



Systems Strengthening Working Group

During RHSC Membership Meeting (Addis Ababa, 21 June 2011)

0930 – 1115: EARLY MORNING SESSION – JOINT SESSION WITH MDAWG

Welcome and brief introductions

David Smith welcomed everyone to the meeting and passed on introductions as the meeting was already starting late and because there were nearly 90 participants in attendance from both the working groups. Prequalification and quality issues cut across both the working groups and hence the reason for this first joint session.

Prequalification

[1] Condoms and IUDs [Morten Sorenson-UNFPA PSB]

As of end of 2010 there were 23 prequalified male condom manufacturing sites (19 companies) in eight countries. This represents more than half of the serious manufacturers of male condoms and constitutes a very large pool of choice for procurement. It is not expected that UNFPA will add further sites/ manufacturing companies but concentrate on the scheduled re-visits to existing sites mandated by the prequalification programme. For IUDs UNFPA have prequalified eight manufacturers in three countries – this constitutes 100% of the IUD manufacturers that market their products internationally. Again it is not envisaged that more companies will be added and re-inspections will take place as scheduled to the existing sites.

[2] Female Condoms [Morten Sorenson]

Only one female condom is currently approved by WHO (FC2) but there is likely to be up to 10 new brands on the market in the next 2-3 years including a copy of the FC1 whose patent is about to expire meaning that generic companies can produce them.

[3] Hormonal methods (Pills, PoPs, EC, injectables, implants) [Peter Hall – Concept Foundation]

There are 8 separate hormonal RH medicines that are currently prequalified by WHO as in the table below:

International Non-propriety Name (INN)	Formulation and Strength	Applicant	Date of Pre-Q	Common type
Ethinylestradiol+Levonorgestrel	150/30µg tablets	Bayer Schering	26/05/09	Combined Pill
Ethinylestradiol+Desogestrel	150/30µg tablets	NV Organon	29/09/10	Combined Pill
Etonogestrel	68mg 1-rod implant	NV Organon	02/06/10	Implant
Levonorgestrel	75mg x 2 rod implant	Bayer Schering	23/09/09	Implant
Levonorgestrel	750µg tablets	Gedeon Richter	20/08/10	Emergency Contraception
Levonorgestrel	30µg tablets	Bayer Schering	26/05/09	Progestin-only Pill (PoP)
Lynestrenol	0.5 mg tablets	NV Organon	02/06/10	Progestin Only Pill (PoP)
Medroxyprogesterone acetate	150mg/ml injection	Pfizer	20/08/10	Injectable

And the status of dossiers received by the WHO Pre-qualification programme is as follows:

Product	Submitted	Not accepted	Cancelled	Pending	Approved
Levonorgestrel/ ethinylestradiol, 150/30 µg tablets	16	5	5	5	1
Desogestrel/ ethinylestradiol, 150/30 µg tablets	1	—	—	—	1
Levonorgestrel, 750 µg tablets	5	2	2	0	1
Levonorgestrel, 30 µg tablets	4	1	2	0	1
Lynestrenol, 0.5 mg tablets	1	—	—	—	1
Levonorgestrel, 150 mg 2-rod implant	2	—	—	1	1
Etonogestrel, 68 mg implant	1	—	—	—	1
Medroxyprogesterone acetate, 150 mg injection	5	—	4	—	1
Norethisterone enantate, 200 mg injection	2	1	—	1	—
Norethisterone enantate/estradiol valerate, 50/5 mg injection	2	2	—	—	—
Oxytocin, 10 IU/ml	3	—	1	2	—
Total	42	11	14	9	8

There is one combined pill very close to prequalification – and two others waiting on some quality information from the manufacturer. One injectable and an implant are currently under assessment – so its actually looking hopeful that we will have a number of generic hormonal methods prequalified over the coming year. There are 18 priority companies for Finished Pharmaceutical Products (FPPs).

[4] Other drugs and issues [Peter Hall]

Last year a number of maternal health items were added to the types of commodities that WHO wanted to prequalify. These included Misoprostol, mifepristone, Oxytocin and Magnesium Sulphate. There are two Oxytocin products that have been assessed for efficacy/safety and are just awaiting further information on quality. As yet there have been no applications from manufacturers of the other products.

