REPORT

WORKSHOP FOR PACIFIC ISLAND COUNTRIES ON THE EUROPEAN COMMUNITY-WHO PARTNERSHIP ON PHARMACEUTICAL POLICIES AND THE IMPLEMENTATION OF THE REGIONAL STRATEGY FOR IMPROVING ACCESS TO ESSENTIAL MEDICINES

Nadi, Fiji
3-5 November 2004

Manila, Philippines
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The views expressed in this report are those of the participants in the Workshop for Pacific Island Countries and Areas on the European Community-WHO Partnership on Pharmaceutical Policies and the Implementation of the Regional Strategy for Improving Access to Essential Medicines and do not necessarily reflect the policy of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the Workshop for Pacific Island Countries on the European Community-WHO Partnership on Pharmaceutical Policies and the Implementation of the Regional Strategy for Improving Access to Essential Medicines, which was held in Nadi, Fiji, from 3 to 5 November 2004.
SUMMARY


Thirty-five representatives from 18 Pacific island countries and areas, one temporary adviser, one consultant and two observers participated in the workshop. The WHO secretariat included six persons: two from the WHO Headquarters (Essential Drugs and Medicines Policy) and four from the Western Pacific Region of the WHO.

The objectives of the workshop were:

(1) to exchange experiences and identify problems, gaps and priorities to improve access to essential medicines;

(2) to prepare collaborative work plans for the European Community-WHO partnership project and for implementation of the Regional Strategy for Improving Access to Essential Medicines; and

(3) to prepare national work plans in drafts, for the European Community-WHO partnership project and for implementation of the Regional Strategy for Improving Access to Essential Medicines.

The workshop comprised plenary presentations and discussions, individual country and group work, and exercises on national and intercountry collaborative work plans for the EC-WHO partnership project and implementation of the Regional Strategy for Improving Access to Essential Medicines. The approach was problem-oriented and problem-solving. Participants reviewed the conclusions of the November 2003 workshop in Fiji (e-drug network, pooled procurement, human resources development, and quality assurance) and those of the small working group on human resources development, which met in Fiji from 1 to 2 November 2004. They also received an update from the Pacific Island Forum Secretariat on its intellectual property development plan.

By the end of this workshop participants had reviewed and presented:

- national draft work plans of actions within the framework and format of the Regional Strategy and technical areas for 2005-2010, and the EC-WHO partnership (detailed plans for 2005), to be submitted to WHO in final version by January 2005; and

- collaborative intercountry priority activities and an intercountry plan of action under the EC-WHO partnership, with cross-referencing to technical areas in the Regional Strategy. The intercountry plan of action (Annex 7) was consolidated by WHO after the workshop, circulated to participants in the workshop and approved.

The three discussion groups formed during the workshop consolidated their proposals and agreed on the following intercountry activities for 2005:
• Exchange information on and distribute national drug policy guidelines and documents, and e-mail exchange/start of communication network.

• Liaise with the Pacific Island Forum Secretariat on matters relating to intellectual property, with the aim of developing expertise in countries.

• Carry out a situation analysis on procurement in Pacific island countries and areas, make recommendations for improving current procurement and draft terms of references for a working group on procurement/quality assurance.

• Establish a working group on procurement/quality assurance. The countries wishing to be part of this group are: Cook Islands, Fiji, Kiribati, Papua New Guinea, Samoa, Solomon Islands and Tonga. Initially the group will work through e-mail contact, coordinated by the WHO Suva office.

• Compile and review training tools and materials on drug supply management and rational drug use. Develop training tools for technicians and nurses. Establish regional and in-country training on drug supply management and rational use. WHO and Pacific island working group to identify training and prepare material which can be used through the open learning centres. Identify available inventory systems already in use and exchange information on these.

• Develop model medicines regulations, including drug registration requirements, based on review of existing regulations.

• Hold an intercountry one-week workshop to discuss model medicines regulations and draft country-specific regulations, including requirements for drug registration.

• Hold an intercountry workshop on review/evaluation of applications for registration, in particular evaluation of certificates.
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1. INTRODUCTION

The workshop for Pacific Island Countries and Areas on the European Community (EC)-WHO Partnership on Pharmaceutical Policies and the Implementation of the Regional Strategy for Improving Access to Essential Medicines, was held in Nadi, Fiji, from 3 to 5 November 2004.

1.1 Background information

The meeting was held in the context of and to provide guidance for implementation of the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region, 2005-2010 in each individual country, and among countries. More specifically and within the strategy, the workshop defined priority activities for 2005 for the EC-WHO Partnership on Pharmaceutical Policies in Pacific island countries and areas.

Moreover, the workshop was a follow-up and status review of major activities following the Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries, held in Fiji from 25 to 27 November 2003. Human resources development was identified at that workshop as a priority action, and this workshop would also review the report of the small Human Resources Development working group that met for the first time from 1 to 2 November 2004, in Fiji.

1.2 Objectives

The objectives of the workshop were:

(1) to exchange experiences and identify problems, gaps and priorities to improve access to essential medicines;

(2) to prepare collaborative work plans for the European Community-WHO partnership project and for implementation of the Regional Strategy for Improving Access to Essential Medicines; and

(3) to prepare national work plans in drafts, for the European Community-WHO partnership project and for implementation of the Regional Strategy for Improving Access to Essential Medicines.

1.3 Participants

The workshop was attended by 35 participants from 18 Pacific island countries and areas: American Samoa, Cook Islands, Fiji, French Polynesia, Kiribati, the Federated States of Micronesia, the Commonwealth of the Northern Mariana Islands, the Marshall Islands, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tokelau, Tonga, Tuvalu and Vanuatu. There were also one temporary adviser, one consultant, two observers and a WHO secretariat of six persons; two from the WHO Headquarters (Essential Drugs and Medicines Policy), and four from the Western Pacific Region (Annex 1).
1.4 Organization and workshop methodology

The workshop programme consisted of plenary presentations and discussions, group work and exercises on the European Community (EC)-WHO partnership project and on the Regional Strategy for Improving Access to Essential Medicines. The approach was problem-oriented and problem-solving.

The agenda/timetable for the workshop is in Annex 2 and the list of documents and presentations in Annex 3. Participants received presentations and other material in hard copy and on CD.

1.5 Opening ceremony

The WHO Representative in the South Pacific opened the meeting and welcomed the participants on behalf of the WHO Western Pacific Regional Director. He said that over the years, in the Western Pacific Region, improving access to good quality essential medicines and vaccines and ensuring their appropriate use had become one of the priorities.

He was happy to announce that, during its fifty-fifth session in Shanghai from 13 to 17 September 2004, the Regional Committee for the Western Pacific had endorsed the Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region, 2005-2010. The overall objective of the Regional Strategy is to provide operational and practical guidance to Member States and WHO on improving access to essential medicines.

He was very pleased that the European Community and WHO had negotiated and agreed upon a project which would benefit countries in Africa, the Caribbean and the Pacific, the EC-WHO Partnership on Pharmaceutical Policies. Fourteen countries in the Pacific will benefit from this project, which will last until the end of 2008. Project support will be provided under headings corresponding to those in the Regional Strategy. He concluded by expressing his sincere thanks to the European Community for providing this opportunity to strengthen the pharmaceutical sector in Pacific island countries and areas.

On behalf of the Fiji Ministry of Health, Mr Peter Zinck, Chief Pharmacist of the Fiji Pharmaceutical Services, then welcomed all participants to Fiji and the workshop.

1.6 Appointment of Chairperson, Vice-Chairperson and Rapporteur

The workshop elected Mrs Melanaite Mahe, Principal Pharmacist, Tonga, as Chairperson, Mr Biribo Tekanene, Chief Pharmacist, Palau, as Vice-Chairperson and Mrs Stella Tulo, Lecturer, Pharmacy Discipline at the University of Papua New Guinea, as Rapporteur.

2. PROCEEDINGS

2.1 The European Community-WHO Partnership on Pharmaceutical Policies

The speaker, Dr E. Carandang, Medical Officer, EDM, WHO Headquarters, briefly introduced the current global pharmaceutical situation before discussing the overall goal and objectives of the EC-WHO Partnership on Pharmaceutical Policies.
The major global issues are:

- In spite of progress, 2 billion people still have no access to essential medicines; around 50% of them living in Asia.
- New essential drugs, such as antibiotic, antimalarial, antituberculosis and antiretroviral medicines are expensive.
- Irrational drug use is widespread and a hazard to health.

However, there has also been much progress over the years: - the essential drugs concept is now nearly universal. More than one hundred countries have essential drug lists (EDL) and most of these have updated their lists within the last five years. The same applies to standard treatment guidelines on clinical practice. The 2004 CD-ROM of WHO Medicines Bookshelf, with links to the web-based Essential Medicines Library, is an excellent source of valuable and useful information.

The overall goal of the EC-WHO Partnership programme is to help save lives and improve health by closing the huge gap between the potential that essential medicines have to offer and the reality that for millions of people, particularly the poor and disadvantaged, medicines are unavailable, unaffordable, unsafe or improperly used.

The EC-WHO Partnership programme covers 49 countries in Africa, 17 in the Caribbean, and 14 in the Pacific region (Cook Islands, Fiji, Kiribati, the Federated States of Micronesia, the Marshall Islands, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu and Vanuatu). It is guided by the WHO general programme of work 2003-2007, the WHO Medicines Strategy and regional strategies, and is supported by results-based management.

Dr Carandang reviewed the forms that WHO had asked countries to try to fill in before the workshop. She then discussed expected results (see Appendix 1 for details), priority and other activities, and indicators within the seven categories of work agreed upon in the EC-WHO pharmaceutical policies and programmes: (1) national drug policy (NDP) implementation; (2) international trade agreements - monitoring, legislation and regulation; (3) affordability and financing; (4) drug supply management; (5) norms and standards; (6) effective drug regulation; and (7) rational use of medicines by health professionals and control of microbial resistance.

