Medicines for women and children

Quality and availability of selected life-saving reproductive health medicines in developing countries

The UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) has identified 13 life-saving commodities that could save the lives of more than 6 million women and children in low-income countries over a five-year period if they were more widely available and used appropriately.

The WHO Department of Essential Medicines and Health Products organized two surveys to gain a better understanding of the availability and quality of these products in Member States. An overview of the methodology, findings and recommendations of the two surveys is provided in the annexes.

Background
The Every Woman Every Child (EWEC) movement aims to address the major health challenges facing women and children. In 2012 the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) identified 13 life-saving commodities that, if more widely accessed and properly used, could save the lives of more than 6 million women and children over a five-year period (1). These commodities include medicines to treat post-partum haemorrhage and eclampsia, injectable antibiotics for neonatal sepsis, antenatal corticosteroids to accelerate lung maturation in premature infants, chlorhexidine for cord care, amoxicillin to treat children with pneumonia, oral rehydration salts and zinc to treat children with diarrhoea, as well as contraceptive implants, emergency contraceptives and condoms.

The Commission recommended 10 time-bound actions to improve access to these commodities in EWEC countries, i.e. the 49 countries of the world with the lowest income. Two of the 10 recommendations are within the normative mandate of WHO: Recommendation 4 on quality strengthening (“By 2015, at least three manufacturers per commodity are manufacturing and marketing quality-certified and affordable products”) and Recommendation 5 on regulatory 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”).

The surveys
In collaboration with a wide range of stakeholders, the WHO Department...
of Essential Medicines and Health Products organized two surveys aiming to understand the quality and availability of the UNCoLSC-identified commodities in EWEC countries:
• a quality control testing survey of a total of 204 samples collected in 10 countries (Annex 1); and
• a questionnaire-based online survey on regulation and procurement of the commodities (Annex 2). These are the first surveys of this kind to be conducted since the inception of the UNCoLSC. The full survey reports will be published on the WHO website.

Main findings
The survey on regulation and procurement found that many countries had the formal structures and procedures required to purchase products and to control their quality, but staff and funding limitations affected their operational efficiency.

Registration coverage was reasonable for most products, although none of 22 respondent countries had all 18 UNCoLSC-recommended products on their registers. There were many brands of most injectable antibiotics, but the choice was much more limited for some other commodities. More than half of the registered products identified in the survey came from India and China; 11% were manufactured locally.

Most UNCoLSC-recommended commodities were being procured; some but not all were tracked by logistics management information systems (LMIS) at least at the central level. In most countries, and for the majority of commodities, at least one stock-out had occurred at the central level during the three years preceding the survey.

The quality control testing survey found that of total of 204 samples, 157 (77%), including all 11 samples of WHO-prequalified products, complied fully with the specifications set for the survey. Of the remaining 47 that failed one or more of the tests, five (2%) had extreme deviations in content and/or dissolution which were likely to affect the therapeutic effect of the product. The criteria to define these deviations were the same as those used in two earlier surveys organized by the WHO Prequalification Team (PQT) (2, 3).

Three of the five extreme deviations occurred with oxytocin injection, which also had the highest failure rate overall (14 of 22 samples). On the other hand, no failures at all were found for samples of procaine benzylpenicillin injection (including Fortified Procaine Penicillin), amoxicillin dispersible tablets, zinc tablets, zinc syrup and mifepristone tablets.

The results were analyzed in collaboration with the regulatory authorities of the participating countries. Regulatory action was taken in line with the survey findings, and jointly agreed survey recommendations were adopted.

Conclusions
While the findings highlight once more the ubiquitous resource constraints in national regulation and procurement systems, they also show that most of the UNCoLSC medicines were available on the markets of EWEC countries and that extreme quality deficiencies were relatively rare.

