN COMMISSION

Humanitarian Aid

GFE
CONSULTING WORLDWIDE

Gesellschaft für Forschung und Entwicklungsprojektierung GmbH
Grüner Weg 13, D-52070 Aachen, Germany
Tel.: 0049–(0)241–918300 Fax: 0049–(0)241–9183050
E-mail: INFO@gfe.de Internet: http://www.gfe.de

Aachen, June 2006

Review of Quality Assurance (QA) Mechanisms for Medicines and Medical Supplies in Humanitarian Aid

Concept Paper

Countries visited: Europe (Belgium, France, Denmark and Switzerland), Africa (Kenya and DRC) and Asia (Indonesia)

Project Duration: December 2005 – June 2006

Contract No: ECHO / ADM / BUD / 2005 / 01212

Authors: Mrs. Véronique POMATTO (Team Leader)
Dr. Claudio SCHUFTAN, MD(Medical Expert)

This report has been financed by and produced at the request of the European Commission's Directorate-General for Humanitarian Aid (DG ECHO). The comments contained herein reflect the opinions of the consultants only.

TABLE OF CONTENTS (1 OF 2)

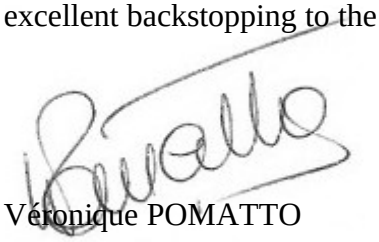
PAGE

TABLE OF CONTENTS (2 OF 2)

PAGE

ACKNOWLEDGEMENTS

The consultants want to thank the staff of DG ECHO for the support received from them, both at the DG ECHO headquarters in Brussels and in the field. They are also grateful for the help received from the staff of the Humanitarian Procurement Centres visited and from the numerous DG ECHO partners, including international organisations and European NGOs, who came to 'round table' discussions organised for this review and/or who facilitated them in their field visits. Special thanks are also due to the staff of GFE who gave excellent backstopping to the mission.



Véronique POMATTO

Dr. Claudio SCHUFTAN, MD

LIST OF ACRONYMS

ASAP	As soon as possible
ASRAMES	Association Régionale d'Approvisionnement en Médicaments Essentiels
ARV	Antiretrovirals
CHMP	Centrale Humanitaire Médico-Pharmaceutique
CRO	Contract Research Organization
DG ECHO	European Commission's Directorate-General for Humanitarian Aid
DRC	Democratic Republic of Congo
EC	European Commission
EMEA	European Medicines Agency
EU	European Union
FPA	Framework Partnership Agreement
GCP	Good Clinical Practices
GFE	GFE Consulting Worldwide GmbH
GDP	Good Distributing Practices
GMP	Good Manufacturing Practices
GSP	Good Storage Practices
HAC	Health Action in Crisis
HPC	Humanitarian Procurement Centre
IAPSO	Inter-Agency Procurement Services Office
ICRC	International Committee of the Red Cross
IDA	International Dispensary Association
IFRC	International Federation of Red Cross and Red Crescent Societies

IRC	International Rescue Committee
ISO	International Organisation for Standardization
LRMD	Logistics and Resource Mobilisation Department
MDM	Médecins du Monde
MoH	Ministry of Health
MoU	Memorandum of Understanding
MSF	Médecins sans Frontières
MQAS	Model Quality Assurance System for Procurement Agencies
NGO	Non-governmental Organisation
NRCS	National Red Cross Societies
Partner	Implementing partner, i.e. Humanitarian Organisation funded by DG ECHO (United Nations, International Organisation, or Non-governmental Organisation)
Partner NGO	NGO that has signed DG ECHO's Framework Partnership Agreement
PHO	Provincial Health Office
PSF	Pharmaciens sans Frontières
QA	Quality Assurance
SGS	Société Générale de Surveillance
TA	Technical Assistant
TB	Tuberculosis
TRIPS	Trade-related aspects of Intellectual Property Rights
UNDP	United Nations Development Programme
UNHCR	United Nations High Commission of Human Rights
WHO	World Health Organization
WTO	World Trade Organization

1. INTRODUCTION

1.1 DG ECHO'S HUMANITARIAN MANDATE AND ITS ROLE IN PROMOTING THE USE OF QUALITY MEDICINES AND MEDICAL SUPPLIES

1. The European Commission's Directorate-General for Humanitarian Aid (DG ECHO) is the world's largest humanitarian donor. It has also to be taken into consideration that other services of the European Commission (EC) fund activities that are humanitarian in nature, albeit with different legal bases and operational contexts. When the EC decides to intervene in a humanitarian context, this intervention can often be decisive due to: the guarantee of independence and impartiality in DG ECHO's Legal Basis; DG ECHO's needs based approach; the professionalism of its partners; and the magnitude of the funds at its disposal.

2. Although DG ECHO's legal mandate allows it to implement humanitarian operations either directly itself or through partner organisations, it only exceptionally carries out implementation itself. DG ECHO prefers to finance United Nations (UN) and International Organisations (IOs) and Non-governmental Organisations (NGOs), which possess administrative and logistical capacities.

3. In recent years DG ECHO has funded several thematic reviews to assist its partners in maintaining and improving their capacities in matters such as, water and sanitation and the security of humanitarian personnel. As a part of DG ECHO's commitment to capacity building, this review has been undertaken to promote the issue of quality assurance (QA) of medicines and medical supplies. This review is in particular intended to assist its Partner NGOs.

4. In the humanitarian operations that DG ECHO finances, under its mandate, the health sector is the most important - in terms of the priority given to life saving and the alleviation of suffering. The volume of funds accorded to health activities is telling. In most countries receiving DG ECHO's support, health absorbs from 30 to 50% of DG ECHO's funding, depending on the year. Of the amounts devoted to health, from 20 to 30% of the funds go for the purchase and management of medicines and medical supplies (i.e. between 40 and 90 million Euro, again depending on the year).

5. The international context for the procurement of medicines and medical supplies is presenting challenges from: the increase in counterfeit medicines; and globalisation leading to production shifting rapidly, with new producers entering the market. Further, the emergency context under which partners often work, including both IOs and European NGOs, may also prevent them from applying the QA procedures required in procurement. This brings to the fore the possibility of them giving insufficient attention to the correct management of drug supplies - ultimately potentially affecting the safety of intended beneficiaries.

6. For the reasons given above and the reliance that DG ECHO places on its implementing partners professionalism, this review has been commissioned to support its Partner NGOs in order that they are aware of the best practices and standards where existing

and the means to achieve them. Under the terms of the Framework Partnership Agreement (FPA), signatory Partner NGOs are required to respect "*Article 17 – Essential procedures for the implementation of humanitarian operations. Signatory organisations commit to implement humanitarian operations in accordance with the best practices in the sector and taking into account the particular operating environment, based on the concept of quality in aid.*"

7. DG ECHO has made it clear that, under the rules and procedures applicable to property, supply, works and service contracts financed by the general budget of the European communities in the course of humanitarian aid operations, "*The Humanitarian Organisation has the sole responsibility for complying with any contractual obligation incumbent on it. The respective rights and obligations of the Humanitarian Organisation and the contractors are governed by the tender documents and the contracts signed by the Humanitarian Organisation with those contractors. The Commission is not bound by these contracts and recognises no contractual link between itself and the Humanitarian Organisation's contractors.*" (See Annex V to the FPA, article 3.2.)

8. Thus under the requirements of its FPA, DG ECHO requires that its Partner NGOs respect best practices and standards, where they exist. The QA of medicines and medical supplies cannot be compromised upon. This review's products, namely a Concept Paper and the accompanying Guidelines, are to bring clarity in this issue. However, it is the implementing partners' ethical and legal responsibility towards the beneficiaries to achieve quality assurance of medicines and medical supplies, to do the intended good and to prevent doing any harm.

1.2 THE GROWING PROBLEM OF COUNTERFEIT MEDICINES AND MEDICAL SUPPLIES

9. The World Health Organization (WHO) defines "• *counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products. And counterfeit products may include: products with the correct ingredients; or with the wrong ingredients; without active ingredients; with insufficient active ingredients; or with fake packaging.*"

In September 2002, the *San Francisco Examiner* reported on a patient in China who died after albumin was administered intravenously by the physician. Police found the albumin bottle to be counterfeit. It was falsely labelled to look like a local Chinese pharmaceutical brand, but contained an unknown liquid that proved fatal in the human bloodstream. In the same year, drug quality problems in China's pharmaceutical industry gained international attention when five women in Japan and Singapore died and 60 more became sick after taking Chinese-made diet pills. In 2001, the *Shenzhen Evening News* reported 192,000 deaths in China due to the use of bogus or poor quality drugs.[1]

In India, between April and June 1998, 36 children under the age of six suffered from unexplained acute renal failure; 33 died despite peritoneal dialysis and supportive treatment. Subsequent investigation determined that locally manufactured "cough syrup" contaminated with diethylene glycol had been administered to the children[2]

10. Although it is difficult to obtain precise figures, estimates put counterfeits at more than

1 FACKLER, M., "*China's fake drugs kill thousands*", San Francisco Examiner, June 29th, 2003. Available from: http://www.examiner.com/sfx/templates/printer.jsp?story=n.bogus.0729w

2 SINGH, J., DUTTA, A.K., KHARE, S., et al., "*Diethylene glycol poisoning in Gurgaon, India, 1998*", Bull WHO, 79(2), p. 88-95, 2001.

10% of the global medicines market. They are present in all regions, but developing countries bear the brunt of the problem. An estimated 25% of the medicines consumed in developing countries are believed to be counterfeit. In some countries, the figure is thought to be as high as 50%.

11. The Centre for Medicines in the Public Interest, in the United States, predicts that counterfeit drug sales will reach 75 billion Dollars globally in 2010, an increase of more than 90% from 2005.[3]

12. The International Pharmaceutical Federation (FIP), the European Commission's Directorate-General for Enterprise and Industry and the Directorate-General for Health and Consumer Safety, the European Medicines Agency (EMEA) and the WHO, have committed themselves in the struggle against this problem.