Relevant points from the discussion that followed the presentation were:

- The successful Caribbean drug supply and procurement system could be a model for the Pacific island countries and areas.
- The Pacific island countries and areas are very interested in using the WHO Bookshelf and the web-based Essential Medicines Library for information on quality, pricing, selection of medicines etc.
- Work on Trade Related Intellectual Properties (TRIPS) compliance legislation in countries must involve people from the health and other sectors, in addition to those from the trade sector. A global technical group looking at aspects and implications of TRIPS has now been formed at WHO Headquarters.
- The smallest Pacific island countries and areas feel that the EC-WHO Partnership and Regional Strategy forms were too complex for their conditions and that they are likely to benefit more from intercountry and regional collaboration.
2.2 Report on implementation of the 2004 contribution from the European Community

Mr Truls Eriksen, Technical Officer, WHO Suva Office, and coordinator of Pacific island activities under the EC-WHO project, reviewed the 2004 draft work plan developed in the WHO Western Pacific Regional Office and finalized by WHO Headquarters. The plan defines expected results (details on these are in Appendix 1) and activities. In 2004, implementation within the defined categories of work (see above under 2.1) covered:

1. (a) the current workshop; (b) a workshop in September 2004 on improving access to essential medicines (instead of projected monitoring survey on NDP implementation); and (c) the Fiji 1 to 2 November 2004 informal meeting on HRD;
2. technical support to review and amend patent legislation (Samoa);
3. (a) a pricing survey methodology in Fiji in September-October 2004, using WHO/Health Action International (HAI) price survey methodology; and (b) a survey on comparative analysis of public and private expenditures in Pacific island countries and areas;
4. (a) computers and printers for Vanuatu provincial hospitals to improve drug management; (b) computers and printers for Solomon Islands for the government pharmacy; (c) participation in an international course in the Netherlands for Solomon Islands; (d) expansion of the Fiji Bulk Purchasing Scheme by visiting and marketing the Scheme to policy-makers in neighbouring countries;
5. support for revision of medicines legislation in three countries (the Federated States of Micronesia, Kiribati and Samoa); and
6. participation of two persons from Fiji in a rational drug use (RDU) course for communities, held in South Africa.

By 29 October, the implementation rate for 2004 was 68% and it was likely to be 100% by the end of the year.

In the discussions, key points and recommendations were:

- The RDU course should be brought to the Region and the Pacific.
- There is a need to improve training in drug supply management; training is a must and it was suggested that experts be brought to the Pacific islands.
- Many pharmacists in Pacific island countries and areas were not taught inventory/stock management as part of their undergraduate education. The curricula of Fiji School of Medicine and the University of Papua New Guinea include drug management.
- It was suggested that, for pharmacy technicians, consideration should be given to adapting the courses in New Zealand and other countries (e.g. in the United States of America) to Pacific island needs, and to reviewing Pacific local curricula, such as those in Fiji, Papua New Guinea, Solomon Islands and Tonga. This was also recommended by the 1 to 2 November 2004 HRD working group.
2.3 Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region (2005-2010)

The WHO Regional Adviser in Pharmaceuticals, Dr Budiono Santoso, presented the development process and endorsement of the Regional Strategy for Improving Access to Essential Medicines for 2005-2010. He recalled that, on 17 September 2004, the Regional Committee for the Western Pacific had endorsed the strategy (WPR/RC55.R4). He underlined that the Strategy aims to provide operational and practical guidance to Member States and WHO; that it will intensify and consolidate efforts to improve access to essential medicines; and that it also is a guide for working with WHO Headquarters and international partners to improve access to antiretroviral medicines in the Region.

He outlined the content of the Regional Strategy, which includes issues, challenges, strategies and actions for countries and WHO, within the following eight technical areas of work:

- rational selection;
- rational use;
- affordable prices;
- access to medicines, trade globalization and Trade Related Aspects of Intellectual Property rights (TRIPS);
- sustainable financing;
- supply and management systems;
- quality; and
- monitoring and evaluation.

The Regional Adviser asked participants to consider priority actions under the above technical areas when drafting their national work plans. He referred to the guide for implementation, which he introduced (2.4).

A Technical Advisory Group for implementation of the Regional Strategy will be appointed in 2005 and country experiences in implementing the Strategy will be included on the WHO Western Pacific Regional website.

2.4 Guide to implementation of the Regional Strategy

The Regional Adviser introduced the Guide and the general principles for implementation of the Regional Strategy for Improving Access to Essential Medicines.

Important considerations in implementation of the Regional Strategy include:

- setting priorities;
- being realistic;
- considering the potential for success, the magnitude of impact, the risk of unintended effects, and feasibility (technical, political and cultural, cost and economics);
• starting with easy actions first;
• considering how the priority actions will be implemented;
• implementing step by step;
• pilot testing before using a nationwide approach – considering the effects of decentralization and implementation at different levels;
• separating priorities (funded and unfunded); and
• tapping potential resources - in the EC-WHO project, and also considering other donors.

He drew participants’ attention to the different categories of action:
• development and implementation of policies, tools, legislation;
• training, education and awareness raising;
• review and analysis;
• monitoring and evaluation;
• collaboration among stakeholders; and
• sharing of information.

The Regional Adviser also gave an example (within the area of rational selection) of how to complete an action in a national work plan under the Regional Strategy (2005-2010).

Exercise: Participants were then asked to write down priority actions for their own countries, to indicate steps in implementation on a given format, and to discuss among themselves in groups.

The draft country action plans, with detailed plans for 2005, will be submitted in final to the WHO at the end of 2004, or at the latest January 2005.

2.5 Review of findings from the November 2003 workshop in Fiji

The findings and conclusions on essential medicines from the 25 to 27 November 2003, Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries and Areas concerned: (1) e-drug network and information exchange; (2) pooled procurement; (3) human resources development; and (4) quality assurance.

2.5.1 E-drug network and information exchange

It was reported that the E-drug network and information exchange intended for Pacific island countries and areas had been tried for one year but did not work. Apart from the costs that would be incurred if Pacific islands were to become part of the existing international E-drug network, no e-mails had come in from a Pacific island country or area during the trial period, according to the volunteer coordinator and observer from Australia at this workshop. The workshop learnt that only half of the people in the proposed Pacific network had access to direct
e-mails. Fax was dismissed as an inefficient alternative. Instead, it was agreed to take a pragmatic approach and start an e-mail communication network, coordinated by the WHO Suva Office, for discussion and exchange of information on relevant issues, such as procurement, quality, prices etc. For those who did not have their own e-mail addresses, it was proposed to use the Pacific Open Learning Health Net in the computer laboratories provided by WHO for ten Pacific island countries.

2.5.2 Pooled procurement feedback, and update on antiretrovirals (ARV) procurement for the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)

The 2003 Fiji workshop noted the need for cooperation on regional contracting, and combining of purchasing power to achieve economies of scale, with multi-drop delivery, as an alternative option worth exploring within pooled procurement. It also proposed strengthening of the small island states (SIS) and Fiji Bulk Procurement Scheme, and the formation of a procurement working group (Annex 8 in Report RS/2003/GE/37(FIJ), April 2004).

Mr Peter Zinck, Chief Pharmacist, Fiji Pharmaceutical Services gave a presentation on critical success factors for a pooled bulk procurement concept.

He first told the participants that nothing had changed within Pacific pooled procurement efforts since the 2003 workshop. Neither had the proposed working group met.

To enable better understanding on how to approach problems, solutions and options for a suitable Pacific pooled procurement scheme, he explained the complexity of the pharmaceutical supply system, at international, national, regional, district and community levels, and the interaction between players and institutions involved in the public and private sectors, and partners, such as donors, etc.

He gave examples of major critical success factors, including political will, accurate estimates of drug requirements, and monitoring and evaluation, and spoke of lessons learnt from successful multi-state procurement systems. He proposed a mechanism for payments and also drew attention to potential obstacles to joint procurement. He concluded his presentation by giving details on three kinds of purchasing options: (1) informed buying; (2) coordinated buying; and (3) central negotiations.

Moreover, he informed the workshop that purchasing options had been put forward to the Global Fund to Fight AIDS, Tuberculosis and Malaria and that the Fund could contract Fiji Pharmaceutical Services to purchase medicines. The current status is that orders have been placed for antiretroviral drugs and a pharmacist has been contracted and will be working at the Fiji Pharmaceutical Services. The Global Fund will pay for that pharmacist. The ordering of medicines had not gone through the Country Coordinating Mechanism (CCM) and the ARV purchases had been based on selected items. He added that the visit of the WHO consultant who had helped Fiji to review and draft legislation with regard to TRIPS had been very timely; the public health clause under the agreement could be incorporated into the draft before it was presented to Parliament.

After discussions at the end of the session, the workshop agreed on the need for WHO to create the working group on procurement that was proposed in 2003 as soon as possible. However, its tasks should be extended to cover quality assurance and regulatory matters (PQAR), and relevant issues and tasks related to TRIPS. Since the working group’s tasks would cover many and complex issues, participants requested WHO to recruit a consultant on procurement to do the preliminary work before the first meeting of the working group. The consultant’s work should include: a situation analysis in Pacific island countries and areas; a visit
to pooled procurement systems, such as in the Caribbean; a review of quality assurance and regulatory issues; and drafting of the terms of reference for the small working group.

2.5.3 Human resources development: Report from the small group, Fiji, 1 to 2 November 2004

The Regional Adviser for Pharmaceuticals recalled the HRD findings of the November 2003 meeting in Fiji (Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries). He informed participants about the deliberations of the small HRD working group that met for the first time from 1 to 2 November 2004, in Fiji. Its Chairperson, Mr Ray Skinner, from Solomon Islands, then presented the group’s recommendations on human resources development and issues which fall under the following main subject areas and actions: (1) general management and specific drug management; (2) legislation and regulation; (3) increasing the workforce by tapping certain sources; (4) crediting and taking advantage of experience; (5) learning from a study on migration of skilled health professionals in the Pacific; (6) consistency among the Pacific islands pharmacy technician curricula; (7) drug management and rational drug use course for nurses in health services and in nursing curricula; (8) continued networking and collaboration of the Pacific islands/HRD pharmaceutical working group; (9) pursuing estimation of pharmacy workforce needs in Pacific island countries and areas; (10) the need for technical working groups to meet regularly addressing priority areas; and (11) Pacific island countries and areas to complete table to identify priority human resource needs.

