Malaria Policy Advisory Committee Meeting
2–4 October 2019, Geneva, Switzerland
Background document for Session 6

Meeting report of the WHO technical consultation on malaria case management in the private sector in high-burden countries

1–3 May 2019, WHO Headquarters, Geneva, Switzerland

Summary

In February 2018, the World Health Organization (WHO) convened a Technical Consultation on "Universal access to core malaria interventions in high-burden countries" *(1).* It concluded that the private sector plays an important role in delivering malaria care in many high-burden countries, both in urban areas and in remote rural areas underserved by formal health care facilities.

In malaria-endemic countries, a large proportion of patients with fever first seek treatment through private health care providers, especially pharmacies, authorized and informal drug shops, and other medicine sellers. These providers are often collectively referred to as private medicine retailers (PMRs). The quality of case management in these facilities varies widely and is often poor, especially in terms of access to quality artemisinin-based combination therapies (ACTs) and malaria diagnostic testing prior to treatment.

There is limited evidence on the most effective methods to improve malaria case management in the PMR sector. Under the Affordable Medicines Facility–malaria (AMFm) pilot (2010–2013), medicine subsidies improved both the availability and affordability of treatment, especially when combined with a significant behaviour change communication (BCC) programme promoting the use of quality ACTs for malaria treatment. AMFm was transitioned into the Global Fund's Private Sector Co-Payment Mechanism (CPM), but countries have been terminating or decreasing their investments in ACT subsidies for the private sector because of competing health priorities. With the demise of the CPM, there is a risk of reduced affordability and availability of quality ACTs in the private sector.

During the Technical Consultation, country representatives were concerned that the requirement by international funding agencies for medicines and diagnostics to be approved by a stringent regulatory authority (SRA) or prequalified by WHO was reducing competition for quality ACTs in the antimalarial market and thus reducing access. The representatives felt that there were products whose quality was assured by the national registration process, but because they were not WHO-prequalified, such products were denied for procurement with international funds. Furthermore, country representatives felt that the term "quality-assured ACT (QAACT)" should not be equated with SRA approval or WHO prequalification, as there are quality-assured products that are only approved by national regulatory authorities (NRAs). At the same time, it was noted that NRAs frequently lack the resources required to review and update regulatory requirements or enforce regulations. There was general consensus that pricing needs to reflect manufacturing quality requirements in order to ensure a sustainable supply of high-quality drugs and malaria rapid diagnostic tests (mRDTs) in the medium to long term.

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The AMFm did not include malaria diagnostic testing. As a result, a considerable number of febrile patients without malaria were given ACTs and many with malaria were not. Evidence on how to increase testing with mRDTs in the private sector is limited. Testing in the private sector is hampered by policies and regulations that restrict where mRDTs can be sold and performed, as well as by the lack of clear protocols for managing non-malarial febrile illnesses, and the lack of financial and non-financial incentives to support malaria testing prior to treatment. Studies have shown that non-medical staff in a variety of private health care settings can administer an RDT and adhere to the test result (often better than doctors and nurses), provided they have been well trained and receive follow-up supervision. Evidence from other disease programs also supports the need for strong BCC programmes in order to change the health care expectations and behaviour of the general public, which have a major influence on the behaviour of providers in the private sector.

PMRs could also be a valuable source of data for national surveillance systems, particularly where they are a common source of care; however, there is very little experience in including these providers in national health management information systems.

The integration of PMRs into national efforts to reduce the burden of malaria was seen to be an important area of intervention, paving the way for the sector's wider involvement in supporting countries to achieve universal health coverage (UHC).

Based on the high proportion of patients accessing care for febrile illness in the formal and informal private sectors in Chad, Democratic Republic of the Congo (DRC), Kenya, Ghana, Niger, Nigeria, United Republic of Tanzania and Uganda, participants were asked to identify the main bottlenecks in accessing quality malaria case management in the private sector in their country and to prioritize steps to reduce barriers, promote best practice and increase access. Each country situation is unique, but certain common themes were identified, as presented below.

Common vision

- All patients, irrespective of their social status or where they live, have the right to access quality malaria case management.
- As many patients seek treatment for febrile illness first through the private sector, this sector must be able to deliver quality malaria case management.
- Private sector health care providers need to be considered an integral part of a country's national health system.

Key themes

- **Promotion:** Governments, national malaria control programmes (NMCPs) and other key stakeholders need to generate demand among the population for better quality care in the private health sector. BCC activities targeting the general public need to continue to promote malaria diagnostic testing and compliance with the results.
- **Quality:** The confidence of all stakeholders in the quality of care that can be delivered by the private sector can be enhanced through:
    - accreditation systems for drug shops;
    - training in malarial and non-malarial fever case management and professional development schemes for private health care providers;
    - supervision of private health care providers, ideally by existing government health care workers;
    - increasing the availability and affordability of quality diagnostics and medicines.

- **Policy and regulation:** Country policies and regulations should be reviewed and revised to support and promote the implementation of appropriate case management in the private sector.
    - There should be clarity and consistency of policies and regulations on where mRDTs can be sold and who can perform them, and where antimalarials can be accessed and who can prescribe and/or sell them, taking into account client care-seeking practices.
    - Policy makers and regulators should be aligned on the technical specifications required for health products (diagnostics and medicines).
    - Policies and regulations should support the extension of quality malaria testing to ensure the rational use of malaria medicines.
    - Guidance should be developed and behaviour change promoted to ensure that health care providers and patients know what should happen in the event of a negative malaria test result.
    - There should be robust supervision and enforcement of existing and new regulations, supported by training and follow-up programmes.
- **Market information:** The lack of detailed current information on private sector antimalarial and RDT market dynamics, especially outside the large urban areas, should be addressed and results should be disseminated among all stakeholders. As countries differ, each needs to undertake an in-depth market review, with periodic updates to monitor progress and inform future actions.
- **Surveillance:** Simple systems should be developed to allow the private sector to be fully integrated into national malaria surveillance systems, and providers should be supported to report complete, accurate and timely data through training, supervision and appropriate incentives.
- **Pricing and incentives:** Countries should ensure that:
    - quality-assured products crowd out poor-quality and inappropriate products through pricing and other measures that make them preferred by patients and providers;
    - the cost to the caregiver/patient of the testing and treatment package is affordable and promotes appropriate case management;
    - tax and tariff systems for finished products are aligned so that diagnostics are not disadvantaged compared to quality ACTs or other pharmaceutical products.
- **Coordination:** Different stakeholders are not always aligned on how to involve the private sector in delivering quality case management. It will be necessary to bring all groups together so as to work out ways to overcome this constraint, under the stewardship of government.

The meeting also identified areas where the participants would like to see support and guidance from WHO.

Key requests to WHO

- **Advocacy:** Advocate for the importance of the private sector in order to ensure that quality case management is available to all, as an essential component of achieving UHC.
- **Support and guidance**: Provide support to governments (including sharing best practice) on how best to engage the private sector in terms of:
    - facilitating cross-sectoral coordination through country-based forums;
    - making investment decisions for improving access to malaria case management in the private sector in relation to other health priorities.
- **Quality case management:**
    - Provide guidance on how to assess the quality of care in the private sector, not just the quality of health products.
    - Ensure continued promotion of appropriate use of malaria diagnostics in order to deliver quality care for febrile illnesses in malaria-endemic countries.
    - Make recommendations on the correct protocols to follow in the event of a negative mRDT, acknowledging the actual pressures on the ground.
- **Affordability:** Based on a range of business models/pricing strategies, make recommendations on how quality case management can be made affordable to patients, while ensuring a reasonable return to private health care providers.
- **Innovation:** Develop innovative systems and incentives to promote best practice for case management and reporting from the private sector and to integrate the sector into national surveillance systems.
- **Local manufacturing:** Support technology transfer in malaria-endemic countries in order to increase local production of ACTs and mRDTs that meet the quality requirements needed for procurement with international funds.

Ideally, this guidance should be brought together into a **Roadmap** (similar to the TB Roadmap) for integrating the private health care sector into national strategies to improve malaria case management. This guidance should provide direction to ministries of health and other national agencies on how best to engage the private sector, especially PMRs, to deliver quality diagnosis and treatment, and contribute to surveillance and routine reporting of malaria.