13. The WHO has recently created the International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT). This initiative functions on the basis of existing structures/institutions, is a global task force of public, private and international institutions. IMPACT works on the following five main axes: Technology, Legislative, Enforcement, Regulatory, and Risk Communication.

14. To assure the quality of the supply of medicines is also a mean to contribute to eradicating this scourge.

1.3 OBJECTIVES OF THIS REVIEW

15. In this context, the specific objectives of this review were to assess:

- The current practices of DG ECHO's partners for QA mechanisms;
- The degree to which these practices are in line with the international standards and more specifically with WHO guidelines;

16. On the basis of this assessment the consultants had to propose to DG ECHO's implementing partners, particularly Partner NGOs concrete steps to establish a realistic, standardised and coherently applied system for QA of medical supplies based on existing international and WHO guidelines.

17. The expected products are contained in:

- A Concept Paper setting out the relevant issues;
- A set of Model Guidelines; and
- A bibliography with references and links for further consultation.

18. In carrying out this review the consultants have considered not only the QA issues

[3] http://www.who.int/mediacentre/factsheets/fs275/en/

covered here below, but they have also considered the respective strengths and weaknesses of procurement managed by DG ECHO's partners themselves and when they use what are termed 'Humanitarian Procurement Centres[4]' (HPCs). This is with the aim of suggesting improvements for the QA aspects of both methods of managing procurement.

1.4 WHY QA IN THE SELECTION, PROCUREMENT, DISTRIBUTION, RATIONAL USE AND DISPOSAL OF MEDICINES IS VITALLY IMPORTANT IN HUMANITARIAN AID

19. In the financing of humanitarian operations DG ECHO is obliged to respect wherever relevant and appropriate, and thus also its partners, international rules and best practices on procurement. These rules and the rules set out in the EU's Financial Regulation are reflected in the FPA's Annex V, procedures for the award of contracts, adapted for the specificities of humanitarian aid.

20. International rules and standards for QA of medicines exist and the most important of them are listed in the accompanying Guidelines. Under Annex V (see 4.4. Supply contracts, Article 4.4.1. Specific requirements for the procurement of pharmaceutical products and medical devices):

a) *"Humanitarian Organisations shall abide by international norms for the procurement of pharmaceutical products and respect patents and national drug regulations in the individual countries;*

b) *The purchase of medicines shall be based on the pre-qualification of pharmaceutical manufacturers who comply with the World Health Organisation Good Manufacturing Practice (GMP) Guidelines; and*

c) *The award criteria shall give priority to suppliers of medical devices that comply with ISO certification 9001/EN46001 or ISO 9002/EN46002. In respect to Medical equipment, the award criteria shall give priority to suppliers that comply with essential requirements described in the Council Directive 93/42/EEC of 14 June 1993, concerning medical devices.*

This enumeration of international standards is neither exhaustive, nor definitive. Humanitarian Organisations shall take as a reference any internationally recognised standard that may be set and the updates and revisions of the standards mentioned hereof."

21. In the new version of the FPA's Annex V underway at the dates of this review, it is important to note that the compliance for the purchase of medicines is not limited to WHO standards and the award criteria for medical devices are updated.

22. Given the above, in the opinion of the consultants, only very exceptionally are partners really in a situation where speed and the local/regional availability of medicines is such that they are

[4] Humanitarian Procurement Centres are non-profit making, autonomous and professional structures, specialised in the technical and commercial management of supplies necessary for the implementation of humanitarian operations. They provide technical assistance in procurement to Humanitarian Organisations, putting at their disposal pre-established stocks, purchasing and logistics capacity.

forced, as a dire exception, to overlook the strict QA standards. In all other cases of humanitarian aid, procurement of medicines of sub-standard quality is basically the result of a lack of attention or a lack of knowledge and understanding of the importance that QA of medicines has.

23. For the purposes of this Concept Paper, the focus of QA thus covers the full management cycle of medicines, namely from the selection, procurement, distribution, storage and rational use to the disposal of unfit medicines. Assuring the quality of each of these steps is necessary, but not sufficient: all have to be addressed, and the review looked into each of them. These QA principles also apply to the medical supplies used by DG ECHO's partners.

24. The evidence found in this review is convincing as to why DG ECHO's partners must give due attention to the application of internationally accepted standards to guarantee the quality of medicines and medical supplies they or their local partners dispense/use. DG ECHO, with its partners' feedback, is herewith developing a set of accompanying Guidelines based on international standards to help address the shortfalls found in QA procedures being used by its partners. A balance between mandatory respect for international standards, the minimum QA levels necessary and the realities that DG ECHO's implementing partners face in the field is being sought. These model guidelines are not exhaustive and they will require periodic updating in the future.

25. As regards the rational use of medicines, i.e. rational use includes - diagnosing, prescribing, dispensing, and proper consumption by the patient, this is a very difficult area. Rational use is often not possible, because staff salaries in health centres at field level are often so low, (or sometimes not paid at all), that they often resort to poly-pharmacy (i.e. more than three medicines) in their prescriptions to make an extra income. This can happen even if a cost-recovery scheme is in place with only a nominal mark-up on the medicines. Also, the quality of the staff at field level in terms of using treatment protocols and making accurate diagnoses is a problem. It is noted by the consultants that, in the health facilities visited by them which are supported by DG ECHO's Partner NGOs, the supervision given (and sometimes the salary top-ups given) seem to reduce the problem of poly-pharmacy and make rational use a bit better.

Chapter 5: Minimum standards in health services:

- Health systems and infrastructure standard 5: Clinical services: People have access to clinical services that are standardised and follow accepted protocols and guidelines.
  - *A standardised essential drug list is established by the lead health authority, and adhered to by health agencies (see guidance note 4);*
  - *People have access to a consistent supply of essential drugs through a standardised drug management system that follows accepted guidelines (see guidance note 7); and*
  - *Drug donations are accepted only if they follow internationally recognised guidelines. Donations that do not follow these guidelines are not used and are disposed of safely.*
- Guidance Note 4: ***Standardised treatment protocols and essential drug lists:*** Most countries have established essential drug lists, and many have treatment protocols. These protocols and drug lists should be reviewed in consultation with the Ministry of Health early in the disaster response to determine their appropriateness. Occasionally, alterations to established national protocols and drug lists may be necessary. If protocols and/or essential drug lists do not exist, guidelines established by WHO or the UNHCR should be followed.
- Guidance Note 7: ***Drug management:*** In addition to utilising the essential drug list, health agencies need to establish an effective system of drug management. The goal of such a system is to ensure the efficient and rational use of drugs. This system should be based on the four key elements of the drug management cycle: selection, procurement, distribution and use (see Management Sciences for Health (1997), *Managing Drug Supply. Second Edition).*

As can be seen, these statements are of a general nature and are non-contributory to this Concept Paper.

What SPHERE standards say about QA of Medicines (*www.sphereproject.org*)

2. CURRENT SITUATION

2.1 BACKGROUND AND DG ECHO'S PARTNERS' EXPERIENCE IN THE QA OF MEDICINES AND MEDICAL SUPPLIES

26. Part of the background is given in the introduction above. One can add here that DG ECHO is the first European Commission's Directorate-General (DG) dealing with international aid to delve into these problems of QA. To the best of the knowledge of the consultants, no other institutional donor has looked into the issue of QA of medicines and medical supplies. Relevant activities are being carried out by other DGs to combat counterfeit medicines in European Union (EU) countries. QA issues in the EU are still being harmonised and regulations on multi-source medicines earmarked for exports are still weak and under the control of national regulatory bodies. Fortunately, DG ECHO's partners have never yet had to face a serious international situation in which the QA of medicines supplied was at the centre of a failure in health sector provision. But, this is bound to happen if the necessary measures are not taken.

27. It is further noticed that the issue of QA of medical supplies is a much more complicated one given the dearth of international standards for the whole range of these products. Nevertheless, the review found International Organization for Standardization (ISO), EU, and US standards to be in use by HPCs and partners and certification of products by Crown Agents and Société Générale de Surveillance (SGS) was also found. This seems to be the best that can be done for now (see Recommendation HPC 11).

28. Here below, relevant information obtained as part of this review is presented.

2.1.1 ANONYMOUS QUESTIONNAIRE SENT TO DG ECHO'S PARTNERS AND FINDINGS FROM INTERVIEWS WITH SELECTED PARTNERS

29. The consultants sent out an online survey on QA issues to approximately 60 partners immediately after their first mission in Europe and before going to the field. (See the full questionnaire in Annex A.8.). Twenty-three partners responded to the survey on time. The salient points from it are described in the Guidelines accompanying this Concept Paper.

30. The preliminary survey results were used by the consultants to double-check some of the questionnaires' problems, weaknesses and gaps anonymously recognised by partners in their own QA procedures. In general, it can be said that this field verification was an important supplement for the consultants to get a fuller picture of the realities that partners and HPCs outside Europe face in their daily operations. These findings are incorporated in the sections below and are at the base of certain of the recommendations being made towards the end. A sample of some of the good and some of the poor practices found by the consultants is presented in an annex in the accompanying Guidelines. The same is true for a list of definitions of the technical terms used here.

2.2 PROBLEMS WITH TENDERING FOR MULTI-SOURCE ESSENTIAL MEDICINES IN THE GLOBAL MARKET

31. Many of the potential risks of QA outlined above could arise when DG ECHO's partners set up their own tendering for medicines and select providers that have not been pre-qualified. This is especially a risk when price rather than the price/quality ratio is the determinant in awarding the contracts. (Please note that, under Article 11.2 of the FPA it is set out that, "*Humanitarian Organisations must award the contract to the tender offering the best value for money, that is to say, the best price-quality ratio.*" DG ECHO's partners are NOT obliged to accept the lowest price, quality is factored in.) Even when a manufacturer has been pre-qualified in one production site, purchasing products under tender that are actually produced in other - non-pre-qualified site(s) - is a breach from the QA perspective. The profusion of new, aggressive actors in the pharmaceutical industry -especially, but not only, those based in developing countries- makes anything but a formal pre-qualification process a risky endeavour. The question this raises is: How financially and technically capable are Partner NGOs to carry out these pre-qualifications? The answer is quite clearly negative given the relatively small volumes that individually these NGOs procure. If today an organisation is tendering for medicines without having a thorough knowledge to master the process the global market of medicines is indeed a dangerous place to be active these days, with almost certainly lethal consequences for some unfortunate beneficiaries.