Participants agreed that it was very useful to have the small HRD group reviewing problems and issues before a large meeting is convened, recommended that the small HRD working group continues it work and accepted its recommendations with some additions/modifications as follows, and in broad terms:

• bring training programmes to Pacific island countries and areas, as far as feasible, instead of having people travel elsewhere;

• review existing training tools and develop suitable ones in drug management and rational drug use for technicians and nurses, and start in-country training for these target groups;

• use regional expertise for training;

• compile distance on-line learning packages;

• submit a request to the European Community for volunteers and scholarship grants for capacity building.

Exercise: At the end of the session, participants received a form for country human resource development (HRD) plans of action to complete for the Thursday 4 November session and presentation (see Annexes 4a and 4b for examples of two completed HRD forms). The purpose of the form was to list functions in pharmaceutical services, based on the technical area headings in the regional strategy (selection, rational use, access to medicines etc.), to spell out who does what now, and where, and what is needed in the form of HRD strategies, actions, grades of priority (high, medium, low) and available courses/resources.

2.5.4 Quality assurance

The 2003 Fiji workshop concluded that there was a need to explore a common approach to supplier and/or product registration and a joint policy on essential medicines procurement, as a
move towards harmonization of requirements for Pacific island countries and areas and possible mutual recognition.

Dr Valerio Reggi, EDM, WHO Headquarters, gave a presentation with the title, "A harmonized approach to regulation of medicines in the Pacific?" The talk was divided into three parts: (1) what is harmonization; (2) relying on other drug regulatory authorities (DRA); and (3) two case studies.

Dr Reggi defined harmonization of drug regulation as “a process aimed at narrowing differences in regulatory requirements which may not necessarily lead to identical regulatory decisions”. The goals of harmonization of drug regulation are to “improve protection of public health and promote public health by facilitating faster availability of new drugs, development of the pharmaceutical industry and trade, research and development of drugs”. He told the workshop of the ongoing efforts, conditions, advantages and limitations of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). ICH has six co-sponsors (from Europe, Japan and the United States of America) and four observers (from Australia, Canada, New Zealand and WHO). Among the specific objectives mentioned, “reduction of workload and cost for the drug regulatory authority” might be the most relevant for Pacific island countries and areas.

Among four possible approaches to harmonization of drug regulation and drug registration, two would seem to be most suitable and realistic for the Pacific, as they can be used with limited resources and expertise. They are:

- accepting the assessment of or decision on drug registration made by another country (reference country); and

- the WHO Certification Scheme.

However, these require the Pacific island countries and areas to develop proper procedures and identify reference countries.

Dr Reggi explained the background, procedures and prerequisites for participation in the WHO Certification Scheme (current 1992 version - the Scheme dates back to a 1963 WHA resolution), gave examples of the three types of certificate that exist, institutions issuing these and what the certificates say and imply. A total of 142 countries currently participate in the Scheme, but no more than 50 of those have developed reliable self-assessment methods and procedures to date.

He highlighted operational and practical aspects of the WHO Certification Scheme, such as information that should not be missed; what to do when in doubt; what to do and what not to do; and what to do if a problem arises after marketing authorization has been granted.

The advantages of the WHO Certification Scheme are that a standardized format defines what information should be provided, that it is a mechanism to improve interchange of information, and that it offers follow-up on complaints. The limitations are that a certificate is as good as the certifying authority and that there is no mechanism to “screen” a certifying authority. Each country must therefore identify its own reference countries.

From the presentation and the two case studies, workshop participants were given three clear messages:

- identify your own reference countries;
• monitor importation and produce meaningful statistics; and

• develop a policy based on facts.

Dr Reggi concluded his talk by asking if Pacific islands want a harmonized approach and, if so, what WHO should do to help them improve the situation in their countries and areas.

From the discussion that followed, it is clear that the Pacific island countries and areas are interested in collaborating in quality assurance and drug registration. In reply to a question on the value on sampling and testing the WHO Certification Scheme, the speaker replied that it would not be feasible to do this because of extreme costs and the absence of a strong legal basis for doing so. The best solution is to identify reliable reference countries and sources, as well as using “twinning” with certain countries.

Participants agreed that the procurement consultant and the small procurement and quality assurance/regulatory matters (PQAR) working group, as well as individual countries in their national implementation plans, should address issues and weakness in quality assurance and regulations for imported medicines, particularly requirements for pre-packed drugs, which have not been registered or gone through the regulatory system in the exporting country.

At the end of the session, some participants brought up the problem of what to do with expired drugs, which mostly but not exclusively, are donated drugs. Apart from using the WHO Guidelines for Donations, it was recommended that procedures for destruction of expired and certain other drugs should be developed in PICs and that this would be a task for the small PQAR working group.

2.6 Pacific Island Forum countries

2.6.1 Intellectual property development plan and update from the Pacific Island Forum Secretariat

The presentation by Ms Gail Olssen, Pacific Island Forum Secretariat, was divided into three parts: (1) Forum mandate on intellectual property (IP); (2) implementing IP policies in the region – challenges; and (3) the Forum’s programme to address challenges.

The Forum’s mandate from the 1999 meeting of trade ministers, addresses intellectual property as an enabling mechanism for trade and investment, sets out to improve core intellectual property issues, such as patents, trademarks, copyrights and geographical indications, and was also established to protect indigenous intellectual property rights and traditional knowledge. The Forum notes the World Trade Organization (WTO) as the most important international forum for negotiation of trade and commercial policies. The WTO members in the Pacific are Fiji, Papua New Guinea and Solomon Islands. Samoa, Tonga and Vanuatu are acceding WTO members.

Since patent laws affect accessibility to essential medicines, the 2001 Forum of Trade Ministers prepared for the DOHA/WTO rounds, agreeing to participate actively in the TRIPS and public health negotiations to secure access to affordable drugs. In 2002, Forum leaders directed the Secretariat to develop the Pacific Regional Plan of Action against HIV/AIDS, in cooperation with other regional and international organizations. The leaders endorsed the HIV/AIDS Regional Strategy in 2004 and an implementation plan followed. The 2005 Forum will discuss implementation progress and areas requiring additional attention.

Pacific island countries and areas face several capacity-related challenges such as:
• a lack technical and human resource capacity in countries to deal with IP issues;
• slow progress of IP initiatives – other development issues take greater priority;
• importance of IP is not limited to trade and investment objectives – enlarged IP focus to take on public health concerns; and
• legislative reform is imperative – laws are outdated and technical assistance is needed.

Ms Olssen spoke of other challenges, in particular those relating to the patent rules of the WTO TRIPS Agreement. She analysed these, pointing out the competing interests in the agreement and the effects these will have on access to affordable medicines. In spite of some achievements, cumbersome and complex procedures remain as one of several operational challenges, for example the use of compulsory licenses and remuneration to a patent owner.

The Forum Secretariat IP Programme responds to challenges, for example, by providing regional technical assistance and forming strategic alliances with others. Annual trade policy courses, addressing TRIPS-related concerns, are conducted. In 2005, there will be a special workshop on TRIPS, in Fiji, which will be supported by the World Intellectual Property Organization (WIPO) and WHO. A newly established Forum office in Geneva has been created to facilitate submission to the WTO, WIPO and other forums. In its efforts to continue the process of enabling access to affordable medicines, the Forum will step up its cross-cutting efforts and activities with relevance to public health issues.

After the presentation, participants discussed the need for linkages between trade and other government departments, health in particular, to address public health issues and access to medicines. Participants learned more about Fiji's experience with TRIPS and patent legislation.


Prior to the workshop, countries had been asked to prepare draft country plans of actions, with details for 2005. The plans will be finalized after the workshop and submitted to WHO at the latest in January 2005. Two examples of these draft country plans of action on the EC-WHO Partnership collaboration can be seen in Annex 5. The results of exercises mentioned above under 2.4 (Regional Strategy) and 2.5.3 (Human resources development) also served as input in the reviews and presentations of the draft country plans of action.

Summary of country presentations (situations, problems and issues, planned actions and priorities, need for assistance etc.):

American Samoa: Uses the United States Food and Drug Administration (FDA) system.

Cook Islands: Lack of staff. In HRD issues liaise with Fiji for secondment of personnel to Ministry of Health.

Fiji: Recommendations for Pacific island countries and areas on bulk procurement and consultant for this. Human resources, training, capacity building for drug regulatory staff a priority. Requests assistance from WHO for model for drug registration, for adverse drug reaction (ADR) workshop, for twinning, and for market surveillance on counterfeit drugs, assessment and training.
French Polynesia: Main difficulties are rational drug use and good practices in dispensing and prescribing. Training of staff locally is needed and assistance required. Requests information of exchange on promotion of pharmaceutical policies and improving supplies management.

Kiribati: Technical support required for indicators for monitoring national drug policy and for update of essential medicines list and formularies. Patent legislation to be reviewed and other relevant sectors to be included. Guidance required for generic policies. Training required for procurement and for rational drug use, pharmacotherapy and pharmacoeconomics. Interested in bulk procurement from Fiji.

The Federated States of Micronesia: Federal Government is the coordinating agent. No national drug policy and need assistance. Dispensing and rational drug use issues, particularly on outer islands where health officials prescribe and dispense. Training for pharmacists and pharmacy assistants required, especially in forecasting, which is a big problem.

