

**EVERY WOMEN EVERY CHILD**

**UN COMMISSION ON LIFE-SAVING COMMODITIES  
FOR WOMEN AND CHILDREN**

**Implementation plan**

**September 2012**



**EVERY WOMAN  
EVERY CHILD**

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## Abbreviations

AMREF	African Medical and Research Foundation
CHAI	Clinton Health Access Initiative
CHX	chlorhexidine
CIFF	Children's Investment Fund Foundation
COMESA	Common Market for Eastern and Southern Africa
DFID	Department for International Development, UK
EAC	East African Community
ECOWAS	Economic Community of West African States
EMA	European Medicines Agency
EML	Essential Medicine List
ERP	Expert Review Panel
EWEC	Every Women Every Child
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	good manufacturing practices
GNHE	Global Network for Health Equity
HAI	Health Action International
HRP	UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction
ICT	information and communication technology
iERG	independent Expert Reference Group of the UN Commission on Information and Accountability
ILEMD	Interagency List of Essential Medical Devices
IWG	Innovations Working Group (of the EWEC)
LMIS	Logistics Management and Information System
MgSO <sub>4</sub>	magnesium sulfate
MSH	Management Sciences for Health
NMRA	National Medical Regulatory Agency
ORS	oral rehydration salts
OTC	over-the-counter
PMNCH	Partnership for Maternal, Newborn and Child Health
PmRN	Paediatric medicines Regulators' Network
PPH	post-partum haemorrhage
PPP	public private partnerships
PQ	pre-qualified
PQR	Price and Quality Reporting
RHSC	Reproductive Health Supplies Coalition
SADC	Southern African Development Community
SBCC	Social and Behaviour Change Communication
SC	Save the Children
SRA	Stringent Regulatory Agency
UAFC	Universal Access to Female Condoms
UN	United Nations
UNDP	United Nations Development Programme
UNFPA	United Nations Population Fund
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organization
USAID	United States Agency for International Development
WHO	World Health Organization
WHO-PQ	WHO Prequalification of Medicines Programme
WHO-EML	WHO Model List of Essential Medicines

## Executive summary

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The United Nations (UN) Commission on Life-Saving Commodities for Women and Children (the Commission) was set up in response to the call in the UN Secretary-General's *Global Strategy for Women's and Children's Health* for increasing access to and appropriate use of medicines, medical devices and health supplies that effectively address leading avoidable causes of death during pregnancy, childbirth and childhood. The Commission's report, published on 26 September 2012, identified 13 essential commodities that could save the lives of millions of women and children and made 10 recommendations for how to get these commodities to those who need them most. This Implementation Plan builds on the Commission's analyses and recommendations, applying them to the 13 commodities and providing cross-cutting and commodity-specific actions.

For each recommendation, the Commission has identified an initial implementation plan, priority and key activities, commodities prioritized for immediate intervention and examples of milestones. In order to ensure dialogue and avoid overlap between the cross-cutting and commodity-specific areas of work, convening organizations have been identified for each area, and particular attention will be paid to ensuring further inclusion of representatives from Every Woman Every Child (EWEC) countries, the private sector and civil society. The Plan provides terms of reference for these working groups.

At the country level, detailed implementation plans will be developed and shaped during stakeholder meetings in each of the EWEC countries, building on existing and on-going national planning exercises. The actions provided in this Plan are indicative and not inclusive; prioritization of commodities will vary from region to region and country to country and will therefore have to be grounded in local realities. The Commission recommends that countries develop plans with a particular focus on priority commodities and on highlighting the potential for local manufacturing, market shaping and regulatory improvements. This Plan includes a suggested outline/ checklist for country-level implementation.

Potential criteria for prioritizing commodities for investment include: products that have fewer regulatory, market and user adoption challenges; products that can be used by a variety of health-care providers; products that are already in demand by users and health providers; and products that can be packaged with others to make more effective 'bundles'.

The cross-cutting areas highlight the importance of taking action across the spectrum – from global market shaping and financing through streamlined regulation and improved local supply and demand. Some of the country-level implementation activities and most of the commodity-related implementation plans therefore need support and coordination at the global level. These also need to be linked to other health systems strengthening interventions.

Since the implementation of the full set of recommendations will require significant political, advocacy and resource mobilization support, a high-level Champions Group of key stakeholders will be established to provide strategic and political support at the global and country level and to advocate for and raise additional resources. A financing facility will also be put in place to fill financial gaps in the implementation plan and, as resources permit, fill gaps in the procurement and roll-out of these life-saving commodities.

## Introduction

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The United Nations (UN) Secretary-General's *Global Strategy for Women's and Children's Health* highlights the inequitable access to life-saving medicines and health supplies suffered by women and children around the world and calls on the global community to work together to save 16 million lives by 2015.<sup>i</sup> Recognizing the stark reality that millions of unnecessary deaths could be prevented, the Strategy identifies the need for increased access to and the appropriate use of essential medicines, medical devices and other commodities that could save these lives. Experiences from countries suggest that three commodity-specific types of barriers prevent women and children from receiving appropriate interventions: **(1) the insufficient supply of high quality health commodities where they are most needed; (2) the inability to effectively regulate the quality of these commodities; and (3) the lack of access and awareness of how, why and when to use them.**

The UN Commission on Life-Saving Commodities for Women and Children (the Commission) took on the challenge outlined in the UN Secretary-General's *Global Strategy* of saving lives through improving equitable access to life-saving commodities. The Commission, which is part of the Every Woman Every Child (EWEC<sup>ii</sup>) movement, published its report on 26 September 2012. It estimated that an ambitious scaling up of these 13 commodities over five years would cost less than US\$2.6 billion and would cumulatively save over 6 million lives, including 230,000 maternal deaths averted through increased access to family planning. This would catalyse an accelerating reduction in deaths for women and children. Achieving these goals would save an extra 1.8 million child lives a year, reducing the estimated 7.1 million deaths in 2010 to 5.3 million. Likewise, the estimated 287,000 maternal deaths in 2010 would be reduced to 213,000 by increased access to maternal health and family planning commodities.<sup>iii</sup> The estimated costs per lives saved are low and represent excellent global development investments. Thus, the scaling up of these commodities is not solely a moral obligation but one of the most effective ways of getting more health for the money invested. It would make a significant contribution to putting maternal and child health on a trajectory to end these preventable and tragic deaths.

The present **Implementation Plan for Life-Saving Commodities for Women and Children** builds on the analyses and 10 recommendations of the Commission, applying these recommendations to each of the 13 essential commodities identified.

## Implementation plan

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As recommended in the Commission's report, this draft implementation plan unpacks the 10 recommendations for the 13 commodities and provides cross-cutting and commodity-specific actions (set out in Tables 1 and 2, with more details in the Annexes). In order to ensure exchange and avoid overlap between the cross-cutting and commodity-specific areas of work, convening organizations have been identified for each area. These organizations will constitute working groups as per the terms of reference found in Annexes 3 and 4. Particular attention will be paid to the further inclusion of representatives from EWEC countries, the private sector and civil society.

**Summary budget:** Building on the activities detailed in this document, the total cost for implementing the UN Commission's recommendations is preliminarily estimated at about US\$200 million for three years (this amount does not include the cost of procurement of these commodities and/or capital health systems investments such as building or refurbishing of facilities). Detailed commodity- and recommendation-specific budgets will be developed in the autumn of 2012.

This implementation master plan will be used to formulate detailed regional and global plans. In the EWE countries, detailed country plans will be developed and shaped during in-country stakeholder meetings, building on existing and on-going national planning exercises such as those emanating from the Child Survival Call to Action, the Family Planning Summit and other events referenced in the Commission's report. For example, a meeting of the Commission is taking place in Abuja in October 2012, hosted by the Government of Nigeria, during which country-level implementation will be discussed, and similar exercises will take place in other countries during the third quarter of 2012 and early 2013 (see Annex 5).

## Priority actions

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The sample of 13 life-saving, overlooked commodities demonstrates the wide-reaching need across maternal, newborn, child and reproductive health. However, to get these commodities to those who need them most, a strategic approach must be taken to fast track a few at a time. The fast-tracking/ prioritization of commodities will vary from region to region and country to country and will therefore have to be grounded in country realities and decided upon through local stakeholder decision-making processes. Success with a few 'early win' commodities will energize the global community to succeed and garner support to get all the 13 products reliably to market.

Potential criteria for prioritizing commodities for investment include: products that have fewer regulatory, market and user adoption challenges; products that can be used by a variety of health-care providers; products that are already in demand by users and health providers; and products that can be packaged with others to make more effective 'bundles' (e.g., ORS and zinc).

The cross-cutting areas highlight the importance of actions needed along the end-to-end spectrum – from global market shaping and financing through streamlined regulation and enhanced local supply and demand. Whilst these areas are inter-linked and equally important, global attention and financing will jumpstart a chain of events across the end-to-end spectrum and across countries. Some proposed prioritized activities in certain cross-cutting areas include those listed below (as previously noted, these are only indicative and will be finalized through a fully participatory process).

Global market shaping (GMS): Some critical commodities, such as contraceptive implants, will benefit greatly from rapid, strategic market interventions. The GMS working group, in close collaboration with the respective technical reference teams, will quickly engage with stakeholders and manufacturers to achieve significant reductions in price and improvements in availability of contraceptive implants. Probable mechanisms include multi-year volume guarantees with one or more manufacturers.

**Priority milestones: *Signing of a volume guarantee with at least one manufacturer for contraceptive implants by the middle of 2013; 40 per cent increased availability of contraceptive implants by the end of 2014.***

Innovative financing: Most life-saving commodities will benefit from focused and increased financial resources to increase supply and demand and investments in required product and delivery innovations. Interested donors will agree on the most appropriate and effective mechanism to manage and administer these funds.

**Priority milestone: *The architecture and operating modalities of a life-saving commodity-focused financing mechanism have been agreed upon by key partners and donors by the end of 2012.***

Regulation: Some critical commodities, including contraceptive implants, misoprostol, magnesium sulfate (MgSO<sub>4</sub>), chlorhexidine (CHX), zinc and oral rehydration salts (ORS), would hugely benefit from streamlined regulation in line with current task-shifting practices. This includes the use of maternal health and family

planning commodities by nurses and midwives and OTC or general sale for products such as zinc and ORS. Under the leadership of the WHO and with support from multiple partners and stakeholders, ERP and joint reviews will be of strategic importance to ensure access to and use of these life-saving commodities where needed most.

Medical devices such as newborn resuscitation devices are generally poorly or not regulated, and specific action on regulatory harmonization for devices is urgently required. Since regulation and guidelines for development and registration have been issued by SRAs, the need for adaptation is limited.

***Priority milestones: ERP for dispersible amoxicillin by the end of 2012; joint reviews of OTC for zinc, ORS and CHX by the end of 2013; regulatory harmonization of newborn resuscitation devices – building on regulation and guidelines from SRAs – is obtained in 10 EWEC countries by 2013.***

These layers of prioritization are underpinned by EWEC countries' engagement, and the Commission recommends that high-burden EWEC countries organize stakeholder meetings to discuss the implications of its recommendations and develop implementation plans with a particular focus on priority commodities and on highlighting the potential for local manufacturing, market shaping and regulatory improvements.