32. The potential problems of individual NGOs tendering without applying minimum QA procedures were a reason for including specific requirements for the procurement of pharmaceutical products and HPCs in Annex V[5] to the FPA signed in 2003 between the European Commission (DG ECHO) and NGOs. DG ECHO is offering its Partner NGOs the attractive alternative of shifting the pre-qualification burden, expertise and costs to specialised HPCs and, as an added incentive, allowing Partner NGOs to purchase from them by a single bid procedure without losing their prerogative to charge overheads on the funds used to purchase their medicines and medical supplies from HPCs.

33. This is a clear reaching-out by DG ECHO showing its genuine commitment to quality medicines and medical supplies in its programmes worldwide. It is noted that these purchases by single bid procedure are possible without an obligation for the Partner NGO to conduct an in-depth investigation of the operations of the selected HPC(s).

34. Partner NGOs however, must continue to exercise the requisite degree of care, efficiency and diligence when buying from an HPC, as is the case for other purchases. Partner NGOs must inform the European Commission (DG ECHO) whenever offers made by the HPC do not seem to comply with the basic principles of satisfactory quality, timely delivery or completion and a price in accordance with market prices. Partner NGOs must also avoid any conflicts of interests or double funding, and must signal any possible irregularities encountered in the procurement process to the Commission.

5 Annex V establishes the procurement rules and procedures to be followed by DG ECHO's partners in the framework of DG ECHO-funded humanitarian aid operations.

3. POSITION OF DG ECHO ON QA OF MEDICINES AND MEDICAL SUPPLIES PROCURED WITH DG ECHO FUNDING

3.1 DG ECHO'S POLICIES THAT HAVE AN IMPACT ON QA OF MEDICINES AND MEDICAL SUPPLIES

35. As already said DG ECHO is a major actor in the humanitarian aid scene, and again, health interventions are an important part of that aid. The EC considers it very important to safeguard the quality of the supplies and other aid it funds in humanitarian interventions[6]. And DG ECHO considers that, HPCs have the potential to assist most NGOs to better deliver this quality in the case of medicines and medical supplies, than most NGOs would achieve acting by themselves.

36. The basis for this review, including the preparation of this Concept Paper and of the accompanying Guidelines, clearly arises from under Article 18 of Council Regulation (EC) N° 1257/96 on humanitarian aid ('Humanitarian Aid Regulation'), "*The Commission shall regularly assess humanitarian aid operations financed by the Community in order to establish whether they have achieved their objectives and to produce guidelines for improving the effectiveness of subsequent operations.*" This review is based on an assessment of DG ECHO financed humanitarian aid operations, looking at whether they have achieved their objectives (actually sanctioning 'checks on the spot') and, at the same time, producing guidelines that will improve the effectiveness of subsequent operations. Several other articles of the Humanitarian Aid Regulation indirectly pertain to issues related to the QA of medicines and medical supplies. The principal objectives of humanitarian aid operations referred to in the Regulation include: to prepare for disasters ("*ensure preparedness*"), facilitate the transport of aid by all logistical means available (in practice this may include storage, international and national transport and distribution of relief items), and protecting humanitarian goods. It further mentions facilitating small-scale training schemes, exchange of technical know-how and exemption of taxes of humanitarian goods. Partner NGOs' eligibility criteria are also clearly spelled out in the mandate, as are the relationships of DG ECHO with international agencies and organisations. All these are, of course, relevant to this review[7].

37. At a more specific level for DG ECHO's Partner NGOs, the legally binding instrument covering the QA of medicines is the FPA's Annex V concerning procedures for the award of contracts and its section on supplies. The consultants take this Annex V as a basis for the Concept Paper.

6 Communication of Mr. Poul Nielsen to the European Commission, EC (2003)3951.

7 Articles 1, 2, 3. 4. 7, 8, 10 and 12 respectively of DG ECHO's mandate.

3.2 THE NEED FOR PROVIDERS TO BE PRE-QUALIFIED: EXISTING SOURCES OF PRE-QUALIFIED MEDICINES AND MEDICAL SUPPLIES

38. Providers - be they manufacturers, distributors, wholesalers or HPCs - should be pre-qualified. This statement is reinforced by the differences this review found in the way HPCs carry out the pre-qualification of the manufacturers they buy from. As of mid-2006, there are nine HPCs dealing with medicines, plus one HPC active in Food Aid, Food Security and Emergency programmes, which have been recognised on a preliminary basis, following a documentary check based on a questionnaire completed by the HPCs and supplied together with corresponding supporting documents.

39. These HPCs are:

- Médecins sans Frontières Logistique (MSF Logistique), France;
- Ex-Transfer Relief Supplies and Services (formerly known as Transfer, but now called MSF Supply), Belgium;
- Centrale Humanitaire Médico-Pharmaceutique (CHMP), France;
- International Dispensary Association (IDA Foundation), Netherlands;
- Association Régionale d'Approvisionnement en Médicaments Essentiels (ASRAMES), Democratic Republic of Congo;
- Logistics and Resource Mobilisation Department of the International Federation of Red Cross and Red Crescent Societies (LRMD), Switzerland;
- United Children's Fund, Supply Division (UNICEF Supply Division), Denmark;
- Inter-Agency Procurement Services Office of the United Nations Development Programme (IAPSO), Denmark;
- Deutsches Medikamenten-Hilfswerk Action Medeor (Action Medeor), Germany; and
- Operational NGO Food Security Network EuronAid (EuronAid), Netherlands.

40. Financial audits of several HPCs are now ongoing by DG ECHO-contracted auditors. But it is also recommended that HPCs make available to any person or party who would request it, the evidence that they are following the WHO's standards on pre-qualification of suppliers. (See Recommendation ECHO 1)

The pre-qualification process can be sub-divided in two parts, i.e. product-related assessment and manufacturer-related assessment:

- The **product-related assessment** should ensure that the correct product is specified by the Procurement Agency. The Procurement Agency should then assess whether the manufacturer is offering a product that meets the pre-determined norms and standards in terms of safety, quality and efficacy; and
- The **manufacturer-related assessment** should ensure that the manufacturer is able to manufacture the product as specified in the Product Information package and in accordance with good manufacturing practices (GMP) as recommended by the WHO. The manufacturer must be capable of carrying out the activities routinely to the specified standards, to ensure batch-to-batch consistency of the product.

Assessment of contracted-out services, e.g. by storage and distribution agents, contract research organisations (CROs) and quality control laboratories for compliance with good manufacturing practices (GMP), good clinical practices (GCP) and good laboratory practices (GLP), are further elements that may supplement the pre-qualification process.

41. To the above it must be added that, it is the national regulatory authorities of each country that are supposed to certify that the storage and distribution practices of these HPCs are in compliance with the respective national standards. The consultants found that although this may be happening, these authorities do not necessarily look into pre-qualification issues as these pharmaceutical products are for export (see Paragraph 42).

42. A few years ago, the WHO began a pre-qualification scheme for certain medicines. The list of pre-qualified medicine/supplier pairs is already on the web for Antiretrovirals (ARV), Tuberculosis (TB) and malaria drugs[8] and the list is continuously being updated.

43. The Model Quality Assurance System (MQAS) for Procurement Agencies of the WHO[9] is another useful output document that provides procurement agencies with guidelines on how to assure the quality of the multi-source pharmaceutical products they buy. (The accompanying Guidelines closely follow these standards). It should be discussed between the HPCs and the WHO in order to see whether enter the HPCs could enter into some voluntary arrangement with the WHO under which the WHO could qualify the pre-recognised HPCs to make sure they are all complying with the MQAS. It should be noted that, DG ECHO has no legal mandate or internal capacity to carry out such pharmaceutical controls. (see Recommendation HPC 3)

44. As regards to the cost of the above-mentioned controls of HPCs' pharmaceutical QA systems, costs of this nature would be recovered through an addition to the cost of the products sold.

45. Each HPC, and some of DG ECHO's partners, have already pre-qualified (and do so on an ongoing basis) a whole range of manufacturers for different molecules. It is recognised that the pre-qualification criteria used are not always the same, but neither are these so far apart for this problem not to be overcome. There is a need for the recognised HPCs to meet to work out this issue in order that they can in the future, share their pre-qualification reports of existing sources of the different molecules. (see Recommendation HPC 4) This would avoid duplications in the pre-qualification of manufacturers and would save money and time, as well as increase the number of manufacturers that can be pre-qualified. The legality of sharing these reports has to be addressed. Further, periodic semi-annual meetings of all HPCs are desirable to discuss issues of their mutual and of DG ECHO's interest. (See Recommendation HPC 4) Such mechanism already exists, in part, through the Interagency Pharmaceutical Coordination Group[10], which at present only involves pharmacists from four HPCs: WHO, UNICEF, the ICRC and MSF.

46. Both pre-qualifications and controls of pharmaceutical QA systems are expensive and time-consuming. The option considered viable by the consultants, is for HPCs to recover the costs of the pre-qualifications they carry out as part of their direct costs. What this procedure will also require is that, the financial accounting of HPCs in fact identifies and documents these pre-qualification direct costs so that auditors can review them. (See Recommendation ECHO 9) Note that this is different from the HPCs charging an itemised handling fee to DG ECHO's partners of

8 http://mednet3.who.int/prequal/

9 "*A Model QA System for Procurement Agencies*", WHO, November 2004, Draft 5.

10 http://www.who.int/medicines/areas/policy/ipc/en/index.html

up to a maximum 7% (at dates of drafting) on top of the purchase price of the products.

47. The issue of pre-qualifying medical supplies is more intricate though. No real equivalent to the universally accepted WHO minimum standards for the QA of medicines exists. Nonetheless, different HPCs may use ISO, US and EU standards.