The Commonwealth of the Northern Mariana Islands: United States/FDA-approved medicines. No flexibility to buy out of this approval. Have a federal supply schedule. Prime vendors used. Access to medicines not a problem. Quality and drug registration by FDA. Expired drugs sent back to vendor. Lessons learnt: twice a year procurement created huge inventory, but procurement every two months reduced inventory.

The Marshall Islands: No problems with money, but there is a need for money to be managed well. Have expert in health care services but need support. Recommend that the country concentrate on regulatory affairs for patient safety. Should continue to expand rational drug use requirements to all levels of health. Urgent needs for a national drug policy. Need regulatory body to monitor. Require regional or international assistance for capacity building in drug supply management.

Nauru: Need capacity building. National drugs policy is a priority. Procurement training required, especially forecasting. No problems with access.

Niue: Need to update legislation in accordance with public health. Requires effective drug registration. Require training in rational drug use.

Palau: Need to look at cost of irrational prescribing. Need to understand issues of international trade agreements and would like a workshop on this. Requires training in financial management. Will seek assistance from the Commonwealth of the Northern Mariana Islands in drug management and in the handling of expired drugs. Interested in pooled procurement, but will have to consider pros and cons. Require assistance with effective drug regulation and scheduling of drugs. Problems with disposal facilities for expired drugs/medicines or confiscated medicines.

Papua New Guinea: Human resources are a problem in implementing the national drug policy. Procurement is a huge task. Rational drug use, pharmacotherapy and pharmacoeconomics training can be done locally, but will need support to facilitate the training.

Samoa: National drug policy not yet implemented – will review patent legislation to include public health issues. Public health insurance approved, but pricing policy assistance required. Need to update essential medicines list.
**Solomon Islands**: Logistics is a problem. Wish to see regional collaboration and technical working groups formed as a result of this workshop. Priorities are: updating standard treatment guidelines; undertaking antibiotic reviews; reforming and starting drug and therapeutics committees; conducting a national pharmacy assessment survey; addressing budget issues; extending network of medical stores; and strengthening import control and quality assurance.

**Tokelau**: Will revise and update the essential medicines list and initiate a programme to review it every three years. Nurse dispensers to receive education on site using distance learning courses, but they will also need to go to New Zealand for experience. Inventory control to be upgraded with computer installations. Drug and therapeutic committees not established. Rational drug use and drug supply management for nurses need strengthening; the diploma in nursing in Fiji is an excellent opportunity to introduce this. Overuse of antimicrobials is a problem. Quality assurance is handled by New Zealand - therefore no problems.

**Tonga**: Retention of pharmacists and assistants very good in Tonga. Will review essential medicines list. Therapeutic goods act established. Technical assistance required with drug registration. Will introduce new indicators to measure access to medicines. Differential pricing and looking at experiences in countries in the region important. Need for short-term workshops and training in drug supply management. Some things cannot be done by one small country alone and require a regional approach. This workshop is an important milestone for looking at regional issues and collaboration.


**Vanuatu**: Has no national drug policy. Stresses need for regional collaboration (because of size of countries) to share resources. Stock management for nurses important. Laws updated. Survey of consumers on prices/charges, perceptions of service, etc. undertaken. Requires technical support for procurement. Good manufacturing practices (GMP) not followed. Wishes to have regional courses. Interested in pooled bulk procurement. Disposal of expired drugs a big problem. Rational drug use, drug supply management and legislation high priorities. Recommends regional e-mail links. Stresses involvement of nongovernmental organizations in community education on rational drug use.

Annex 6 shows the updated summary of selected pharmaceutical-related information in the WHO Western Pacific Region/Pacific island countries and areas.

**Issues arising from the country presentations:**

(1) **Human resource development:**

- Areas for human resource development include:
  
  (a) Availability of human resources to actually do the work
(b) Rational drug use – good practices in dispensing and prescribing
(c) Drug supply management for different levels of health workers dealing with drug supplies, especially nurses
(d) Drug regulation – attachments to selected authorities in the Asia-Pacific region
(e) TRIPS/International Trade Agreement – need for education
(f) Pharmacotherapy and pharmacoeconomics
(g) Training of pharmacy assistants
(h) National drug policy advocacy and formulation
(i) Financial management
(j) Computer training

(2) Regional collaboration:
   • Areas for collaboration include:
     (a) HRD
     (b) Pooled bulk procurement
     (c) Information exchange/e-mail link between regional members
     (d) Quality assurance
     (e) TRIPS/International Trade Agreement – accessibility of medicines

(3) Safe disposal of expired/confiscated medicines and inappropriate drug donation
   • Policies for safe disposal and, if policies are available, procedures and implementation of these.

The draft country action plans and the common issues identified above served as a basis for subsequent group work (2.8) on intercountry activities and plans of action.
2.8 Group work

Participants were divided into three groups for intercountry planning and identification of intercountry collaboration. All three groups were given the same tasks which were to identify intercountry collaboration, basing it on: (1) the Regional Strategy for Improving Access to Essential Medicines (2005-2010); (2) the EC-WHO Partnership for 2005-2008 (detailed plan for 2005); (3) issues arising from the workshop's presentations and discussions; and (4) the country presentations. To help in correlating and cross-referencing between the Regional Strategy and the EC-WHO Partnership collaboration, the groups received relevant excerpts (Appendix 1).

2.9 Presentation of group work and consolidation into intercountry plans of action

The three groups presented their proposals for intercountry collaborative activities, consolidated their proposals and agreed on the following intercountry activities for 2005:

- Exchange information on and distribute national drug policy guidelines and documents, and e-mail exchange/start of communication network.

- Liaise with the Pacific Island Forum Secretariat on matters relating to intellectual property, with the aim of developing expertise in countries.

- Carry out a situation analysis on procurement in Pacific island countries and areas, make recommendations for improving current procurement and draft terms of references for a working group on procurement/quality assurance.

- Establish a working group on procurement/quality assurance. The countries wishing to be part of this group are: Cook Islands, Fiji, Kiribati, Papua New Guinea, Samoa, Solomon Islands and Tonga. Initially the group will work through e-mail contact, coordinated by the WHO Suva office.

- Compile and review training tools and materials on drug supply management and rational drug use. Develop training tools for technicians and nurses. Establish regional and in-country training on drug supply management and rational use. WHO and Pacific island working group to identify training and prepare material which can be used through the open learning centres. Identify available inventory systems already in use and exchange information on these.

- Develop model medicines regulations, including drug registration requirements, based on review of existing regulations.

- Hold an intercountry one-week workshop to discuss model medicines regulations and draft country-specific regulations, including requirements for drug registration.

- Hold an intercountry workshop on review/evaluation of applications for registration, in particular evaluation of certificates.

The conclusions of the workshop (chapter 3), and the consolidated intercountry work plan of action (Annex 7), which WHO finalized and circulated for participants’ approval after the workshop, contain more detail.
3. CONCLUSIONS

The workshop, held in Fiji from 3 to 5 November 2004, familiarized Pacific island countries and areas with details and benefits of the European Community-WHO Partnership on Pharmaceutical Policies and the implementation of the Regional Strategy for Improving Access to Essential Medicines (2005-2010).

By the end of this workshop participants had reviewed and presented:

- national draft work plans of actions within the framework and format of the Regional Strategy and technical areas for 2005-2010, and the EC-WHO Partnership (detailed plans for 2005);
- collaborative intercountry priority activities and an intercountry plan of action under the EC-WHO partnership, with cross-referencing to technical areas in the Regional Strategy. The intercountry plan of action was consolidated by WHO after the workshop, circulated to participants in the workshop and approved. (Annex 7).

The workshop came to several general and specific conclusions, which follow below:

(1) Human resources development: Cuts across and appears in all eight technical areas in Regional Strategy (RS), and in the EC-WHO Partnership on Pharmaceutical Policies

Participants reviewed the recommendations of the small working group on Human Resources Development on Pharmaceuticals (held in Fiji from 1 to 2 November) and concluded that the EC-WHO should bring training programmes to the Pacific island countries and areas, instead of having people from the Pacific travel to Asia and elsewhere. This would be easier and cheaper for the Pacific islands.

(2) Rational drug use course in Pacific island countries and areas: Technical area “Rational use” in the Regional Strategy and “Result 7: Rational use and control of antimicrobial resistance” in the EC-WHO Partnership project.

Participants concluded that it would be useful for WHO to bring the rational drug use course “Promoting Drug Use in Communities”, most recently held in South Africa, to the Region and the Pacific.

(3) Supply management training: Technical area “Supply and management systems” in the Regional Strategy and “Result 4: Drug supply management, efficient drug supply management promoted” in the EC-WHO Partnership project.

Participants concluded that there is a great need for improvement in drug supply management, and that training in the Pacific island countries and areas is essential. It would be very useful to bring expertise and training courses in supply management to the Pacific, including, not only lectures, but also hands-on training.

The teaching and training of drug management and in particular Inventory/Stock management is generally not taught in schools of pharmacy, except in Fiji and Papua New Guinea pharmacy and pharmacy technician education, which include these subjects. The pharmacy technician course in New Zealand and elsewhere (e.g. the United States of America) could also be adapted to Pacific island needs.

Participants concluded that the small Human Resources Development (HRD) working group should prioritize this issue and propose suitable drug management curricula for pharmacy technicians and other health personnel, primarily nurses.


Participants concluded that it is necessary for TRIPS-compliance legislation work to involve people from the health sector and other sectors, in addition to those from the trade sector.

The Pacific Island Forum secretariat could help in developing expertise on intellectual property (IP) issues for better understanding of the implications of IP issues and TRIPS. The Forum could look at countries that are affected and those that will be affected by IP issues in the future, and bring that information to PIC/WHO Partnership collaboration.

It would be useful for the outcome from this workshop to be reported to the Forum Trade meeting in 2005. Apart from trade officials from the various Pacific Island countries, nationals with pharmaceutical expertise should be invited to the 2005 Forum meeting to inform and alert participants to relevant public health issues and medicines.

The small working group on procurement and quality assurance/regulatory matters should also look at relevant issues related to TRIPS.