List of abbreviations

ACT	artemisinin-based combination therapy
ADDO	accredited drug dispensing outlet
AL	artemether-lumefantrine
AMFm	Affordable Medicines Facility–malaria
BCC	behaviour change communication
CHAI	Clinton Health Access Initiative
CHW	community health worker
CIP	coalition of interested parties
CPM	Co-Payment Mechanism
DHIS	District Health Information System
DHS	Demographic & Health Survey
DRC	Democratic Republic of the Congo
FLB	first-line buyer
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GMP	Global Malaria Programme
HMIS	health management information system
HoG	head of government
IMCI	Integrated Management of Childhood Illness
IVD	in-vitro diagnostics
MIS	Malaria Indicator Survey
MPAC	Malaria Policy Advisory Committee
mRDT	malaria rapid diagnostic test
NMCP	national malaria control programme
NRA	national regulatory authority
ORS	oral rehydration salts
OTC	over-the-counter
OTCMS	over-the-counter medicine seller
PMR	private medicine retailer
POM	prescription-only medicine
PPMV	patent and proprietary medicine vendor
QAACT	quality-assured artemisinin-based combination therapy
SRA	stringent regulatory authority
SSA	sub-Saharan Africa
TB	tuberculosis
UHC	universal health coverage
WHO	World Health Organization
WHO-PQ	WHO Prequalification

Background

In February 2018, the World Health Organization (WHO) convened a Technical Consultation on "Universal access to core malaria interventions in high-burden countries" *(1)*. The Technical Consultation responded to the upward trend in the number of malaria cases in 2016 and 2017, which reversed a decade of downward trend. The meeting's findings and conclusions were reported to the Malaria Policy Advisory Committee (MPAC) at its April 2018 meeting *(1)*.

One conclusion of the February 2018 meeting was the importance of the private health sector, especially private medicine retailers (PMRs)[1], for delivering malaria case management. PMRs are often the part of the health care system in closest proximity to the patient, located in their village or urban suburb. This is especially true in areas that are underserved by the general government-run health and community services. Therefore, PMRs are often the first place that many patients and caregivers go to seek treatment for febrile illness. However, the specific needs and differences of private health services are not usually addressed in national strategies and plans for delivering appropriate and quality care close to the patient. The principal challenges to the uptake of national strategic plans and policies among PMRs are:

- the poorly regulated, unsupervised nature of the private sector, which leads to non-conformity with national policies and guidelines, as well as:
    - overall poorer quality of available products and quality of care
    - low use of diagnostics for malaria in retail treatment outlets;
- no clear guidance or policies to support collaboration between the public sector and PMR outlets.

A key challenge in improving access to appropriate diagnosis and treatment through PMRs is ensuring that quality products are available and affordable, and can compete with poor-quality products. Co-payments for quality artemisinin-based combination therapies (ACTs) have often been used, for example, in the Affordable Medicines Facility–malaria (AMFm) and more recently in the Global Fund's Co-Payment Mechanism (CPM). However, the lack of dedicated funds and competing priorities for malaria funding have caused national malaria control programmes (NMCPs) to deprioritize this type of approach.

The meeting concluded that, in order to expand access to quality care for malaria patients, it is important for the private health sector to be seen as a valid and essential health delivery platform that complements the public health sector. However, many government and public-sector agencies have little experience of working with the private sector and need guidance and advice on how to properly engage with private providers.

Objectives of the Technical Consultation

1. Review the data supporting the rationale for an international effort to engage private sector players in malaria case management and the evidence base that this can be done safely and effectively.
2. Review the laws, regulations and policies influencing the use of medicines and point-of-care diagnostic tests in malaria case management in a set of high-burden countries in Africa.

[1] Private medical retailers are defined as pharmacies, authorized drug shops and outlets in the informal private sector (shops, markets, kiosks, itinerant drug vendors, etc.).

3. Based on this review, identify the main bottlenecks and outline steps, including research priorities, to reduce barriers and thus enable improved quality of care for malaria across the entire health sector.
4. Draw upon documented lessons learned from major global, regional and country initiatives to improve malaria case management in the private sector, including the Global Fund CPM, the Unitaid project *Creating a private-sector market for quality-assured RDTs*, Population Services International's (PSI) *A roadmap for optimizing private sector malaria rapid diagnostic testing,* the accredited drug dispensing outlet (ADDO) project in the United Republic of Tanzania, and the Global Fund's framework for engaging the private sector in malaria case management.
5. Review the results of recent private sector outlet surveys, and the main determinants of supply chain and distribution mechanisms for malaria medicines and diagnostics in the private sector, taking into account the experience of pharmaceutical and diagnostic companies in priming the market in high-burden malaria-endemic countries.
6. Identify key lessons learned and best practices from other public health programmes, including childhood diarrhoea and tuberculosis (TB), with a long history of private sector stakeholder engagement.

Process

The meeting was attended by representatives of the five countries in sub-Saharan Africa (SSA) where, according to countrywide household surveys conducted in 2014–2017, the majority of febrile children (under 5 years) seek treatment in the private sector: Chad, Democratic Republic of the Congo (DRC), Ghana, Nigeria and Uganda. Two other African countries were added to the list of selected countries – the United Republic of Tanzania and Kenya – due to multiple initiatives that have been undertaken in the private sector in recent years.

In preparation for the meeting, the WHO Global Malaria Programme (GMP) asked the collaboration of Clinton Health Access Initiative (CHAI), the Malaria Consortium and PSI to prepare profiles of each of the seven countries with respect to their policies, regulations and practices in the use of antimalarial medicines, antibiotics and in-vitro diagnostics (IVDs) through both desk reviews and interviews with selected officials at the ministries of health, national regulatory authorities (NRAs) and other relevant bodies. The individual country reports, a multi-country comparative analysis of findings, and selected published materials were circulated in advance of the meeting to participants *(2)* (see Annex 1). Most of the sessions began with a short summary presentation of the evidence based on the relevant pre-reads, followed by a discussion involving all participants. CHAI and PSI presented on their survey of first-line buyers (FLBs) involved in sustained procurement of medicines as part of the Global Fund CPM in Ghana, Kenya, Nigeria, Tanzania and Uganda. Several manufacturers of WHO-prequalified ACTs and rapid diagnostic tests (RDTs), who supplied products to the seven countries represented at the meeting, were invited and contributed their views through a dedicated panel session for manufacturers (see list of participants in Annex 2).

In the second part of the meeting, participants were assigned to breakout groups by country in order to discuss the role of the private sector in delivering high-quality malaria case management in each country (see agenda of the meeting in Annex 3). Using a methodology adapted from PSI's "Keystone Design Framework"[2], they identified the main bottlenecks/market constraints along the antimalarial and RDT supply chains that hinder the provision of high-quality private sector case management.

[2] See https://www.psi.org/2018/11/the-key-to-effective-health-solutions/

They next discussed how to prioritize steps to reduce these barriers and promote best practice in order to improve sustainable access to quality care for malaria in the private sector (see Annex 4 for Framework templates). The aim was not to define a comprehensive, prioritized list of actions in each country, but rather to stimulate thinking and identify common constraints across countries that need to be addressed and could inform a global roadmap for improving access to malaria case management in high-burden countries.

The report of the meeting was prepared by Ian Boulton and shared with all participants for comment; their inputs were taken into consideration in finalizing the report.

Private sector involvement in malaria case management

Current situation

The private health care sector is a major provider of diagnosis and treatment of malarial and non-malarial fevers in many malaria-endemic countries. The private sector is typically considered to include any facility, outlet or individual that provides health services, but is not managed by the government. The private sector is very diverse, ranging from private for-profit and not-for-profit health facilities and laboratories, to pharmacies and drug stores, to general stores, street vendors and traditional practitioners. In some settings, care providers may be highly trained and qualified, with access to state-of-the-art diagnostic and treatment options, while in other settings, providers may have no formal training or qualifications. Data from nationally representative Demographic and Health Surveys (DHS), Malaria Indicator Surveys (MIS), and ACTwatch surveys in 2014–2017 were reviewed for the Technical Consultation.

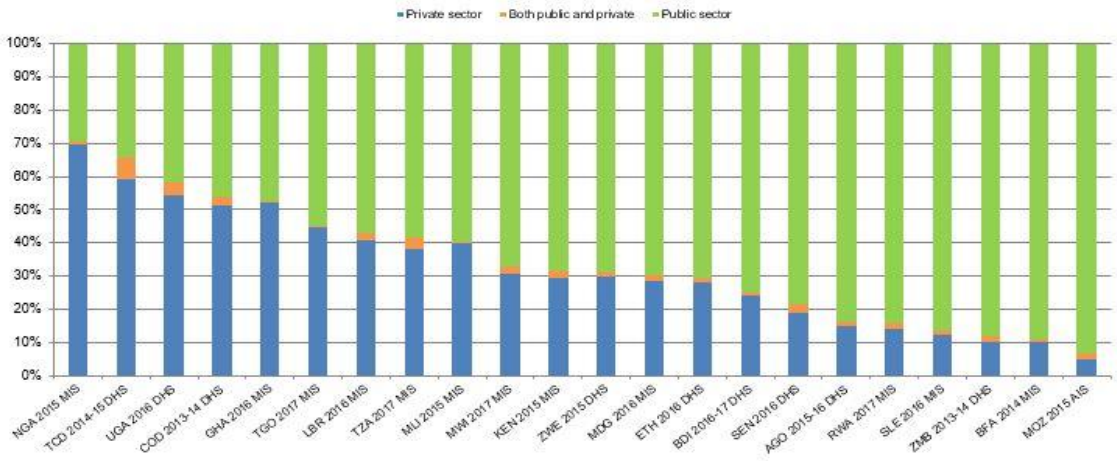
For the purpose of the analysis, the private sector was classified into three groups: i) formal medical private health facilities (hospitals, clinics, doctors, nurses, etc.); ii) pharmacies and authorized drug shops, and iii) informal private sector (shops, markets, kiosks, itinerant drug vendors, etc.).

