GMP Policy making and Dissemination process updates

Malaria Policy Advisory Committee
Geneva, Switzerland

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11 April 2019
Presentation Outline

1. Brief reminder of rationale and objectives of the policy review
2. Key findings of the review and choice of focus areas
3. Key activities started in 2019
4. Detailed update on the GMP Policy Path
5. Key questions for discussion
Why did GMP review its policy making process?

- Perceived lack of transparency and lengthy process
- Inconsistencies in review standards
- Sub-optimal use of GMP output at country level
Informed by interviewing 80+ stakeholders across value chain

How the review was done

Co-constructed with GMP staff & BCG to ensure accurate depiction

Built leveraging previous work on VCAG, I2I
Interview consensus: GMP policy making and dissemination process has dramatically improved since introduction of MPAC...

**Organisation**
- MPAC fulfils its purpose in that it has the highest calibre of technical experts
  - Procurer
- The role of VCAG has become clearer over the past 1.5 years
  - Procurer

**Evidence & Expertise**
- Overall, evidence-based guidelines have been a huge step in the right direction for WHO
  - PDP
- ERGs have quicker approach for understanding a very specific topic, gathering best experts, and go in depth on issues. They really expedite and quality check the process
  - GMP

**Dissemination**
- WHO website has made good progress & GMP's newsletter is useful in disseminating new material
  - Country Programme Manager
- It is a good thing GMP produces Guidelines since this gives a framework for use by countries and prevents them from being flooded with products they won’t know what to do with
  - Manufacturer

Source: Interviews
...and brings unique value to countries

“All countries we work with look at WHO for the last word as per intervention selection”

Implementer

“WHO is an indispensable partner for low-income countries”

Technical Partner

“WHO plays an absolute key role in malaria endemic countries”

Manufacturer
Analytical framework, 7 focus areas were identified

**Upstream**
- Academics, Donors, Innovators
- Manufacturers
- Regulatory Authorities
- WHO Bodies

**1. Policy Pathways**
- 1a. Entry Point
- 1b. Review Standards
- 1c. Roles & Responsibilities
- 1d. Process Sequence

**2. Review of Evidence**
- 3. WHO Bodies Composition

**Perceived lack of transparency and lengthy process**

**Downstream**
- Procurers
- Technical Partners
- Implementers
- Countries

**4. Policy Products**
- 4. Policy Products
- 5. Dissemination
- 6. Mechanisms & Network
- 7. Prioritisation Framework
- 8. Operational Execution

**Sub-optimal use of WHO output at country level**
High level diagram of the GMP Policy Pathway – new products
(draft in discussion)

- Define the problem (unmet public health needs)
- Define what do we need to solve the problem (PPC/TPP)
- Identify pipeline of new tools and strategies
- Formalize engagement with developers and agree on performance criteria
Unmet and (partially met) Public Health needs related to malaria

**Purpose:** to frame the prioritization of our work
**How:** inclusive process with a convening and online consultation

**Result:**
- Prioritized list of unmet and partially met public health needs related to malaria
- Builds on previous work of malERA and other analyses
- Provides a basis to map existing target product profiles
- Identifies gaps where preferred product characteristics could stimulate innovation

**Action:**
- Background analyses to inform consensus-building consultation
- Open portal to submit ideas (3 month pilot)
Purpose: to identify tools/strategies in development to inform the timing for potential policy recommendation development

How: Three key areas to monitor regularly

1. Product development pipelines (human trials?) – with support from product development partners
2. New evidence to update existing recommendations (tools/strategies)
3. Evidence to develop new recommendation – strategies
Preferred Product Characteristic (PPC)
• GMP proposes to lead consensus development to address gaps
• product profile informs product developers, procurement agencies and funders on R&D and public health priorities
• intended to facilitate product development and evidence generation addressing the greatest and most urgent public health need – products and strategies

Target Product Profile (TPP)
• GMP proposes to collect and lead review of existing TPPs owned by partners
• Map against unmet/partially met public health needs for malaria to identify gaps
• Use TPPs to have a joint scientific dialogue with developers and PQ to inform performance criteria and evidence required for policy recommendation & PQ listing
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**Better Anticipate**
- Unmet public health needs

**Horizon scanning**
- Horizon scanning to anticipate product pipeline and when evidence is available to support a policy recommendation

**PPC/TPP development**
- Mapping of existing TPPs and development of PPCs/TPPs based on public health needs – to steer innovation

**Product development**
- R&D - Product development
  - Scientific advice
    - Jointly PQ & GMP
      - VCAG

**Develop Policy**
- Open & transparent process
  - Application submission for PQ
- Prequalification assessment
  - Joint review of application
  - PQ & Policy recommendation activities

**Shortened timelines**
- Evidence review and policy recommendation development activities
  - Increased coordination between GMP & PQ

**Support and monitoring activities**

**Implementation**

**Mapping of existing TPPs and development of PPCs/TPPs based on public health needs**

**Scientific advice**

**Reg. Auth.**

**Reg. Auth.**

**Jointly PQ & GMP**

**VCAG**

**GMP-PQ Coordination Committee**

- **GMP**
  - Jointly PQ & GMP
  - VCAG

**PQ**

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**World Health Organization**