**Table 1. Summary implementation plan and lead conveners**

	<b>Draft activities per Commission's recommendations</b>	<b>Lead convening agency</b>	<b>Agencies that have expressed interest in co-convening/ participating</b>
<b>01</b>	<b>Shaping global markets: By 2013, effective global mechanisms such as pooled procurement and aggregated demand are in place to increase the availability of quality, life-saving commodities at an optimal price and volume</b>	<b>CHAI, DFID</b>	<b>Gov. of Norway, WHO, RHSC, CIFF, UNICEF, UNFPA</b>
01.a	Identify priority commodities amenable to immediate, global market-shaping efforts and analyse markets to identify the most effective global market-shaping mechanism for the prioritized commodities		
01.b	Apply proposed market-shaping mechanisms to selected commodities		
01.c	Develop robust demand/ forecast systems for each commodity and build an info-mediary for the 13 essential commodities		
<b>02</b>	<b>Shaping local delivery markets: By 2014, local health providers and private sector actors in all EWEC countries are incentivized to increase production, distribution and appropriate promotion of the 13 commodities</b>	<b>CHAI, Gov. of Nigeria</b>	<b>WHO, UNICEF, UNFPA</b>
<b>02.a</b>	Create incentives for national and regional wholesalers and large distributors to actively promote commodities over sub-optimal alternative treatments and to accelerate distribution through private channels		
<b>02.b</b>	Perform WHO-supported global or regional joint regulatory reviews of safety for national approval of low-level and OTC use		
<b>02.c</b>	Conduct large-scale demand generation campaigns through collaborations between public and private actors		
<b>03</b>	<b>Innovative financing: By the end of 2012, innovative, results-based financing is in place to rapidly increase access to the 13 commodities by those most in need and foster innovations</b>	<b>World Bank, Gov. of Norway</b>	<b>UNICEF, UNFPA, GNHE, PMNCH, USAID, CHAI, SC</b>
<b>03.a</b>	Review the use of the results-based financing mechanism to improve access to the 13 commodities; solicit country interest and applications for results-based financing and enter into agreements with relevant countries		
<b>03.b</b>	Ensure linkages between the results-based financing mechanism and funding mechanisms identified for the procurement of commodities and work with the private sector		
<b>03.c</b>	Include commodities in various monitoring systems; develop and use simple scorecard on access; link to other accountability recommendations		
<b>04</b>	<b>Quality strengthening: By 2015, at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products</b>	<b>WHO, Gov. of Nigeria</b>	<b>USAID, PATH, UNICEF, UNFPA, EMA</b>
<b>04.a</b>	Review quality of current products in the market and identify quality risks from dossier review; landscape manufacturer base to identify key quality gaps, costs and solutions		
<b>04.b</b>	Support committed manufacturers in developing good products and dossiers; where needed, give investment support (GMP, bioequivalence studies)		
<b>04.c</b>	Pre-qualify three products each for selected commodities; apply the ERP process or other mechanisms for products where full pre-qualification is not desirable or possible		
<b>05</b>	<b>Regulation efficiency: By 2015, all EWEC countries have standardized and streamlined their registration requirements and assessment processes for the 13 live-saving commodities with support from stringent regulatory authorities, the WHO and regional collaboration</b>	<b>WHO, Gov. of Nigeria</b>	<b>UNFPA, PmRN, EMA, World Bank</b>
<b>05.a</b>	Update global clinical guidelines, the WHO-EML and the Interagency list of Essential Medical Devices for Reproductive Health; EWEC countries adapt national clinical guidelines and national essential medicines and medical devices lists		
<b>05.b</b>	Perform WHO-supported global or regional joint regulatory reviews of new commodities, in support of national regulatory assessment, including review for lower-level use		
<b>05.c</b>	Standardize and streamline the national regulatory process of new products through regional regulatory collaboration and harmonization		



<b>06</b>	<b>Supply and awareness: By 2015, all EWEC countries have improved the supply of life-saving commodities and built on information and communication technology (ICT) best practices for making these improvements</b>	<b>USAID, UNFPA</b>	<b>UPS, Gov. of Norway, PATH, Rockefeller, IWG, UNICEF, RHSC</b>
<b>06.a</b>	Conduct landscaping assessment and organize global and/or regional consultations to discuss and share best practices that enable countries to review, adapt and adopt ICT solutions to address supply chain bottlenecks		
<b>06.b</b>	Organize EWEC country-level assessment of supply chain-related problems and possible ICT and communication solutions and develop costed plans; conduct government-led stakeholder discussions including with organizations that can reach families and care-givers to assess commitment, readiness and resources		
<b>06.d</b>	Establish indicators/ scorecard to monitor regional data around supply chain management and ICT contribution to improve supply chain performance		
<b>07</b>	<b>Demand and awareness: By 2014, all EWEC countries in conjunction with the private sector and civil society have developed plans to implement at scale appropriate interventions to increase demand for and utilization of health services and products, particularly among under-served populations</b>	<b>USAID, Gov. of United Republic of Tanzania</b>	<b>IWG, USAID, UNFPA, PMNCH, WHO, MDG Health Alliance, SC</b>
<b>07.a</b>	Review and collate evidence of supply- and commodity-related communications including those that combine social and behavioural change communication (SBCC) and commercialization, social networking, franchising and marketing		
<b>07.b</b>	Establish innovative PPPs to address SBCC needs and develop materials and messages for the 13 commodities to enhance consumer and provider demand through high-impact marketing and promotion, including private sector providers		
<b>07.c</b>	Support government agencies in EWEC countries to establish a sustainability roadmap and build capacity to develop, monitor and sustain SBCC and mass-media activities		
<b>08</b>	<b>Reaching women and children: By 2014, all EWEC countries are addressing financial barriers to ensure the poorest members of society have access to the life-saving commodities</b>	<b>Gov. of Uganda, SC</b>	<b>Gov. of Norway, UNFPA, WHO, World Bank</b>
<b>08.a</b>	Apply a commodity-lens to existing work on financial barriers and the WHO's work on universal access, and ensure that commodities are appropriately included in global and national financial protection mechanisms (e.g., conditional cash transfers)		
<b>08.b</b>	Assist EWEC countries in establishing financial mechanisms to ensure equitable access to commodities by the poorest segments of society		
<b>08.c</b>	Establish indicators and a scorecard and use these to assess progress towards increased access to commodities by the poorest segments of society		
<b>09</b>	<b>Performance and accountability: By end 2013, all EWEC countries have proven mechanisms such as checklists in place to ensure that health-care providers are knowledgeable about the latest national guidelines</b>	<b>AMREF</b>	<b>Gov. of Norway, IWG, USAID, WHO, UNFPA, CIFF, SC</b>
<b>09.a</b>	Support EWEC countries to develop and adapt national clinical guidelines to reflect international guidance on the use of the 13 commodities		
<b>09.b</b>	Develop and use national checklists, job aids, training programmes and supervision structures to promote and monitor the use of clinical guidelines by public and private providers		
<b>09.c</b>	Strengthen EWEC country accountability mechanisms to monitor scale-up and use of the 13 commodities, including improved regulation and oversight of the private sector and mechanisms for community-level monitoring and feedback around service provision, availability and affordability		
<b>10</b>	<b>Product innovation: By 2014, research and development for improved life-saving commodities has been prioritized, funded and commenced</b>	<b>PATH</b>	<b>USAID, Bill &amp; Melinda Gates Foundation, WHO, SC</b>
<b>10.a</b>	Establish incentives for further commodity research and product innovation		
<b>10.b</b>	Invest in product innovation, including translational research, formulation development, new technological product development, stability studies and bioequivalence		
<b>10.c</b>	Use the public health need for new formulations, packaging or technological update of the 13 commodities as a practical example and justification in the global discussion on financing research and development		
<b>10.d</b>	Facilitate technology and knowledge transfer, together with financial incentives, to reinforce national and regional efforts in research, development, regulation and manufacturing of life-saving commodities		

**Table 2. Conveners for commodity-specific technical reference groups**

Product	Lead convener	Agencies that have expressed interest in participating
Oxytocin	USAID	Bill & Melinda Gates Foundation, UNFPA, WHO, PMNCH
Misoprostol	UNFPA	Bill & Melinda Gates Foundation, UNFPA, MacArthur Foundation, USAID, WHO, PMNCH
Magnesium sulfate (MgSO4)	USAID	Bill & Melinda Gates Foundation, UNFPA, MacArthur Foundation, WHO, PMNCH
Injectable antibiotics	Saving Newborn Lives as chair of injectable antibiotics working group	WHO, USAID
Antenatal corticosteroids	Save the Children as chair of Born too Soon follow-up group on ANC	
Chlorhexidine (CHX)	PATH as chair of the CHX working-group	USAID and Bill & Melinda Gates Foundation (both members of the CHX working group), CIFF, SC
Newborn resuscitation equipment	USAID	CIFF, WHO-Essential Medicines and Health Products Department, SC
Amoxicillin	UNICEF as co-convener of the pneumonia and diarrhoea treatment working group	SC, USAID
Oral rehydration salts (ORS)	CHAI as co-convener of the pneumonia and diarrhoea treatment working group	AMREF
Zinc	CHAI as co-convener of the pneumonia and diarrhoea treatment working group	AMREF
Female condoms	UNFPA	USAID, WHO, RHSC, PATH, UAFC Joint Programme
Contraceptive implants	Bill & Melinda Gates Foundation/ DFID on behalf of the Family Planning 2020 Reference Group	DFID, USAID, UNFPA, CIFF, WHO, RHSC
Emergency contraception	WHO	UNFPA, RHSC

## Implementation support

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Implementation of the full set of recommendations will require significant political, advocacy and resource mobilization support and hence engagement of high-level supporters. To this end a high-level Champions Group of key stakeholders will be established to provide strategic and political support at the global and country level and to advocate for and raise additional resources.

A financing facility will be put in place to fill financial gaps in the implementation plan and, as resources permit, fill gaps in the procurement and roll-out of these life-saving commodities. Commodities benefiting from market-shaping mechanisms will be given priority.

During the initial phase of work the current hosts of the UN Commission, UNICEF and UNFPA, will take the lead in providing support and co-ordination of the different implementation groups under the overall direction of the Champions Group.

### **Convening agencies, technical teams**

Several agencies have indicated their interest in acting as the convener or a participant in cross-cutting and technical reference groups (see Table 1 above). Terms of reference for these convening roles are presented in Annexes 3 and 4.

Given the need for country engagement and ownership and the creation of different groups, a clear articulation of roles and responsibilities, and a related accountability mechanism with schematic architecture, will have to be defined. Further clarification on roles relative to fundraising and financial management will also be required.

## Annexes

### Annex 1: Implementation plan per recommendation (cross-cutting areas)

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Several cross-cutting barriers identified by the Commission are related to market failures, the regulatory environment and user supply and demand challenges. For example, quality products will only be developed and wide regulatory uptake will only be achieved if there is a guaranteed strong market that incentivizes manufacturers to invest in product development and regulatory approval. Interplay between regulation, market dynamics and innovation is needed. Some of the country-level implementation activities and most of the commodity-related implementation plans therefore need support and coordination at the global level. To fully optimize access, this interplay needs to be linked to other health systems strengthening interventions. Annex 1 presents the global, regional and country level implementation plan following the 10 recommendations made by the Commission. As countries will have different challenges, an important next step is to define priority countries for these cross-cutting areas.