Based on 19 nationally representative surveys conducted between 2015 and 2017 in SSA, initial treatment-seeking behaviour for a febrile child was *(3)*:

- no treatment sought (median: 40%)
- treatment sought in the public sector, including community health workers (CHWs) (median: 39%)
- treatment sought in the formal and informal private sector (median: 15%).

However, the results on where treatment was sought for febrile children varied widely between countries (Fig. 1). In Chad, DRC, Ghana, Nigeria and Uganda, caregivers of febrile children sought initial treatment in the private sector in more than 50% of cases.

Fig. 1. Where treatment is initially sought for febrile children



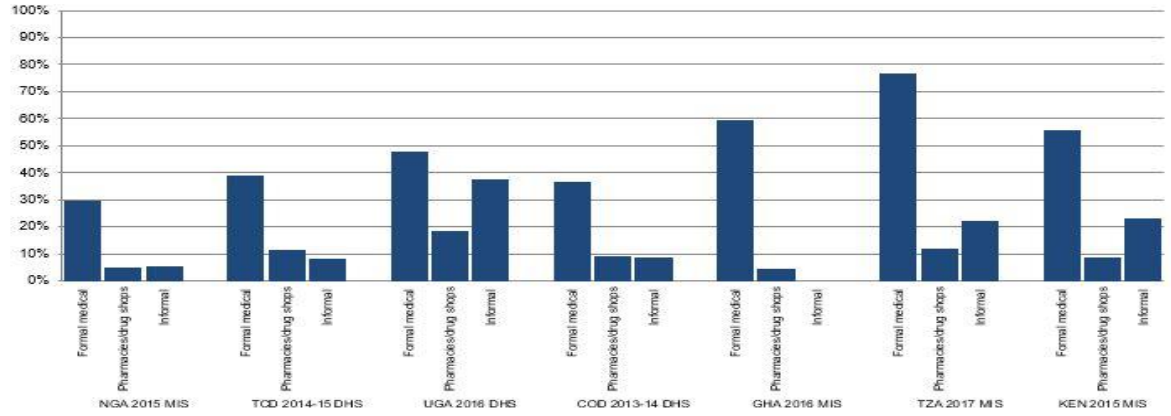
Source: Nationally representative household survey data from Demographic Health Survey (DHS) and Malaria Interview Survey (MIS)
Country codes: AGO: Angola; BDI: Burundi; BFA: Burkina Faso; COD: Democratic Republic of Congo; ETH: Ethiopia; GHA: Ghana; KEN: Kenya; LBR: Liberia; MDG: Madagascar; MLI: Mali; MOZ: Mozambique; MWI: Malawi; NGA: Nigeria; RWA: Rwanda; SEN: Senegal; SLE: Sierra Leone; TCD: Chad; TGO: Togo; TZA: United Republic of Tanzania; UGA: Uganda; ZMB: Zambia; ZWE: Zimbabwe.

The split between formal private sector, pharmacies/drug stores and informal private sector also varied significantly between countries. This difference is driven by a range of factors, which underlines the need for each country to conduct a situation analysis in order to fully understand its particular private sector situation. Only then should plans be developed to incorporate the private sector into the delivery of malaria case management.

The quality of case management, especially malaria testing prior to treatment with antimalarials and/or other medicines, also varied and needs to be better understood. About 50% of febrile children had a blood test administered prior to treatment. However, among children seeking care in pharmacies and the informal sector, this percentage was only about 10–11% compared to 50–60% for those seeking care in the public sector and formal private medical health facilities.

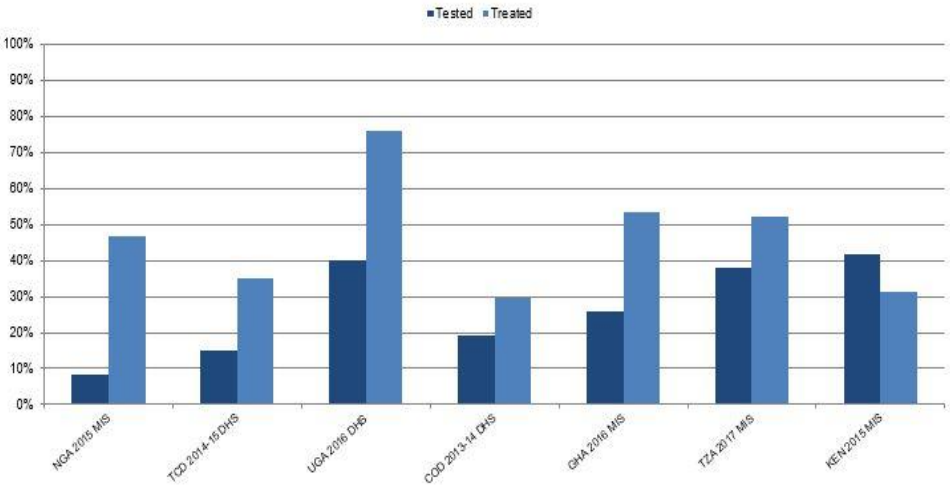
Focusing on the countries represented at the meeting, there were also great differences (Fig. 2). Formal medical facilities were more likely to administer a blood test prior to initiating treatment, but this varied widely between countries (30–77%).

Fig. 2. Diagnostic testing in the private sector



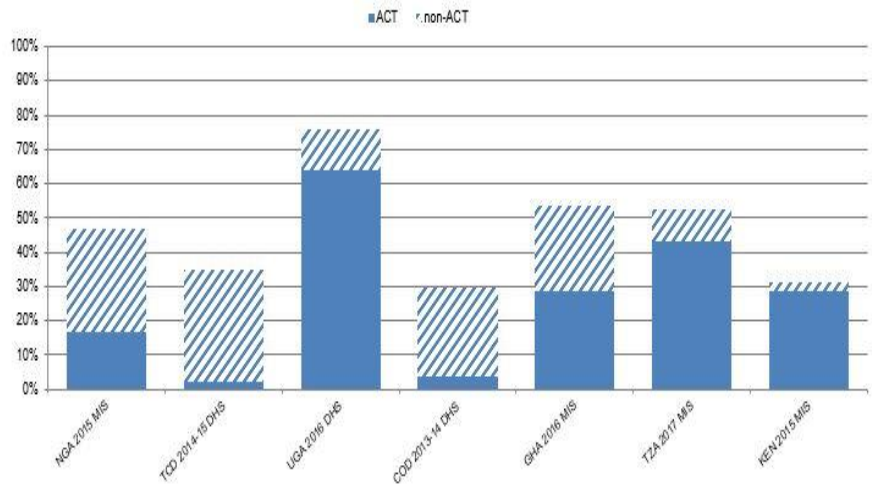
Source: Nationally representative household survey data from Demographic Health Survey (DHS) and Malaria Interview Survey (MIS)
Country codes: AGO: Angola; BDI: Burundi; BFA: Burkina Faso; COD: Democratic Republic of Congo; ETH: Ethiopia; GHA: Ghana; KEN: Kenya; LBR: Liberia; MDG: Madagascar; MLI: Mali; MOZ: Mozambique; MWI: Malawi; NGA: Nigeria; RWA: Rwanda; SEN: Senegal; SLE: Sierra Leone; TCD: Chad; TGO: Togo; TZA: United Republic of Tanzania; UGA: Uganda; ZMB: Zambia; ZWE: Zimbabwe.

Fig. 3. Children tested and treated



Regrettably, across all types of private facilities, the proportion of febrile children treated was higher than those who received a blood test, with the only exception being Kenya (Fig. 3). Furthermore, the percentage of febrile children under 5 who received a diagnostic test did not exceed 40% in any of the seven countries.

Fig. 4. Antimalarial usage among children in the private sector



There were also some significant differences between the seven countries in terms of the types of antimalarials being prescribed to febrile children in the private sector (Fig. 4).

In Kenya, United Republic of Tanzania and Uganda, there was an encouraging level of ACT usage in the private sector.

In urban areas, use of the private sector is generally higher among people with higher income and education levels, but in rural areas, the private sector is the primary source of care for a significant proportion of people who are among the poorest and have low education levels.

