Consultancy Terms of Reference:
Documenting case studies on medicine quality assurance mechanisms in humanitarian settings

This consultancy is requested by:

Unit:	Global Health Cluster
Department:	Emergency Operations

1. Purpose of the Consultancy

The purpose of the exercise will be to better understand what bottlenecks, challenges, solutions and opportunities have occurred in procurement of medicines and quality assurance in humanitarian situations. All outputs derived from this exercise will be utilised as preparatory work to be reviewed by the Global Health Cluster Quality Improvement Task Team (QITT) members prior to a workshop in July 2019 (TBC). Findings will be discussed in the workshop so the task team may clearly define objectives and prioritise activities for the forthcoming year. Outputs from the exercise will also serve as useful background documents for Health Cluster Coordinators.

2. Background

The need for the improvement of quality in humanitarian health response has been a continuous goal for the humanitarian community as it is acknowledged in many responses that there are clear gaps. Quality of health care is also a key component of the right to health and critical to the achievement of universal health coverage (UHC) iterated in the Sustainable Development Goals[1]. Previous discussions on quality within the Global Health Cluster (GHC) amongst partners as well as health cluster coordinators resulted in the formation of the GHC Quality Improvement Task Team (QITT). The GHC QITT had its first meeting on 27th March 2019. It was acknowledged that the scope of 'quality' is large but as a priority the following areas should be examined

- Quality of health care
- Medicines quality assurance mechanisms of national (domestic) suppliers or manufacturers

It was agreed better understanding is needed on current status, gaps and challenges with the above in humanitarian crises to help determine how the QITT should proceed. As such two mapping exercises will be conducted (one for each of the above). This consultancy is relating

[1] Sustainable Development Goal Target 3.8: "*Achieve universal health coverage (UHC), including financial risk protection, access to quality essential health care services, and access to safe, effective, quality, and affordable essential medicines and vaccines for all"*

to 2) understanding medicine quality assurance mechanisms of national suppliers or manufacturers.

Quality assured, safe and effective medicines are fundamental to quality health care provision. However as globalised trade increases with manufacturing and distributing systems becoming more complex the problem of substandard and falsified medical products continues to increase. This is especially noted in resource limited settings[2]. Increasing demand, complex supply chains with the trade of medicines or active pharmaceutical ingredients and excipients needed to manufacture medicines spanning multiple countries, as well as the growth of ecommerce, creates opportunities for falsified medicines to be introduced. Poor manufacturing and distribution practice results in substandard products[3].

Mechanisms to address medicine quality assurance

National governments through national medicine regulatory authorities (NMRAs) are responsible to ensure medicines are of the required quality, safety and efficacy, and perform many functions including those to ensure medicines are appropriately manufactured, stored, distributed, dispensed and utilised. However, capacities vary. WHO provides regulatory support by developing international norms and guidelines, as well as technical assistance and training to NMRAs.[4]

WHO also performs prequalification[5] of individual products (of a particular dosage, produced by a manufacturer at a specific site) including reviewing safety and efficacy data, site inspections to ensure good manufacturing practice. However, this currently only covers medicines for HIV, TB, malaria, some reproductive health products, and some antibiotics used to treat opportunistic infections associated with HIV[6]. An assessment by an Expert Review Panel (ERP) can be requested if the above products are needed urgently and are not yet prequalified.

To assist procuring agencies (e.g. NGOs) needing quality assured medicines outside of those prequalified by WHO or ERP, WHO developed a Model Quality Assurance System (MQAS)[7] to help agencies formulate and implement their own quality assurance mechanism including the self-prequalification of products and manufacturers/suppliers[8]. This requires the procuring agency to have significant technical expertise for example in good

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[2] *Essential medicines and health products, Regulation* WHO

[3] For further information see *A Study on the Public Health and Socioeconomic Impact of Substandard and Falsified Medical Products* WHO 2017 and *WHO Global Surveillance and Monitoring Systems for Substandard and Falsified Medical Products*, WHO 2017

[4] *Essential medicines and health products, Medicines Regulatory Support* WHO

[5] *Essential Medicines and Health Products, Prequalification of medicines* WHO

[6] *WHO Global Surveillance and Monitoring Systems for Substandard and Falsified Medical Products*, WHO 2017

[7] *Model Quality Assurance System for procurement agencies* WHO 2014

[8] *Essential Medicines and Health Products: Prequalification of medicines, Procurement Agencies*, WHO

manufacturing practice[9] and distribution practice[10]. It also requires manufacturers, suppliers and relevant bodies agreeing to being assessed.