**1. Shaping global markets: By 2013, effective global mechanisms such as pooled procurement and aggregated demand are in place to increase the availability of quality, life-saving commodities at an optimal price and volume**

**Initial implementation plan:**

Identify priority commodities amenable to immediate global market shaping efforts and define their most effective respective market-shaping mechanisms.

**Priority activities:**

- **Contraceptive implants:** Negotiate a multi-year volume guarantee (with appropriate pricing) on behalf of a group of donors with one or more manufacturers of contraceptive implants and conduct additional scoping of necessary complementary investments in local service delivery capacity.
- **Amoxicillin, injectable antibiotics and zinc:** Scope the potential for global market-shaping interventions:
  - Map out current suppliers of optimal formulations and overall market shares;
  - Work with suppliers to analyse key categories of production and distribution costs, responsiveness of costs to increasing volumes of production, and product profitability vs. company benchmarks.
- Compile info-mediary data and demand forecasts for priority commodities (implants, amoxicillin, injectable antibiotics, zinc, MgSO<sub>4</sub> and oxytocin).

**Key activities:**

- Develop knowledge-sharing mechanisms and materials to consolidate expertise on market-shaping interventions, with on-going updates.
- Convene regular discussions between Global Market Shaping and Commodity groups to identify potential market-shaping interventions, including local and regional manufacturing initiatives.
- Select appropriate partnership structures to implement market-shaping interventions for each selected commodity.
- Build an info-mediary for the 13 essential commodities, including information in line with the GFATM PQR and MSH Price Index.
- Develop and publish robust demand forecasts for priority commodities, ensuring coordination with all groups currently doing global forecasting work.
- Ensure market intelligence is regularly communicated to relevant partners, including manufacturers.
- Monitor and evaluate the success of applied market-shaping mechanisms.

**Commodities prioritized for immediate intervention:** contraceptive implants. **Prioritized for further scoping work:** amoxicillin, injectable antibiotics, zinc, MgSO<sub>4</sub>, oxytocin (female condoms and misoprostol may be included after further consultation with commodity experts).

**Examples of milestones:**

- Sign volume guarantee with at least one manufacturer of contraceptive implants, if appropriate pricing and volume terms can be agreed upon (2013).
- Build info-mediary and forecasts and scope global market-shaping opportunities for amoxicillin, injectable antibiotics, zinc, MgSO<sub>4</sub> and oxytocin (2013).
- Evaluate the increase in availability and affordability of contraceptive implants (2014).
- Compile info-mediary data for remaining seven commodities (2014).

## 2. Shaping local delivery markets: By 2014, local health providers and private sector actors in all EWEC countries are incentivized to increase production, distribution and appropriate promotion of the 13 commodities

### Initial implementation plan:

Given the specific situation and opportunity for each commodity, the implementation plan for this recommendation is presented by commodity. Through the Commission, work will be supported in a handful of prioritized countries for each set of commodities. Where relevant, synergies and linkages will be sought across commodities and across recommendations – in particular 3, 5, 7 and 9 – as this work develops at country level. Where appropriate, technology and expertise transfer will be facilitated to support regional and national manufacturing capacities. Beyond the market-shaping interventions, it will also be important to build local and regional capacity across public and private stakeholders.

### Key activities:

- **Zinc and ORS.** In order to overcome market failures that lead to the under-utilization of zinc and ORS, a full range of market-shaping interventions will be implemented in a number of prioritized countries. For example, to increase demand zinc and ORS will be integrated into existing public health service delivery platforms and an oversupply to every new mother will be ensured (since several episodes of diarrhoea are expected); innovative demand generation efforts will be rolled out; and the capacity and awareness of health providers will be increased to change prescription behaviour. To strengthen the supply of zinc and ORS, performance-based incentive mechanisms for local manufacturers and distributors will be designed and tested tied to, for example, sales of products; private sector distribution channels will be made more efficient; and local product formulation enhancements will be supported.
- **Oxytocin, dispersible amoxicillin, chlorhexidine and MgSO<sub>4</sub>.** Increased access through local market-shaping interventions may be possible across these commodities, but further analysis is required to determine feasibility and impact. For oxytocin, integration into the vaccine cold chain is essential to enable quality supply – this will be supported in prioritized countries. Across all these products, business cases will be developed in prioritized countries assessing opportunities to strengthen local production capacity, improve formulations and introduce incentives for manufacturers and distributors to actively promote commodities over sub-optimal alternatives and to accelerate distribution through private channels.
- **Contraceptive implants.** Though a number of local delivery challenges need to be addressed in support of global market-shaping efforts (Recommendation 1), these can be better addressed through other recommendations of the Commission (e.g., 5, 9 and 10).
- Further analysis and discussions are necessary to determine the extent to which local market-shaping interventions can impact other life-saving commodities.

### Examples of milestones:

- Develop a toolkit for possible incentive mechanisms for local private supply-chain from production to retail, based on analysis in a few countries (2012).
- Implement supply-side incentive mechanisms for relevant life-saving commodities in each of the prioritized countries (2013).
- Ensure baselines in 2012 and evaluate the increase in availability of (a sub-set of) life-saving commodities in prioritized countries (2014).

### **3. Innovative financing: By the end of 2013, innovative, results-based financing is in place to rapidly increase access to the 13 commodities by those most in need and foster innovations**

#### **Initial implementation plan:**

Review the use of a results-based funding mechanism to improve access to the 13 commodities. Building on experiences from GAVI Alliance and the GFATM, application processes need to be simple and flexible to accommodate the participation of all market players.

**Priority activity:** Solicit country interest and applications for results-based financing, volume guarantees, push funding and other supplier- and demand-based incentives and enter into agreements with committed EWEC countries.

#### **Key activities:**

- Ensure linkages between the identified funding mechanism and existing domestic and international funding mechanisms for the procurement of commodities; work with the private sector for supply and distribution through the public and private sectors.
- Include access to and use of life-saving commodities in various monitoring systems based on a simple scorecard and linked to other recommendations from the UN Commission on Information and Accountability.
- Monitor and evaluate the success of the results-based financing mechanisms.

**Priority commodities:** all.

#### **Examples of milestones:**

- Agree on the host of a result-based funding mechanism for life-saving commodities (2012).
- At least 10 EWEC countries enter into an agreement with the funding mechanism to increase access to the life-saving commodities (2013).
- Evaluate increase in accessibility in the concerned EWEC countries (2014).

#### 4. Quality strengthening: By 2015, at least three<sup>iv</sup> manufacturers per commodity are manufacturing and marketing quality-certified and affordable products

##### **Initial implementation plan:**

Insufficient quality of medicines or devices can lead to incomplete treatment or adverse effects such as antibiotic resistance. It is therefore imperative to ensure that the life-saving commodities have clear quality assurance and regulatory plans to ensure that the products are both safe and effective.

**Priority activity:** Rapidly perform initial quality surveys of the most commonly available forms of the life-saving commodities in EWEC countries and provide manufacturers with incentives to submit their product dossiers for review by a competent authority such as an ERP or WHO-PQ. The outcomes of the quality surveys and risk-based review processes will identify common quality challenges, costs and solutions and guide further work on quality improvement and regulatory control.

##### **Key activities:**

- Support committed national and regional manufacturers with technical advice and training on improving GMP, bioequivalence studies and other essential components of a regulatory application dossier. Where needed for the production of a vitally important commodity, efforts will be made to facilitate the necessary financial investment through development banks, UNIDO and bilateral agencies.
- Include life-saving commodities in the WHO-PQ or similar programmes. This approach will first be applied to essential commodities with potentially large global volumes as well as those that pose challenges to national regulators. It may also be used for regulatory assessment of innovative products (e.g., single-use, pre-filled syringes, patches) in order to facilitate streamlined registration in EWEC countries. For products that either have a broad base of existing country registrations or are registered differently from medicines (e.g., zinc, chlorhexidine, certain medical devices), other mechanisms – for example, ERP process, market surveillance approach – will be used to certify products of acceptable quality.
- Medical devices such as newborn resuscitation devices are often poorly or not regulated and specific action on regulatory harmonization for medical devices is urgently required. SRA models for regulation of medical devices exist and will be used to guide adaptations for countries.
- Support the WHO-PQ process and ensure appropriate staffing to avoid delays.
- Build clear agreement with global and national procurement agencies and wholesalers in EWEC countries to use quality and supplier performance as key selection criteria (in addition to price), and work towards full implementation of the procurement standards laid down in the WHO Model Quality Assurance System and other appropriate global standards.
- Certify quality products through PQ, ERP and other innovative approaches such as regional regulatory harmonization initiatives and post-market surveillance to better understand safety and quality risks, and define the levels of quality to be enforced for manufacturers.
- Develop technology transfer platforms for off-patent products to facilitate open access for quality producers of generics.
- Monitor and evaluate the success of the various support activities to manufacturers.

**Priority commodities:** oxytocin, misoprostol, amoxicillin, zinc, contraceptive implants.

##### **Examples of milestones:**

- ERP for dispersible amoxicillin (2012).
- Development of optimal quality assurance for zinc (e.g., market surveillance approach, ERP) (2012).
- ERP for chlorhexidine (2013).



## 5. Regulation efficiency: By 2015, all EWEC countries have standardized and streamlined their registration requirements and assessment processes for the 13 life-saving commodities with support from stringent regulatory authorities, the WHO and regional collaboration

### Initial implementation plan:

Rapidly perform surveys on the status of life-saving commodities in the WHO-EML, clinical guidelines, other international guidelines and the IEMD and align policies and guidelines for the life-saving commodities. Similarly, develop a regulatory pathway for each of the commodities focusing on rapid global systems such as the ERP, engagement in harmonized and joint implementation among national regulatory systems in EWEC countries, and regional regulatory collaborations.

**Priority activity:** Perform joint regulatory reviews of some prescription-only commodities for use by nurses, midwives, pharmacists and community health workers (e.g., oxytocin injection, misoprostol, amoxicillin tablets) and for OTC or general sale (e.g., chlorhexidine, zinc tablets, ORS/zinc co-packs).

### Key activities:

- Regularly (at least biennially) update global clinical guidelines and the WHO-EML and IEMD and facilitate exceptional reviews where needed.
- EWEC countries adapt national clinical guidelines and national EMLs and actively promote task-shifting so lower-level health workers can use life-saving commodities.
- Ensure that at least three different quality products are registered as appropriate in the EWEC countries to allow for competition and supplier security.
- Perform global or regional joint regulatory reviews of new products, in support of national regulatory assessment; promote the use of standardized regulatory dossiers following internationally agreed standards and work to strengthen regional regulatory cooperation and harmonization in EAC, ECOWAS and SADC and facilitate the reduction of the regulatory burden on applicants by the use of common formats.
- Standardize and streamline the national regulatory process for new product (medicines and medical devices) approvals through regional regulatory collaboration and harmonization. This can be done, for example, through judicious use of information from SRAs and the WHO and by joint reviews that will facilitate the national approval of new and innovative priority commodities. The joint reviews will also support the rapid update of national clinical guidelines by, for example, including newly developed formulations and products.
- Monitor and evaluate the success of the various regulatory streamlining and harmonization efforts and EWEC countries' efforts to task-shift.