WHO have also begun a prequalification scheme for manufacturers of Active Pharmaceutical Ingredients (API) especially because one of the main reasons that many generics have not got through the prequalification process is because there needs to be CGMP certification around API's – hence some of these companies fall at the first hurdle because they cannot guarantee the quality of the APIs they are using. WHO are focussing on 9 priority companies manufacturing APIs.

Quality RH Medicines

[5] UNFPA's new quality Policy [Morten Sorenson]

A new quality policy has been unveiled by UNFPA that sets out exactly the new Quality Assurance Policy that is fully supportive of the need to wherever possible procure RH medicines and devices that are WHO/UNFPA prequalified. A comprehensive document (amongst others) is included on the disks entitled "Guidance Sources for Reproductive Health Commodities" that shows the full QA Policy.

[6] Quality project – AQAS to QuRHM [Lester Chinery – Concept Foundation]

A new quality project that extends the work already undertaken with the assistance of the “Innovation Fund” at the RHSC will begin shortly – after funding is assured. The new project will be called Quality Reproductive Health Medicines (QuRHM) and is being supported by DFID (through the RHSC) and will further identify priority generic manufacturers of RH commodities in order to assist them, encourage them and walk them through the WHO prequalification scheme. There are also components to support the WHO prequalification scheme itself – and some support for UNFPA with its quality approach.

Some discussion took place with clarification on some issues. Some participants could not understand why the companies that were going through or applying for WHO prequalification were not known – or that the companies that were being approached by the Concept Foundation for the QuRHM project were kept secret. Confidentiality is an utmost priority until the company gets prequalified and although people may be able to make “educated guesses” all the members of the steering group must maintain that protection of company names and locations.

[7] Quality of EC – New IBP forum [Elizabeth Westley - ICEC]

There was announced a new IBP forum concerning quality of Emergency Contraception (and participants were reminded that a presentation on this would be made on Friday morning at the Coalition meeting). It is hoped that by holding a forum around this subject that the problems of counterfeiting and sub-standard products would be found for various countries.

1115 – 1145: COFFEE BREAK

1145 – 1300: MID-MORNING SESSION

[The SSWG re-convened after coffee on their own with 42 participants attending]

Pledge Guarantee for Health (PGH)

[8] PGH update [Aron Betru – UN Foundation]

A brief update of the progress of PGH was given including the brief details of the first “deal” that was done using the mechanism for Malaria Bednets in Zambia. Although this was not strictly in the area of RH the successful financing of bednets has contributed to the “proof of concept” stage of the project. This is going to be extended for a little while yet until we have one or two examples for RH commodities – and perhaps these deals may also be tied into AccessRH. It seems that that the African Development Bank and others are interested in supporting this initiative and it was stated that there also seems to be adequate resourcing for the second stage of the proof of concept. A brief presentation was given outlining the advantage of the mechanism.

UNFPA/PSB issues

[9] Common UN Activities and new initiatives [Eric Dupont – UNFPA]

The working group was appraised of new practices on procurement under the UN system – these included a Procurement Accreditation Programme; Contract Review by one committee in UNOPS; and a review of vendors by UNOPS. In addition there are likely to be huge savings in the future because of joint tendering for LTA’s and regular procurement meetings between UNFPA, UNDP, UNOPS and UNICEF all based in Copenhagen. For example there will be a Procurement Policy and Procedures Harmonization and to begin with some collaborative procurement of vehicles.

AccessRH and RHI

[10] AccessRH/RHI [Campbell Bright – UNFPA]

AccessRH is now up and running – fully staffed – and has processed 25 shipments since inception. Orders have been conducted for a variety of contraceptives and related RH items, described in the AccessRH catalogue. Condoms shipped from AccessRH stock have resulted in an average saving of 10 weeks on shipment time. More products will be added to stock shortly, and the plan is to have a managed inventory of RH supplies at the manufacturers' premises in order to further reduce lead times. Further market analysis and the encouragement of new customers will be maintained – and there may be possible links with the Pledge Guarantee for Health for the financing for some countries. Being integrated into AccessRH is the RH Interchange – now fully operational at UNFPA – it has \$1.5 billion worth of contraceptives on the data base spread over more than 140 countries. An on-line function for AccessRH is on the way and this will meet clients needs for multiple types of products from a variety of manufacturers at prices pre-negotiated by UNFPA. Some design work and software building needs to be undertaken, but progress is generally good. UNFPA will continue to conduct advocacy and marketing of this product.