These results do come with some important qualifiers:

- There are potential biases due to the timing of the surveys and the seasonality of malaria in the respective countries.
- Information on the treatment-seeking behaviour of under-5s is not representative of the population as a whole, as it differs for older children and adults.
- The results are based on surveys and so will be affected by the concept of fever, which differs between countries and populations.
- There is also a problem of recall bias or mistakes in reporting the medicines by the caregiver.

Key Conclusions

- The private sector, especially PMRs, represents an important source of care for febrile patients in SSA. The malaria care provided by different private health care providers varies in the formal medical facilities, pharmacies and authorized drug shops, and the informal sector. It also varies considerably between countries, driven often by ease of access and affordability.
- Diagnostic testing before treatment for fever in PMRs remains at a low level (about 10% across the seven participant countries).

Current evidence base to support improving private sector case management

Given the importance of the private sector in delivering malaria case management to febrile patients, it is important to understand the factors and levers that will improve this delivery. The Global Fund technical brief for malaria case management in the private sector *(4)* considers that engaging with the private sector has the following objectives:

1. *Product quality:* Ensure that only quality antimalarial medicines and diagnostic testing are available from private providers.
2. *Availability and affordability:* Increase the availability and affordability of quality-assured antimalarials and diagnostic services.
3. *Quality of care:* Improve case management by private providers.
4. *Consumer knowledge:* Increase consumer knowledge and awareness of appropriate treatment seeking, diagnosis, medicine choice and adherence.
5. *Surveillance:* Improve malaria surveillance in the private sector.

There is some evidence on effective approaches and best practices to achieve these objectives.

Product quality: This is achieved through proper regulation and its enforcement by the national and state regulatory authorities. However, as is well established, many countries have insufficient resources to achieve this objective, even if the regulations themselves are adequate. Regulatory and screening efforts have had a positive effect in reducing the market share of oral artemisinin monotherapies. Mechanisms to assess quality and information on multiple suppliers of quality ACTs and RDTs are available, and the procurement of quality medicines and diagnostics is supported by international donor funds.

Availability and affordability: The most extensive study on increasing the availability of quality-assured antimalarials was the AMFm, which ran in seven countries in SSA between 2010 and 2013 *(5)*.

The AMFm was fundamentally a mechanism designed to crowd out non-ACTs and substandard drugs. It had three elements to increase the availability and affordability of ACTs in the private sector:

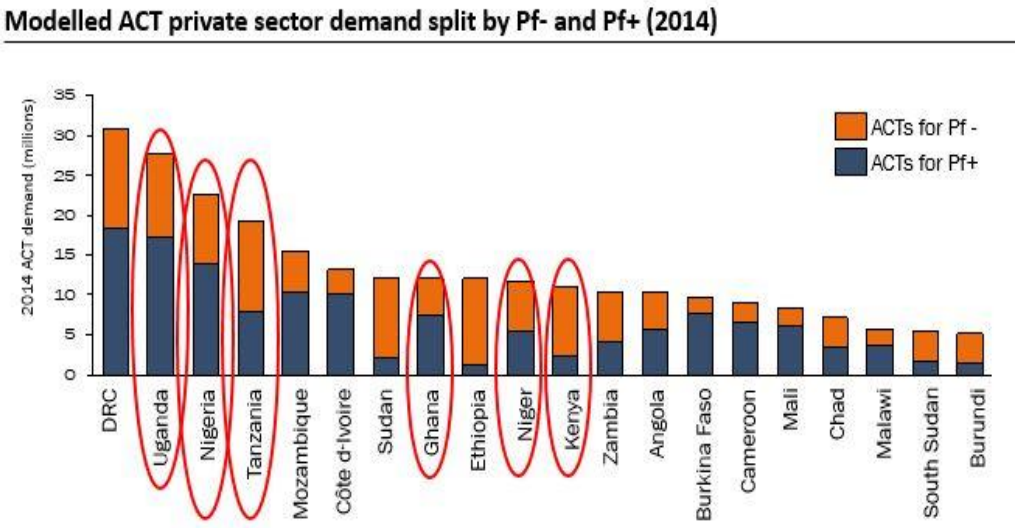
- negotiated lower prices from manufacturers for quality-assured ACTs (QAACTs)[3]

[3] In the AMFm, QAACTs were defined as ACT products that had been approved by a stringent regulatory authority (SRA) or prequalified through the WHO Prequalification (WHO-PQ) procedure.

- manufacturer-level subsidies to reduce the price-to-consumer to an affordable level similar to other antimalarials
- extensive behaviour change communication (BCC) activities in the general public to promote the use of QAACTs over other antimalarial treatments (including non-QAACTs).

It was shown that the AMFm approach could achieve great reductions in the median price-to-consumer, and large increases in QAACT availability and the market share of antimalarials sold. Following the pilot, the approach was incorporated into the regular Global Fund grant system as the CPM. However, countries have found it difficult to allocate funding to the CPM. Without a dedicated funding stream as in the AMFm, the CPM is part of the same grant funding and thus competes with other priorities.

Fig. 5. High levels of inappropriate use of QAACTs



A problem with the AMFm approach was that it did not directly incorporate malaria testing prior to treatment. Consequently, there was significant consumption of QAACTs for non-malarial fevers, wasting valuable resources and increasing the risk of resistance development (see Fig. 5[4]) *(6)*. In addition, many PMR patients with malaria failed to obtain QAACTs. While drug availability and affordability are necessary conditions, they are not sufficient to ensure appropriate use and quality malaria case management.

Unitaid's Private Sector RDT Project attempted to investigate ways to improve the availability of RDTs. Visser et al. *(7)* reviewed this project, along with other studies targeting PMRs. The results of the review showed that the level of RDT uptake in the private retail sector ranged from 100% to below 15%. Subsidies were used in most of the implementation projects. Price to patient/caregiver varied across the studies – between US$ 0.00 and US$ 1.50. Broadly, the lower the cost to patient, the higher the level of uptake; but the length of training and frequency of follow-up also had an influence (see below).[5]

[4] Countries that participated in the AMFm are ringed. Methodology was taken from Cohen et al. *(6)*, and the model has been updated using 2014 data.

[5] Recently, Prudhomme et al. *(8)* published a study on the use of vouchers to promote testing before treatment for patients with fever. Results showed that this approach could have a positive impact on the uptake of pre-testing.

A major challenge in operationalizing the Unitaid project was that countries would not permit staff in many types of private sector outlets (e.g., pharmacies and accredited drug shops) to perform malaria RDTs (mRDTs) and so waivers were needed before the project could be implemented. Continued efforts during the project's lifespan resulted in regulatory changes in Nigeria, Uganda and Madagascar that allow for long-term continued use of rapid diagnostic testing services in PMRs. However, in Kenya, PMRs could not continue to administer the tests legally after the end of the project.

The uptake of RDTs in the private retail sector varies widely. Moreover, the market for diagnostics in the private sector is hampered by consumer expectations and demand for medicines, low profits, and no clear protocols for managing a negative mRDT result.

Quality of care: To deliver quality case management in PMRs, providers must be supported by training, supervision and protocols that are appropriate to the characteristics of the delivery channel and the providers. The Unitaid Private Sector RDT Project also tested a range of approaches to strengthen case management quality and concluded that:

- The introduction of schemes to improve case management must be accompanied by adequate training for staff, which needs to be followed-up and reinforced on a regular basis. Training that lasted four to five days and was followed up weekly for one to two months showed significantly better results than shorter training periods with less frequent follow-up. Adequate training and follow-up address the principal issues related to staff turnover and staff members' lack of confidence when dealing with caregivers.
- Lay workers in PMRs can administer mRDTs successfully and adhere to test results, often better than health professionals in formal medical health facilities. This finding was also related to the length of training and follow-up, as well as emphasis on adherence in the training.
- There is a need for therapeutic alternatives in the event of a negative test result in order to avoid frustration on the part of both the PMR staff and the caregivers.
- Caregivers may ignore the advice of the PMR staff and simply go to another shop where they may be able to obtain some medicines, even if they are inappropriate.

There is a need for a more holistic approach to engaging with the private sector on diagnosis – one that includes management of non-malarial febrile illnesses. However, more guidance is needed, especially for resource-poor settings.

Consumer knowledge: The AMFm Independent Evaluation documented the extent of the supporting interventions involving communications with the general public about malaria case management (although these did not cover the need for prior diagnosis). In the AMFm areas, communication campaigns that lasted longer showed the greatest increase in the market share of QAACTs delivered by the programme.

Many programmes to introduce ACTs and RDTs in the private sector have included BCC activities, but there is limited evidence on the effectiveness of the different approaches implemented in private sector settings.