It should be borne in mind that any deviations from specifications most likely indicate problems with adherence to good manufacturing practice (GMP) and other international quality standards in manufacturing operations, or with product formulation. The findings of the quality survey highlight once more the importance of comprehensive, proactive regulatory oversight, including both
dossier assessment and risk-based GMP inspections, to ensure that products are designed and manufactured in such a way that they will consistently meet their specifications. For example oxytocin injections – which had the highest failure rate in the survey – were often found to contain large amounts of related substances. While this could have been at least partly due to inadequate storage and degradation in some of the samples, the sum of oxytocin and related substances was often well above 100% suggesting that there may have been large API overages in manufacture. This practice is not normally acceptable and should have been controlled by regulators during the registration process. Similarly, the presence of visible particles in three of 22 oxytocin samples, as well as some of the failures found with other medicines in this survey, pointed to problems in GMP compliance that should be detected and corrected through regulatory inspections. A full discussion of the findings is provided in the survey report that will be published on the WHO website.

Overall the results of the two surveys show that donor-funded programmes have contributed to bridging the gaps in access to quality-assured medicines for all who need them. In recent years – largely thanks to WHO-supported initiatives and WHO prequalification – there has also been encouraging progress towards good quality regulatory reviews in line with internationally accepted standards, harmonization of regulatory requirements and collaboration in EWEC countries, for example in Africa. The results of the two surveys highlight the importance of continuing this work. They provide valuable feedback to regulators, manufacturers, WHO and the UNCoLSC on remaining gaps in making good quality reproductive health medicines widely available.

References

1 UN Commission on Life-Saving Commodities For Women And Children - Commissioners’ Report. Geneva: UNFPA; September 2012.


http://apps.who.int/prequal/ - Quality monitoring
Annex 1: Survey of the quality of medicines identified by the UN Commission on Life-Saving Commodities

Description of the survey

Objectives
Primary: Identify products of good quality already available in selected EWEC countries.
Secondary: Evaluate the quality of target medicines collected at the first level of distribution chain.

Method
The survey was organized by the WHO Prequalification Team (WHO PQT) in cooperation with National Medicines Regulatory Authorities. A total of 205 samples of selected medicines from the list of 13 life-saving commodities identified by the UN Commission on Life-Saving Commodities for Women and Children (UNCoLSC) were collected at a total of 82 public, private and NGO sites at the first level of the distribution chain, where the influence of potentially inappropriate storage and transport conditions was considered minimal. The samples were tested in WHO-prequalified laboratories in Germany, Kenya and Belgium according to the monographs of the International Pharmacopoeia (Ph. Int), British Pharmacopoeia (BP), US Pharmacopoeia (USP), or a laboratory-validated method.

Note: The survey was not designed to distinguish between substandard and counterfeit products.

Survey period
Sample collection: September to November 2013; sample testing: December 2013 to April 2014
Joint debriefing and analysis of survey results: July 2014

Participating countries

Overview of findings

Table 1. Availability of target medicines for sampling

<table>
<thead>
<tr>
<th>Product</th>
<th>Abbreviation</th>
<th>Countries where sampled</th>
<th>Total samples</th>
<th>Origin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxytocin injection (inj)</td>
<td>OXT</td>
<td>10</td>
<td>22</td>
<td>India</td>
</tr>
<tr>
<td>Gentamicin inj</td>
<td>GEN</td>
<td>10</td>
<td>29</td>
<td>China</td>
</tr>
<tr>
<td>Ampicillin inj</td>
<td>AMP</td>
<td>10</td>
<td>26</td>
<td>Other</td>
</tr>
<tr>
<td>Ceftriaxone inj</td>
<td>CEF</td>
<td>10</td>
<td>30</td>
<td>imported</td>
</tr>
<tr>
<td>Magnesium sulfate inj</td>
<td>MS</td>
<td>9</td>
<td>19</td>
<td>Other</td>
</tr>
<tr>
<td>Dexamethasone inj</td>
<td>DEX</td>
<td>9</td>
<td>19</td>
<td>imported</td>
</tr>
<tr>
<td>Levonorgestrel tablets</td>
<td>LNG</td>
<td>8</td>
<td>14</td>
<td>China</td>
</tr>
<tr>
<td>Zinc dispersible tablets / syrup</td>
<td>Zn-tab Zn-zyr</td>
<td>8</td>
<td>21*</td>
<td>Other</td>
</tr>
<tr>
<td>Procaine penicillin inj**</td>
<td>PBP</td>
<td>5</td>
<td>6</td>
<td>Other</td>
</tr>
<tr>
<td>Amoxicillin dispers. tablets</td>
<td>AMX</td>
<td>3</td>
<td>10</td>
<td>Other</td>
</tr>
<tr>
<td>Mifepristone tablet</td>
<td>MIF</td>
<td>1</td>
<td>8</td>
<td>Other</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>204*</td>
<td>68</td>
<td>52</td>
</tr>
</tbody>
</table>