Specific recommendations – priority intercountry collaborative activities and actions:


(a) It would be very useful if Pacific island countries and areas with no national drug policy were able to access WHO guidelines and model national drug policies. National drug policy development is a common framework for the pharmaceutical sector of a country. There should be an officially approved document to guide the actions of government agencies and other stakeholders involved in the pharmaceutical sector.

WHO will distribute its guidelines on developing national drug policies, and distribute documents from countries with an official drug policy to those with no policy and those needing to update their policies (>10 years).

(b) It would be helpful if the WHO office in Suva could coordinate the national drug policy work and start an e-mail Pacific communication network for this and other information.

(c) At the request of Pacific island countries and areas WHO will, upon request, provide technical assistance to Pacific island countries and areas on the national
drug policy development process: formulation, implementation plan, baseline assessment, and evaluation using indicators.

(7) E-mail Pacific communication network and exchange of relevant information: Cuts across and appears in several technical areas in the Regional Strategy - “Monitoring and Evaluation” is chosen to start with. The same applies to EC-WHO Partnership project - “Result 1: National drug policies implementation and monitoring” chosen.

The “E-drug” network and information exchange did not work well in the trial period, 2003-2004, and it was decided not to pursue the use of E-drug at the moment. Instead, it would be useful to start an e-mail communication network, coordinated by the WHO Suva office, for discussion and exchange of information on relevant issues. The Pacific Open Learning Health Net computers provided by WHO could be used for such e-mail exchanges for those who do not have their own e-mail addresses.

An e-mail discussion group from among the participants will be used to post concerns, issues, questions, information that can be shared regarding national drug policies and other components, specifically on the conclusions and action points agreed in this November 2004 planning workshop. Initially, the aim is for participants to be able to get in touch with each other for timely assistance, to provide help and share relevant/needed information. The WHO Essential Medicines Library website, linking information on quality, pricing, international pharmacopoeia, etc. is also a good resource.

Starting with simple short e-mail exchanges, depending on responsiveness of participants with e-mail facilities, the discussion group could evolve into a more organized system of information exchange, with a moderator. Later and as it evolves, the discussion group could be used to initiate development and discussion papers and decide on the scope of issues, and could also be used by small technical working groups to gather information.

(8) Human resource development: Cross-cutting activity, but technical areas “Supply and management systems” and “Rational Use” especially chosen in the Regional Strategy, and “Result 4: Drug supply management, efficient drug supply management promoted” in EC-WHO Partnership project.

(a) WHO and small working groups will compile and review existing training tools and materials on drug supply management and rational drug use, for technicians and nurses, and get assistance from a consultant to write up the modules. Currently available international two-week course modules could be adapted as shorter regional or country training modules.

(b) In the collaborative activities, regional expertise should be used, whenever feasible, for in-country and regional training. Regional training of trainers will suit bigger countries while small countries could benefit from local/in-country training with consultants and regional experts.

(c) Starting in-country training of technicians and nurses is a clear priority and a particular need for countries/settings with very limited or no pharmacists. Pharmacy technicians manage drugs and nurses “dispense” and even “prescribe” drugs.

(d) WHO and the Pacific island human resource development group will identify, compile and list available packages e.g. for pharmacy technicians and nurses and for pharmacists who cannot leave their workplace for various reasons.
WHO will find out which European Community member countries are sending volunteers to developing countries for capacity building. WHO should make a regional request for volunteers to be sent to some Pacific island countries and areas for capacity building. Scholarships and fellowships will also be requested for pharmacists, and for training technicians and nurses undertaking pharmacy activities.

Procurement – quality assurance/regulatory matters: Cross-cutting activity, but technical area “Supply and management” in the Regional Strategy was chosen initially. The same applies to the EC-WHO Partnership project. “Result 4: Drug supply management, efficient drug supply management promoted” was chosen.

(a) It would be useful to establish a small Pacific island technical working group on procurement and quality assurance/regulatory matters (in line with the small group on HRD). Terms of references for the group need to be drafted and tasks of group members clearly specified. The countries wishing to be part of this group are: Cook Islands, Fiji, Kiribati, Papua New Guinea, Samoa, Solomon Islands and Tonga. Initially the group will work through e-mail contact, coordinated by the WHO Suva office.

(b) The uniqueness of country situations, such as transportation costs and payments have to be considered in deciding whether procurement of medical supplies should be pooled or not. Currently three ways of purchasing are recognized: 1. through the Fiji Pharmaceutical Services Center, 2. through group purchase or 3. through individual purchase.

(c) It would be best for countries which find benefit in their current schemes to continue them, but information exchange on supplies, quality, prices and list of suppliers should start under the e-mail communication network, and eventually good practice and standards for each purchasing scheme can be developed.

(d) It would be useful for a consultant on procurement to do preliminary work – carry out a situation analysis in Pacific island countries and areas, and look at other pooled procurement systems, such as the Caribbean one, and quality assurance and regulatory issues, etc. – before any meeting of the proposed small working group. The consultant could also draft terms of reference for the small working group on procurement and quality assurance/regulatory matters (PQAR), to include relevant issues and tasks related to TRIPS.


(a) Addressing quality assurance and regulations weaknesses concerns importing as well as exporting countries: weakness in importing countries as they accept pre-packed drugs which have not been registered or gone through the regulatory control system in the exporting country. The procurement consultant and the small technical PQAR working group should address these issues, as should individual countries in their national implementation plans.

(b) Procedures need to be developed within Pacific island countries and areas for destroying expired drugs, which are mostly, but not exclusively, donated drugs. This will be one of the tasks for small PQAR working group.

(a) A list of inventory control software systems currently known and used will be compiled by the Solomon Island participants in the workshop and circulated to the workshop participants, through the WHO Suva office. The list will include cost and training needs. Country needs for specific software such as inventory, sales, dispensing, labels and packaging, including the needs of big and small islands and atolls will be considered in compiling the list.

(b) WHO will prepare an intercountry collaborative plan of action and circulate to the workshop participants for their comments. Urgent replies will be requested. This will be a test to see how quickly the e-mail communication works. (This was completed shortly after workshop and is included as Annex 7).
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AGENDA

1. Opening ceremony
2. Meeting objectives, expectations and methodology
3. The EC-WHO Partnership on Pharmaceutical Policies
4. Report on activities on EC contributions in 2004
6. Guide to implementation of the strategy
7. Review of recommendations from the Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries (PICs), Nadi, Fiji, from 25 to 27 November 2003 and report on collaboration:
   a) E-drug network and information exchange (WHO feedback)
   b) Pooled procurement feedback and update on ARV procurement for the GAFTM
   c) Human resource development report from small group meeting
   d) Quality assurance: A harmonized approach to regulation of medicines in the Pacific
8. Pacific Islands Forum countries
   - Intellectual Property Development Plan – and update from the Pacific Islands Forum Secretariat
9. Presentations of country plans of actions
   - EC plan for 2005-2008 (detailed plans for 2005)
   - Regional strategy for improving access to essential medicines 2005-2010
10. Group work
    Introduction:
    Intercountry planning: Identification of intercountry collaboration
    - EC plan for 2005-2008 (detailed plans for 2005)
    - Regional strategy for improving access to essential medicines 2005-2010
11. Presentation of intercountry plans for identified areas
12. WHO collaborative work plan
13. Conclusions, next steps
14. Closing ceremony
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<th>Time</th>
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<td>0800</td>
<td>9. Presentations of country plans of actions</td>
<td>11. Presentation of intercountry plans for identified areas</td>
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<td>1. Opening ceremony: WHO and EC reps</td>
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<td>- Regional strategy for improving access to essential medicines 2005 - 2010</td>
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<tr>
<td>0845-0900</td>
<td>Tea/coffee break</td>
<td>1200</td>
<td>10. Group work</td>
<td>13. Conclusions, next steps</td>
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<tr>
<td>1200 to</td>
<td>4. Report on activities on EC contributions in 2004 (Mr T. Eriksen, STP/PHA/SP)</td>
<td>1200</td>
<td>Intercountry planning: Identification of inter-country collaboration</td>
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<tr>
<td>1330 to</td>
<td>7. continued.</td>
<td>1330 to</td>
<td>- Regional strategy for improving access to essential medicines 2005-2010</td>
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<tr>
<td>1500</td>
<td>c) Human resource development report from small group meeting</td>
<td>1500</td>
<td>10. Group work continued.</td>
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<tr>
<td>1500-1530</td>
<td>Tea/coffee break</td>
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<td>10. Group work continued.</td>
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<td>Author</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004/IB/1</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004/IB/2</td>
<td>Provisional list of Participants, Consultant, Temporary Adviser, Observers and Secretariat</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.1a</td>
<td>Tentative Agenda</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.1b</td>
<td>Tentative Timetable</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.1c</td>
<td>Meeting objectives, expectations and methodology</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.2a</td>
<td>The EC-WHO Partnership on Pharmaceutical Policies</td>
<td>Dr. E. Carandang, WHO/EDM</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.3a</td>
<td>Report on activities on EC contributions in 2004</td>
<td>Mr T. Eriksen, STP/PHA/SP</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.4a</td>
<td>Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region of the World Health Organization (2005-2010)</td>
<td>Dr B. Santoso, PHA/WPRO</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.5a</td>
<td>Guide to implementation of the strategy</td>
<td>Dr B. Santoso, PHA/WPRO</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.6a</td>
<td>Review of recommendations from the Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries, Nadi, Fiji, 25 to 27 November 2003 and report on collaboration: -E-drug network and information exchange (WHO feedback)</td>
<td>Mr P. Zinck</td>
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<tr>
<td>WPRIICP/HTP/5.1/001/PHA(2)2004.6b</td>
<td>Review of recommendations from the Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries, Nadi, Fiji, 25 to 27 November 2003 and report on collaboration: -Pooled procurement feedback and update on ARV procurement for the GAFTM</td>
<td>Mr P. Zinck</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.6c</td>
<td>Review of recommendations from the Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries, Nadi, Fiji, 25 to 27 November 2003 and report on collaboration: -Human resource development report from small group meeting</td>
<td>Dr V. Reggi, WHO/EDM</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.7a</td>
<td>Pacific Islands Forum countries: Intellectual Property Development Plan – and update from the Pacific Islands Forum Secretariat</td>
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<td>WPRIICP/HTP/5.1/001/PHA(2)2004.8a</td>
<td>Presentation of country plans of actions: - EC plans for 2005-2008 (detailed plans for 2005)</td>
<td>Ms G. Olssen</td>
<td></td>
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<tr>
<td>WPRIICP/HTP/5.1/001/PHA(2)2004.8b</td>
<td>Presentations of country plans of actions: - Regional strategy for improving access to essential medicines 2005-2010</td>
<td></td>
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</tr>
<tr>
<td>Functions</td>
<td>Who does it</td>
<td>HR Issues</td>
<td>Strategies</td>
<td>Actions</td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-------------------------------------------------</td>
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<td>----------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Rational selection</td>
<td>DTC + Director Pharmacy</td>
<td>DTC not participatory</td>
<td>Activate DTC and set clear tasks and functions</td>
<td>Guidance and provision of training materials for advocacy and training</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Introduce essential medicines concept and the NMP into the curricula and</td>
<td>Formulate the EML and STG and formularies</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>continuing education programs for nurses and Medical Assistants</td>
<td>Involves all stakeholders in the development, evaluation and revision</td>
</tr>
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</tr>
<tr>
<td>Rational use</td>
<td>Policy-makers and health care providers at all</td>
<td>Most not aware of concept of</td>
<td>Promote RDU awareness</td>
<td>Conduct trainings on RDU</td>
</tr>
<tr>
<td></td>
<td>levels and consumers and Pharmacy staff</td>
<td>RDU</td>
<td></td>
<td>Investigate medicine practice use at different levels of health care</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>providers</td>
</tr>
<tr>
<td>Access to medicines, trade</td>
<td>Department of Pharmacy and other relevant sectors</td>
<td>Unclear about TRIPS agreement</td>
<td>Collaboration between the health and others (trade, finance) in domestic</td>
<td>Consultancy visits to review Intellectual Property Rights legislation</td>
</tr>
<tr>
<td>globalization and the TRIPS</td>
<td>(trade and commerce)</td>
<td>relation to safeguard of public health</td>
<td>policy preparation to ensure that national health objectives are taken into</td>
<td>If and when necessary, TRIPS compliant health sensitive legislation will</td>
</tr>
<tr>
<td>agreement</td>
<td></td>
<td></td>
<td>account during WHO agreement</td>
<td>be developed to enable purchase of expensive patented medicines that are</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>are needed to address the health problems of I-Kiribati</td>
</tr>
</tbody>
</table>

