SUMMARY MEETING REPORT

Annual stakeholders and partners meeting
AIDS Medicines and Diagnostics Service

Geneva, 7–8 May 2013

Department of HIV/AIDS
HIV Technologies and Commodities
May 2013
1. Introduction

Strengthening procurement and supply management of HIV-related medicines and diagnostics in developing countries requires effective partnership at global, regional and country levels. The AIDS Medicines and Diagnostics (AMD) Network convenes on an annual basis. At these meetings, AIDS Medicines and Diagnostics Service (AMDS) partners and stakeholders foster collaboration, information sharing and mutual support in areas related to procurement and supply management to ensure an uninterrupted supply of antiretroviral (ARV) drugs and HIV diagnostics in an efficient manner.

Since the last AMDS partners and stakeholders meeting, held in June 2012, several events have occurred including implementation of activities by AMDS partners to improve the supply of medicines and diagnostics. New challenges have also arisen, causing partners and countries to face new challenges in sustaining their treatment programmes owing to financial and systemic constraints.

The annual AMDS partners and stakeholders meeting held in Geneva, 6-7 May 2013, covered these issues in various presentations.

Dr Hiroki Nakatani, Assistant Director-General, HIV/AIDS, Tuberculosis, Malaria and Neglected Tropical Diseases (HTM), made the opening remarks of the meeting, inviting participants to continue collaboration to achieve the international target of providing ARV treatment to 15 million people by 2015. Participants were also encouraged to have a productive meeting with practical and useful recommendations.

The presentations, final agenda, final list of participants and concept note can be accessed at:

After each presentation, participants discussed issues emerging from the presentation and agreed on action points, which are presented in the next section.
2. Next steps and action points

2.1. Procurement and supply management

2.1.1 Procurement and supply management implications of the new WHO consolidated guidelines for HIV treatment, care and prevention

Meg Doherty (WHO) presented the evolving landscape for HIV treatment beginning with where HIV treatment is now; where it is going in 2013 with the WHO consolidated guidelines for HIV treatment, care and prevention; and what the outlook is for antiretroviral therapy (ART) beyond 2015 and in the more distant future. Key elements of the new guidelines include: (1) the increased threshold for initiation of ART from CD4 count of \( \leq 350 \) cells/mm\(^3\) to \( \leq 500 \) cells/mm\(^3\); and (2) the recommended use of efavirenz (EFV), lamivudine (3TC) or emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF) as the preferred first-line regimen for adults, adolescents, pregnant women and older children. These recommendations were discussed in relation to the expected increase in global need for TDF-based fixed-dose combination regimens due to initiations under the new guidance and movement of those on non-recommended regimens to the newly recommended drugs. Group recommendations included the following:

- Based on lessons learnt from phasing out stavudine (d4T), participants proposed that a paper be developed by the HIV Department to assist countries and implementing partners in the transition from old ARV regimens to the newly recommended ARV regimens. AMDS partners are willing to provide technical contributions to the development of this paper.

- While d4T phase out was anticipated and forecasted, an unforeseen development is that many countries are now moving from zidovudine (AZT) to TDF-based regimens. Shortage and long delivery times for TDF-based formulations are occurring. Rather than an active pharmaceutical ingredient shortage, it was felt that the problem was the unrealistically short delivery times requested by countries and big buyers. It was proposed that the three big buyers (the Supply Chain Management System [SCMS]; the Global Fund to Fight AIDS, Tuberculosis and Malaria; and South Africa) organize a meeting to discuss their forecasts and procurement plans to alert manufacturers on the quantities needed and their required delivery times. The Global Fund will liaise with partners to organize a meeting with the relevant stakeholders.
2.1.2 AMDS portfolio

Jos Perriëns (WHO) presented the AMDS portfolio’s major products with achievements and challenges. He discussed with AMDS partners about the priority of various AMDS products. In order of priority, AMDS should focus on the WHO survey on the use of ARVs and diagnostics; forecasting of ARVs and diagnostics; the global price reporting mechanism database; and the drug regulatory status database. The active pharmaceutical ingredients database, the opioid substitution therapy/morphine database and the opportunistic infection database were given a lower priority.

Suggestions to improve specific products included:

- **Global price reporting mechanism:** in view of the increasing use of domestic funds in procurement of ARVs, AMDS should include procurement data from national governments that have small or no donor funding support.
- **Drug regulatory status:** the information in the drug regulatory status database was seen as requiring validation by manufacturers. Procurement agencies prefer to check directly with manufacturers about countries in which their products are registered before buying them, to prevent products being blocked at the port. It was suggested that WHO tries to conclude a memorandum of understanding with companies to ensure that their data are up to date.
- **Forecasting:**
  - It was decided that specific forecasting for paediatric ARVs needs to be developed and this should involve the paediatric working group.
  - ARV forecasting should include forecasts not only of ARV formulations (active pharmaceutical ingredients) but also of ARV regimens.
  - The forecasting exercise should consider including diagnostic products.

2.1.3 Procurement strategy

SCMS presented its procurement strategy. In pooled procurement and tendering processes, several partners have begun sourcing from several suppliers, citing concerns about excluding suppliers and hurting competition as they have reasons to do so (not giving the whole market to the winner of the tender but including some suppliers even if their price is little bit higher).
It was agreed that the principle\(^1\) that “winner takes all or lowest price” may not always be the best procurement strategy for products purchased on a regular basis. Such a procurement strategy should be amended or clarified as it may have a negative impact on innovation, global production capacity, market competition and ensuring adequate and timely availability of product by countries. Experience has shown that the judicious use of “split tenders” within a tight competitive range for frequently procured drugs may be more advantageous to both the buyer and the manufacturer. Split tenders can increase competition, strengthen the global market and provide the buyer with alternative source(s) of supply in the event that one vendor is unable to deliver on time and/or in sufficient quantity. It was agreed that WHO’s HIV/AIDS Department should bring this to the attention of the Director of WHO’s Essential Medicines Policy Department, put it on the agenda of the Interagency Pharmaceutical Coordination group and brief the Assistant Director-General’s HTM and Health Systems and Innovation (HIS) on this issue, so that WHO can consider altering or clarifying its guidance.