Notes: * An additional sample of zinc dispersible tablets was excluded from the survey due to inconclusive testing results. ** This included procaine benzylpenicillin injection and procaine benzylpenicillin + benzylpenicillin sodium injection

In each country at least one of the medicines recommended by the UNCoLSC could not be identified for collection. Some medicines were available in different strengths than those recommended by the UNCoLSC (e.g. oxytocin, magnesium sulfate) or in different dosage forms (e.g. amoxicillin). Betamethasone injection was available as an innovator product in some countries, but according to the survey protocol innovator products were excluded from sampling. - The survey outcomes related to the availability of target medicines may underestimate the reality due to the sampling methodology used.
Figure 1.  Numbers of compliant samples, and of samples with minor, moderate and extreme deviations

The overall rate of non-compliance with the specifications set for the survey (23%) was quite high. However, the share of extreme deviations from the specifications which most likely impact the therapeutic effect due to the low content of active principle or its limited release from the dosage form was relatively low (2%).

Table 2. Numbers of samples that failed each test

<table>
<thead>
<tr>
<th>Medicine:*</th>
<th>OXT</th>
<th>GEN</th>
<th>AMP</th>
<th>DEX</th>
<th>LNG</th>
<th>MS</th>
<th>CEF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total samples tested</td>
<td>22</td>
<td>29</td>
<td>26</td>
<td>19</td>
<td>14</td>
<td>19</td>
<td>30</td>
</tr>
<tr>
<td>Total samples failed**</td>
<td>14</td>
<td>12</td>
<td>9</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Visible particles</td>
<td>3</td>
<td>0</td>
<td>n.p.</td>
<td>0</td>
<td>n/a</td>
<td>0</td>
<td>n.p.</td>
</tr>
<tr>
<td>Assay</td>
<td>8 (3)</td>
<td>6</td>
<td>3</td>
<td>5 (1)</td>
<td>0</td>
<td>0</td>
<td>2</td>
</tr>
<tr>
<td>Related substances</td>
<td>14</td>
<td>n/a</td>
<td>8</td>
<td>n/a</td>
<td>0</td>
<td>n/a</td>
<td>0</td>
</tr>
<tr>
<td>pH</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>n/a</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Extractable volume</td>
<td>0</td>
<td>n.p.</td>
<td>n/a</td>
<td>0</td>
<td>n/a</td>
<td>n.p.</td>
<td>n/a</td>
</tr>
<tr>
<td>Uniformity of mass</td>
<td>n/a</td>
<td>n/a</td>
<td>1</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>0</td>
</tr>
<tr>
<td>Water content</td>
<td>n/a</td>
<td>n/a</td>
<td>0</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>0</td>
</tr>
<tr>
<td>Composition of gentamicin</td>
<td>n/a</td>
<td>4</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Free dexamethasone</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>3</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Dissolution</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>2 (1)</td>
<td>n/a</td>
<td>n/a</td>
</tr>
<tr>
<td>Content uniformity</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>n/a</td>
<td>1</td>
<td>n/a</td>
<td>n/a</td>
</tr>
</tbody>
</table>

* See abbreviations in Table 1. — ** Some samples failed more than one test.