**Priority commodities:** oxytocin, misoprostol, magnesium sulfate, chlorhexidine, amoxicillin, resuscitation devices, zinc, contraceptive implants.

### Examples of milestones:

- WHO-EML includes all 13 life-saving commodities (2013).
- Joint reviews of OTC for zinc, ORS and chlorhexidine (2013).

## 6. Supply and awareness: By 2015, all EWEC countries have improved the supply of life-saving commodities and built on information and communication technology (ICT) best practices for making these improvements

*This plan focuses on providing assistance to governments and regions to strengthen their national supply chains. Where supply systems are functioning, ICT can assist and provide additional benefits. Linked to Recommendation 3, innovative financing mechanisms could be used to remove some persistent supply chain challenges, such as rewarding timely disbursement for procurement.*

### **Initial implementation plan:**

Provide technical and financial assistance to governments and regions in order to improve their self-determined commodity supply chain needs.

### **Key activities:**

- Map existing supply chains present in EWEC countries with suggestions of potential synergies (including cold chain), with a special focus on key barriers and reaching the community.
- Technical assistance and country activities will depend on each country's supply chain assessment and could include:
  - Improving forecasting/ quantification systems to create more predictable supply;
  - Incorporating maternal, newborn and child health commodities into national Commodity Security Committees (such as contraceptive security committees) to ensure monitoring of availability of commodities to prevent stock-outs;
  - Examining the use of existing private-sector distribution chains for public or private-sector health commodities;
  - Strengthening institutional capacity of procurement and distribution agencies in-country;
  - Assessing existing examples of LMIS solutions (including m- and e-health) for potential national roll-out;
  - Tracking the flow of commodities through the supply chain in order to determine authenticity (for quality purposes);
  - Linking the LMIS with the health management information systems and the country's m- and e-health strategy.
- Identify critical success factors for LMIS.
- Conduct an assessment of ICT innovations and best practices that address key supply chain bottlenecks.

**Priority commodities:** to be defined by EWEC countries.

### **Examples of milestones:**

- Perform a landscaping assessment of ICT innovations and best practices for supply chains (2013).
- Perform a mapping assessment of existing supply chains present in the priority countries (2013).
- Develop a work plan for each priority country based upon its priorities and secure financing for implementation (2013).
- Undertake the implementation in priority countries and assess as appropriate (2014–2015).

**7. Demand and utilization: By 2014, all EWEC countries in conjunction with the private sector and civil society have developed plans to implement at scale appropriate interventions to improve demand for and utilization of health services and products, particularly among under-served populations**

**Initial implementation plan:**

Develop an evidence-based ‘best to next practice’ toolkit/ guide on demand creation through social and behaviour change communication (SBCC) and marketing, integrating varied and innovative demand-side interventions with supply-side approaches such as commercialization. Highlighted approaches will cross-cut communication channels (mass media, community-level activities and interpersonal communication) and utilize emerging approaches such as ICT/ new media and social network interventions.

**Key activities:**

- Review and collate evidence of successful practices in demand creation, including approaches drawn from the fields of SBCC and marketing. This synthesis should include lessons learned in the promotion of priority commodities as well as more general guidance pertaining to the introduction of new commodities and expansion into new market segments. Cross-cutting areas such as effective engagement of men and strategies for addressing social and gender norms should be addressed.
- Develop global or regional demand creation roadmaps for each priority commodity, outlining types of key audiences, essential information, illustrative channel or format options and guidance for adaptation and operationalization in country contexts.
- Develop sets of adaptable communication materials for each priority commodity; such resources could include not only sample communication materials but also sample planning tools and adaptation guidelines.
- Identify opportunities for innovative global, regional or country-level PPPs to support improved demand for priority commodities.
- Provide technical support to government agencies, civil society partners and private sector businesses in EWEC countries to develop and implement country-level strategies and implementation plans for promotion of priority commodities. Technical support could include formative research, research-to-action planning, message development/ harmonization or monitoring and evaluation planning.

**Priority commodities:** chlorhexidine, amoxicillin, ORS, zinc, female condoms, contraceptive implants and emergency contraception; other commodities to be considered per country interest.

**Examples of milestones:**

- Develop SBCC strategies for priority commodities in at least five EWEC countries (2013).
- Sign PPP agreements to address SBCC needs in at least five EWEC countries (2013).
- Evaluate change in demand for and utilization of priority commodities in a subset of EWEC countries (2015).

## 8. Reaching women and children: By 2014, all EWEC countries are addressing financial barriers to ensure the poorest members of society have access to the life-saving commodities

### **Initial implementation plan:**

Develop an evidence-based toolkit to assess the impact of financial barriers on access to and use of life-saving commodities and list the most effective interventions to overcome those barriers.

**Priority activity:** Establish indicators and a scorecard and use these to assess progress towards increased access to commodities by the poorest segments of society. This can be done by regular monitoring of price and availability of life-saving commodities in public and private health-care facilities in line with the recommendations of the UN Commission on Information and Accountability and using standard monitoring tools such as the WHO and Health Action International (HAI) medicine price, availability and affordability surveys, among others. It can be supported by monitoring national policies that provide commodities at low or no cost to poor and low-income households and the adherence to these policies by health-care providers.

### **Key activities:**

- Apply a commodity lens to existing work on financial barriers and the WHO's work on universal access, and ensure that commodities are appropriately included in global and national financial mechanisms (e.g., conditional cash transfers, voucher systems).
- Assist EWEC countries in establishing financial mechanisms to ensure equitable access to commodities by the poorest segments of society.

**Priority commodities:** all.

### **Examples of milestones:**

- Eight EWEC countries have financial protection programmes with a commodity focus (2013).
- Evaluate the increase in use of (a sub-set of) life-saving commodities in concerned countries (2014).

**9. Performance and accountability: By end 2013, all EWEC countries have proven mechanisms such as checklists in place to ensure that health-care providers are knowledgeable about the latest national guidelines**

**Initial implementation plan:**

In close collaboration with the UN Commission on Information and Accountability, develop, promote and facilitate the uptake of an evidence-based guide on supply- and commodity-related checklists and other support systems to promote and monitor the use of clinical guidelines by public and private providers.

**Priority activity:** Develop country-level tools, job aids, training programmes and supervisory structures based on adult learning and skills retention approaches to promote and monitor the use of national clinical guidelines. Focus on checklists, pictorials and protocols for certain conditions (e.g., post-partum bleeding), supported by on-the-job mentoring, use of mobile technology, e-learning, performance-based incentives and facility management improvement to overcome persistent barriers to use of life-saving commodities. This will go hand-in-hand with regulatory review and approvals of lower-level use (adoption of task-shifting) of life-saving commodities detailed under Recommendation 5.

**Key activities:**

- Support EWEC countries to develop and adapt national clinical guidelines to reflect international guidance on the use of the 13 commodities, within the broader framework of improving performance and efficiency such as through task-shifting.
- Develop, test and use national checklists, job aids, training programmes and supervision structures to promote and monitor the use of clinical and task-shifting guidelines by public and private providers.
- Work with existing country task teams that include civil society to begin work on commodity checklists and their implementation.
- Strengthen EWEC country accountability mechanisms to monitor scale-up and use of the 13 commodities, including improved regulation and oversight of the private sector and the introduction of social audits.

**Priority commodities:** contraceptive implants, amoxicillin, injectable antibiotics, oxytocin and MgSO<sub>4</sub> in the first year; all commodities in three years.

**Examples of milestones:**

- The status of international consensus on use of the 13 commodities and available guidelines in countries for their use have been analysed (by December 2012).
- Development of generic checklists for implants and safe birth, including use of MgSO<sub>4</sub>, has begun (by December 2012).
- Training and scalable strategies for checklist use including e- and m-learning have been developed and deployed (by December 2013).
- Feasibility assessments on the use of social audits to improve accountability have been carried out in 10 countries (by December 2013).

## 10. Product innovation: By 2014, research and development for improved life-saving commodities has been prioritized, funded and commenced

### Initial implementation plan:

Review, adapt and cost the list of recommended product improvements (listed in the Commission's report) as well as identify innovation gaps, including new formulations, packaging and/or delivery devices and technologies, in alignment with consumer market research and target product profiles.

**Priority activity:** Award innovation funding and/or invest in research and development for product improvement for at least one initiative in each of the four thematic areas; focus for investment may include (1) product development/ adaptation, (2) product attribute testing using existing programmatic platforms and (3) RTC/ multi-centre studies.

### Key activities:

- Review product improvements for those commodities with existing target product profiles.
- Review market research and establish target product profiles for remaining commodities; compare existing products to target product profiles to identify innovation gaps and foster product improvement recommendations.
- Conduct outreach to national policy makers through regional workshops to assess needs and emerging innovations.
- Prioritize areas for investment within each of the four thematic areas (child health, maternal health, newborn health and reproductive health); prioritization criteria include ability of product innovation/ improvement to contribute to increased (1) uptake, (2) efficacy and (3) safety.
- Facilitate technology and knowledge transfer, together with financial incentives, to reinforce national and regional efforts in research, development, regulation and manufacturing of life-saving commodities.
- Link with Recommendations 1 and 3 to establish a financing/ incentive mechanism for further commodity research and development.
- Link with the Commission on Information and Accountability for Women's and Children's Health ERP for monitoring.

**Priority commodities:** oxytocin, MgSO<sub>4</sub>, amoxicillin, injectable antibiotics, ORS/zinc, contraceptive implants.

### Examples of milestones:

- Form a coordinating group to lead reviews, prioritization and monitoring of product improvements/ innovations (2012).
- Prioritize four product improvement/ innovation areas (2013.)
- Secure commitments including donor and private industry earmarks for innovation and research and development (2013).
- Issue call and award funding for innovation and/or formulate and award funding for product development partnerships for one priority product by thematic area (2014).

### **Problem statement**

Most commodities suffer from a series of common problems, which usually include the following: insufficient patient demand and use; low and fragmented market volumes leading to low commercial interest by manufacturers; insufficient or inefficient regulation and quality assurance leading to compromised quality of products in the market; lack of appropriate or patient-friendly formulations; lack of market volume to stimulate innovation; and slow market approval and uptake of new essential products. The problem can be summarized as a lack of use of essential medicines with great potential to save the lives of women and children.

### **Programme objective**

For each of the 13 essential commodities the overall objective is uninterrupted universal access by all mothers and children to an effective, safe, patient-friendly, affordable commodity of assured quality and its cost-effective use by prescribers and consumers.

### **Implementation plans per commodity**

To achieve this goal, general and global activities can be identified that support universal access and use for all (or most) commodities. These challenges are especially addressed in Recommendations 1, 3, 8, 9 and 10 dealing with issues of pooled procurement, innovative results-based financing, product monitoring and financing of research and development. Commodity-specific challenges addressed under Recommendations 4 (quality) and 5 (regulation) will be coordinated and partially executed at the global level.

In this annex, the main commodity-specific problems and actions are identified and addressed. For each commodity, a technical reference agency/ group will be identified (see Table 2).