Surveillance: The third pillar of the WHO Global Technical Strategy for malaria *(9)* is to transform surveillance into a core intervention. Currently, there is very limited reporting on malaria case management in the private sector, especially from PMRs. Even where PMRs are able to perform malaria tests, reporting into the health management information system (HMIS) has yet to be fully implemented. There is little evidence on how best to enable and encourage PMR providers to report data as part of the national surveillance system. In Uganda, PMRs in three districts were trained and equipped to report to the national HMIS system – and this was made mandatory. In the United Republic of Tanzania, ADDOs were also equipped and trained to report into the District Health

Information System (DHIS2), but this was not made mandatory. Over the three months in 2018 immediately after its introduction, reporting rates from the ADDOs fell from 69% to 53%. Frequent follow-up and an easy reporting system seem to be keys to successfully integrating PMRs into national surveillance systems.

Potential approaches to achieve the objectives: Montagu and Goodman *(10)* proposed that it is possible to classify strategies for improving private sector performance into four approaches: prohibit, constrain, encourage and purchase (see Fig. 6).

Improving clinical quality is challenging and requires strong incentives. Working with the formal private sector will only reach the poor if a significant financing component is included. The use of demand-side financing (such as voucher schemes) can facilitate scale-up of services in the private sector but requires strong governmental capacity to manage this successfully. It is therefore important to also consider links with other financing mechanisms such as social health insurance.

Fig. 6. Approaches and devices for private sector engagement

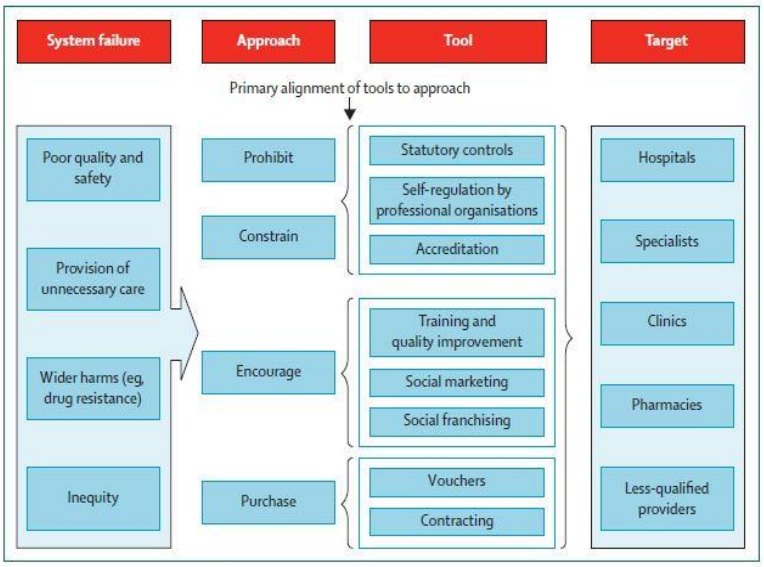


Figure: Approaches and devices for private sector engagement

Source: Montagu D, Goodman C. Prohibit, constrain, encourage, or purchase: how should we engage with the private health-care sector? Lancet. 2016;388:613–21.

Guidance and recommendations on approaches for better engagement with the private sector in delivering quality malaria case management have been published by the Global Fund *(4)* and PSI *(11)*.

Key Conclusions

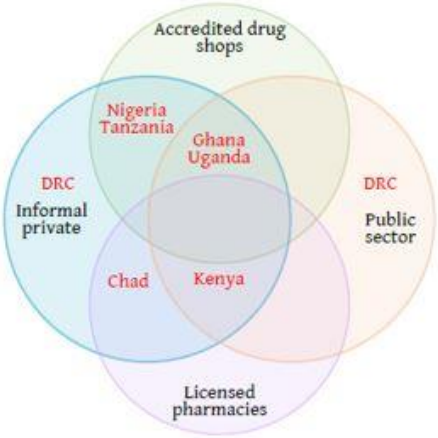
- There is a limited amount of evidence to support the different ways to improve case management in PMRs.
- If research and pilot projects are ever to move to scale, regulatory restrictions on who can test, treat and sell health products need to be removed so that tasks can shift to where patients are accessing care.
- **Availability and affordability:**
    - Lowering the purchase costs (through co-payments or subsidies) of quality-assured antimalarials and diagnostic services or providing quality-assured commodities free of charge to providers and patients (together with associated BCC programmes) can increase availability and affordability.
    - However, in the absence of pre-treatment diagnostic testing, increased availability and affordability of ACTs may lead to a high level of inappropriate treatment of non-malarial fevers.
- **Quality of care:**
    - There is less evidence on the best way to introduce mRDT testing into PMRs. The Unitaid project and other studies have shown that PMR staff can successfully administer tests and adhere to the results, often better than formal health care workers. However, as in the public sector, there needs to be adequate training and regular follow-up.
    - Appropriate protocols for the management of non-malarial fevers are also required.
        - Patients testing negative for malaria may go elsewhere to get treatment.
        - PMRs may feel legitimized to diagnose and treat other diseases without proper guidance.
    - Thus, a more holistic approach is required – one that goes beyond malaria to include other aspects relevant to real-life settings where resources are limited.
- **Consumer knowledge:**
    - BCC is crucial to changing consumer behaviours and expectations when seeking care in PMRs.
    - Demand for testing services does not exist everywhere and testing is often not perceived as a service that has to be paid for.
- **Surveillance:**
    - There is little experience on developing appropriate surveillance for the private sector, with appropriate tools, incentives and systems.

Regulation and enforcement

The analysis of policies and regulations that affect malaria case management in the private sector was based on the country surveys conducted in Chad, DRC, Ghana, Nigeria, Kenya, Uganda and United Republic of Tanzania. The surveys analysed regulatory aspects related to antibiotics, antimalarials and IVDs *(2)*. The analysis classified the primary sources of care into four groups: public sector, licensed pharmacies, accredited drug shops and informal private sector outlets. Fig. 7 shows the primary sources of care according to the surveys. For example, in Nigeria, accredited drug shops

and the informal private sector were the primary sources of care, whereas in Kenya, it was the public sector, licensed pharmacies and informal private sector.

Fig. 7. Primary source of care in the seven countries



All the countries have regulations in place for ACTs and IVDs, but legislation and regulatory bodies for IVDs are still evolving. Countries still lack the capacity to fully enforce the regulations and controls, especially for post-marketing surveillance. This means that practice, especially around diagnostic testing and prescription of antibiotics, is often inconsistent with laws and regulations.

All countries (except for Chad) have some plans for regulating PMRs. Ghana, Nigeria and United Republic of Tanzania already have a system of accreditation for drug stores in place (see next section). However, the surveys and meeting discussions highlighted the presence of regulatory restrictions that need to be overcome in order to ensure that PMRs can provide access to quality malaria case management.

The countries differed in the risk classifications for ACTs and antibiotics, as shown in Table 1.

Table 1. Risk classifications for ACTs and antibiotics in seven participating countries

Country	ACTs	Antibiotics
DRC	OTC	POM
Ghana	OTC	POM
Kenya	POM	POM
Nigeria	OTC	POM
United Republic of Tanzania	AL = OTC, all others = POM	Amoxicillin = OTC, all others = POM
Uganda	AL = OTC, all others = POM	Amoxicillin = OTC, all others = POM

Note: OTC = over-the-counter; POM = prescription-only medicine; AL = artemether-lumefantrine

Within these classifications, the countries also differed in terms of which types of health care professionals (doctors, pharmacists, nurses, midwives, etc.) are allowed to sell and prescribe these drugs. Together with client expectations, the difference in risk classifications between ACTs and antibiotics is a significant barrier in providing appropriate care for non-malarial febrile illnesses, including pneumonia, in the event of a negative malaria diagnostic test result.

In all seven countries, there are also restrictions as to what types of facilities are allowed to perform mRDTs (see Table 2[6]).

Table 2. Where and by whom mRDTs can be distributed/performed/sold in the seven countries

Country	Premises where mRDTs can be administered	Professionals permitted to perform mRDTs	Professionals permitted to sell mRDTs
Chad	Health centres Clinics Private laboratories	All health care workers (incl. CHWs)	Accredited pharmacists
DRC	Hospitals Clinics Registered pharmacies with accredited pharmacists	Accredited pharmacists CHWs	Accredited pharmacists
Ghana	Hospitals Clinics Pharmacies Accredited drug stores	All health care workers in the formal sector	All health care workers in the formal sector
Kenya	Community level Level 1–3 health facilities	Laboratory technicians CHWs	Hospitals Pharmacies
Nigeria	Pharmacies Clinics Dispensaries Hospitals Accredited drug stores	All formal health care workers	Staff in PPMVs, pharmacies, clinics, dispensaries, hospitals
United Republic of Tanzania	Formal health facilities Clinics Private laboratories	Health laboratory practitioners People with specialized training (incl. licensed registered drug shops staff and CHWs)	People registered with the Tanzania Food and Drugs Authority, including ADDOs
Uganda	Hospitals Clinics Pharmacies Accredited drug stores Private diagnostic facilities	Health laboratory practitioners People with specialized training	Pharmacists Pharmacy technicians Nurses

WHO is supporting Member States to strengthen their NRAs in order to ensure access to affordable medical products that are safe, good quality and effective for all diseases. WHO's work to help countries improve their regulatory strengthening efforts involves the benchmarking of NRAs, formulation of institutional development plans, provision of technical support and training, and monitoring of progress and impact. These activities are supported by a coalition of interested parties (CIP). WHO also coordinates the Global Surveillance and Monitoring System for Substandard and

[6] The exact legal designations are not used in the table for the sake of simplicity and for ease of comparison.