3.3 THE FRAMEWORK PARTNERSHIP AGREEMENT AND THE UPDATE OF ANNEX V

48. It is noted that procurement from non-HPC providers is not banned by Annex V, but these providers have to be credibly pre-qualified, and the 'regular' Annex V procurement procedures (open, restricted, negotiated,…) have to be followed by Partner NGOs purchasing from such providers. In addition, the 'best value for money' principle has to be demonstrably respected, i.e. highest price/quality ratio as is the case for HPCs.

49. In applying Annex V, HPCs (and Partner NGOs) find themselves in the situation where they have to, on an ongoing basis, pre-qualify new providers of different molecules in the international market place (see Recommendation HPC 2). This is to ensure that, applying the best value for money price/quality ratio principle; HPCs find the cheapest quality assured supplies in today's competitive quality drugs market. The caveat here is the cost in time and money to carry out these pre-qualifications. It could therefore make financial and administrative sense that recognised HPCs get together and sort out any differences regarding pre-qualification standards, thus reducing costs by standardising their criteria and dividing up the workload of pre-qualifying manufacturers and sharing this information among themselves.

50. As said, DG ECHO, in consultation with its Partner NGOs, has made drafting changes to the 2003 FPA's Annex V that sets out the procurement rules and procedures applicable in humanitarian aid operations benefiting from DG ECHO financing. DG ECHO will take into account this Concept Paper and some final WTO negotiations on food aid (that also have repercussions for Annex V) before finalising the draft revised Annex V. [It is noted that partner UN agencies and International Organisations are not bound by Annex V].

51. The key-elements that have been changed in the latest version are:

- The recognition of HPCs in 2005 (ten so far, but open to change). In fact, DG ECHO found in 2002 by means of an independent study that, HPCs provide medicines applying lower mark-up costs than the commercial sector.[11];
- Annex V includes a reference to the difference between 'handling fees' charged by HPCs and 'indirect costs' charged by Partner NGOs. This is an important financial clarification that does not deprive partners from charging DG ECHO justified overheads in their procurement of medicines and medical supplies. However, both must cover justified, real and verifiable expenses. At the dates of drafting of this review, the difference between the handling fee charged by HPCs to Partner NGOs

11 "*Procurement Cost Study, for the attention of ECHO*", Helm Corporation, December 2001.

and indirect costs charged by Partner NGOs to DG ECHO is already referred to in the Background Document on HPCs, available on DG ECHO's Website; and

- The level of compliance necessary for the QA purchase of medicines is not exclusively limited to WHO standards. In the future, once established by the WHO, the award criteria for medical devices, should also comply with it.

52. As a result of this current review, it seems of mutual benefit to consider the following additions/modifications to the current advanced draft of Annex V:

- Annex V to incorporate a paragraph explicitly stating that the pre-qualification of molecules is to be site-specific;
- Annex V to specify that partners are expected to consult DG ECHO's Concept Paper and Model Guidelines (2006), where relevant, as far as the selection, procurement, distribution and rational use of medicines and medical supplies is concerned; and
- Annex V also to specify that when one HPC buys from another HPC (or a subsidiary buys from the parent central HPC), only one is to charge the 7% handling fee or the fee to be divided among the two HPCs conducting such a transaction.

3.4 WHY HUMANITARIAN PROCURMENT CENTRES ARE TECHNICALLY BETTER QUALIFIED TO DO PROCUREMENT

53. Nine pre-recognised HPCs are handling medical supplies, and another HPC is dealing with non-medical supplies. They all have years of quality-assured pharmaceutical procurement experience. Most of them are major, highly professional, ethical, non-profit organisations, and are well respected by their users and by DG ECHO. To use a colloquialism, it is safe to say that they have been instrumental in 'writing the book' on QA of medicines. The WHO has also had close ties with them. In short, they have the technical personnel, the facilities, the know-how and the organisation to be considered top in their qualifications to procure safe medicines. If any of them still have shortcomings, the proposed independent control of pharmaceutical quality assurance systems here recommended should put them all at the same level in the near future. (See Recommendation ECHO 1)

54. It is in recognition of their good standing that DG ECHO has recommended its partners to procure from these HPCs.

3.4.1 EXISTING AND NEW HUMNAITARIAN PROCUREMENT CENTRES

55. The ten already pre-recognised HPCs are likely not to be the only ones to be recognised for future inclusion in the recommended list by DG ECHO. As some may choose not to continue being a recognised HPC for DG ECHO, other HPCs will most probably seek to join the group. Annex V foresees these courses of events. The minimum requirements for a medical procurement agency to become an HPC are clearly stated in Annex V and do not need to be amended. (See 4.1. below).

4. RESPONSIBILITIES OF HUMANITARIAN PROCUREMENT CENTRES AND DG ECHO'S PARTNER NGOS IN THE PROCUREMENT OF MEDICINES

4.1 HUMANITARIAN PROCUREMENT CENTRES

56. As mentioned earlier, the 2003 FPA offered DG ECHO's Partner NGOs the (preferred) alternative to purchase medicines and medical supplies from HPCs in DG ECHO-funded operations, using a single-bid (single-sourcing) procedure. It was in 2005 and 2006 that applicant HPCs received DG ECHO's preliminary recognition, following a documentary check, including a verification of the financial statements: A proof of the importance DG ECHO gives to this QA matter. As a pre-condition to use this sourcing for procurement, DG ECHO set out to verify whether HPCs that had applied complied with the basic criteria of Annex V to the FPA. According to Annex V, HPCs must:

- Be non-profit, autonomous and professional organisations;
- Be specialised in the technical and commercial management of supplies necessary for the implementation of humanitarian aid operations;
- Guarantee equal treatment of suppliers and humanitarian organisations;
- Guarantee high standards of integrity, transparency, pricing practices, performance and quality;
- Respect a number of well-defined ethical, procedural and economic requirements in their operations and in the constitution of stocks; and
- Accept the controls, including on the spot checks.

57. The consultants visited the facilities of four HPCs: CHMP (in Clermont Ferrand and Nairobi), LRMD, UNICEF Supply Division, and ASRAMES. Additionally, the consultants met with representatives of MSF International's pharmaceutical cell IDA (in Nairobi) and IAPSO (the central buying agent for UNDP specialising in TB drugs). The only HPC dealing with medicines not contacted was Action Medeor. All these HPCs have framework agreements with their pre-qualified suppliers.

58. As related to QA, the HPCs' responsibility is to, at least, follow the WHO standards in their systems for the procurement and handling of medicines; they are also responsible for the pre-qualification of product/supplier pairs, and it is now suggested that they share their conclusions of such exercises with other DG ECHO-recognised HPCs. (See Recommendation HPC 4.)

59. It is to be noted that, as HPCs get more and more partner clients, they will be

procuring bigger quantities and may increasingly have the advantages of economies of scale. The constraint, of course, is that they need to be capable to expand capacity to manage an increased demand in the near future. They accepted the likelihood of such an increased demand when responding to the DG ECHO questionnaire that led to them being pre-recognised as HPCs.

60. It is also noted that manufacturers in Europe can export medicines that are not licensed in their country of origin (i.e. have no market authorisation). Therefore, a medicine that 'comes from Europe' is no guarantee of QA per-se. For medicines for export, the respective national European pharmaceutical regulatory agencies only check the adequacy of storage conditions at HPCs to make sure they are up to standards. Conversely, when HPCs import a non-European medicine to their warehouses in Europe for re-exporting it later, current regulations require that every batch has to have a sample laboratory quality control check. This is one of the reasons why one HPC is considering moving its operations to India, where they are already building a new laboratory.

61. As relates to medical supplies and equipment, HPCs are responsible for the quality of the material and devices they procure and are expected to disclose the standards they use to do so. The WHO is said to now be working on setting the standards for the pre-qualification of reagents and medical devices.

62. In general, HPCs are liable for the quality of the products they sell to customers (DG ECHO's partners) until the customer takes delivery of the same. When the international standards cannot be followed for a justified reason, the HPC should be transparent on the quality dossier of the pharmaceutical product and the customer itself should understand that it is solely liable for the use of any such product. (See Recommendation PART 9)

63. An observation worth sharing is that, DG ECHO's partners are highly discouraged to buy from certain HPCs when the same require payment up-front as the order is placed. And they are further discouraged when the HPC cannot guarantee the price at the time of delivery, especially when the delivery time is deemed too long by the same buyer.

4.2 DG ECHO'S PARTNER NGOS

64. The consultants visited the headquarters of Pharmaciens sans Frontières - Comité International (PSF) and of Association Tulipe (not a Partner NGO), and met with VOICE (the coalition of DG ECHO's Partner NGOs), the Fritz Institute (not a partner of DG ECHO, but an organisation that helped the IFRC to set up software that follows key-performance indicators of logistic operations) and MSF Belgium. In their field visit to Kenya, the DRC and Indonesia, the consultants met with PSF, MSF, Médecins du Monde (MDM), Merlin, CARE, GOAL, World Vision (not a Partner NGO) and the International Rescue Committee (IRC) and met with some of them in more than one country.

65. As relates to QA, the responsibility of DG ECHO's Partner NGOs is also to, at least, comply with WHO standards in the selection and the handling of medicines and medical supplies, i.e. their storage, transport, rational use, pharmaceutical or medical devices vigilance

reporting and the destruction of pharmaceutical products unfit for use. (See further details in the Guidelines). (See Recommendations PART 6 and PART 10)

66. Partner NGOs are liable for the quality and specifications of the products they select and later for preserving the quality of the products they purchase from HPCs or other providers. (See details in the Guidelines: Selection, Distribution, and Rational Use).

67. Partner NGOs are also liable to buy at reasonable prices. It is noted that, local/regional wholesalers at field level -from which partners sometimes procure- often buy from HPCs themselves (e.g., materials for injections). Hence, the prices the Partner NGOs pay are obviously higher than if the partners had bought directly from HPCs.

68. As relates to medical equipment, Partner NGOs are responsible for the proper use of the material they procure and for the maintenance of the equipment received. It is expected that partners select equipment that will be easy to maintain in the country of use. For this, they should make sure they select equipment:

- That is of a known brand;
- That has a presence of a specific distributor in the country of use;
- For which training of users is provided by the supplier;
- For which trained biomedical personnel exists locally (when applicable); and
- For which maintenance and spare parts contracts are signed in the country or region of use.