• Compliant with all specifications
• Minor deviations: Failed in assay only, with content below the lower acceptance limit of BP but above the lower acceptance limit of USP
• Moderate deviations: Deviations that were not classified as minor or extreme in this survey
• Extreme deviations: Deviations that were not classified as minor or extreme in this survey

Shaded dark grey: The most frequently failed test for each medicine
Shaded light grey: n/a: Not applicable for the respective medicine; n.p.: Not performed
(x) Samples with extreme deviations, included in the numbers of samples that failed each test. Five of 204 samples (2%) had extreme deviations (as defined in the notes to Figure 1):
• Three oxytocin samples (content, of labelled amount: 52.0%; 78.6%; and 0-68.7% in the individual ampoules of an extremely heterogeneous sample)
• One dexamethasone phosphate injection (content: 64.4% of labelled amount)
• One sample of levonorgestrel tablets (average dissolution value: 10% of the labelled API amount)
Numbers of locally manufactured and imported samples that failed one or more tests

<table>
<thead>
<tr>
<th>Import</th>
<th>40 of 165 (24%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locally manufactured</td>
<td>7 of 39 (18%)</td>
</tr>
</tbody>
</table>

Among the locally manufactured samples there were no failures for zinc, amoxicillin, ceftriaxone and mifepristone. Minor or moderate deviations were found for magnesium sulfate, gentamicin, ampicillin, dexamethasone and levonorgestrel. There were no extreme deviations (see definition in Figure 1 on page 328).

Numbers of registered and unregistered samples that failed one or more tests

| Registered | 45 of 189 (24%) |
| Unregistered (donations, special import permits) | 2 of 15 (13%) |

These findings suggest that donors’ and procurement agencies’ quality assurance measures are effective.

Proportion of samples that failed one or more tests in countries

<table>
<thead>
<tr>
<th>Country</th>
<th>Proportion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zimbabwe</td>
<td>7%</td>
</tr>
<tr>
<td>Tanzania, Tajikistan, Uganda, Nepal</td>
<td>14–20%</td>
</tr>
<tr>
<td>Viet Nam, Burkina Faso, Kenya, Madagascar, Nigeria</td>
<td>29–35%</td>
</tr>
</tbody>
</table>

In some cases testing according to relatively strict pharmacopoeial specifications may have led to non-compliant findings which would not have occurred if the nationally approved manufacturers’ specifications had been used. The findings may reflect market complexity and/or varying levels of regulatory scrutiny and standards enforced in countries. The numbers of samples per country were relatively small, and samples were not collected randomly due to the limited availability of some of the products. The results are therefore not representative of the quality of medicines in the countries participating in the survey.

Table 3. WHO-prequalified medicines

<table>
<thead>
<tr>
<th>Survey-relevant products invited for WHO-prequalification</th>
<th>Number of WHO-prequalified products at the time of the survey</th>
<th>Number of samples collected in the survey</th>
<th>Number of samples that failed one or more tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levonorgestrel tablets</td>
<td>4</td>
<td>8</td>
<td>Zero</td>
</tr>
<tr>
<td>Zinc dispersible tablets</td>
<td>2</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Ceftriaxone injection</td>
<td>4</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Dexamethasone injection</td>
<td>1</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Oxytocin injection</td>
<td>0</td>
<td>n/a</td>
<td></td>
</tr>
<tr>
<td>Magnesium sulfate injection</td>
<td>0</td>
<td>n/a</td>
<td></td>
</tr>
</tbody>
</table>

Recommendations

A complex approach is necessary to improve the availability and quality of UNCoLSC target medicines. Apart from recommendations of a technical nature, the survey participants agreed on the following approaches and recommendations:

To support demand and promote appropriate use by clinicians:
• Update therapeutic guidelines and train health care professionals.
• Clearly specify the needed medicines by their dosage form and strength (and API form e.g. salt or base).