### 2.1.4 Procurement of condoms

Condom procurement was presented by the United States Agency for International Development (USAID) | DELIVER PROJECT. The lack of coordination among partners and the fragmentation of condom procurement (e.g. some plan condom needs for family planning purpose and others for HIV and sexually transmitted infection prevention) were highlighted. Distribution is based on previously delivered quantities without taking into account consumption.

It was agreed that condom procurement should not be included in the collaborative activities pursued by AMDS as it is already covered by the United Nations Population Fund and its partners, where WHO is represented by its Department of Reproductive Health and Research.

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2.1.5 Toxicity monitoring and HIV drug resistance

USAID’s Systems for Improved Access to Pharmaceuticals and Services (SIAPS)–Management Sciences for Health (MSH) identified toxicity monitoring and HIV drug resistance as areas of possible collaboration with WHO. Bilateral discussions between WHO and SIAPS–MSH will follow to define a framework for possible collaboration.

2.2 Diagnostics

2.2.1 Laboratory tests in ART

Nathan Ford (WHO) presented the current WHO recommendations on the use of laboratory tests in ART and WHO’s likely 2013 recommendations. Viral load measurement is being recommended as the preferred monitoring test. In the absence of point-of-care viral load technology, it was proposed that countries use dried blood spot testing as an option to increase the number of viral load tests. Kenya and South Africa are already using dried blood spot testing. The Clinton Health Access Initiative (CHAI) and WHO’s HIV/AIDS Department will work together to document a country case study on the use of dried blood spot testing and its impact on the increased number of viral load tests.

2.2.2 Diagnostic forecasts

In view of the increased demand for laboratory tests that will follow the implementation of the WHO consolidated guidelines for HIV treatment, care and prevention, it was proposed that the ARV forecast technical working group also includes diagnostics. The Global Fund and the United States President’s Emergency Plan for AIDS Relief expressed a strong interest in this work. SCMS suggested that it would be advisable to link this work with the early infant diagnosis working group convened by CHAI and the United Nations Children’s Fund. SCMS also recommended ensuring that the assumptions for diagnostic forecasts are clearly described and that sources and quality of data are well defined in view of the limited data available.

2.2.3 Point-of-care technologies

Point-of-care technologies have a limited lifetime (3–5 years). Implementing partners (United Nations Development Programme, USAID/SIAPS–MSH, and Centers for Disease Control and Prevention) are concerned about the safe disposal of laboratory equipment after it is obsolete, as it takes up significant storage
space in medical stores. Various options to manage this problem were envisaged, including returning obsolete equipment to manufacturers for recycling. In many cases, this will require a change in asset management rules.

- It was agreed that WHO’s HIV/AIDS Department should discuss this issue with the WHO department in charge of environmental health hazards and seek clarification on whether WHO has guidance on the safe and effective disposal of obsolete equipment.

### 2.2.4 Harmonization of diagnostic procurement

Based on experience of harmonization of laboratory items to facilitate procurement, it was proposed that the guidance on harmonization published by the USAID | DELIVER PROJECT be reviewed and updated if required. The USAID | DELIVER PROJECT agreed to consider publishing an update as a multiagency document endorsed by WHO and other partners. The USAID | DELIVER PROJECT will send the current version to AMDS partners and the African Society for Laboratory Medicine for review.

### 2.2.5 Diagnostic tools

Diagnostic tools were mentioned during the discussion on the procurement of diagnostics. WHO and AMDS partners, including CHAI, SCMS and the USAID | DELIVER PROJECT, have produced a tool on specifications and quantities for efficient procurement of essential equipment and commodities for HIV. The USAID | DELIVER PROJECT informed participants that a tool on quantification of laboratory commodities has also been produced by CHAI in collaboration with the USAID | DELIVER PROJECT and SCMS. As laboratory technologies move fast, updating these tools is essential.

- It was suggested that WHO and CHAI ask manufacturers to review their respective technologies in the updating process. This will require making their content accessible on-line and providing manufacturers with access passwords to enable them to update their information on each technology.

- As the WHO survey on the use of diagnostics showed that a lot of point-of-care technologies and equipment are not installed or deployed, it was proposed to develop technical briefs to assist countries on how to deploy and efficiently use point-of-care technologies and other laboratory equipment. As WHO has a guide on the selection of laboratory technology in draft, it was agreed that the WHO Diagnostics and Laboratory Technology team share the draft document with AMDS partners and the African Society for Laboratory Medicine (ASLM) for review. Following the review, a decision on whether to develop a document on specific technologies will be made.
USAID | DELIVER PROJECT agreed to follow up with CHAI regarding sharing the quantification tool with AMDS and ASLM.

2.2.6 Diagnostic quality assurance

During the discussion on diagnostic quality assurance, participants raised the importance of both types of quality: quality of products and quality of tests. The National Reference Laboratories are used for monitoring both types of quality. A protocol with detailed procedures for post-marketing quality assurance is needed. The WHO Diagnostics and Laboratory Technology team has a draft and will share it with AMDS partners.

2.2.7 Call for proposals

Brenda Waning (UNITAID) mentioned in her presentation that her organization supports several diagnostic-related projects. Participants were informed that UNITAID’s next call for proposals is due on 22 May 2013.