4.3 SPECIFIC INTERVENTIONS NEEDED TO SECURE THE QA OF MEDICINES

69. These are covered in the accompanying QA Guidelines. Here, only some of the more conceptual issues are covered.

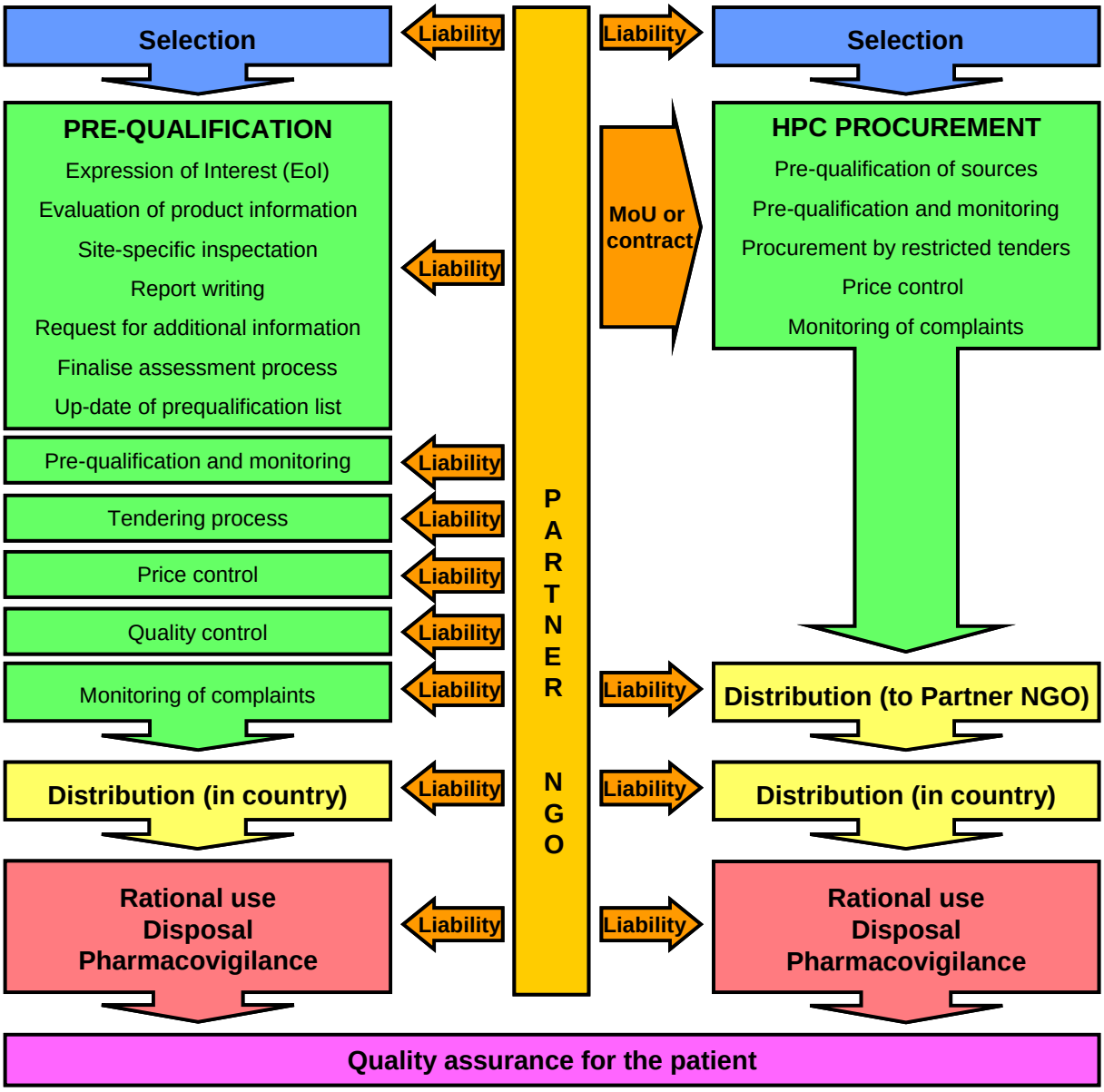
70. It is to be kept in mind that DG ECHO-funded National Red Cross Societies (NRCS) can buy from the IFRC's LRMD as an HPC, (as can any other Partner NGO).

4.3.1 UPSTREAM (HPCS) AND DOWNSTREAM (PARTNER NGOS) RESPONSIBILITIES IN QA OF MEDICINES FUNCTIONS

71. Any rupture in the QA along the management cycle of drugs ends up exposing the users to a varying degree of risk. It is the concerted effort of many actors along the cycle that assures the user will get the expected maximum effect from the medicine prescribed. The division into upstream and downstream responsibilities is centred at the point where the partner takes delivery of the product; it is a useful distinction with the exception that the selection of the product (the first step in the cycle) is the responsibility of the downstream

handler, i.e. the Partner NGO. The point being made here is that, it is a total waste of effort and of financial and other resources when the upstream QA of medicines and medical supplies is followed according to international standards only for the same to be disregarded downstream by the Partner NGO. It is precisely this concern that prompted DG ECHO to call for this current review. The need to pay equal attention to QA issues both up and downstream is, therefore, here strongly reiterated. What this entails is at the very base of DG ECHO having requested that this Concept Paper be accompanied by detailed QA Guidelines written in simple language for Partner NGOs to follow, (including a short, simple summary, presented in tabular form, for use in the field).

72. Alternative pathways for management of the drug cycle:



4.3.2 QA OF MEDICINES IN THE ACUTE, POST-ACUTE AND CHRONIC PHASES OF HUMANITARIAN EMERGENCIES

73. QA standards ought to be applied the same way in any humanitarian (and also development!) aid operation. Humanitarian interventions do have some specific features though, due to the fact that they are often mounted in response to dire emergencies and are then followed on for varied periods of time. Annex V under Article 5.1. Emergency and primary emergency operations, allows the following exception, "*In the framework of emergency and primary emergency operations… Humanitarian Organisations may place their orders on the basis of a single quote*." In this case, the Humanitarian Organisation must be able to present the reasons that prevented a larger consultation. This foresees the possibility of granting derogations when partners have to single source from providers other than HPCs in acute emergencies, but it does not relax the QA requirements.

74. Under Annex V Article 5.2 Stocks: constitution and use, it is stated "*Expenditure incurred by the Humanitarian Organisation before the date of submission of the project proposal and related to the constitution of stocks of goods and equipment for use in connection with proposal and related to the constitution of stocks of goods and equipment for use in connection with the operation for which the grant is awarded is eligible for Community financing*." For the consultants stock piling is the preferred approach in disaster-prone areas to have quality assured products at hand for use when the emergency strikes. This Concept Paper considers this article as a potential strong support for Partner NGOs operating under those circumstances who wish to invest in stock piling. (See Recommendation ECHO 6)

4.3.3 QA OF DONATED MEDICINES

75. The WHO has long set standards for donated medicines[12]. It is disheartening to see how in disaster after disaster these guidelines are ignored by many humanitarian actors. In Banda Aceh -a site visited during this review- PSF (with DG ECHO funding) documented the logistical, pharmaceutical and financial burden this created in a formal survey (see the examples of poor practices in the accompanying Guidelines) and in a documentary DVD entitled "*The Second Tsunami*", which can be accessed on the web at http://www.psfci.org/new/index.htm. Definitely, more decisive action needs to be taken in this area and the consultants cannot think of any other way to do it (as a palliative measure) than by undertaking actions in this domain as a part of Disaster Preparedness activities. To get to the roots of this problem, though, the consultants also made a couple of concrete recommendations (See Recommendation ECHO 1).

12 "*Guidelines for Drug Donations*", WHO, Interagency guidelines WHO/EDM/PAR/99.4 - Revised 1999.

"*The Second Tsunami*" is a 23-minute movie produced by Pharmaciens Sans Frontières that looks at possible solutions to avoid the repetition (for the nth time) of problems with donated medicines and medical supplies in major emergencies.

- The DVD will be widely distributed shortly for its high impact;
- Training is needed of pharmacists and pharmaceutical assistants who would be "*on call*" and available when a disaster occurs. Such training should be internationally recognised as a bona-fide disaster preparedness activity. It could be initially spearheaded by the respective NRCSs. Also as a part of Disaster Preparedness activities warehouses should also be identified in disaster-prone countries to safely store the inflow of drugs in accordance with international standards. The trained emergency pharmaceutical staff should be the ones to receive, sort and list the donations - with or without international help. It is even conceivable to set up a Crisis Pharmaceutical Cell in disaster-prone countries. (See Recommendation HPC 7);
- Medical waste management should also be part of the knowledge (and the responsibility) given to these trainees, since much of the donated material is unfit for use. The preparedness activities should also include advocacy with the national authorities to set up regulations on this waste management in compliance with WHO standards; and
- The above being only a palliative measure, **the ultimate aim still is to avoid the flood of donations of medicines in major disasters.** "*The Second Tsunami*" calls for the international community to pass an international law regulating and curbing these donations.

The consultants think such a regulation is more likely to succeed as a WHO Resolution passed by all the ministers of health of the world at a forthcoming World Health Assembly meeting in the coming year or two. WHO guidelines already exist on this, but need to be enforced and, eventually, sanctions need to be applied to donor countries who do not respect them.

Alternatively and/or additionally, the European Parliament could be approached by humanitarian NGOs to pass such a law that would be binding for the members of the EU; that would set an important precedent towards a global international law. (In either case, donors should only be allowed to send donations based on specific requests by the affected country and always respecting the above WHO guidelines; ideally, cash would be more desirable).

Such a regulation and/or law should include a specific disposition that would mandate the donor country to quickly repatriate, at their own expense, any inappropriate donations for destruction back home.