To support efficient regulatory review:
• Harmonize regulatory requirements and procedures.
• Promote cooperation and information exchange among regulators on post-marketing control (e.g. exchange of assessment and inspection reports, cooperation in sample testing, consultations before adopting regulatory actions against substandard medicines).

To incentivize manufacturers to register products in EWEC countries:
• Clearly list needed commodities and possible alternatives to signal the demand to industry.
• Medicines that are relatively easy to produce and control (for example zinc products) can be manufactured locally with pragmatic regulatory requirements.
Annex 2: Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries

Description of the survey

Objectives
(i) Understand the activities related to the regulation and procurement of the life-saving commodities that contribute to availability and quality medicines in the EWEC countries
(ii) Describe the barriers to access to the life-saving commodities.

Method
Online questionnaire, developed collaboratively across agencies working to support the UNCoLSC recommendations on the basis of existing assessment tools. Structured questionnaires and MS Excel™ sheets were provided to respondents through the WHO “Data Col” online data collection portal.

Aspects included in the survey
1. Regulatory environment (16 respondent countries)
2. Registration status of the UNCoLSC-identified commodities (22 respondent countries)
3. Procurement systems and processes (17 respondent countries)
4. Procurement and supply status of the UNCoLSC-identified commodities (11 respondent countries)

Survey period
August 2013 to March 2014

Participating countries
Afghanistan, Bangladesh, Burkina Faso, Comoros, Democratic Republic of Congo, Ethiopia, Ghana, Guinea, Guinea-Bissau, Kenya, Kyrgyzstan, Lao People's Democratic Republic, Liberia, Madagascar, Malawi, Nepal, Nigeria, Pakistan, Rwanda, Senegal, Sierra Leone, Somalia, Tajikistan, Tanzania, Togo, Uganda, Uzbekistan, Viet Nam, Zambia and Zimbabwe (not all countries responded to all four parts of the survey).

Overview of findings

1. Regulatory environment
   The country / regulatory authority: Number of countries:
   • Had a national essential medicines list (EML) 15 of 16
   • Had a system for registration of medicines 14 of 16
   • Assessed dossiers with quality, safety and efficacy data 14 of 16
   • Took less than 24 months on average to register a product 14 of 16
   • Took less than 12 months on average to register a product 12 of 16
   • Had a fast-track system for medicines registration 11 of 16
   • Had a system to control importation of medicines 15 of 16
   • Required that all imports must correspond to an import license 13 of 16
   • Conducted pre- and/or post-shipment inspections 13 of 16
   • Had a post market surveillance system 11 of 16
   • Had a system for medicines quality complaints reporting 12 of 16
   • Had a functional laboratory 13 of 16
   • ...that was certified by a standards accreditation body 6 of 16
   • ...that was WHO- prequalified 1 of 16

   Overall, in terms of regulating the UNCoLSC-identified commodities, the environment was found to be:
   - Favourable (11-14 of the above criteria met) in Tanzania, Nigeria, Uganda, Ethiopia, Ghana, Liberia, Sierra Leone, Zimbabwe, Bangladesh
   - Partially favourable (9-10 of the above criteria met) in DRC, Malawi, Senegal, Kyrgyzstan, Rwanda
   - Limited (2-3 of the above criteria met) in Somalia, Comoros
2. Registration status of the UNCoLSC-identified commodities

Figure 1. Number of countries that had products of each commodity registered
(n=1113 registered products identified in the survey corresponding to the
18 commodities shown in the figure.)