Falsified Medical Products, in which ACTs rank second only to systemic anti-infectives in the number of reports to WHO.

There was general agreement that there is still a lot of work to be done to ensure that regulations are aligned with the vision of improving access to quality malaria case management in PMRs. The challenge is that malaria treatment is effectively an OTC market, whereas diagnostic testing and antibiotic treatment are restricted in many countries to the formal medical health care system (public and private).

It was agreed that investing in good regulatory practices, flexible regulatory frameworks that can respond to the particular needs and circumstances of each country, and robust enforcement should be a high priority for national health budgets.

Key Conclusions

- There is a lack of proper alignment in most countries between the regulations that govern the availability of antimalarial drugs and diagnostic testing in PMRs. This needs to be corrected to ensure that PMRs can administer proper care management legally.
- The regulatory framework also needs to encompass case management of non-malarial febrile illnesses, especially those that need to be treated with antibiotics.
- Investment in good regulatory practices, flexible frameworks and robust enforcement should be a high priority.

Accreditation programmes

Three of the countries present at the meeting have accreditation systems in place for drugstores and similar second-tier PMRs. These are:

- Ghana: OTC Medicine Sellers (OTCMSs)
- Nigeria: Patent and Proprietary Medicine Vendors (PPMVs)
- Tanzania: Accredited Drug Dispensing Outlets (ADDOs)

The Tanzanian ADDO system was launched in 2003. Its goal is to improve access to affordable, quality medicines and pharmaceutical services in drug shops in rural or peri-urban areas where there are few or no registered pharmacies. To achieve this goal, the ADDO model takes a holistic approach that develops the capacity of owners and dispensers who work in retail drug shops, as well as the institutions that regulate them. For shop owners and dispensing staff, this is achieved by combining training, incentives, consumer pressure and regulatory enforcement with efforts to influence client demand for and expectations of quality products and services. The benefit that the ADDO owners value the most is the training *(12)*. The system achieved nationwide scale-up in 2013 when 60% of all drug shops were accredited *(13)*. By 2016, over 9000 shops were part of the system and over 19 000 dispensers had been trained. ADDOs have been used as a platform for public health interventions, including to increase access to ACTs for malaria, and they have been incorporated into multiple public health strategies, from family planning to achievement of the Millennium Development Goals *(12).*

Both the Ghanaian and the Nigerian systems are broadly similar in terms of the design of the programme and the types of products that can be sold in the OTCMSs and PPMVs, respectively, but the programmes differ in their details.

In Nigeria, there are 120 000 drugstores, of which about 40 000 are registered as PPMVs with the Pharmacists' Council of Nigeria. Unfortunately, unregistered drugstores usually operate in remote areas, making training, supervision and enforcement difficult.

In 2019, there were approximately 10 000 OTCMSs in Ghana, regulated by the Pharmacy Council. As described in the next section, the private retail sector has been an important part of the successful implementation of the WHO-recommended treatment for paediatric diarrhoeal diseases.

The ADDO model has been shown to be scalable, sustainable and transferable to other countries *(13)*. Accredited drug shops have been shown to be of value in introducing new case management approaches more widely (e.g., in the introduction of zinc/oral rehydration salts (ORS) for diarrhoeal disease in Ghana or ACTs for malaria in United Republic of Tanzania). Accreditation, if supported by the necessary BCC programmes to communicate its objectives, is an indication of quality to the general public and so can increase business for the accredited PMRs. However, studies on appropriate case management have been limited and have produced mixed results.

Learning from other disease programmes

Caring for the sick child: Data from the USAID SHOPS Plus project indicate that globally 42% of caregivers rely on the private sector for care of their sick children. Among private sector users, approximately 36% use pharmacies or drug shops and 14% use informal PMRs. This extends to all economic groups, with 40% of the poorest relying on the private sector for initial care *(4)*.

The SHOPS Plus[7] project seeks to catalyse public–private engagement to improve family planning, HIV/AIDS, maternal and child health, and other public health priorities. From its work in improving the integration of PMRs into national health care systems, the project has identified the following key lessons:

- The key to successful integration is to obtain the buy-in of all sectors through continuous engagement (public sector, donors, implementing partners, civil society, and the private sector).
- The size and scope of the private sector is often poorly understood, and a proper evaluation of this needs to be done at the outset of any engagement programme.
- Government stewardship and ownership of the integration is vital for success.
- Engagement is best achieved by identifying a lead focal point organization within both the public and private sector. This might be a Pharmacy Council, a specific department in the Ministry of Health such as a public–private partnership unit, or a pharmacy trade association.
- Policy and regulatory barriers limit the integration of drug shops into the general health care system.
- Policy is often focused only on the sale of medicines and is "silent" on the provision of services (such as diagnostic testing, counselling and referrals).
- Training and supervision need to be properly designed with private sector needs in mind (e.g., the timing of sessions outside of peak business hours).
- Addressing the customers' influence on prescription decisions and changing their behaviour is also essential to successful integration. Consumers have been shown to have a greater influence in PMRs for three reasons:

[7] See https://www.shopsplusproject.org/

- Staff in PMRs have less depth of knowledge and so are less confident in giving advice to customers compared to pharmacists and staff in hospitals and clinics.
- Customers also view staff as less knowledgeable and so are less willing to accept their advice.
- PMRs need to keep their customers satisfied in order to sustain their business and so may prefer to defer to customers' preferences.

In Ghana, 40% of caregivers seek care for their sick children in the private sector. Of those, 76% seek care in PMRs. The SHOPS Plus project in Ghana has successfully "moved the dial" in the treatment of paediatric diarrhoea away from the use of antibiotics and towards the WHO-recommended treatment of zinc plus ORS. SHOPS Plus worked closely with the Pharmacy Council and the Ministry of Health to design and deliver the relevant training, BCC and regulatory changes to make the programme a success (see Fig. 8).

Changing customer behaviour was achieved by BCC directed at the consumer through the media and/or by strengthening PMR staff's knowledge and confidence in giving advice to consumers. This was also reinforced by appropriate communications materials for display in PMRs and other medical facilities.

Fig. 8. Result of the implementation of the SHOPS Plus Diarrhoeal Treatment Programme in Ghana

The project was launched in 2012 with training programmes. As shown in Fig. 8, the programme resulted in increases in the recommendations of zinc and ORS. Most significantly, there was a sharp drop in the recommendation of antibiotics for childhood diarrhoea.

TB "public–private mix": TB is the top infectious disease killer globally, with 2.6 million deaths in 2017. TB is responsible for high mortality in people living with HIV and is a leading cause of antimicrobial drug resistance. However, a major challenge to reducing the global TB burden is finding all the patients who have contracted TB and initiating them on treatment. In the United Republic of Tanzania, it is estimated that 56% of new infections are not detected (85 000 in 2017); yet, of patients who were put on first-line treatment, 90% were treated successfully.

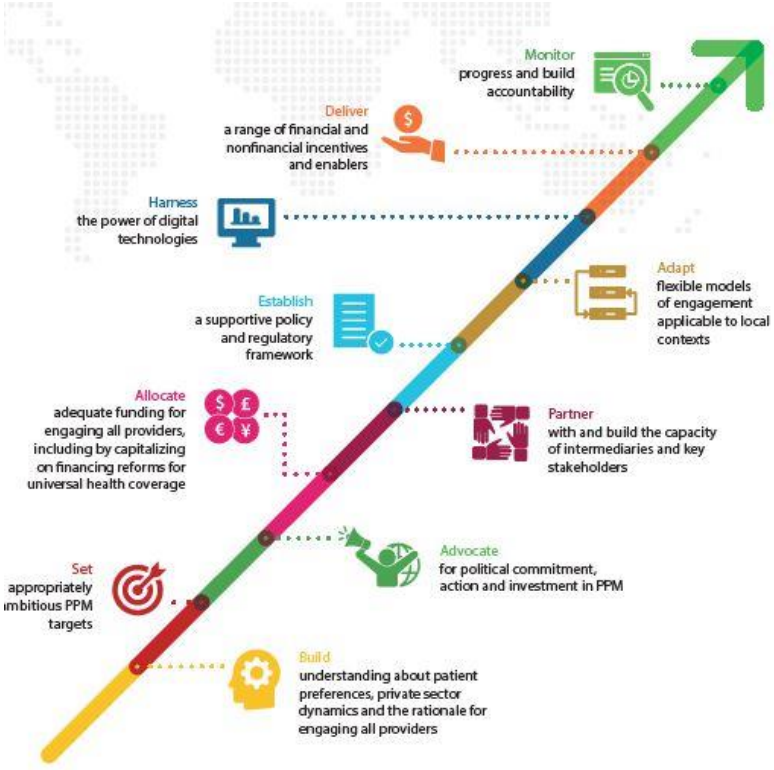
Private health care dominates in many high-burden countries, and so a large proportion of the "missing cases" are seeking treatment in this sector. WHO estimates that in the seven countries with 62% of the "missing cases", private providers account for 65–85% of initial care-seeking by people with TB, but these providers only contribute 19% of TB notifications.