5. CONCLUSIONS

76. In summarising the key messages that can be drawn from this review, the consultants highlight the following:

I. The problems with the QA of medicines and medical supplies are such that Partner NGOs cannot be addressed separately from HPCs on issues pertaining to QA. Therefore, the recommendations in this Concept Paper cover both such organisations;

II. The WHO's QA standards should remain the reference point for QA of pharmaceutical systems used by Partner NGOs;

III. Trying to improve the QA aspects of their management of medicines and medical supplies has been found to be a genuine interest on the part of DG ECHO's partners contacted;

IV. The biggest QA challenge still ahead is that of the local procurement carried out in beneficiary countries by Partner NGOs when the import of medicines is banned by beneficiary countries' governments, (see Recommendation PART 4 and 5);

V. The commissioning of this Concept Paper and accompanying Guidelines was indeed very timely; the Guidelines are clearly needed for use domestically and in the field;

VI. The FPA's Annex V and the amendments under way, at the dates of the review, are an important, clear and pioneering contribution of DG ECHO to the QA debate and to overcoming the remaining shortcomings to properly applying QA standards;

VII. The provisions allowing Partner NGOs to single-source from HPCs that pre-qualify the product/supplier pairs are a significant positive step towards achieving QA;

VIII. Improvements are needed both for the QA of medicines and of medical supplies and equipment;

IX. One aspect that was not addressed in the pre-recognition of HPCs was the control of pharmaceutical QA systems. This review has put forward suggestions as to how this is to be corrected, by the HPCs voluntarily under going such a control;

X. A missing option to be vigorously advocated for is the joint pre-qualification of manufactures by HPCs; the consultants base this argument on cost and efficiency grounds, i.e. that HPCs should share their pre-qualification information, (see Recommendation ECHO 2);

XI. DG ECHO cannot remain alone as the sole institutional donor in insisting on -and paying for- QA of medicines and medical supplies, DG ECHO has to reach out and articulate to other agencies the need to also share this burden;

XII. It is clear to the consultants that all HPCs should be obliged to have the services of a qualified pharmacist for their operations, (see Recommendation HPC 9);

XIII. It is also clear to them that quality medicines come at a cost, as and when they come from pre-qualified manufacturers, and that this cost has to be accepted;

XIV. Much training is still needed in the QA of medicines and medical supplies -both for partners and their associates in the public sector- in the counties Partner NGOs work in (see Recommendation HPC 6 and PART 8);

XV. The procurement, distribution and QA model set up by DG ECHO with its Partner NGOs in Lokichoggio and in Southern Sudan was the best the consultants found in their review, (see the best practices in the Guidelines and Recommendation DG ECHO 7);

XVI. There are serious (and since some considerable time) problems with the donation of medicines and medical supplies in the cases of major disasters; these call for more aggressive efforts of the international community to solve them. Two innovative possible solutions are explored in this Concept Paper; and

XVII. On-line partner surveys using the European Commission's Interactive Policy Management (IPM) software tools are extremely helpful.

6. RECOMMENDATIONS

77. Recommendations for DG ECHO:

I. Recommendation ECHO 1 – HPCs to be encouraged to have regular independent controls of their pharmaceutical quality assurance systems to confirm their ongoing compliance with the WHO's QA standards for procurement agencies[13], (these controls are needed at least every three years and starting as soon as is possible). The HPCs would have to submit to this on a voluntary basis. The report on the control of their pharmaceutical quality assurance systems should provide, where necessary, the concerned HPC with a list of improvements required, and a deadline for making corrections should also be given. Technical Assistance to the HPC from one of the other HPCs already fully recognised and/or Partner NGOs could be a way to bring their quality assurance practices up-to-par.

A technical involvement in the controls on the part of the European Medicines Agency (EMEA)[14] is not possible since, except for the 'extra-territorial' status of the Red Cross Movement, all the European HPCs depend on their national regulatory authorities. The WHO actually already has a proposal for this (The WHO Pre-qualification Project, Fact Sheet No. 278, WHO, May 2004) but the project seems to never have taken off due to lack of funding. DG ECHO could explore using its thematic funding tool with the WHO to engage the WHO in the tri-annual pre-qualification of HPCs. (Moreover, WHO interim guidelines for the assessment of procurement agencies already exist, WHO Technical Report Series No. 917, Annex 8, 2003).

If the above is not possible, other solutions can be explored as, for example, the engagement of the services of associations of senior pharmacists as Office Technique d'Etudes et de Coopération Internationales (OTECI)[15], or of specific external evaluators who can be hired to assess the compliance of the HPCs with the WHO's MQAS;

II. Recommendation ECHO 2 – DG ECHO should encourage joint pre-qualification of suppliers by joint HPC teams and accept the pre-qualification costs, incurred by HPCs, as direct costs that can be recovered in the drug prices (HPCs charge Partner NGOs). DG ECHO would insist that, HPCs keep detailed financial records of these pre-qualification costs and recovery methods to see that only actual costs are recovered;

III. Recommendation ECHO 3 – DG ECHO should facilitate an annual meeting amongst the recognised HPCs to enable cooperation in terms of exchange of information on the suppliers QA and stock availability;

13 "*WHO Technical Report Series*", WHO, No.917, Annex 8, 2003.
14 http://www.emea.eu.int
15 http://www.oteci.asso.fr

IV. Recommendation ECHO 4 – As a means of increasing visibility, DG ECHO should consider endorsing with its logo the following existing WHO guidelines on QA of drugs, subject to WHO agreement:

- Operational Principles for Good Pharmaceutical Procurement, WHO/EDM/PAR/99.5;
- The WHO's MQAS (when the final version becomes available); and
- The new emergency health kits.[16]

Thereafter, the procedure(s) to be followed should be negotiated;.

V. Recommendation ECHO 5 – DG ECHO should advocate to national authorities in beneficiary countries' that HPCs located in their country are recognised as Humanitarian Organisations and that they should not be taxed in their provision of medicines and medical equipment, as per provisions of the Lome and other Conventions;

VI. Recommendation ECHO 6 – DG ECHO should advocate to other donors that they should also contribute to covering the pre-qualification costs of certifying manufacturers that HPCs incur and that they should allow cost recovery by HPCs through a prorating of these costs into their sales prices of medicines to Partner NGOs;

VII. Recommendation ECHO 7 – In future contracts with Partner NGOs, DG ECHO should consider the possibility of replicating the pharmaceutical supply model established by PSF in Lokichoggio in other parts of the world, (see good practices number 1 in annex to the accompanying Guidelines); and

VIII. Recommendation ECHO 8 – DG ECHO should brief its controllers about what a pre-qualification is and why only pre-qualified manufacturers can participate in restricted tenders launched by HPCs. It should also to brief them that, in medicines, quality comes at a price, i.e. the market price is not the same as the quality market price.

78. Recommendations for HPCs:

I. Recommendation HPC 1 – HPCs and Partner NGOs should at least follow the WHO's QA guidelines and should not infringe any pertinent patent laws;

II. Recommendation HPC 2 – HPCs and Partner NGOs should follow the new EC regulation COD/2004/0258; "*pharmaceutical products: compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*" which is following the TRIPS agreement.[17]

III. Recommendation HPC 3 – HPCs should give equal opportunity to professional manufacturers in developing countries to be pre-qualified;

16 http://www.who.int/hac/techguidance/ems/new_health_kit_content/en/index.html
17 http://www.europarl.europa.eu/oeil/file.jsp?id=5212722

IV. Recommendation HPC 4 – Every 2-3 years, instead of just re-qualifying a current supplier, HPCs should explore the market and decide whether to pre-qualify new manufacturers. HPCs should also launch calls for new Expressions of Interest (EoI), requiring already pre-qualified suppliers to re-apply, so as to select the cheapest source for each molecule (with the possibility obviously still existing for the current supplier to be re-qualified). In practice, HPCs should consider sending out special pre-qualification questionnaires to manufacturers that appear to have the needed qualifications. Then, according to the responses, select those that will actually be site-visited and pre-qualified;

V. Recommendation HPC 5 – All HPCs should cooperate to share pre-qualification information on suppliers by molecule and by manufacturing site, to avoid duplications in this work. (For example, ASRAMES already uses suppliers pre-qualified by MSF and PSF, and MDM shares pre-qualification information with MSF in Indonesia). This sharing of information has to be negotiated a-priori to respect the tenets of confidentiality (DG ECHO could play a catalyst role in this, see Recommendation ECHO 3). HPCs should hold at least annual meetings to exchange information about manufacturers and other developments, as well as to explore the possibility of setting up a password-controlled internet site for information on pre-qualified suppliers. The best vehicle for this would be the existing Inter-agency Pharmaceutical Coordination Group (including WHO, UNICEF, ICRC and MSF) that should be asked to incorporate all HPCs (See http://www.who.int/medicines/areas/policy/ipc/en/).

When there are local manufacturers, then local HPCs and Partner NGOs should share any information that they have on quality assurance of local products;

VI. Recommendation HPC 6 – HPCs and Partner NGOs should consider the benefits of having a formal framework MoUs. The MoU should include clauses on the proper management of the medicines received, so as to ensure that the partner takes pharmaceutical responsibility after it takes delivery from the HPC or the manufacturer directly, (the latter, as for example, in the case of IAPSO and the IFRC). This responsibility should be assigned to a designated office within the partner organisation, since the pharmaceutical responsibility of the provider ceases when the definitive reception certificate is issued by the recipient. It is noted that, the use of MoUs has to be voluntarily entered into between HPCs and Partner NGOs;

VII. Recommendation HPC 7 – Selected HPCs should be encouraged to set up follow-up systems with their clients, i.e. Partner NGOs to provide ‘drug management chain’ support, as needed to ensure downstream quality of the medicines delivered. In practice, this means that selected HPCs should, as much as possible, get involved in the QA training of Partner NGOs (conceivably even paid by DG ECHO), i.e. these DG ECHO supported HPCs could provide technical training/internships to the pharmaceutical and logistical staff of Partner NGOs (e.g. ASRAMES staff -that already received a one month of technical assistance from PSF in 2003- could go to France, to CHMP, since this HPC already provides this kind of training. And the training is actually followed-up with the trainees as they return to implement the

new system in their workplaces of origin. The UNICEF Supply Division also manifested it can provide technical assistance of this kind to Partner NGOs);

VIII. Recommendation HPC 8 – HPCs (and/or Partner NGOs) should seek financing to do national-level training on the regulation and management of donated goods, especially medicines, in the case of major emergencies in disaster-prone countries;

IX. Recommendation HPC 9 – As therapeutic food is to be considered a medicine, the WHO's Good Manufacturing Practices (GMP) have to be followed during manufacturing, be it produced centrally or in the field. Technology transfer is going on in this area and it is to be encouraged, provided partners can make sure that the local manufacturers are in the list of the manufacturer of origin as being licensed for the work;

X. Recommendation HPC 10 – All HPCs dealing with medicines should have the services of at least a pharmacist in their operations, both at central level and in their subsidiaries in developing countries, if they have these; and

XI. Recommendation HPC 11 – As a part of the pre-qualification of manufacturers by HPCs, the QA of their medical supplies should be based on any one of the three most frequent standards (ISO, EU and US) to be judged at the discretion of the pre-qualification team. (The WHO's Pre-qualification Project, Fact Sheet No. 278, WHO, May 2004, seems to never have taken off, possibly due to a lack of funding. Not to be confused with WHO's QA standards for procurement agencies).