REPRODUCTIVE HEALTH:
1. Female condoms
2. Levonorgestrel 75mg implant
3. Levonorgestrel 1.5mg tab
4. Levonorgestrel 0.75mg tab
MATERNAL HEALTH:
5. Misoprostol 200g tab
6. Oxytocin injection (inj.) 10IU
7. Magnesium sulfate inj. 500mg
8. Calcium gluconate inj. 100mg/ml
NEWBORN HEALTH:
9. Betamethasone inj. 4 or 6 mg/ml
10. Dexamethasone inj. 4mg/ml
11. Ampicillin inj. 250mg, 500mg or 1g
12. Ceftriaxone inj. 250mg, 500mg or 1g
13. Gentamicin inj. 10, 20 or 40mg/ml
14. Procaine penicillin inj. 1g
15. Chlorhexidine 4% gel or solution
CHILD HEALTH:
16. Amoxicillin dispersible tab
17. Oral rehydration salts
18. Zinc

Three or more products registered
At least one product registered

* Figure 1 excludes Somalia and the Comoros (no registration system) and Sierra Leone (all except one marketing
authorization was pending or expired at the time of the survey.

Total registered products identified in the survey, per country
73-133
Kyrgyzstan, Nepal, Uganda,
Nigeria, Uzbekistan, Viet Nam,
Kenya
40-66
Ghana, Ethiopia, Zimbabwe,
Madagascar, Tanzania, Tajikistan
Guinea, Malawi, Zambia, Burkina
11-28
Kenya

Number of UNCoLSC-identified commodities with at least one product registered
14-16 of 18
Madagascar, Tanzania, Burkina,
Faso, Zimbabwe, Uganda,
Zambia
12-13 of 18
Malawi, DRC, Nepal, Ethiopia,
Uzbekistan, Kenya
8-11 of 18
Senegal, Tajikistan, Ghana,
Guinea, Kyrgyzstan, Nigeria,
Viet Nam

Figure 2: Origin of UNCoLSC-identified products
(n=1089 products identified in the survey for which the manufacturer and country was known)

India (392)
China (173)
Other imported (409)*
Locally manufactured (119)**

* Top five: Korea, Russia (30 each), Germany (26), Bangladesh (21),
France (20), Pakistan (19)

** Top five: Viet Nam (22), Nigeria (21), Kenya (17), Nepal (16),
Uzbekistan (14)
### 3. Procurement systems and processes

For the commodities included in the survey:

- A coordination mechanism existed for procurement and supply management: 12 of 17
- The procurement agency followed public procurement policies: 16 of 17
- The procurement agency had financial autonomy: 14 of 17
- There was a logistics management system (LMIS) for essential commodities: 15 of 17
- Evidence of current good manufacturing practice was required for procurement: 15 of 17
- A forecasting tool or method was used routinely: 14 of 17
- There was an indicator used to track stock-outs at national level: 12 of 17
- There were financial/tax incentives for importation of raw materials: 6 of 16
- There were financial/tax incentives for finished products: 13 of 17