Therefore, engaging with the private sector (which, in this case, includes private hospitals and clinics) is crucial to finding the "missing" people with TB and putting them on treatment. In the United Republic of Tanzania, the national strategic plan has a target to engage 50% of private health facilities (hospitals, clinics, PMRs) in TB services by 2020. They should then be contributing 25% of case notifications (vs. 5% in 2014).

Engagement in TB services is centred on training PMR staff to recognize the signs of TB and refer the patient to an appropriate medical facility for proper diagnosis and treatment. PMR staff usually have a low awareness of TB, its signs and symptoms. Other necessary actions are to ensure that the regulatory environment is aligned with the engagement programme and that the PMRs have the necessary financial and non-financial incentives to engage.

With PMRs (ADDOs in the United Republic of Tanzania), the focus is on engaging them in case referrals, not in treatment. As such, the role of PMRs differs in malaria case management. Malaria is often an OTC market in SSA and thus there is an additional focus on ensuring that quality-assured antimalarials are available in a way that crowds out poor-quality or inappropriate drugs.

Fig. 9. WHO TB public–private mix (PPM) roadmap priorities for action



WHO has published a roadmap for developing private sector engagement and building a "public–private mix" for TB *(14)*. Fig. 9 shows the priorities for action articulated in the roadmap.

Opportunities and concerns for the future

The survey of FLBs in Ghana, Kenya, Nigeria, United Republic of Tanzania and Uganda was completed a few months before the meeting. FLBs were able to provide their perspectives on increasing the availability of QAACTs and mRDTs in the private sector. At the meeting, panels of ACT manufacturers and mRDT manufacturers also discussed this issue.

Availability and access – ACTs

FLBs expressed concern over the reduction in support for co-payment systems in several countries. The AMFm and Global Fund CPM have been successful in both increasing the market share and reducing the price of QAACTs (Figs. 10 & 11).

Fig. 10. QAACT market share

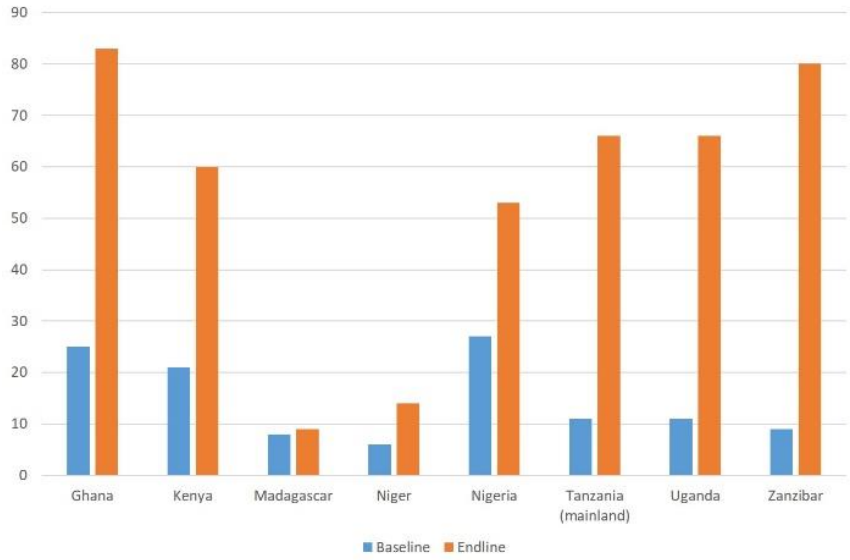
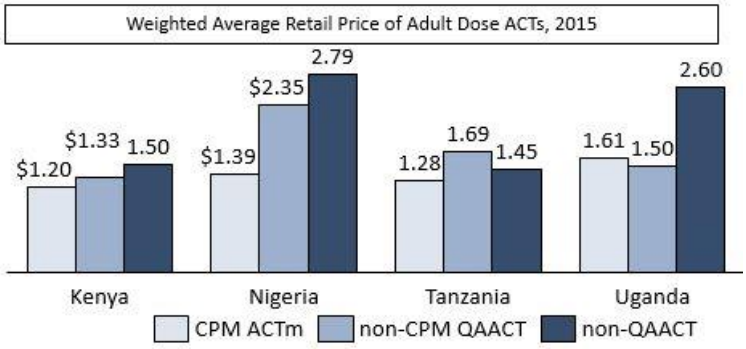


Fig. 11. ACT pricing



Since 2017, the CPM has been terminated in Nigeria and is being reduced significantly in Kenya and Uganda. For QAACTs no longer supplied through the CPM, the import costs have increased and are now higher than for non-QAACTs (Fig. 12). Importers estimated that non-QAACTs cost 20–50% less than QAACTs not supplied through the CPM. Because 70–90% of the market is price-sensitive, this may mean a shift to non-QAACTs.

Importers fear the following outcomes:

- Suppliers will now reduce the number of importers that they work with and this will reduce availability and access.
- Waivers of import duties that applied under the CPM will be removed and this will further increase prices.
- Customers may not be able to afford unsubsidized imported QAACTs because of the high cost of distributing to rural areas, and access to medicines in rural areas will suffer.

Fig. 12. ACT importers' costs

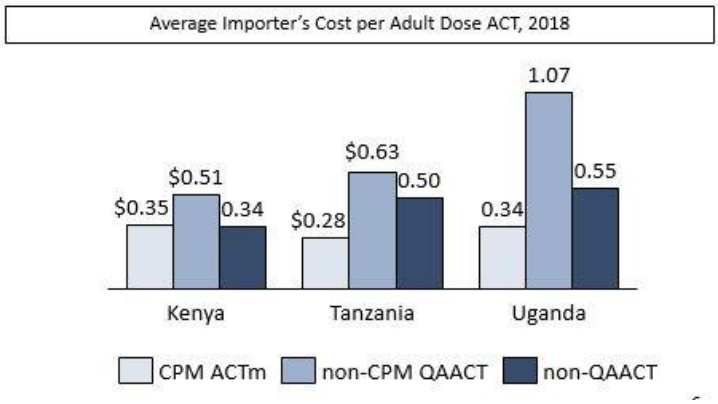
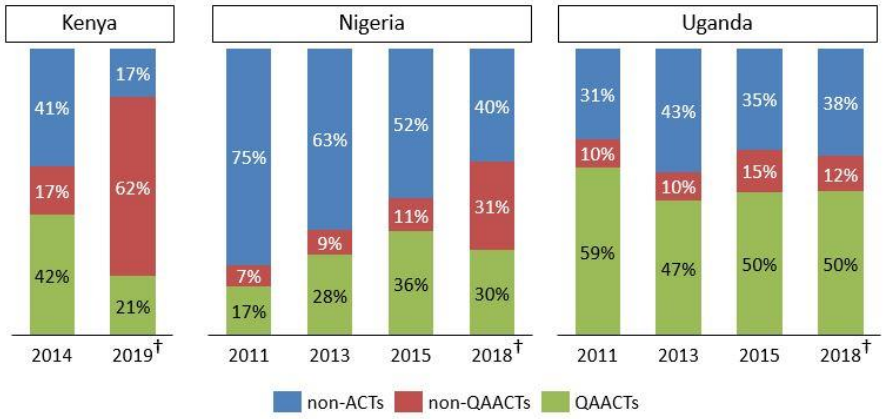


Fig. 13. Market share of QAACTS, non-QAACTs and non-ACTs (all shops)



ACTwatch and CHAI have also carried out market surveys to evaluate the impact of CPM implementation. They have shown that in Nigeria and Kenya the use of non-QAACTs has expanded at the expense of QAACTs (Fig. 13).

It is important to note, and encouraging, that thus far there has been no increase in the market share of non-ACTs.

Product quality - ACTs

The findings on how the relative market shares of QAACTs and non-QAACTs have changed following discontinuation of the CPM have raised questions about the quality of ACTs that are becoming increasingly available in countries, compared to ACTs that are SRA-approved or WHO-prequalified. CHAI is currently testing samples collected in Kenya, Nigeria and Uganda to evaluate this issue.