Similar to for the recommendations/ cross-cutting areas, detailed work plans will be developed for each commodity by the technical reference agency and partners. These plans will build on the initial implementation plans listed below and include:

- Technical reference agency/ group
- Key activities
- Key milestones
- Estimated impact
- Estimated cost

## 1. Oxytocin injection for prevention and treatment of post-partum haemorrhage

### Problem statement

The key issues with oxytocin injection are the lack of reliable needs estimations and quantification, lack of quality in many products on the market and lack of availability and/or routine use in the third stage of labour, particularly in rural facilities.

### Specific issues identified

#### Provider issues

Lack of availability and/or use for all births, especially in rural clinics and home deliveries;  
Product often misused for induction of labour.

#### Quality:

Serious quality defects found (e.g., in Ghana 34/46 samples failed on low content);  
Many products moderately unstable under tropical conditions if not refrigerated;  
Variations in storage requirements between different manufacturers and products;  
No products pre-qualified by the WHO (two submitted).

#### Evidence/ regulatory issues:

Many unregistered products on the market, of unknown quality and therefore not quality assured;  
Use of oxytocin injection by midwives is not allowed in some countries;  
Oxytocin in single-dose injection device is not registered in many countries;  
In some countries, the single-dose injection device itself may need to be registered as a new device.

#### Product development/ market shaping:

Temperature time indicators are not included on ampoules or boxes of oxytocin;  
Heat-stable products and single-dose injection would be beneficial.

*NB: For rural areas, misoprostol tablets may be used as an alternative – but these are often not available.*

#### Awareness/ demand

Poor needs estimation and quantification, forecasting and delivery mechanisms lead to stock-outs;  
Oxytocin is not included in the cold chain;  
Providers are not trained in stock management, storage and use for PPH;  
Poor knowledge of appropriate use of uterotonics at community level.

### Implementation plan

As a first priority, assistance will be provided for proper quantification and forecasting of oxytocin to assist in adequate budgeting for the commodity. Additionally, it will also be necessary to strengthen the distribution channels, including incorporating oxytocin into the cold chain.

The WHO and others will support EWEC countries in updating national clinical guidelines based on WHO guidelines on PPH (2012), Task-shifting (2012) and Induction of Labour (2011) and utilizing these for appropriate communications materials and messages, training and supervision to safely use these products at all levels of the health system. The regulatory pathway will be developed (Recommendation 5) to support approval of oxytocin administration by midwives, nurses and low-level providers in rural areas. Quality issues will be addressed (Recommendation 4) through national quality surveys, identification of quality products through the ERP and the WHO-PQ process and stronger national regulation and enforcement.

In view of the product's low cost, partners will help create a sustainable market through advance market commitments, central funding and pooled procurement based on risk-approaches to product quality. Ultimately, EWEC countries will be encouraged and supported in not renewing the registration of oxytocin products of un-assured quality.

Increased support will be given for countries to improve training and supervision of health workers to safely use these products at all levels of the health system. This should be in conjunction with demand creation and improved patient awareness around appropriate use of uterotonics at community level.



In parallel to these first-priority activities, the search for better products will be intensified. Innovations in product promotion and production, use of innovative single-dose injection devices, co-packing with a temperature monitoring device and more heat-stable non-injectable formulations such as nasal sprays should be explored.

## 2. Misoprostol for prevention and treatment of PPH

### **Problem statement**

Misoprostol is a medical product with multiple indications (e.g., stomach pain, induction of labour, prevention and treatment of PPH, induced abortion, treatment of incomplete abortion, miscarriage, intrauterine foetal death, cervical ripening). Dosing regimens vary depending on the medical indication, creating the potential for incorrect dosing if users do not have accurate information. Concerns over misoprostol's use for abortion in legally restrictive settings have resulted in registration delays or even in its being prohibited in certain countries despite its great medical potential. For some indications (prevention of PPH, induction of labour) it has been recognized by the WHO as an essential medicine; for other indications (treatment of PPH) it is seen as a secondary option where oxytocin injection is unavailable (e.g., rural settings). The picture is further complicated by the presence of large numbers of unstable and ineffective products on the market, partly due to its black-market potential. The medical benefits of the product cannot be realized without addressing product quality issues and proper training and information provision to women and health-care workers.

### **Specific issues identified**

#### Provider issues:

Can be used for medical abortion (off-label, self-administered);  
Wrong dosages used for induction of labour.

#### Quality:

Serious quality problems (rapid degradation) in 34/76 samples from 12 countries;  
No products pre-qualified by the WHO; four products to be submitted in 2012–2013.

#### Policy/ regulatory issues:

Is included in the WHO guidelines for prevention of PPH and listed on WHO-EML for prevention only, due to clinical inferiority over oxytocin;  
Comes in many different and large-size packages; re-packing in single units requires re-registration.

#### Formulation/ market shaping:

No economic interest in costly bioequivalence studies needed for regulatory approval;  
Recommended 25mcg dose for induction not widely available.

### **Implementation plan**

The first issue to be tackled is that of quality. This will be addressed by quality surveys in all EWEC countries, technical support to committed manufacturers (including technical and financial support for the necessary bioequivalence studies) in producing 25 and 200 mcg tablets only, prequalification of selected producers, identification of good quality products and stricter national regulatory control. Global identification of good quality products through the ERP and the WHO/UN PQ should also take place, and national procurement lists should be updated based on WHO guidance. Any additional research needed to answer implementation questions should get priority so that further evidence-based global guidance on the use of misoprostol for PPH in rural settings can be developed by the WHO and promoted for adoption into national clinical guidelines. Ultimately, EWEC countries will be encouraged and supported in not renewing the registration of misoprostol products in other dosages or of un-assured quality.

Another issue is the promotion of misoprostol for its agreed indications: prevention of PPH as an alternative to oxytocin injection in situations where oxytocin injection cannot be given. To this end the WHO will maintain and promote updated global clinical guidelines. The WHO and relevant partners will support EWEC countries in promoting national regulatory approval of use by nurses and midwives, updating national clinical guidelines and establishing procurement, training and supervision programmes.

In view of misoprostol's limited economic potential, relevant procurement agencies and partners will help create a sustainable market through advance market commitments, central funding and pooled procurement based on products reviewed through an ERP. The aim is to do this for a few years only, after which it is hoped that extended use in EWEC countries will have created a sustainable market.

### 3. Magnesium sulfate for prevention and treatment of severe pre-eclampsia and eclampsia

#### **Problem statement**

The main issue with magnesium sulfate is insufficient use by health workers. Despite global evidence from over a decade ago that it is superior to diazepam in treating severe pre-eclampsia and eclampsia, magnesium sulfate is still not used in many settings. There are also inconsistencies in product dosage and strengths. Additionally, the product is so simple and inexpensive that manufacturers are not interested in investing in further product development and marketing.

#### **Specific issues identified**

##### Provider issues:

Not widely used by specialists and midwives (diazepam still widely in use);  
Potential safety risk due to various strengths and complicated dilutions.

##### Quality:

Field quality is largely unknown; no pre-qualified products.

##### Policy/ regulatory issues:

Use by midwives not allowed in many countries;  
No WHO support yet for community use.

##### Formulation/ market shaping

No commercial interest due to low price and small market volumes in most EWEC countries;  
Many formulations are available that require complicated dilutions (e.g., 15, 20 and 40 per cent), increasing fear of use by providers and the chance of error;  
Need for product package for emergency use with needle, syringe and calcium gluconate.

##### Awareness/ demand

Health workers are often not trained and adequately supervised in the correct use of magnesium sulfate and have fears around toxicity;  
Communities are unaware of the potential benefits of this drug in the case of eclampsia.

#### **Implementation plan**

The first necessary step is that the WHO will convene international experts to establish the required product strength and presentation (20 or 50 per cent content, packaged with calcium gluconate and clear instructions, all packed in an eclampsia kit) and simplified recommended treatment (correct dilution, administration by IV injection or infusion, duration) through further research in support of updating the 2011 *WHO Recommendations for Prevention and Treatment of Pre-eclampsia and Eclampsia* guidelines. These will then be promoted in EWEC countries through development of national clinical guidelines, pictorials, training and supervision. Such renewed and clear guidance on formulation and presentation will help guide manufacturers and consolidate the market as well as target quality surveys and national regulatory support for introduction and use of the eclampsia kit by nurses and midwives. Global identification of good quality products through the ERP and the WHO-PQ should also take place.

In view of the current limited use and low price of magnesium sulfate, relevant procurement agencies and partners will initiate market-shaping activities to create a sustainable market, such as advance market commitments, central funding and pooled procurement based on ERP or other risk-based approaches. The aim is to do this for a few years only, after which it is hoped that extended use in EWEC countries will have created a sustainable market. Ultimately, EWEC countries will be encouraged and supported in not renewing the registration of magnesium sulfate products in other dosages or of un-assured quality.

## 4. Injectable antibiotics for neonatal sepsis

### Problem statement

The main issues with injectable antibiotics are insufficient use and lack of appropriate products for neonates and lack of economic interest because of small and fragmented markets. The very low recognition of neonatal sepsis by mothers and other family members, and even lower care-seeking, is a huge barrier to scaling up this intervention. A further issue is lack of national regulatory approval for the use of antibiotics by nurses and midwives.

### Specific issues identified

#### Provider issues:

Overdose of gentamycin is ototoxic, and standard of care is to monitor blood levels and adjust dosing;

Blood level monitoring in low-level or resource-poor settings is not possible, but extended interval dosing is generally a safe and efficacious approach in community settings.

#### Evidence/ regulatory issues:

Procaine penicillin: widespread experience treating newborns with sepsis and congenital syphilis but actually limited evidence from clinical trials on safety and efficacy in neonates; limited evidence on use by community health workers but safety profile and efficacy seem favourable;

Gentamycin toxicity (primarily hearing damage) when overdosed in neonates; greater risk in preterm and asphyxiated babies;

Innovative delivery systems (pre-filled, single-use syringe, auto-disable, small syringes, safe retractable syringes, intravenous line) for gentamicin are technically feasible but there are regulatory barriers;

Ceftriaxone has an excellent safety profile and efficacy when used once daily;

Efficacy and safety studies in neonatal sepsis are complicated and expensive;

Recent studies of community-based 'packages' reducing mortality reduction included injectable antibiotics (gentamicin, procaine penicillin).

#### Formulation/ market shaping

Limited sources of quality and affordable products and no economic interest in view of small and fragmented markets;

Small dosage of gentamicin for neonates is not available; special small syringe needed.

### Implementation plan

The first priority actions are linked to promoting the correct use of available products (procaine penicillin, gentamicin and ceftriaxone injection). The WHO will review and update global clinical guidelines as needed and, with partners, will support EWEC countries in using model guidelines to develop and implement national clinical guidelines and pictorials, training and supervision plans. Specific attention will be given to give practical advice on how to dilute and administer the potent antibiotics to small neonates. A regulatory pathway will be developed to streamline national regulatory approvals, including administration by nurses and midwives.

The second phase in the approach is to support the development of new formulations for community-based administration to neonates, such as gentamicin in single-use, pre-filled injection devices or micro-needle patches. In order to incentivize such product innovations in small and fragmented markets, relevant procurement agencies and partners will use market-shaping techniques such as advance central funding, market commitments and pooled procurement. The development and marketing of new products will be supported by the WHO through technical support in developing the requirements for a standard common product dossier and by joint regulatory reviews to facilitate national registrations. Ultimately, the new products will be included in the ERP, WHO-PQ and other quality assurance efforts.