1300 – 1400: LUNCH

1400 – 1530: EARLY AFTERNOON SESSION

Workstreams: Updates and Way Forward

David Smith to facilitate, workstream leaders

Brief Updates of Workstreams; Way Forward; Timelines; Roles and responsibilities

[11] Coordinated Assistance for Reproductive Health Supplies (CARhs) [Kaitlyn Roche – USAID]

An update was given for the success of the CARhs over the past year including the number of issues dealt with and resolved, the time/resources needed to continue the CARhs and its transition for the secretariat to UNFPA in the next month or two. Highlights were the high success rates for informational items (97.5%) and Action Items (63.5%); and the transshipment of implants from Rwanda to Mali that saved around US\$ 2.1 million. There was a call for more country involvement and to bring in more countries into the PPMR process (the PPMR being one of the bases of the CARhs group calls).

During discussion it was noted that the running of the CARhs Group was transferring to UNFPA NY (Joe Abraham) and there was a big “well done and thank you to Kevin Pilz and Kaitlyn Roche for their enthusiasm and energy over the past years without which the CARhs would not be the success that it is.

[12] Professional Development of Supply Chain Managers [Benoit Silve]

An update was given on the progress of this workstream which, as part of its activities, is holding a major meeting at WHO in Geneva next week (28/29 June) called “People That Deliver” that is being attended by over 150 people including some Permanent Secretaries of Health. The workstream is an example of something that although originating in the RHSC is for the benefit of all commodity types and across all agencies as it works to professionalise the personnel working with different and sometimes integrated supply chains. Much progress has been made and the outcomes of the conference next week should shape further advances with a call to action of its own.

[13] Forecasting for New and Underused Methods (Innovation Fund work) [Victoria Jennings]

Work has begun on this workstream which is being undertaken by Georgetown University with assistance from JSI and PATH to produce a guide on some of the techniques to use for forecasting the demand for a new RH technology in a country – or one that has been little used before. This is currently being put together and will be available shortly.

1530 – 1600: COFFEE BREAK

1600 – 1730: MID AFTERNOON SESSION

Workstreams: Updates and Way Forward - Continued

[14] Public Procurement Reform [Paul Dowling – JSI]

Together with Todd Dickens from PATH and Maya Jaffe from Crown Agents – Paul Dowling has begun initial discussions in bringing together a group to look at Public Procurement Reform specifically for RH supplies but which will be probably applicable to other commodity groups. It is in its early stages and anyone who is interested in developing the ideas and terms of reference for this workstream is welcome to join – please let Paul Dowling know if you are interested.

[15] Data Requirements

a) LMIS Source Software [Steve Kinzett] – No progress on this workstream pending a synopsis of the recent PATH report on “Common requirements “ to be developed to kickstart the workstream.

b) Hormonal Contraceptive Database [David Smith – ICON/IPPF and Todd Dickens -PATH] – Using an innovation fund grant work has begun in IPPF to re-constitute the Hormonal Contraceptive Database with information direct from the manufacturers as far as possible. At the same time USAID have commissioned PATH to write up a brief on the hormonal contraceptives available and therefore IPPF and PATH are collaborating and comparing notes so that duplicative work is avoided.

[16] Expanded Financing for Systems [Alan Bornbusch] – No progress on this workstream as yet

[17] Decentralisation and systems [TBD] – this workstream was to be headed up by someone who has now left the RH Supplies arena – unless someone comes forward to take ownership of this proposed workstream during the next six months it will be consigned to the back burner.

Briefing on Access for All/Coalition meeting

[18] Overview of Access for All meeting and “Calls to Action” [Steve Kinzett-RHSC]

An outline of the meetings to take place over the next three days were made including drawing to the attention of the SSWG that they had several ways in which to suggest Calls to Action – either here in the SSWG meeting; at the “Access for All” meeting during discussion or breakout groups; or by completing a suggestion card that is in your welcome packs. This year the Coalition meeting will be only one day because of the “Access for All” meeting and so the technical agenda is a little diminished this year.

[19] SSWG 10-minute statement [David Smith – ICON]

At the membership meeting on Friday there is only a 10-minute slot for Working Group reports – so David will do a synopsis of today's meeting (no powerpoint) for the participants assembled – these are due to be done immediately following John Skibiaks statement on the Coalition so there may be some overlap depending on what he picks out as highlights (e.g CARhs group). This approach was agreed by the SSWG members present.

There being no other business the meeting closed at 17.15 pm.