**Country: KIRIBATI**
<table>
<thead>
<tr>
<th>Sustainable financing</th>
<th>Director of Pharmacy, Health Account Department, Ministry of Finance</th>
<th>Department of Pharmacy have no understanding of cost efficiency and cost effectiveness analytical tools in the analysis of medicines expenditure. The Department of Pharmacy not involved in medicine financing meetings</th>
<th>Equip relevant staff with appropriate analytical tools. Pharmacy staff to take part in national meetings to share major policy issues in medicine financing.</th>
<th>Maintain sufficient public financing for essential medicines.</th>
<th>High</th>
<th>Support courses on pharmacoeconomic available through distance learning.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supply and management</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procurement</td>
<td>Director Pharmacy &amp; procurement unit (senior procurement officer, procurement officers)</td>
<td>Inadequate system-untrained staff, poor estimation of needs based on past consumption figures. WHO Certification not used. Geographic problems.</td>
<td>Upgrade staff procurement skills. Use appropriate quantification methods Use WHO Certification.</td>
<td>Establish procurement unit and train staff. Develop procedures manual to facilitate management and procurement.</td>
<td>High</td>
<td>TA to review current procurement practices and International procurement trainings.</td>
</tr>
<tr>
<td>Inventory Management</td>
<td>Pharmacy technician, pharmacy store-men</td>
<td>Inadequate stock management leading to wastage and stock-outs. Transport and distribution problems due to difficult geographical and remote areas.</td>
<td>Strengthen inventory and distribution system.</td>
<td>Training of appropriate staff</td>
<td>High</td>
<td>TA support</td>
</tr>
<tr>
<td>Distribution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substandard drugs</td>
<td>Pharmacist</td>
<td>No quality testing facilities.</td>
<td>Information exchange with other island states on product quality.</td>
<td>Regional collaboration to take advantage of inspections and product that have been carried out.</td>
<td>High</td>
<td>Facilitation of information exchange</td>
</tr>
<tr>
<td>Monitoring and</td>
<td>Director of Pharmacy</td>
<td>Do not have sufficient capacity to evaluate impact of interventions designed to improve access to essential medicines.</td>
<td>Establish technical advisory group to provide recommendation to improve.</td>
<td></td>
<td>High</td>
<td>Assistance or guidelines from WHO</td>
</tr>
<tr>
<td>evaluations</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
Table to identify functions, who does what, where and what is needed in form of strategies, actions etc.

Country: Papua New Guinea

<table>
<thead>
<tr>
<th>Functions</th>
<th>Who does it</th>
<th>HR Issues</th>
<th>Strategies</th>
<th>Actions</th>
<th>Priority</th>
<th>Avail. Courses/Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td>Selection</td>
<td>Pharmaceutical Advisory Committee</td>
<td></td>
<td>Proper composition of the committee</td>
<td>Include relevant stakeholders in the committee</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Registration/Inspection</td>
<td>Trained pharmacist inspectors</td>
<td>no trained inspector available/fail of skilled HR</td>
<td>*Regional collaboration on drug registration</td>
<td>Attachments in selected establishments</td>
<td>Medium</td>
<td></td>
</tr>
<tr>
<td>Procurement/Tendering</td>
<td>Pharmacist, Procurement officers &amp; finance</td>
<td>lack of skilled finance and management HR</td>
<td>Inadequate staffing</td>
<td>*Regional exchange of information on prices, suppliers and manufacturers</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*Participation in regional international courses on procurement</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>*training in medicines management including quantification &amp; costing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inventory Management</td>
<td>Pharmacist, pharmacy technicians, Health extension Officers, Medical Lab managers, Officers in charge-Radiology, Dental Clinics</td>
<td>lack of stock management skills especially in forecasting</td>
<td>training in inventory management of medicines</td>
<td>*monitor prices of medicines and contribute actively to regional information exchange</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>undertake training on inventory management</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Functions</td>
<td>Who does it</td>
<td>HR issues</td>
<td>Strategies</td>
<td>Actions</td>
<td>Priority</td>
<td>Avail. Courses/Notes</td>
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<tr>
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</tr>
<tr>
<td>Quality Assurance</td>
<td>Pharmacists</td>
<td>lack of skilled staff</td>
<td>*campaign against counterfeit medicines targeting health care providers, policy makers &amp; general public</td>
<td>*Collaborate with law enforcement agencies and undertake training on how to deal with counterfeit medicines</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rational Drug Use</td>
<td>Policy makers, Academics</td>
<td>Insufficient understanding of RDU and rationale</td>
<td>*inter-country collaboration between medicine regulatory authorities &amp; other law enforcement agencies</td>
<td>*Attachments with quality assurance experts in selected setting</td>
<td></td>
<td></td>
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</tbody>
</table>

Guidelines on RDU Activation of DTCs

Actions:
- Collaborate with law enforcement agencies and undertake training on how to deal with counterfeit medicines
- Attachments with quality assurance experts in selected setting

Priority: High

Avail. Courses/Notes:
- WHO guidelines on RDU training
## EC Result 1: National drug policies implementation and monitoring
Adequate support provided to countries to develop, implement, and monitor the impact of national drug policies

<table>
<thead>
<tr>
<th>EC Result</th>
<th>Country Activities</th>
<th>Timeline</th>
<th>Budget US $</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Implementation of National Drug Policies</td>
<td>Need for technical assistance to further develop and guide the implementation of NDP.</td>
<td>Q3/2005</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>1.2 Monitoring access and policy impact</td>
<td>I think this must come much later when the NDP has been approved and implemented. This could take a few years. I would suggest Q2/2008</td>
<td>Q3/2005</td>
<td></td>
<td>High</td>
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</table>

## EC Result 3: Affordability and financing
Guidance provided on financing and affordability of essential medicines in both the public and private sectors

<table>
<thead>
<tr>
<th>EC Result</th>
<th>Country Activities</th>
<th>Timeline</th>
<th>Budget US $</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Development of new indicators to measure access to medicines (affordability, availability, and other measures)</td>
<td>Technical assistance and guidance is required</td>
<td>Q4/2005</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>3.2 Implementation of generic policies and other measures to improve affordability in public and private sectors</td>
<td>Technical assistance and guidance is required</td>
<td>Q4/2005</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>3.3 Mechanisms for monitoring differential pricing (&quot;lowest possible price&quot;) arrangements</td>
<td>Technical assistance and guidance is required</td>
<td>Q4/2005</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>3.5 Policy guidance and technical support to increase public drug financing</td>
<td>Technical assistance and guidance is required</td>
<td>Q4/2005</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>3.6 Comparative analysis of public and private pharmaceutical expenditures as an input to policy process</td>
<td>Technical assistance and guidance is required</td>
<td>Q4/2005</td>
<td></td>
<td>High</td>
</tr>
<tr>
<td>3.7 Advocacy tools for national drug budgets</td>
<td>Technical assistance and guidance is required</td>
<td>Q4/2005</td>
<td></td>
<td>High</td>
</tr>
</tbody>
</table>

## EC Result 4: Drug supply management
Efficient drug-supply management systems promoted for the public sector to ensure continuous availability of medicines and contribute to the overall improvement of access to medicines