79. Recommendations for Partner NGOs:

I. Recommendation PART 1 – Partner NGOs should be asked to progressively (and as soon as possible) comply with the recommendations in this Concept Paper and with the Guidelines that accompany this Concept Paper, where ever appropriate and relevant;

II. Recommendation PART 2 – When Partner NGOs use traditional local medicines, this has to be mentioned in their proposals to DG ECHO and, because nobody is able to assure the quality of such products, it has to be understood that their use is also under the partner's exclusive responsibility;

III. Recommendation PART 3 – As far as quality assured products are available in the field, DG ECHO is positive about local purchase, as long as standards are met.

IV. Recommendation PART 4 – In the acute and post-acute emergency phase of humanitarian aid, partners who have inspected and selected local, in-country or regional manufacturers should share this information (the issues of liability and confidentiality have to be addressed and respected), with DG ECHO's other partners in the country, as they may also have to buy drugs locally for their interventions. Regular meetings should be held among Partner NGOs for this purpose. (Ideally such meetings -which could possibly be called by the locally based DG ECHO Technical Assistant- would facilitate the Partner NGOs to find

the needed best possible medicines, the quantities in which they are available, and who locally has them in stock);

V. Recommendation PART 5 – In beneficiary countries where the importation of medicines is banned, Partner NGOs should at least procure through manufacturers which are registered by the national regulatory agencies of the country concerned. It is noted that:

- Buying from the Central Medical Store of a the national Ministry of Health (MoH) is no guarantee of QA, as 'registration' does not necessarily mean pre-qualification; and
- It is often not possible for Partner NGOs to get three quotations on a medicine. Therefore, if one of DG ECHO's Partner NGOs has one of its pharmacists inspect local manufacturers' production lines with certain regularity, the results of these should be shared with all Partner NGOs (the issue of any liability for the Partner NGO that performed the assessment has to be addressed).

VI. Recommendation PART 6 – Partner NGOs and HPCs can strengthen the capacity of local/regional third world manufacturers, wholesalers and distributors on the QA of the products they provide by advising them on the best way their, either public or private enterprises, can progressively reach the WHO's GMP (or GDP and GSP) and also how to apply to become pre-qualified when ready;

It is noted that many good manufacturers in developing counties cannot afford all tests required for WHO qualification, especially the bio-equivalence tests;

VII. Recommendation PART 7 – Partner NGOs are encouraged to carry out training of the staff of government health facilities in their places of work on the management cycle of drugs;

VIII. Recommendation PART 8 – Partner NGOs should understand that they can use more than one HPC for different molecules to fulfil their needs in the course of one DG ECHO contract;

IX. Recommendation PART 9 – Partner NGOs (and HPCs) as implementing actors- but not DG ECHO, as it does not implement itself- should understand that they are considered liable for any problems arising with the QA of medicines when they procure pharmaceutical products without following the WHO standards; and

X. Recommendation PART 10 – Partner NGOs should make a continuous effort to abide by the principles of pharmacovigilance as described i.a. in the accompanying Model Guidelines.

ANNEX I – QUESTIONNAIRE ON QA PRACTICES

SECTION 0: THE ORGANISATION							
Q.1	**WHAT IS YOUR (THE RESPONDENT) POSITION IN THE ORGANISATION?** *(Tick all that apply)*						
	Manager		Operations Manager				
	Pharmacist		Person in charge of procurement				
	Other (please specify)						
Q.2	**WHAT IS YOUR ANNUAL AVERAGE BUDGET FOR MEDICINES?**						

SECTION I: HOW DO YOU SELECT YOUR PHARMACEUTICAL PRODUCTS?							
Q.3	**WHAT ARE THE QUALIFICATIONS AND FUNCTIONS OF THE PERSON IN CHARGE OF THE SELECTION OF MEDICINES?**						
Q.4	**IN YOUR SELECTION, DO YOU FOLLOW ANY STANDARD LIST OF MEDICINES?**						
	No		Yes		If 'Yes', which method?		
	WHO Essential Medicine List		Host country EML		Own list		Other

SECTION II: HOW DO YOU PROCURE YOUR PHARMACEUTICAL PRODUCTS?							
Q.5	**DO YOU DO FORMAL MEDICINE NEEDS ASSESSMENTS?**						
	No		Yes		If 'Yes', which method?		
Q.6	**DO YOU USE KITS FOR 10,000 PERSONS/3 MONTHS IN ACUTE EMERGENCY RESPONSE SITUATIONS?**						
	No		Yes				
Q.7	**DO YOU ACCEPT DONATED MEDICINES?**						
	No		Yes				
Q.8	**IF YES, DO YOU APPLY THE WHO GUIDELINES FOR MEDICINE DONATIONS** (see http://whqlibdoc.who.int/hq/1999/WHO_EDM_PAR_99.4.pdf)?						
	No		Yes				
Q.9	**WHO IS SPECIFICALLY IN CHARGE OF THE PROCUREMENT OF MEDICINES IN YOUR ORGANISATION?**						
	Pharmacist		Medical Doctor		Logistician		Nobody
	Other, please specify						
Q.10	**ARE YOU FAMILIAR WITH THE WHO GUIDELINES ON QUALITY ASSURANCE FOR PROCUREMENT AGENCIES (see http://mednet3.who.int/prequal/procurement_agencies_prequal.htm)?**						
	No		Yes				

Q.11	**WHAT IS YOUR PROCUREMENT POLICY?**							
	Humanitarian Procurement Centre(s) (HPC)							
	International procurement							
	Local procurement (including regional procurement)							
Q.12	**IF YOU USE LOCAL (INCLUDING REGIONAL) PROCUREMENT, PLEASE EXPLAIN UNDER WHICH CIRCUMSTANCES?**							
Q.13	**IF YOU USE LOCAL OR REGIONAL PROCUREMENT, DO YOU SELECT ONLY NATIONAL AUTHORISED SUPPLIERS?**							
	No		Yes					
Q.14	**DO YOU USE HPCS?**							
	For all your needs		For some of your needs		Never			
Q.15	**WHICH HPC(S) DO YOU USE?**							
	Action Medeor		ASRAMES		CHMP			
	IAPSO		IDA		IFRC's LRMD			
	MSF Logistique		MSF Transfer		UNICEF			
	Other							
Q.16	**ARE YOU DOING A SELECTION OF YOUR SOURCES?**							
	No		Yes					
Q.17	**WHAT ARE YOUR SELECTION CRITERIA?**							
	Product information							
	Manufacturer's information							
	Visit of the manufacturer							
Q.18	**DO YOU DEMAND…?**							
	WHO Good Manufacturing Practices (GMP) compliance							
	National GMP compliance							
	Your own standards. Please specify:							
Q.19	**IS YOUR PREQUALIFICATION OF PRODUCTS LINKED TO THE MANUFACTURING SITE FOR THAT PARTICULAR PRODUCT?**							
	No		Yes		Yes, for some medicines			
	If *'Yes'* only for some medicines, please explain.							
Q.20	**OPTIONAL COMMENTS ON THE SELECTION OF SOURCES?**							
Q.21	**DO YOU HAVE FRAMEWORK CONTRACTS WITH YOUR SUPPLIERS?**							
	No		Yes		If 'Yes', which ones?			
Q.22	**DO YOU HAVE MINIMUM REQUIREMENTS FOR SHIPPING DOCUMENTATION?**							
	No		Yes		If 'Yes', which ones?			

Q.23	**WHICH MINIMUM SHELF LIFE DO YOU REQUIRE WHEN PROCURING?**										
	3 months		6 months		12 months						
	18 months		> 18 months		N/A						
Q.24	**DO YOU HAVE A POLICY FOR PRODUCT LABELLING?**										
	No		N/A		Yes		If 'Yes', please explain.				
Q.25	**DO YOU MONITOR THE PERFORMANCE OF YOUR SUPPLIERS?**										
	No		Yes		If 'Yes', please explain.						
Q.26	**DO YOU FOLLOW STANDARDS FOR THE PROCUREMENT OF MEDICAL SUPPLIES (I.E. SYRINGES NEEDLES, GAUZE, ETC.)?**										
	No		Yes		If 'Yes', please explain.						
Q.27	**DID YOU ESTABLISH WRITTEN PROCEDURES AND GUIDELINES FOR TENDERS/PROCUREMENT?**										
Q.28	**IN YOUR TENDERING PROCEDURES, DO YOU EITHER CONSIDER…**										
	…the lowest price?						…the best quality/price ratio?				
Q.29	**DO YOU WAREHOUSE PHARMACEUTICAL PRODUCTS?**										
	No		Yes								
Q.30	**IF YOU DO NOT HAVE WAREHOUSE FACILITIES, DO SUPPLIERS DELIVER TO YOU**										
	In the receiving country?						Directly to the points of use?				
	N/A		Other, please explain.								
Q.31	**WHAT IS THE CONTROL SYSTEM YOUR ORGANISATION HAS PUT IN PLACE TO CONTROL PRODUCTS AT THE POINT OF RECEPTION?**										
Q.32	**DO YOU DO ANALYTICAL QUALITY CONTROL THROUGH A LABORATORY ON A ROUTINE BASIS?**										
	No		Yes		If 'Yes', please explain.						
Q.33	**DO YOU TRACK THE BATCH NUMBER OF THE MEDICINES YOU DISPATCH TO THE LEVEL WHERE THEY ARE DISPENSED?**										
	No		Yes		Do not know						
Q.34	**HOW DO TRACK EXPIRY DATES OF MEDICINES?**										
	Manually		Using a software		Do not track						
	Other, please explain.										
Q.35	**DO YOU HAVE A BATCH RECALL PROCEDURE IN PLACE FOR MEDICINES?**										
	No		Yes		Do not know						
Q.36	**OPTIONAL GENERAL COMMENTS ON THE SECTION ON PROCUREMENT?**										