Relevant procurement agencies and partners will initiate market-shaping activities to create a sustainable market, such as advance market commitments, central funding and pooled procurement based on ERP or other risk-based approaches. The aim is to do this for a few years only, after which it is hoped that extended use in EWEC countries will have created a sustainable market. In the medium term, the WHO and relevant partners may include injectable antibiotics in an ERP process and WHO-PQ to assist national procurement agencies in identifying a number of reliable products and to support committed manufacturers in exporting into global markets.

## 5. Antenatal corticosteroids to prevent respiratory distress in preterm babies

### Problem statement

The main issue is the lack of use of antenatal corticosteroids (ANCS) in low- and middle-income countries. Antenatal steroids should be given to all women at risk of preterm birth to maximize the chances of child survival by promoting foetal lung development. The necessary drugs are widely used for other indications, especially allergies, and quality issues are not known to be barriers.

### Specific issues identified

#### Provider issues

Coverage data for ANCS use are not widely available, but the existing data show that there is serious underuse in low- and middle-income countries, even in referral facilities, and especially in rural settings. Side effects are rare and minimal.

#### Evidence/ regulatory issues

There is very high quality evidence for the effectiveness of ANCS with 19 trials showing significant neonatal mortality reduction. However, the foetal lung maturation indication is not registered in most countries, including many high-income countries where it is the standard of care.

#### Formulation/ market shaping

Both betamethasone and dexamethasone have high quality evidence of effect and, pending further trials, there is no conclusive proof that one is superior to the other. Dexamethasone is on the WHO-EML (inexpensive, widely available) though not listed for foetal lung maturation. The specific formulation of betamethasone used for this indication (acetate and phosphate) is limited in supply and relatively expensive. A similar formulation of betamethasone phosphate alone (which is easily confused with the acetate suspension in phosphate) has insufficient evidence to merit its use.

#### Awareness/ demand:

In high-income countries, ANCS have been used in around 90 per cent of cases of women in preterm labour since the mid-1990s, but in 75 high-burden countries coverage rates are estimated at around 10 per cent. Barriers to uptake include lack of provider awareness and restricted prescribing. Side effects are not a major concern, so caregivers should be encouraged to err in favour of administration, especially since even a few hours between ANCS and birth has some effect on respiratory distress syndrome, which has high fatality rates especially where intensive care is unavailable. More context-specific drivers of demand are being explored in a number of country case studies.

### Implementation plan

Four immediate actions will help to save lives with this intervention:

1. Prioritize immediate scale-up of dexamethasone for use to reduce deaths for preterm babies: Betamethasone is simpler to administer in only two injections, yet its lower availability and much higher cost are serious challenges. Dexamethasone is already available globally. A 6 mg ampoule or vial may help to increase correct use and decrease wastage. A tracking mechanism to measure use as a percentage of preterm births will facilitate progressive adoption of this best practice.
2. Submit for addition of foetal lung maturation to the indications for dexamethasone on the WHO-EML. Corticosteroids are already on the Priority Medicines list for this indication of reducing the risk of deaths due to preterm birth, but the EML is closely linked to policy change in many countries. The key approach is for the WHO to review the evidence and update global clinical guidelines and the WHO-EML.
3. Increase policy awareness and provider support to correctly administer ANCS: Strong policy promotion and provider education was crucial to the adoption of ANCS in the wealthy world and is a key opportunity now for rapid adoption in the rest of the world as well. Obstetrician leadership is key. Empowering midwives to provide ANCS for women in preterm labour would immediately increase access. A generic set of guidelines and training materials should be developed for adaptation in EWEC countries to promote use. Where needed, the WHO will support EWEC countries in obtaining regulatory approval for use of these medicines by nurses and midwives.
4. Promote implementation with linked research. Scaling up this cost-effective intervention will require investment in understanding context-specific local barriers, in designing innovative strategies capable of overcoming those barriers, and in conducting rigorous research to measure effectiveness and cost of ANCS at all levels of the health-care system, in varying contexts, through various providers and linked to other cost-effective care options to reduce deaths among preterm babies such as Kangaroo Mother Care.

## 6. Chlorhexidine for cord care

### Problem statement

Many unsafe cord-care techniques, such as covering the cord with harmful indigenous substances, lead to unnecessary illness and neonatal death by tetanus and other infections. In addition, provider preference for dry cord care does not sufficiently address newborn sepsis. Application of 4 per cent chlorhexidine (CHX) to the umbilical cord will reduce neonatal mortality and severe infection, but products containing this concentration are not widely available.

### Specific issues identified

#### Provider issues

In September 2012, a WHO consultation meeting reviewed evidence for postnatal care. After reviewing the evidence for CHX cord care, meeting participants made the following recommendation to the WHO:

*Daily chlorhexidine 4 per cent application to the umbilical cord stump in the first week of life is recommended for newborns who are born at home in settings with a neonatal mortality rate greater than 30 per 1,000.*

Awareness of policy makers and providers will need to be raised around this recommendation and country-specific strategies for how to implement these guidelines will need to be devised.

CHX needs to be re-listed on the WHO-EML as: chlorhexidine 7.1 per cent as di-gluconate, delivering 4 per cent chlorhexidine. (This will only be listed if sufficient products are marketed.)

#### Quality

PATH study suggests stability for 24 months at room temperature in all climatic zones.

#### Evidence/ regulatory issues

Clinical evidence from Africa is lacking; surface disinfectant products containing CHX at low concentrations are not registered as a medicine in many countries; new gel and solution presentations containing 4 per cent CHX for human use will need regulatory approval.

#### Formulations/ market shaping

Products containing lower concentrations of CHX are widely available, some in large containers (e.g., one litre); Preferred product: 7.1 per cent in aqueous solution in white plastic bottle with nozzle or as gel in aluminium tube.

#### Awareness/ demand

Many health workers and communities are not aware of the benefits of CHX for umbilical cord care.

### Implementation plan

The first priority is for the WHO to apply their review of the updated evidence on product characteristics and effectiveness (clinical trials in Bangladesh, Nepal and Pakistan have established safety and efficacy) to update the care guidelines and review updated submissions to the WHO-EML. EWEC countries will receive support from the WHO and partners on updating country guidelines and lists and, on that basis, partners will work with domestic manufacturers in EWEC countries to develop and market one of the preferred products (liquid or gel). WHO and partners will identify a regulatory pathway consistent with local production in EWEC countries. For the first three to five years, relevant procurement agencies and partners will use market-shaping methods such as identifying quality sources of active pharmaceutical ingredients (APIs), requiring manufacturers to buy only from the qualified list of API sources and central funding or advance market commitments in the expectation that these will help to shape viable future markets. Integration into essential newborn care programmes, programmes for newborns in crisis settings and clean delivery kits should also be explored.

## 7. Newborn resuscitation devices

### Problem statement

Birth asphyxia, the failure of the newborn to establish breathing after birth, kills 717,000 newborns every year, accounting for almost a quarter of newborn deaths. Proper neonatal resuscitation including bag and mask and suction devices could easily prevent the majority of these deaths. Although quality affordable devices that are meeting international standards are available, the specifications and standardization of such devices are rarely regulated at

national level and product selection guidance is not universally available to national-level procurement leads. Further, the devices themselves are infrequently available and used at every location where deliveries occur. As a medical device, this commodity faces additional supply challenges, including irregular procurement and sterilization, compared to the other 12 focus commodities of the Commission. Additionally, in order to maintain provider skills and ability to manage birth asphyxia, birth attendants require quality practical pre- and in-service training, with routine refresher trainings. This is one of the non-medicines on the list of 13 essential commodities along with the female condom.

### **Specific issues identified**

#### Provider issues

Where available, devices are often incorrectly used by birth attendants;

Quality, practical pre- and in-service training and routine refresher trainings are required to maintain provider skills and ability to manage birth asphyxia.

#### Quality, evidence and regulatory issues

Most low-income countries do not have any regulation or market control of devices;

Resuscitation devices are not on the WHO or Interagency List of Essential Medical Devices.

#### Access/ availability

Resuscitation equipment is not always available at all locations where births occur;

Health workers are often not adequately trained and supervised in the correct management of birth asphyxia.

### **Implementation plan**

The initial step will be to ensure that newborn resuscitation devices, including bag and mask and suction devices, are added to the WHO or Interagency List of Essential Devices. This will assist priority countries to better regulate devices at the national level, with support of the WHO and other partners. In addition, this list and existing global guidance materials such as the WHO's recently updated guidelines on newborn resuscitation, the WHO Essential Newborn Care Course (which is currently being redesigned in a more user-friendly format) and the Helping Babies Breathe course can assist priority countries to provide quality competency-based training and follow-up supportive supervision including continued refresher trainings. A global PPP has introduced Helping Babies Breathe in about 50 countries and needs to be supported to achieve scale and impact. Innovative simpler products that are being designed and evaluated to improve product function and more effective use can be procured when improved effectiveness is fully documented. Unlike medicinal commodities, resuscitation equipment is not procured regularly. However, in priority countries, supply chain systems should be strengthened to ensure that resuscitation devices are available at every service delivery point where births occur and can be replaced as required.

## **8. Amoxicillin tablets for treatment of pneumonia in children**

### **Problem statement**

Childhood pneumonia, often of bacterial origin, can easily be fatal when occurring in rural areas without access to immediate diagnosis and treatment. Newly developed child-friendly antibiotic treatment is now available in the form of amoxicillin dispersible tablets (tablets that easily dissolve in water, replacing bulky antibiotic syrup in glass bottles). However, private sector providers, who provide the majority of care for pneumonia in sub-Saharan African and South Asia, have little incentive to perform differential diagnoses and often prescribe more expensive medicines, sometimes in partial doses. In many EWEC countries the use of antibiotics by community workers is not allowed, which implies that task-shifting to lower-level health workers is officially not possible. Continued use of suboptimal products such as cotrimoxazole hinders the transition to amoxicillin. For countries using amoxicillin, there is a proliferation of treatment guidelines around multiple amoxicillin products.

### **Specific issues identified**

#### Provider issues

The WHO normative guidance for treatment of pneumonia not yet widely disseminated;

Dispersible tablet 250 mg not specifically listed in the WHO-EML;

Dispersible tablet not widely demanded and used; continued use of suboptimal products (e.g., cotrimoxazole and adult tablets/ products);

Users will have to switch from cheaper cotrimoxazole to more expensive amoxicillin.

#### Quality

The quality of the new amoxicillin dispersible tablets is not very well known (amoxicillin is often poorly packaged, leading to degradation after exposure to heat and humidity).

#### Policy/ regulatory issues

Use of antibiotics by low-level health workers not allowed in many countries;

Many countries still recommend cotrimoxazole as first-line pneumonia treatment for children.

#### Formulations/ market shaping

The product needs good packaging to protect against humidity, otherwise unstable;

Dispensing tools that differentiate bodyweight bands for easy dosing needed; this could be in the form of colour codes for individual treatments packs of dispensing pouches;

Small (but slowly increasing) market volumes in most EWEC countries and no existing process for aggregating demand.