<table>
<thead>
<tr>
<th>EC Result</th>
<th>Country Activities</th>
<th>Timeline</th>
<th>Budget US $</th>
<th>Priority</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Operational research on best practices for procurement, supply and distribution systems</td>
<td>Technical support to review current procurement system with an aim to improve this</td>
<td>Q2/2005</td>
<td></td>
<td>Medium</td>
</tr>
<tr>
<td>EC Result 6: Effective drug regulation</td>
<td>Instruments for effective drug regulation and quality assurance systems, aimed at strengthening national drug regulatory authorities promoted</td>
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<td>----------------------------------------</td>
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</tr>
<tr>
<td>6.1 Training and technical support on effective drug regulation</td>
<td>Technical assistance is required for new legislation to cater for private sector Q3/2005 High</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.3 Practical manuals for drug regulatory authorities on effective drug regulation</td>
<td>Technical assistance is required for new legislation to cater for private sector Q3/2005 High</td>
<td></td>
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</tbody>
</table>

EC Result 7: Rational use and control of antimicrobial resistance
Guidance on cost-effective and sound use of medicines promoted with a view to improving rational use of drugs by health professionals and consumers

| 7.2 Training on responsible drug promotion for medical officers | In country workshop for resident Medical Officers and private practitioners Q3/2005 Medium |
| 7.4 Technical support to developing, updating and use EML, STG and national formularies | Technical assistance to review and update existing stg and national formularies Q3/2005 Medium |
| 7.5 Regional training in promoting rational drug use, pharmacotherapy, pharmaco economics translated | In country workshop for resident Medical Officers and private practitioners Q3/2005 Medium |
| 7.8 Consumer role in encouraging and monitor responsible drug promotion and public education for rational use of medicine | In country workshop for resident Medical Officers, private practitioners, public health education unit staff/public health nurses and ngo representatives Q3/2005 Medium |
### Pharmaceutical Policies

#### EC Result 1: Implementation of National Drug Policies
- **1.1 Implementation of National Drug Policies**
- **1.2 Monitoring access and policy impact**
- **1.3 Essential medicines in University curricula**
- **1.4 Diploma on national drug policies**

#### EC Result 2: International Trade Agreements—monitoring, legislation, regulation
- **2.1 Network of local advisors in ACP countries**
- **2.2 Introducing and updating legislation and regulation in accordance with public health objectives**
- **2.3 Implementation of TRIPS monitoring tools**

#### EC Result 3: Affordability and funding
- **3.1 Development of new indicators to measure access to medicines (affordability, availability, and other measures)**
- **3.2 Implementation of generic policies and other measures to improve affordability in public and private sectors**
- **3.3 Mechanisms for monitoring differential pricing ("lowest possible price") agreements**
- **3.4 Implementation of WHO-HAI price survey methodology**
- **3.5 Policy guidance and technical support to increase public drug financing**

#### EC Result 4: Drug supply management
- **4.1 Operational research on best practices for procurement, supply and distribution systems**
- **4.2 Technical support to strengthen procurement, supply and distribution systems**
- **4.3 Diploma programme and scholarships on drug procurement**
- **4.4 Technical support to inter-country bulk procurement schemes for essential medicines, diagnostics, other public health goods**
- **4.5 Guidelines on assessing the feasibility of local pharmaceutical production for essential medicines**
- **4.6 Integration of HIV/AIDS/TB supply systems into national essential medicines programmes**
- **4.7 Assessment of NGO medicines supply strategies and impact on public health**
- **4.8 Operational research, guidance, training materials on access to medicines for chronic diseases**

#### EC Result 5: Norms and standards
- **Global norms, standards and guidelines for the quality, safety and efficacy of medicines strengthened and promoted**
- **5.1 Quality specifications and standards for newer antimicrobials, TB drugs, and HIV/AIDS-related medicines**
- **5.2 Guidelines for quality assurance and generic substitution of fixed dose combination drugs for malaria, TB, other priorities**
- **5.3 Expansion of international safety monitoring, emphasis on newer medicines for HIV/AIDS, malaria, and TB**
### Region: PACIFIC

<table>
<thead>
<tr>
<th>Country name: VANUATU</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>7.1 Training on responsibility drug promotion for students and prescribers</strong></td>
</tr>
<tr>
<td><strong>7.2 Essential Medicines Library links to quality, pricing, international pharmacopoeia, other networks</strong></td>
</tr>
<tr>
<td><strong>7.3 Technical support to developing, updating and use EML, STG and national formularies</strong></td>
</tr>
<tr>
<td><strong>7.4 Regional training in promoting rational drug use, pharmacotherapy, pharmacoeconomics translated</strong></td>
</tr>
<tr>
<td><strong>7.5 Expansion of International Network on Rational Drug Use (INRUD) in ACP countries</strong></td>
</tr>
<tr>
<td><strong>7.8 Consumer role in encouraging and responsible drug promotion</strong></td>
</tr>
<tr>
<td><strong>7.9 Regional training on public education for rational use of medicines</strong></td>
</tr>
<tr>
<td><strong>7.11 Strategies and interventions to promote rational use of anti-infectives and injection by consumers</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Priority</strong></th>
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<tbody>
<tr>
<td><strong>High</strong></td>
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<tr>
<td><strong>High</strong></td>
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<tr>
<td><strong>Medium</strong></td>
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<td><strong>Medium</strong></td>
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<tr>
<td><strong>Low</strong></td>
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<tr>
<td><strong>Low</strong></td>
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</table>
### SUMMARY OF SELECTED PHARMACEUTICAL-RELATED INFORMATION IN THE WHO WESTERN PACIFIC REGION BY COUNTRY/PIC

<table>
<thead>
<tr>
<th>Country/PIC</th>
<th>% Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Samoa</td>
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</tr>
<tr>
<td>Cook Islands</td>
<td></td>
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<tr>
<td>Fiji</td>
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<tr>
<td>French Polynesia</td>
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<tr>
<td>Kiribati</td>
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<tr>
<td>Marshall Islands, Com.of</td>
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<tr>
<td>Nauru</td>
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<tr>
<td>Niue</td>
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<td>Northern Mariana Islands, Co</td>
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<tr>
<td>Palau</td>
<td></td>
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<tr>
<td>Papua New Guinea</td>
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<tr>
<td>Samoa</td>
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<tr>
<td>Solomon Islands</td>
<td></td>
</tr>
<tr>
<td>Tokelau</td>
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<tr>
<td>Tonga</td>
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<td>Tuvalu</td>
<td></td>
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<tr>
<td>Vanuatu</td>
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</tr>
<tr>
<td>Total No. of &quot;Yes&quot; (n=17)</td>
<td></td>
</tr>
<tr>
<td>Percentage (%) Yes</td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>% Yes</th>
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<tbody>
<tr>
<td>81</td>
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<td>81</td>
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<td>81</td>
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</table>

**Notes:**
- Annex 6 SummaryQuickDataNov2004.xls
<table>
<thead>
<tr>
<th>Region: Western Pacific</th>
<th>Intercountry Plan of Action</th>
</tr>
</thead>
</table>

**EC Result 1:** National drug policies implementation and monitoring
Adapted support provided to countries to develop, implement, and monitor the impact of national drug policies

<table>
<thead>
<tr>
<th>EC Country Activities</th>
<th>Timeline/Quarters</th>
<th>Budget US $</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Implementation of National Drug Policies</td>
<td>Exchange information and distribute NMP guidelines and NDPs and e-mail exchange (WHO.SP) start of communication network</td>
<td>WHO.SP</td>
</tr>
<tr>
<td>1.2 Monitoring access and policy impact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.3 Essential medicines in University curricula</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.4 Diploma on national drug policies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EC Result 2:** International trade agreements — monitoring, legislation, regulation
Monitoring of and guidance on the impact of international trade agreements and globalization on access to medicines

<table>
<thead>
<tr>
<th>EC Country Activities</th>
<th>Timeline/Quarters</th>
<th>Budget US $</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1 Network of legal advisors in ACP countries</td>
<td>Use with Pacific Island Forum Secretariat on matters related to IP with the aim of developing expertise in countries</td>
<td>WHO.SP</td>
</tr>
<tr>
<td>2.2 Introducing and updating legislation and regulation in accordance with public health objectives</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.3 Introduction of TRIPS monitoring tools</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EC Result 3:** Affordability and financing
Guidance provided on financing and affordability of essential medicines in both the public and private sectors

<table>
<thead>
<tr>
<th>EC Country Activities</th>
<th>Timeline/Quarters</th>
<th>Budget US $</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.1 Development of new indicators to measure access to medicines (affordability, availability, and other measures)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.2 Implementation of generic policies and other measures to improve affordability in public and private sectors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.3 Mechanisms for monitoring differential pricing (&quot;lowest possible price&quot;) arrangements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.4 Implementation of WHO-HAI price survey methodology</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.5 Policy guidance and technical support to increase public drug financing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.6 Comparative analysis of public and private pharmaceutical expenditure as an input to policy process</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.7 Advocacy tools for national drug budgets</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**EC Result 4:** Drug supply management
Efficient drug-supply management systems promoted for both the public and private sectors, to ensure continuous availability of medicines and contribute to the overall improvement of access to medicines

<table>
<thead>
<tr>
<th>EC Country Activities</th>
<th>Timeline/Quarters</th>
<th>Budget US $</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.1 Operational research on best practices for procurement, supply and distribution systems</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.2 Technical support to strengthen procurement, supply and distribution systems</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion:**