### 4. Procurement and supply status of the UNCoLSC-identified commodities

<table>
<thead>
<tr>
<th>Respondent countries:</th>
<th>11</th>
<th>11</th>
<th>11</th>
<th>8</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of countries where each product was:</strong></td>
<td>On the national EML</td>
<td>Included in national policies with the relevant indication</td>
<td>Included in tenders or procurement contracts in the 12 months before the survey</td>
<td>Tracked by LMIS *</td>
<td>Countries reporting at least one stock-out at the central level in the three years before the survey** (missing data for some products)</td>
</tr>
<tr>
<td>1. Female condoms</td>
<td>5</td>
<td>8</td>
<td>5</td>
<td>8</td>
<td>4 of 6</td>
</tr>
<tr>
<td>2. Levonorgestrel implant</td>
<td>6</td>
<td>8</td>
<td>6</td>
<td>6</td>
<td>5 of 5</td>
</tr>
<tr>
<td>3. Levonorgestrel 1.5mg</td>
<td>3</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>1 of 3</td>
</tr>
<tr>
<td>4. Levonorgestrel 0.75mg</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>3</td>
<td>3 of 5</td>
</tr>
<tr>
<td>5. Misoprostol</td>
<td>8</td>
<td>8</td>
<td>5</td>
<td>3</td>
<td>0 of 5</td>
</tr>
<tr>
<td>6. Oxytocin</td>
<td>11</td>
<td>10</td>
<td>10</td>
<td>7</td>
<td>2 of 9</td>
</tr>
<tr>
<td>7. Magnesium sulfate</td>
<td>11</td>
<td>10</td>
<td>9</td>
<td>4</td>
<td>3 of 8</td>
</tr>
<tr>
<td>8. Calcium gluconate</td>
<td>10</td>
<td>9</td>
<td>9</td>
<td>6</td>
<td>4 of 8</td>
</tr>
<tr>
<td>9. Betamethasone inj</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>1</td>
<td>1 of 1</td>
</tr>
<tr>
<td>10. Dexamethasone inj.</td>
<td>9</td>
<td>8</td>
<td>6</td>
<td>4</td>
<td>2 of 5</td>
</tr>
<tr>
<td>11. Ampicillin injection</td>
<td>7</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>1 of 2</td>
</tr>
<tr>
<td>12. Ceftriaxone injection</td>
<td>1</td>
<td>10</td>
<td>10</td>
<td>5</td>
<td>2 of 7</td>
</tr>
<tr>
<td>13. Gentamicin injection</td>
<td>11</td>
<td>11</td>
<td>11</td>
<td>7</td>
<td>2 of 8</td>
</tr>
<tr>
<td>14. Procaine penicillin</td>
<td>8</td>
<td>8</td>
<td>7</td>
<td>4</td>
<td>2 of 5</td>
</tr>
<tr>
<td>15. Chlorhexidine</td>
<td>5</td>
<td>4</td>
<td>4</td>
<td>1</td>
<td>1 of 2</td>
</tr>
<tr>
<td>16. Amoxicillin disp. tab</td>
<td>6</td>
<td>8</td>
<td>5</td>
<td>3</td>
<td>3 of 4</td>
</tr>
<tr>
<td>17. ORS</td>
<td>11</td>
<td>10</td>
<td>9</td>
<td>5</td>
<td>1 of 7</td>
</tr>
<tr>
<td>18. Zinc</td>
<td>10</td>
<td>10</td>
<td>9</td>
<td>5</td>
<td>2 of 6</td>
</tr>
</tbody>
</table>

* In the respective countries, the national LMIS was reported to be tracking between 7 and 13 of the 18 products included in the survey, although the responses to this section of the survey were often incomplete. Electronic LMIS typically did not extend beyond the central level of the supply chain.

** Six of eight countries that provided data on stock-outs reported at least one stock-out of a survey commodity at the central level at any time during 2010, 2011 or 2012. Products reported to have been out of stock by at least three countries included female condoms, levonorgestrel implant, levonorgestrel 0.75mg tablets, magnesium sulfate injection, calcium gluconate injection and amoxicillin dispersible tablets. Most stock-outs were for products that were being tracked by the LMIS, suggesting some possible under-reporting in this survey of stock-outs for products that were not being tracked.
Recommendations

Regulatory systems
• Promote regulatory efficiency through joint inspections and dossier reviews, building on existing initiatives, such as those currently coordinated by WHO
• Provide evidence packages for products that are yet unregistered or for which prescription authority changes are under consideration, such as emergency contraceptives and amoxicillin.

Procurement systems
• Increase investments in quality monitoring activities commensurately with the increasing number of products on the market
• Promote information-sharing systems (existing or new) on quality complaints, laboratory results and PMS data.

Registration status of specific life-saving commodities
• Develop strategies to encourage registration of needed products in EWEC countries, in a South-South collaborative process.

Procurement status of UNCoLSC-identified products
• Provide forums where market information is shared and market controls are discussed.
• Align national and partner organizations’ quality assurance policies (this may require considerable investment).
• Identify approaches for effective stock management beyond the central supply chain level.
• Ensure continued post-market surveillance especially for commodities such as amoxicillin dispersible tablets and emergency contraceptives that may in future be prescribed by additional categories of health professionals. Model PMS and evidence packages may be useful
• Procurement status of life-saving commodities
• Provide evidence packages to support additions of all UNCoLSC-identified commodities to national EMLs.