### **Implementation plan**

Now that a number of dispersible paediatric products are available in the market, the main issue is to support countries in use and adoption of the global clinical guidelines and the WHO-EML. The WHO has included amoxicillin 250 mg in training guidelines for community health workers. National plans to scale up essential medicines, including amoxicillin for pneumonia, have already been developed for a number of high-burden EWEC countries, calling for key interventions to translate policy into action and ensure widespread access to optimal products. Specific interventions include updating national treatment guidelines to recommend amoxicillin as first-line treatment of pneumonia; developing materials, training and supervision programmes; and developing education programmes directed at increasing awareness of recommended treatments. A forecast of demand will be developed to include parameters for estimation of needs related to disease burden, coverage of interventions and scenarios for uptake in countries. The joint regulatory reviews will be used to further strengthen regional regulatory cooperation and harmonization.

In parallel, the WHO and partners (Recommendation 4) will perform quality surveys of products to identify key risks and support a global ERP. This ERP process will also allow the identification of manufacturers that would benefit from support to complete dossiers (especially for bioequivalence studies). The WHO will develop a regulatory pathway, including ERPs, to streamline national approvals and administration by nurses and community health workers. Relevant procurement agencies and partners will continue to work with selected manufacturers to further adapt the product, e.g., by introducing colour codes for easy dosing of children of different body weights. Relevant procurement agencies and partners will conduct cost of goods analyses to understand key cost drivers of amoxicillin and develop strategies to minimize the price differential compared to alternatives. In the medium term, the WHO will include dispersible amoxicillin tablets in the ERP process and, if needed, the WHO-PQ to assist national procurement agencies in identifying a number of reliable products and to support committed manufacturers in exporting into global markets.

## **9. Oral rehydration salts (ORS) for treatment of diarrhoea**

### **Problem statement**

Despite 40 years of availability and promotion of ORS as the main treatment for childhood diarrhoea, less than 40 per cent of children with diarrhoea actually receive ORS. Especially in the private sector, other treatments are often sold, such as antibiotics and anti-diarrhoeals. Mothers often do not consider ORS to be a real medicine, and prescribers often prefer to sell a more expensive product. ORS needs to become far more ubiquitous in the community and household through both public and private sector channels.

ORS manufacturers and pharmaceutical companies currently spend little to innovate new presentations, market directly to consumers and providers or expand distribution, but they could be motivated to do so with effective risk sharing and incentives. For example, combining ORS sachets with zinc tablets is being considered but such combination products are not yet available widely. Innovative ORS and zinc demand generation efforts to both consumers and providers may give

some new momentum to efforts to promote ORS and reduce the inappropriate use of antibiotics and anti-diarrhoeals. More research is required to understand which demand creation approaches work best, and in which context, to ensure widespread consistent use of ORS. New approaches are needed.

### **Specific issues identified**

#### Provider issues

Inadequate use of ORS in most countries (<40 per cent of diarrhoea cases in children);  
Inadequate adherence at the household level to the prescribed use;  
Overuse of antibiotics and anti-diarrhoeals, especially in the private sector.

#### Quality

No important quality issues known.

#### Evidence/ regulatory issues

ORS/zinc combination pack ('diarrhoea treatment kit') may need separate registration as a new product;  
Lack of consensus on international standard on the level of regulation (e.g., as food or as medicine);  
Need for more favourable regulatory environment to improve access where appropriate (e.g., OTC status or classifying as food product).

#### Formulations/ market shaping

Need for more attractive formulations and packaging (e.g., flavoured, smaller packages of 200 ml, combination packs with zinc tablets) that respond to consumer preference and improve uptake among consumers in both private and public sectors.

#### Access/ availability

Ensuring reliable and affordable supplies are easily accessible;  
Oral rehydration therapy corners in community health centres can improve caregiver knowledge on how to replace fluids, continue feeding and prevent dehydration through counselling.

### **Implementation plan** (see also the section on zinc tablets)

Relevant partners will assist priority EWEC countries in updating their national clinical guidelines with low-osmolarity ORS and zinc and developing innovative demand-generation efforts, in close collaboration with national professional organizations and the private sector. Priority EWEC countries will also work to establish financial and other incentives for the use of ORS/zinc by prescribers. The Diarrhoea and Pneumonia Treatment Working Group will assist countries in developing materials and demand-generation programmes, establishing financial and other incentives for the use of ORS and zinc by prescribers and ensuring widespread availability of supply. Market research will also be undertaken to understand what presentations of ORS would be most attractive in different markets as well as work with companies to market and distribute improved presentations, with evaluation on the impact on uptake.

Relevant partners will work with a number of selected domestic ORS producers to help them improve their GMP; this may include technical and financial support and 'invest to save'. These partners will also work with manufacturers to develop a 'diarrhoea treatment kit' with ORS and zinc. The WHO and relevant partners will develop a regulatory pathway and coordinate joint reviews to facilitate rapid national regulatory approval, emphasizing OTC use or general sale (as food).

## **10. Zinc for treatment of childhood diarrhoea (with ORS)**

### **Problem statement**

Zinc is a newly proven effective adjuvant treatment for childhood diarrhoea, reducing both its duration and severity and the likelihood of subsequent episodes. The main problem is that the product is not widely known and currently used in less than 3 per cent of diarrhoea cases globally. Because of low price and low market volume there are only a few interested manufacturers, some of which have encountered quality problems. In some EWEC countries zinc is registered as a prescription-only medicine, which prevents the legal task-shifting to lower-level health workers or OTC status, both of which would be essential to reach all children with diarrhoea.



## **Specific issues identified**

### Provider issues

Zinc tablets not consistently used (<3 per cent of diarrhoea cases globally);  
Adherence by the caregiver to providing the child with the full 10 days of treatment is low;  
Overuse of antibiotics and anti-diarrhoeals, especially in the private sector.

### Quality

Lack of consensus on the most appropriate quality standard for zinc;  
Some products of un-assured quality on the market;  
Lack of consistent specifications and quality requirements for improved presentations (e.g., taste-masking, scoring of 20 mg tablets, ensuring complete and rapid dispersibility in water).

### Evidence/ regulatory issues

Zinc is not registered in many countries as OTC, which limits widespread distribution and availability because it cannot be sold outside of pharmacies;  
ORS/zinc combination pack ('diarrhoea treatment kit') may need separate registration as a new product;  
Unclear if and by what medium zinc can be advertised in all countries.

### Formulations/ market shaping

Need for more attractive presentations and/or formulations that meet consumer needs (e.g., ORS sachets co-packaged with zinc tablets, taste-masking, co-formulation, alternate dosage forms, standardized syrup dosage and packaging to allow for one bottle/ diarrhoea episode);  
Need to develop combination of ORS/zinc into diarrhoea treatment kit or other ways to co-dispense ORS and zinc (e.g., dispensing pouch for complete ORS and zinc treatment with appropriate instructions);  
Small market volumes in most EWEC countries.

## **Implementation plan** (see also under ORS)

The implementation focuses on further product development, regulatory pathway and increasing demand. The WHO will review updated evidence to revise global clinical guidelines on the standard dosage and duration of zinc treatment for children of various body weights. On that basis, partners will approach committed manufacturers to develop and market new presentations with demonstrated consumer acceptance, affordability and improved consumer adherence to appropriate dosage. As new presentations become available, the WHO and relevant partners will develop a regulatory pathway, including information resource to support OTC approval. ERP and other mechanisms will be considered to mitigate slow uptake of the WHO-PQ for zinc.

At the same time, partners will assist national programmes in priority EWEC countries to create a favourable policy environment for zinc (including securing OTC status) and introduce and promote the use of zinc with ORS in teaching hospitals, health facilities and among other providers in the public and private sectors. Partners will assist priority EWEC countries to start demand generation programmes, in close collaboration with professional associations and the private sector, creating financial and other incentives and using materials to target both consumers and providers. The WHO and relevant partners will also investigate the possibility of more streamlined processes for the registration of zinc than is currently available to encourage a broad supply of available products while ensuring quality and building consensus around a more appropriate quality standard.

## **11. Female condoms**

### **Problem statement**

The female condom is a powerful tool to empower women with partners unwilling to use condoms, protecting her against unwanted pregnancy and sexually transmitted diseases, most notably HIV and AIDS. The problem is that the product is not widely known and the global market is still small; there is lack of support to include female condoms in family planning and dual protection policies and lack of coordination between institutional buyers.

## **Specific issues identified**

### Provider issues

Largely unknown and under used in most EWEC countries.

#### Quality

There are two female condoms pre-qualified (the FC2 of the Female Health Company and the Cupid female condom of Cupid Ltd.).

#### Evidence/ regulatory issues

Not specifically included in the WHO-EML (does not specify 'male' or 'female').

#### Formulations/ market shaping

Small market volumes in most EWEC countries.

### **Implementation plan**

Partners active in family planning will continue to further promote the use of the female condom as an alternative barrier method in the range of family planning alternatives and as part of the choice of family planning methods offered to women. EWEC countries will start or expand innovative demand generation efforts, including free supply of female condoms together with free supply of male condoms. This will also need innovative financing mechanisms.

Conveners will submit evidence to the WHO supporting the need for distinct references for male and female condoms on the WHO-EML. Partners and the WHO will also support countries in developing information for national EML, Interagency List of Essential Medical Devices for Reproductive Health and other policy efforts to advocate for the use of female condoms. Relevant procurement agencies and partners will encourage committed manufacturers to submit their products for prequalification, to identify any common quality problems and create an incentive for manufacturers to submit their product for prequalification. Market-shaping activities, such as volume guarantees, should be considered to drive down cost.

## **12. Contraceptive implants**

### **Problem statement**

Implants are an effective, safe and user-friendly method of family planning that has the potential to widen choices currently available. Widening method mix supports higher overall contraceptive uptake and continuation. Implants are not yet used extensively in EWEC countries, partly because of price and also because health workers need to be trained in inserting and removing them. The product is caught in the market transition from few pre-qualified and more expensive, originator products to a wider range of quality-assured products, including less expensive generic alternatives.

### **Implementation plan**

Priority activities have been identified to enhance availability, affordability and adoption of contraceptive implants. These activities correspond to four specific recommendations by the Commission. Recommendations 1 and 9 are the priorities:

#### Global market shaping (Recommendation 1):

- Negotiate a multi-year volume guarantee with manufacturers of contraceptive implants if appropriate pricing and volume terms can be agreed upon;
- Develop more robust demand forecasting (reflecting the different dimensions of demand of a predominantly donor-financed market for health commodities);
- Increase the number of suppliers meeting global quality standards.

Work should be undertaken jointly with the Global Market Shaping Working Group, the Family Planning Summit implementation arrangements or other stakeholders.

Performance and accountability (Recommendation 9): Actions are required to drive the delivery of quality services within countries. Policy and programme interventions will need to respond to individual country conditions and priorities and are likely to include:

- Appropriate policies and practices on task-shifting and sharing;

- Health worker training accreditation, registration and supervision in both the public and private sectors;
- Strengthened monitoring systems for accurate and timely follow-up for removals;
- Updating of EMLs;
- Product registration, introduction and scale-up.

Key mechanisms for implementation will be national adaptation of global guidance (though clinical guidelines, service delivery protocols, job aids, etc.) and support for adoption through training and capacity building. These processes should reflect the latest evidence, including that set out in a recent set of WHO Policy Briefs.<sup>v</sup> Complementary efforts should be undertaken to further build evidence on experience to support resource allocation and policy-making. This agenda will be pursued in close coordination with partners.