1. Situation analysis on procurement in PICs recommendations for improving current procurement and draft TOR for Proc/QA working group (SC or AW) | WHO/SC | Q1/2005 | 12000 | |
<table>
<thead>
<tr>
<th>Region: Western Pacific</th>
<th>Intercountry Plan of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC Expected Results and Activities</td>
<td>Inter-country Activities</td>
</tr>
<tr>
<td>2. Establish working group on procurement/quality assurance</td>
<td>WHO/PICs</td>
</tr>
<tr>
<td>3. Compile and review training tools and materials on drug supply management and rational drug use.</td>
<td>WHO and HRD WG</td>
</tr>
<tr>
<td>5. Regional and in-country training on drug supply management and rational use (for technicians and nurses) (MD)</td>
<td>WHO</td>
</tr>
<tr>
<td>6. WHO and PIC HRD WG to identify training and prepare material which can be used through the open learning centres (distance learning)</td>
<td>WHO and HRD WG</td>
</tr>
<tr>
<td>7. Identify available inventory systems in use and exchange information on these</td>
<td>WHO/Solomon Islands</td>
</tr>
</tbody>
</table>

4.3 Diploma programme and scholarships on drug procurement

4.4 Technical support to inter-country bulk procurement schemes for essential medicines, diagnostics, other public health goods

4.5 Guidelines on assessing the feasibility of local pharmaceutical production for essential medicines

4.6 Integration of HIV/Malaria/TB supply systems into national essential medicines programmes

4.7 Assessment of NGO medicines supply strategies and impact on public health

4.8 Operational research, guidance, training materials on access to medicines for chronic diseases

<table>
<thead>
<tr>
<th>EC Result 5: Norms and standards</th>
<th>Global norms, standards and guidelines for the quality, safety and efficacy of medicines strengthened and promoted (Corresponding Regional Strategy Technical Area: 7: Quality)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1 Quality specifications and standards for newer antimalarials, TB drugs, and HIV/AIDS-related medicines</td>
<td></td>
</tr>
<tr>
<td>5.2 Guidelines for quality assurance and generic substitution of fixed dose combination drugs for malaria, TB, other priorities</td>
<td></td>
</tr>
<tr>
<td>5.3 Expansion of international safety monitoring, emphasis on newer medicines for HIV/AIDS, malaria, and TB</td>
<td></td>
</tr>
<tr>
<td>5.4 Prequalification of suppliers of medicines for TB, malaria, other priority diseases</td>
<td></td>
</tr>
<tr>
<td>5.5 Regional/sub-regional harmonisation of drug registration in ACP countries</td>
<td></td>
</tr>
</tbody>
</table>

<p>| EC Result 6: Effective drug regulation | Instruments for effective drug regulation and quality assurance systems, aimed at strengthening national drug regulatory authorities promoted (Corresponding Regional Strategy Technical Area: 7: Quality) |</p>
<table>
<thead>
<tr>
<th>Region: Western Pacific</th>
<th>Intercountry Plan of Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>6.1 Training and technical support on effective drug regulation (The details of the proposed activities were specific immediately after 305 November meeting in Nadi, Fiji)</td>
<td>Intercountry activities</td>
</tr>
<tr>
<td></td>
<td>Develop model medicines regulations incl. registration requirements based on review of existing regulations (SC or AW).</td>
</tr>
<tr>
<td></td>
<td>Intercountry WS (one week) to discuss model medicines regulations, draft country specific regulations including requirements for drug registration (MG, SC, AW)</td>
</tr>
<tr>
<td></td>
<td>Intercountry WS on review/evaluation of applications for registration, in particular evaluation of certificates (MG)</td>
</tr>
<tr>
<td>6.2 Development of survey methodology to monitor drug regulation improvements</td>
<td></td>
</tr>
<tr>
<td>6.3 Practical manuals for drug regulatory authorities on effective drug regulation</td>
<td></td>
</tr>
<tr>
<td>6.4 Training/reference centres in for Drug Regulatory Authorities on effective drug regulation</td>
<td></td>
</tr>
<tr>
<td>6.5 Market surveillance and advocacy to control counterfeit and substandard medicines</td>
<td></td>
</tr>
<tr>
<td>EC Result 7: Rational Use and Control of Antimicrobial Resistance</td>
<td>Guidance on cost-effective and sound use of medicines promoted with a view to improving rational use of drugs by health professionals and consumers. (Corresponding Regional Strategy: Technical Area: 2, Rational Use)</td>
</tr>
<tr>
<td>7.1 National containment of antimicrobial resistance</td>
<td></td>
</tr>
<tr>
<td>7.2 Training on responsible drug promotion for students and prescribers</td>
<td></td>
</tr>
<tr>
<td>7.3 Essential Medicines Library links to quality, pricing, international pharmacopoeia, other information</td>
<td></td>
</tr>
<tr>
<td>7.4 Technical support to developing, updating and use EML, STG and national formularies</td>
<td></td>
</tr>
<tr>
<td>7.5 Regional training in promoting rational drug use, pharmacotherapy, pharmacoeconomics translated</td>
<td></td>
</tr>
<tr>
<td>7.6 Expansion of International Network on Rational Drug Use (INRUD) in ACP countries</td>
<td></td>
</tr>
<tr>
<td>7.7 Private practitioners in rational use of medicines</td>
<td></td>
</tr>
<tr>
<td>7.8 Consumer role in encouraging and monitor responsible drug promotion</td>
<td></td>
</tr>
<tr>
<td>7.9 Regional training on public education for rational use of medicines</td>
<td></td>
</tr>
<tr>
<td>7.10 Investigating medicines use practice in the community</td>
<td></td>
</tr>
<tr>
<td>7.11 Strategies and interventions to promote rational use of anti-infectives and injections by consumers</td>
<td></td>
</tr>
</tbody>
</table>

Abbreviations:
- AW = Agreement for Performance of Work
- HRD = Human Resource Development
- MG = Meeting
- EC = European Community
- IP = Intellectual Property
- NDP = National Drug Policy

87600
<table>
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</thead>
<tbody>
<tr>
<td>EC Expected Results and Activities</td>
<td>Intercountry Activity</td>
</tr>
<tr>
<td>Pacific Island Countries: Intercountry Plan of Action for EC-WHO Partnership on Pharmaceutical Policies</td>
<td></td>
</tr>
</tbody>
</table>
Excerpts for easy reference

Regional Strategy technical areas and guide etc. for Improving access to essential medicines in the Western Pacific Region of the WHO, and Categories and expected results in the EC-WHO Partnership project on Pharmaceutical Policies.

Regional Strategy

Regional Strategy content:
Issues & challenges
Strategies
Actions by:
  - WHO
  - Member States

Eight Technical Areas in the Regional Strategy:
  • Rational selection
  • Rational use
  • Affordable prices
  • Access to medicines, trade globalization and TRIPS
  • Sustainable financing
  • Supply and management systems
  • Quality
    – Counterfeit
    – Substandard
  • Monitoring and evaluation

General Guide for Implementing Regional strategy
Reference for Member States to carry out the actions in the Regional strategy

Actions for Member States may be categorized into eight primary objectives:
  • Development/implementation of policies, mechanisms, law/systems, tools, etc.
  • Training/education/awareness raising
  • Review/analysis
  • Monitoring/evaluation
  • Collaboration among stakeholders
  • Sharing information

Priority actions in the 8 technical areas
  • Rational selection
  • Rational use
  • Affordable prices
  • Access to medicines, trade globalization and TRIPS
  • Sustainable financing
  • Supply and management systems
  • Quality
Appendix 1

- Counterfeit
- Substandard
- Monitoring and evaluation

...will be implemented through different categories of actions

1. Development & implementation of policies, tools, legislation
2. Training, education and awareness raising
3. Review and analysis
4. Monitoring and evaluation
5. Collaboration among stakeholders
6. Sharing of information

Example 1 – rational selection

Action 1
Undertake focused advocacy and training for policy makers, providers, consumers and health care managers both in:
public and private sectors on the EM concepts in primary health care and hospital facilities.

At Fiji November 2004 workshop/planning meeting group/individual exercises
- Work on selected priority actions in each area.
- Refer to the guides of implementation
- How this selected priority action will be implemented?
- Sequential steps for implementation

Guides for participants in the Fiji workshop
- Identify groups that represent the target audiences
- Work with each group to estimate the number of targets
- Formulate the advocacy & training program
- Existing materials (WHO and other agencies)

2. EC – WHO Partnership on pharmaceutical policies -collaboration in PICs
### Appendix 1

<table>
<thead>
<tr>
<th>EC category - template:</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>National medicines policies</td>
<td>RESULT No. 1: National drug policies implementation and monitoring</td>
</tr>
<tr>
<td>International trade agreements</td>
<td>RESULT No. 2: International trade agreements - monitoring, legislation,</td>
</tr>
<tr>
<td></td>
<td>regulation</td>
</tr>
<tr>
<td></td>
<td>Monitoring of and guidance on the impact of international trade agreements and globalization on access to medicines</td>
</tr>
<tr>
<td>Affordability and financing</td>
<td>RESULT No. 3: Affordability and financing</td>
</tr>
<tr>
<td></td>
<td>Guidance provided on financing and affordability of essential medicines in both the public and private sectors</td>
</tr>
<tr>
<td>Drug supply management</td>
<td>RESULT No. 4: Drug supply management</td>
</tr>
<tr>
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<td>Efficient drug</td>
</tr>
<tr>
<td>Norms and standards</td>
<td>RESULT No. 6: Effective drug regulation</td>
</tr>
<tr>
<td>Effective drug regulation</td>
<td>Instruments for effective drug regulation and quality assurance systems,</td>
</tr>
<tr>
<td></td>
<td>aimed at strengthening national drug regulatory authorities promoted</td>
</tr>
<tr>
<td>Rational use and control of antimicrobial resistance</td>
<td>RESULT No. 7: Rational use and control of antimicrobial resistance</td>
</tr>
<tr>
<td></td>
<td>Guidance on cost-effective and sound use of medicines promoted with a view to improving rational use of drugs by health professionals and consumer</td>
</tr>
</tbody>
</table>

**WHO will:**

- refine the plans with countries
- allocate funds within the EC contributions based on:
  - Extent of contributions from WHO regular budget
  - considerations on support provided by other organizations

...and will explore with potential donors for unfunded priorities