SECTION III: HOW DO YOU DISTRIBUTE YOUR PHARMACEUTICAL PRODUCTS?						
Q.37	**HAVE YOU EXPERIENCED PROBLEMS WITH CUSTOMS CLEARANCE AT RECIPIENT COUNTRY LEVEL?**					
Q.38	**HAVE YOU EXPERIENCED PROBLEMS WITH IN-COUNTRY TRANSPORTS IN THE RECIPIENT COUNTRIES?**					
Q.39	**DO YOU HAVE SPECIFIC REQUIREMENTS FOR PACKAGING FOR IMPORT AND FOR IN-COUNTRY TRANSPORTATION?**					
	No		Yes, always		Yes, in some cases	

SECTION VI: HOW DO YOU ASSURE THE RATIONAL USE OF THE PHARMACEUTICAL PRODUCTS YOU SUPPLY?								
Q.40	**IN MEDIUM LONGTERM PHASES OF HUMANITARIAN INTERVENTIONS, DO YOU MONITOR RATIONAL MEDICINE USE?**							
	No		Yes		If 'Yes', please explain.			
Q.41	**HAVE YOU OR YOUR LOCAL PARTNER(S) EVER TRAINED LOCAL HEALTH WORKERS ON RATIONAL PRESCRIBING?**							
	No		Yes		If 'Yes', please explain.			
Q.42	**DO YOU HAVE MECHANISMS IN PLACE TO REPORT ADVERSE EFFECTS OF MEDICINES**							
	No		Do not know		Yes		If 'Yes', please explain.	
Q.43	**DO YOU HAVE A DISPOSAL POLICY FOR EXPIRED/DAMAGED/SUB-STANDARD MEDICINES AND FOR MEDICAL WASTE?**							
	No		Yes		Do not know			
Q.44	**ARE YOUR DISPOSAL PROCEDURES IN LINE WITH NATIONAL GUIDELINES?**							
	No		Yes		Do not know			
Q.45	**ARE YOUR DISPOSAL PROCEDURES IN LINE WITH WHO GUIDELINES** (see http://whqlibdoc.who.int/hq/1999/WHO_EDM_PAR_99.2.pdf)**?**							
	No		Yes		Do not know			
Q.46	**WHAT PROBLEMS DO YOU FACE WHEN CARRYING OUT YOUR DISPOSAL POLICY?**							

ANNEX II – BIBLIOGRAPHY, REFERENCES & LINKS

1. "*A Model QA System for Procurement Agencies*", WHO, Draft 5, November 2004.

2. "*Generic Drugs: the Hidden Issues of Quality and Cost*", WHO, WHO Drug Information, Volume 14, N°. 2, 2000.

3. "*A Review of Water and Sanitation Issues Relating to the Funding of Humanitarian Operations under the EC Humanitarian Regulation - Model Guidelines for Mainstreaming Water and Sanitation in Emergencies, Protracted Crisis, LRRD and Disaster Preparedness Operations*", Agua Consult, 2005 (http://europe.eu.int/comm/echo/evaluation/thematic_en.htm#qualitymanag)

4. "*Standards for Quality of Pharmacy Services*", FIP, 1997 (http://www.fip.org/pdf/GPP97_en.PDF)

5. "*A Review of Drug Quality in Asia with Focus on Anti-infectives*", USP, February 2004.

6. "*Estimating Drug Requirements - A Practical Manual*", WHO/DAP, 1995 (http://www.who.int/medicinedocs/library)

7. "*Edition Equipment for: Expanded Programme on Immunization (EPI), Acute Respiratory Infections (ARI), Blood Safety (BLS), Emergency Campaigns (EC), Primary Health Care (PHC) - Product Information Sheets*", WHO, WHO/V&B/00.13, 2000.

8. "*Quality assurance of pharmaceuticals: a compendium of guidelines and related materials*", WHO, Volume 1, Geneva, 1997.

9. "*Good Manufacturing Practices and Inspection*", WHO, Volume 2, updated edition, Geneva, 2004.

10. "*Essential Principles of Safety and Performance Medical Devices (including In Vitro Diagnostic Devices)*", Global Harmonization Task Force (GHTF), GHTF - SG1- N041R6, 2004.

11. "*Labelling for Medical Devices (including In Vitro Diagnostic Devices)*", Global Harmonization Task Force (GHTF), GHTF - SG1(PD) - N043R6, 2004.

12. http://www.hc-sc.gc.ca/dhp-mps/compli-conform/int/part/ghtf_tc-tm_e.html

13. "*International Drug Price Indicator Guide*", Management Sciences for Health (MSH), in collaboration with WHO, 2004.

14. "*WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-eighth report*", WHO, Annex 2 (Technical Report Series No. 917), Geneva, 2003.

15. "*WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-seventh report*", WHO, Annex 9 (Technical Report Series No. 908), Geneva, 2003.

16. "*WHO Pharmaceutical Newsletter - N°1*", WHO, 2006, p.16.

17. "*WHO adverse Reaction Terminology, terminology for coding clinical information in relation to drug therapy*", WHO, December 2003, p.9. (http://www.umc-products.com/graphics/3149.pdf)

18. "*Guidelines for Drug Donations - Interagency Guidelines*", WHO, WHO/EDM/PAR/99.4, Revised, 1999.

19. "*Guidelines for Safe Disposal of Unwanted Pharmaceuticals in and after Emergencies - Interagency Guidelines*", WHO, WHO/EDM/PAR/99.2, 1999.

ANNEX III – ITINERARY AND CONTACTS

Location	Date	Organisation	Contacts
Brussels (Belgium)	January 16th – 19th, 2006	DG ECHO	Peter CAVENDISH, Pablo IBANEZ, Martine FOUWELS and Philip MAUGHAN (Johan HEFFINCK and Jorge CASTILLO by telephone)
		Polaris (Auditing Firm)	Julian RUMMINS, Sarah MORRISON and Peter AARDSMA
		VOICE	Kathrin SCHICK
		MSF	Inma VASQUEZ, Cecile MACÉ and Jean-Michel CAUDRON
		IFRC, BXL	Luc HASKENS and Jeannette ADRIAENSSENS
		Fritz Institute	Remi CARRIER
Clermont-Ferrand (France)	January 20th – 21st, 2006	PSF	Marina BENEDIK, Yacine LOUZ, Jean GAZZOLA and Christine GODEFROY
		CHMP	Helene DEGUI, Alassane BA and Jean-Yves VIDEAU (ex-CHMP, retired)
Paris (France)	January 23rd, 2006	Tulipe	Dominique LEJOYEUX
Geneva (Switzerland)	January 24th – 25th, 2006	WHO	Gilles FORTE, Françoise MAS, Jon CARVER and Marthe EVERARD
		ICRC	Francois MOUNIS, Stephanie ARSAC and Brian TISDALL
		IFRC	François COURTADE, Birgitte STALDER, Armen PETROSYAN, Pieter DE RIJKE and Domitille CADET
		UNHCR	Meeting cancelled
Copenhagen (Denmark)	January 26th – 27th, 2006	UNICEF	Hanne Bak PEDERSEN, Peter Svarrer JAKOBSEN, Ludo SCHEERLINCK, Than SAUNG, Bonface FUNDAFUNDA, Soran HANSEN and Murtada SESAY
		UNFPA	An JANSSENS
		IAPSO	Alfonso FERNANDEZ and Greg SONEFF
		DG ECHO	Johan HEFFINCK
Nairobi (Kenya)	March 6th – 7th, 2006	DG ECHO	Johan HEFFINCK, Enric FREIXA, Jan EIJKENAAR, Cedric VANDERMUELEN and John HAYWARD
		PSF	Nadia OMER and Dennis METZINGER
		CHMP	Francois SEVRANCKX and Nicolas DECOCERCHELLE
		WHO	Michel YAO
		MSF	Raghu KISHNASWAMY
		MEDS (Mission of Essential Drugs and Supplies)	Chris WAMALWA
		IDA	Pascal VERHOEVEN and Talitha HOGEBRUG
		ICRC	Dorothy WAFULA

Goma (DRC)	March 8th – 9th, 2006	MDM	Kalil TOURE and Emanuel RINK
		Merlin	Stephane TEMPERMAN
		ICRC	Beatrice FABER and John KABIJA
		CARE	Denise MAMFA
		WHO	Aboubacar KAMPO
		PSF	Christian BURGLE
		GOAL	Mark CLARK and Annie DEVONPORT
		ASRAMES	Ed VREEKE, Arthur KATAVALI and Leonard MBUSAMWANA
		World Vision	Leonardo SHAMAMBA
Jakarta (Indonesia)	March 13th, 2006	DG ECHO	Linda RUPIDARA
		MSF	Olaf VALVERDE and NURFADLIAH
		MDM	Vincent CAUCHE
		WHO	Vijay NATH
Banda Aceh (Indonesia)	March 14th – 16th, 2006	DG ECHO	Marco LENZI
		PSF	Michelle LAZARD and Christelle MORAIN
		CAM	Caroline ROSE and Bertrand ROSE
		IOM	Kristin PARCO
		Merlin	Yolanda BAYUGO
		MSF – H	Jade PENA
		MSF – B	Kaat DE NIJS
		WHO	S. PRUTAVISH, Tomasz STAREGA and ELHADRAMI
		MDM	Petra WISBE and Stephane FLANDRIN
		AMI	Philippe LEGER