Regulatory efficiency (Recommendation 5): The group will work with others, particularly the WHO as convenor, to address key registration challenges. These may be in terms of priority countries or new products.

Product innovation (Recommendation 10): The group will coordinate with the product innovation group on the longer-term challenges of product development. Potential directions include (i) biodegradability, (ii) securing longer shelf life and (iii) enhancing ease of insertion/ removal. The group additionally notes that success in addressing the market failures highlighted above will also positively impact innovation.

## 13. Emergency contraception

### Problem statement

Emergency contraception, also called the ‘morning-after pill’, is an example of an effective product that is insufficiently known and used in EWEC countries. The product is in the intermediate stage between the early prequalification of expensive originator products and delayed prequalification of more affordable generic alternatives. Emergency contraception is in addition a method available for victims of sexual violence in post-rape situations.

### Specific issues identified

#### Knowledge/ demand

Data show that the majority of women in low-income countries are unaware of the existence of this contraceptive method, and in many countries emergency contraception is not well integrated into family planning programmes.

#### Provider issues

Inadequate use and provision as part of contraceptive method mix in countries;  
 Providers do not have sufficient information and skills to provide the product;  
 Pharmacists and drug-sellers are not trained in advocacy and provision;  
 Consumers are not knowledgeable about effects as an effective method of pregnancy prevention.

#### Quality

There are a large number (>60) of products on the market but few have been qualified by an SRA or the WHO-PQ; the innovator product (2 x 750 µg) is pre-qualified by the WHO and several generics are in the pipeline; there are possible patent issue with 1 x 1.5 mg presentation.

#### Evidence/ regulatory issues

The single-tablet product is listed in several WHO documents (e.g., medical eligibility criteria for use of contraception) and is registered in many countries as a contraceptive method.

#### Formulations/ market shaping

The two-tablet product may be changed into one-tablet formulation.

### Implementation plan

Systematic reviews will be conducted and submitted to the WHO-EML Expert Committee to update the Model List to include the single-tablet presentation. An expert group of topic specialists will be convened to develop appropriate technical specifications to launch the prequalification process (expressions of interest), and specifications for generic products will be developed. National registration of emergency contraception will be facilitated in countries through

work with regional groups of national regulators and joint review of dossiers. Policy recommendations and information materials will be developed to facilitate access to emergency contraceptives, support policy changes and enhance demand. Implementation research and reviews will be conducted on strategies to expand access to emergency contraceptives.

**Examples of milestones:**

- Specifications for generic emergency contraception developed (2013).
- Single tablet emergency contraception product included in EML (2014).
- Emergency contraception is part of contraceptive method-mix in 10 new EWEC countries (2014).

## Annex 3: Terms of reference for convening organizations for recommendations/ cross-cutting areas

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### 1. TITLE

The name of the Lead Organization is \_\_\_\_\_

### 2. PURPOSE

On behalf of the UN Commission Secretariat, to convene and lead a team of self-selected, voluntary organizations to develop a work plan that clearly defines roles and responsibilities of all partners/ team members, with activities that can be completed within a specific timeframe (e.g., annual, bi-annual) to support achievement of the desired outcomes as defined by the recommendations of the UN Commission on Life-Saving Commodities for Women and Children.

### 3. REQUIREMENTS

- Must be an internationally recognized leader in the specific area of relevance or technical expertise to recommendation/ commodity X.
- Must be able to convene a team of interested parties and technical experts, including representatives from EWEC countries' governments, institutions and organizations.
- Must be able to provide technical and administrative support to carry out convening and related activities as required to complete the tasks related to developing and monitoring progress on the team work plan implementation and reporting on progress to the UN Commission Secretariat.
- Must be able to fulfil this role for the duration of the work plan period.

### 4. LEAD ORGANIZATION POINT PERSON

The Lead Point Person shall be identified by the Lead Organization. His/her responsibilities include:

- Schedule meetings and notify team members of critical timelines and events; invite specialists as needed on select tasks;
- Guide the meeting according to the agenda and time available;
- Track timely completion of tasks as required to meet the requirements of the UN Commission;
- Identify barriers or lack of progress and work with partners, and potentially the UN Commission Secretariat, to facilitate progress toward expected outcomes;
- Produce reports.

### 5. DURATION OF TEAM

As needed.

### 6. FUNCTION (SCOPE OF WORK)

- Review the UN Commission Report;
- Initiate and facilitate meetings of the Technical Reference Team;
- Facilitate the development of a detailed, activity-based work plan with corresponding indicators to track progress, to be implemented by designated partner;
- Track timely completion of tasks as required to meet the requirements of the UN Commission;
- Identify barriers or lack of progress and work with partners, and potentially the UN Commission Secretariat, to facilitate progress toward expected outcomes;
- Facilitate coordination with other team leads to avoid duplication of efforts and the optimal use of resources;
- Participate in quarterly meetings of team leads to share and coordinate information across recommendations and commodities;
- Prepare a detailed report to the UN Commission.

### 1. TITLE

Technical Reference Team – Recommendation/ Commodity X

### 2. PURPOSE

To develop a work plan that clearly defines roles and responsibilities of all partners/ team members, with activities that can be completed within a specific timeframe (e.g., annual, bi-annual) to support achievement of the desired outcomes as defined by the recommendations of the UN Commission on Life-Saving Commodities for Women and Children. In addition, the individual members of the team are responsible for carrying out agreed upon activities, including monitoring progress and evaluating outcomes.

### 3. MEMBERSHIP

- Should be voluntary;
- Should be as diverse as possible, including representatives from EWEC countries' governments, institutions and organizations;
- Should be able to contribute to planning and implementation of activities as agreed;
- Should be able to mobilize resources for activities as agreed;
- A quorum (60 per cent) of members must participate in work plan development and implementation decision-making.

### 4. TECHNICAL REFERENCE TEAM

The Technical Reference Team will be convened and led by an agency selected by the UN Commission Secretariat (see separate TOR). The responsibilities of the team members include:

- Participate in meetings;
- Contribute to work planning and identify activities for which they will be responsible and accountable;
- Secure funding for activities;
- Implement activities as per the agreed upon work plan and report on progress accordingly;
- Track timely completion of tasks as required to meet the requirements of the UN Commission;
- Produce reports.

### 5. DURATION OF TEAM

As needed.

### 6. FUNCTION (SCOPE OF WORK)

- Review UN Commission Report;
- Meet at designated times per request of Lead Organization;
- Develop a detailed, activity-based work plan with corresponding indicators to track progress, to be implemented by the designated partner;
- Secure funding and implement activities as per the agreed upon work plan and report on progress accordingly;
- Track timely completion of tasks as required to meet the requirements of the UN Commission;
- Prepare a detailed report to the UN Commission

## Annex 5: Outline/ checklist for country-level implementation plan

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Detailed country plans will be developed and shaped during in-country stakeholder meetings in each of the EWEC countries, building on existing and on-going national planning exercises, such as those emanating from the Child Survival Call to Action, the Family Planning Summit and other events referenced in the Commission's report.

In developing such plans, the following checklist may be of use:

- Establish or identify a national steering group to plan and coordinate work to improve access to life-saving commodities for women and children, in line with the UN Commission's Report.
- Review the national potential for market-shaping mechanisms – such as pooled procurement, multi-year volume agreements and designation of a lead procurement agency – with national stakeholders.
- Consider innovative financing mechanisms, such as results-based financing, to create incentives for prescribers and users.
- Perform a targeted survey of the quality of commonly used commodities to identify potential quality issues, create awareness and target activities to strengthen medicine regulation.
- Participate in global or regional joint regulatory reviews of new formulations and regulatory assessment of use of essential commodities by low-level health workers, to facilitate national regulatory approval.
- Organize country level assessment of supply chain-related problems and possible ICT and communication solutions and develop costed plans.
- Conduct government-led stakeholder discussions including with organizations that can reach families and care-givers to assess commitment, readiness and resources.
- Create financial incentives to remove some persistent supply chain challenges, such as rewarding timely disbursement for procurement, regular updates of supply plans, achieving accurate forecasts and maintaining minimum stock levels.
- Establish innovative PPPs to develop materials and messages for the 13 commodities to enhance consumer and provider demand through high-impact marketing and promotion, including private sector providers.
- Establish a sustainability roadmap and build capacity to develop, monitor and sustain social, behavioural change communications and mass-media campaigns.
- Establishing financial mechanisms to ensure equitable access to commodities by the poorest segments of society.
- Establish indicators and a scorecard and use these to assess progress towards increased access to commodities by the poorest segments of society through regular monitoring of price, availability, quality and use of life-saving commodities in public and private health-care facilities.
- Adapt national clinical guidelines to reflect international guidance on use of the 13 commodities.
- Develop country level tools, training programmes and supervisory structures to promote the use of national clinical guidelines, for example through checklists, pictorials and protocols for certain conditions (e.g. post-partum bleeding).
- Develop social audits to assess service provision, availability, affordability and barriers to access experienced by users, with emphasis on the poorest members of society.
- Use the public health need of further research and development in the 13 commodities as a practical example in the current global discussion of financing research and development.

## Notes

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<sup>i</sup> United Nations Secretary-General, *Global Strategy for Women's and Children's Health*, The Partnership for Maternal, Newborn & Child Health, 2010, <[www.everywomaneverychild.org/images/content/files/global\\_strategy/full/20100914\\_gswch\\_en.pdf](http://www.everywomaneverychild.org/images/content/files/global_strategy/full/20100914_gswch_en.pdf)>, accessed 11 June 2012.

<sup>ii</sup> The EWEC countries are defined as the 49 countries of the world with the lowest income: Afghanistan, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Côte d'Ivoire, Eritrea, Ethiopia, The Gambia, Ghana, Guinea, Guinea-Bissau, Haiti, Kenya, Democratic Republic of Korea, Kyrgyz Republic, Lao People's Democratic Republic, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Nigeria, Pakistan, Papua New Guinea, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Tajikistan, Togo, Uganda, Uzbekistan, United Republic of Tanzania, Viet Nam, Yemen, Zambia and Zimbabwe. The language "all EWEC countries" in the recommended actions means all EWEC countries facing such barriers and where action could drive change. During the implementation planning process, a set of countries will be identified for each recommended action that includes the language "all EWEC countries". The countries will be consulted to ensure their agreement with the classification and their buy-in. Given its importance for the achievement of Millennium Development Goals 4, 5 and 6, India will be included in the country-level stakeholder exercises and data from India will be taken into account for certain calculations.

<sup>iii</sup> See the report of the UN Commission on Life-Saving Commodities for Women and Children, September 2012.

<sup>iv</sup> For products with very small market volumes (e.g., magnesium sulfate), less than three manufacturers might be needed to guarantee volume.

<sup>v</sup> <[www.who.int/reproductivehealth/topics/family\\_planning/policybriefs/en/index.html](http://www.who.int/reproductivehealth/topics/family_planning/policybriefs/en/index.html)>.



**For more information:**

**Visit the UN Commission on Life-Saving**

**Commodities for Women and Children online at:**

**[www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities](http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities)**

**The Commission is part of the Every Woman Every Child movement to save the lives of 16 million women and children and improve the lives of millions more.**