Some donors such as USAID/OFDA[11] require humanitarian partners to utilise already identified and pre-qualified suppliers e.g. IDA.

The WHO Global Surveillance and Monitoring System (GSMS) for substandard and falsified medical products (GSMS) was established in 2013. It provides an interconnected network between countries to investigate alerts to gain oversight in the global medicines supply chain. As of July 2017, it has trained 400 personnel in 126 Member States, produced more than 1500 product reports and issued 20 medical product alerts.[21]

Challenges in medicine quality assurance in humanitarian settings

The GHC QITT agreed that in recent humanitarian crises the procurement of safe and effective medicines have been a challenge, for example, where procurement from domestic manufacturers or utilising domestic suppliers have been insisted upon and where NMRAs have been weak. Given the limited capacity and time of health partners in humanitarian settings to perform pre-qualification assessments of manufacturers, strict requirements by donor bodies to utilise quality assured products, and most importantly the commitment to deliver safe care health cluster partners have requested this issue be examined. As such The GHC QITT agreed a mapping should be performed to better understand the current situation. It is suggested four light case studies be conducted to understand key bottlenecks and challenges but also the solutions developed. Results will help the QITT determine a strategy to address this issue and prioritise actions for the forthcoming year.

3. Planned timelines (subject to confirmation)

The project will be undertaken from June to July 2019 (estimated 20 days).

4. Work to be performed

The main objective of this is to document four light case studies highlighting the bottlenecks, challenges, solutions and opportunities int the procurement of medicines and quality assurance in humanitarian contexts.

Part 1: Report produced of four case studies documenting challenges in procurement of medicines and quality assurance in humanitarian contexts (estimated 12 days)

1. Key informant interviews conducted remotely with partners, health cluster coordinators and key stakeholders from four country clusters

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[9] *WHO Good Manufacturing Practices for Pharmaceutical Products: Main Principles*, WHO Technical Report Series No.986, WHO 2014

[10] *WHO Good Distribution Practices for Pharmaceutical Products*, WHO Technical Report Series, No, 957, WHO 2010

[11] *USAID/OFDA Prequalified Pharmaceutical Wholesalers*, USAID 2016

2. Light case studies produced reflecting

    a. Main challenges and issues face by partners in the procurement of quality assured medicines
    b. roles of different government authorities influencing importation, regulation and quality assurance of international or domestic manufactured or supplied medicines
    c. How health cluster partners have been able to resolve issues, any opportunities created
    d. Brief summary analysis reflecting common themes

Output A: A report of four case studies and summary analysis defining common themes, challenges, solutions and opportunities for procurement of medicines and quality assurance in humanitarian crises

5. Planned timelines (subject to confirmation)

Total number of days: approx. 12 days
Start date: start June 2019
End date: mid-July 2019

6. Technical Supervision

The selected Consultant will work on the supervision of the GHC Coordinator and designated Technical Officer within the GHC unit.

7. Specific requirements

Experience required (minimum 7 years):
Experience in health response in humanitarian contexts
Experience in Cluster Coordination / response at national and/or global level
Experience in inter-cluster coordination or programming
Experience in data analysis and reporting
Experience in report writing

- Skills / Technical skills and knowledge:

- Knowledge of the IASC Protocols and commitments, and the Cluster Approach.
- Knowledge of medicines procurement mechanisms in humanitarian response
- Strong qualitative data research skills
- Strong analytical skills and capacities;
- Strong verbal and written communication skills;
- Strong facilitation
- Ability to independently plan and execute assigned tasks and duties.

- Language requirements:

English.
Knowledge of French an advantage.

8. Place of assignment

The work will be conducted remotely.

9. Medical clearance

The selected Consultant will be expected to provide a medical certificate of fitness for work.

10. Travel

N/A

11. Application deadline

Please send your applications to Carolyn Patten (pattenc@who.int) by 22:00 (CET), 7 June 2019.