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16. **GMP**

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18. **Evidence review and policy recommendation development activities**

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Policy Pathway – Products and Strategies

- Following the standards of the Guideline Review Committee and Norms & Standards department
- Transparent prioritization of policy development via MPAC meetings
- Convene single GMP Guidelines Development Group to ensure consistency and coherence
- Develop guidance on intervention mixes and prioritisation
- Post review standards on GMP website and track process steps for transparency

Products only

- Explore using stringent regulatory authority submission as trigger to begin development of policy
- Contingent on data being made publically available
- Improved coordination between GMP and PQ to publish simultaneous policy recommendation and PQ listing for new tools
Advisory bodies – clarifying functions

Malaria Policy Advisory Committee (MPAC)
• No change – GMP’s highest level advisory body

Development of Policy recommendations:
Guidelines Development Group (3 configurations)
• GDG alone
• GDG + technical experts
• ERG draft + GDG review

*Open call for experts – 30 April deadline for GDG w/ selection by June 2019; remains open for ERGs

Technical advice to GMP: Malaria Elimination Oversight Committee, Malaria Elimination Certification Panel, Vector Control Advisory Group, Strategic Advisory Group on malaria eradication, and other ad hoc technical consultations
GMP Advisory bodies structure

WHO Director-General

Malaria Policy Advisory Committee (MPAC)

GMP Secretariat

Policy

GMP Guidelines Development Group (GDG) + ad hoc ERGs

Advisory

Vector Control Advisory Group (VCAG) w/ NTD/PQ

Malaria Elimination Oversight Committee (MEOC)

Malaria Elimination Certification Panel (MECP)

Strategic Advisory Group on malaria eradication

Malaria Vaccine Advisory Committee (MALVAC) w/ IVB

Other ad hoc technical consultations
High level diagram of the GMP Policy Pathway – new products (draft in discussion)

- Simplify taxonomy and structure
- Engage partner and country networks
- Monitor implementation
- Ensure feedback loops to meet end-user needs
Country survey conducted to understand barriers to uptake & suggestions for improvement - 96 responses

What we heard from National Programmes:
• Difficult to locate relevant information on the GMP website
• Hard to understand how the different documents fit together
• Documents should be shorter/more concise and have consistency in naming
• Preference for digital documents via the website and mobile app; with needs remaining for printed materials
• Insufficient engagement from WHO on new policy at country level
• Feedback mechanisms from end-users are needed

3 key levers identified:
• Improve structure of documents
• Improve GMP website
• Develop new sharing opportunities
How GMP is responding:

1. Improve the taxonomy and structure of GMP documents
2. Develop a compendium of all existing GMP policy guidance to show how the documents fit together – Quick win
3. Redesign the GMP website for accessing policy recommendations and operational guidance with input from end users – NMCP focus group
4. Expanding the World malaria report mobile app to include malaria guidance – December 2019
5. Engage WHO country and region staff in supporting dissemination & monitor uptake
6. Engage all malaria partners in dissemination
Policy Product

- Malaria Guideline – consolidation of all existing malaria policy recommendations
- Policy Recommendation – one recommendation/or group on a specific topic (e.g., treatment of uncomplicated *P. falciparum* malaria)
- Appendix – annex document containing all supporting evidence, GRADE tables, analyses and references supporting the recommendation
- Operational manual – detailed document providing operational guidance on how to implement a policy
- Accompanying documents – webinars, Q&A, powerpoint slides to help raise awareness and dissemination a new policy recommendation
- Information note – document summarizing WHO’s position on a specific topic
Develop a Policy making process website

• To articulate policy process and review standards
• Communicate unmet and partially met public health needs
• Post and update horizon scanning reports for partner use including product pipelines
• Post PPCs and TPPs that are available to be shared
• List topics prioritized for recommendation development and track progress through pathway steps for increased transparency
• Provide a forum for online consultations
• Pilot launched this week with open consultations on unmet/partially met public health needs and nominations for policy recommendations (3 month pilot)

• gmpfeedback@who.int
Redesign the Policy recommendation and guidance dissemination section to facilitate access

- Respond to end-user advice to improve uptake
- Intuitive topic-based navigation to help find relevant information easily
- Options presented to NMCP focus group for input in April
- Consistent with the structure of the Compendium
- Launch of redesigned site June
Energize Dissemination Network

Priority areas of work:

• Partner mapping & identification of upcoming meetings for dissemination opportunities
• Mobilize partner networks to support policy dissemination and uptake
• Orientation and engagement of WHO country staff
• Engagement with national programme managers
• Conduct a follow-up survey:
  • Pulse check to see if GMP response meeting needs
  • Track adoption, implementation and feedback on current WHO recommendations on malaria;
  • Identify technical assistance and training needs
  • Identify barriers to implementation or key challenges that may need updated policy recommendations
• gmpfeedback@who.int