This in turn has raised concerns about the use of the term "quality-assured" to describe medical products that are procured by international donors (e.g., the Global Fund) based on SRA approval or WHO prequalification.

Several participants at the meeting believed that many of the pharmaceutical products and diagnostic devices that are registered and available in countries have been manufactured to country-specified quality standards, but have not been submitted for approval to an SRA or WHO-PQ. There was general consensus that the term QAACT should not only be used to denote ACTs that are SRA-approved or WHO-prequalified; the lack of such approval should not be an indication that products

are of unacceptable quality at the country level. They argued that products that have been approved by an NRA should also be considered quality-assured, and countries need to strike a balance between quality assurance and increasing access by increasing the number of products available on the market.

Strengthening the regulatory agencies – especially the inspection and enforcement arms – could increase access to more quality-assured medicines and diagnostics at competitive prices for use by NMCPs.

Fig. 14. AMFm Green Leaf logo

ACT manufacturers who participated in the panel discussion were very clear on the need to maintain the promotion of high quality standards, but that this should be supported by efforts to make the drugs affordable, especially in rural areas. The AMFm Green Leaf logo (Fig. 14) has played a significant role in enabling customers to identify quality products. However, counterfeiting of the logo has increasingly become a problem. Manufacturers were at pains to emphasize that fair pricing should recognize costs for manufacturing at quality standards and be factored into new initiatives involving procurement of medical products. Pricing also needs to be sustainable for manufacturers over the medium to long term in order to ensure that there are multiple suppliers and competition in the market.

Expanding the market - mRDTs

mRDT manufacturers on the panel were concerned about the level of attention paid to QAACTs – their price, quality, market share, etc. – and the comparative lack of attention paid to the promotion of testing before treatment with mRDTs.

There is a need to establish protocols to enable PMRs to manage patients appropriately if they test negative for malaria. In the absence of such protocols, there is evidence that diagnostic testing for malaria may reduce incorrect treatment with antimalarials but increase the inappropriate use of antibiotics.

Several other issues were raised:

- Complexities in the supply chain (e.g., licenses, approvals and tariffs) add to the cost of the tests when they reach the end-user. Simplification may help to keep the cost down.
- The supply chain has too many layers where margins accumulate and further add to the end-user cost.
- PMRs should make a decent return on testing while addressing the need to maintain affordability of the Test, Treat and Track strategy[8]. Ideally, the costs of testing and treatment should be the same, regardless of the test results.

[8] https://www.who.int/malaria/areas/test_treat_track/en/

- There is a need to change customer expectations and behaviours about testing and receiving drugs when visiting a shop.[9] This underlines the importance of governments and NMCPs in terms of generating demand for testing and educating the general population about the Test, Treat and Track strategy. If there is demand, then manufacturers will meet it.
- There is a need to ensure that there is a proper training and accreditation system in place for PMR staff to be able to safely and effectively perform tests in shops, observing blood safety requirements. The system needs to be regularly followed up to ensure standards are maintained.

Key Conclusions

- Countries have started to reduce or terminate use of co-payments under the Global Fund CPM system due to other priorities. There is initial evidence that reduction or termination of co-payments will produce a shift to the use of non-QAACTs in PMRs. There is no evidence yet showing a shift back to other antimalarials (non-ACTs) to treat malaria.
- The definition of a QAACT often used by global agencies (e.g., the Global Fund, USAID) to indicate an ACT that is SRA-approved or WHO-prequalified should be abandoned. There are ACTs available on the market that are quality-assured but have not been submitted for approval to an SRA or WHO-PQ.
- Manufacturers are keen to clarify that quality comes at a cost and pricing needs to reflect the manufacturing requirements to supply quality products consistently. This will ensure a competitive but sustainable market in the medium to long term.
- Proper protocols need to be put in place to guide PMR staff in the event of a negative mRDT result in order to ensure appropriate application of the Test, Treat and Track strategy.
- Ongoing BCC is needed to change the expectations and behaviours of the general population when visiting PMRs to seek treatment for fevers.
- PMRs need acceptable profit margins for performing mRDTs (and other diagnostic tests). In order to support the implementation of the Test, Treat and Track strategy, the cost to patients/caregivers should ideally be independent of the mRDT test result.

Key themes across countries

Although the findings from individual countries differed, certain key themes emerged. To develop proper country analyses and plans, more work is needed in each country with all stakeholders using the PSI "Keystone Design Framework" or other similar planning approaches.

[9] This challenge is outlined in the discussion of the SHOPS Plus programme in Ghana.

Common Vision

There was general consensus on the vision for the role of the private sector in case management:

- All patients, irrespective of their social status and where they live, have the right to access quality malaria case management.
- As many patients seek treatment for febrile illness first through the private sector, this sector must be able to deliver quality malaria case management.
- Private sector health care providers need to be considered an integral part of a country's national health system.

Key Themes

- **Promotion:** Governments, NMCPs and other key stakeholders need to generate demand among the population for better quality care in the private health sector. BCC activities targeting the general public need to continue to promote malaria diagnostic testing and compliance with the results.
- **Quality:** The confidence of all stakeholders in the quality of care that can be delivered by the private sector must be raised through:
    - accreditation systems for drug shops;
    - training in malarial and non-malarial fever case management and professional development schemes for private health care providers;
    - supervision of private health care providers, ideally by existing government health care workers;
    - increasing the availability and affordability of quality diagnostics and medicines.
- **Policy and regulation:** Country policies and regulations should be reviewed and revised so as to support the implementation of appropriate case management.
    - There needs to be clarity and consistency of the policies and regulations on where and by whom mRDTs can be performed, and who can prescribe and/or sell antimalarials and where.
    - Policy makers and regulators should be aligned on the technical specifications required for health products (diagnostics and medicines).
    - Policies and regulations that support the extension of quality malaria testing services should be coupled with appropriate treatment.
    - There needs to be robust supervision and regulatory enforcement supported by training and follow-up programmes.
- **Market information:** The lack of detailed information on the private sector market, especially outside the large urban areas, should be addressed and results should be disseminated to all stakeholders so as to inform interventions aimed at improving access to

quality malaria care in the private sector. As countries differ, each needs to undertake an in-depth market review.[10]

- **Surveillance:** Simple systems should be developed to allow the private sector to be fully integrated into national surveillance systems.
- **Pricing and incentives:** Countries should ensure that:
    - the pricing of quality-assured products supports the crowding out of poor-quality or inappropriate products;
    - the cost to the caregiver/patient of the testing and treatment package is affordable and promotes the Test, Treat and Track strategy;
    - tax and tariff systems are aligned so that diagnostics are not disadvantaged compared to medicines.
- **Coordination:** Different stakeholders are not always aligned on the best way to involve the private sector in delivering quality case management of malaria. It will be necessary to bring all stakeholders together to develop a coordinated approach.[11]

Support and guidance needed from WHO

The meeting also concluded that WHO could assist countries in integrating the private sector into the delivery of quality malaria case management. The following specific actions were recommended.

Advocacy

The consideration of the private sector as an integral part of the health care delivery system by the NMCPs can be used as a pilot leading to wider recognition of the private sector as an essential platform for delivering universal health coverage (UHC). Unfortunately, in many countries, such efforts are often not high priority and are often crowded out by other public health priorities. It would help for WHO to advocate widely for a strong, appropriate role for the private sector.

It would also be particularly useful for WHO to make the case for strong private sector engagement to heads of government (HoGs). Many of the issues constraining the proper integration of the private sector into the health care system will require cross-government collaboration (e.g., alignment of tax and tariff treatments between mRDTs and ACTs will require participation of the Ministry of Finance). Advocacy could also be carried out through organizations like the African Leaders Malaria Alliance or Asia Pacific Leaders Malaria Alliance in their dialogues with HoGs.

WHO can also assist in involving other organizations, such as the RBM Partnership to End Malaria, and key international donors (Global Fund, USAID, UK DFID, Unitaid, Foundations, etc.) in advocacy and the development of initiatives to support the full integration of the private sector into malaria case management.

Private sector engagement

Sharing the lessons gained from private sector engagement with other diseases (e.g., the public–private mix for TB, SHOPS Plus project) would assist countries in identifying and overcoming challenges. In addition, countries would like to see more guidance on ways to better engage the private sector in delivering quality case management and to properly implement the Test, Treat and

[10] This was also a key recommendation from the SHOPS Plus project in Ghana.

[11] This was also a finding from the SHOPS Plus project in Ghana.

Track strategy. Countries need shared lessons and best practices along with research on how to make private sector engagement attractive both financially and non-financially.

Guidance from WHO on the best ways to strengthen the oversight of the private sector by the public sector would also be welcome.

WHO could also play a role in linking NMCPs to broader conversations about UHC and the potential contribution of the malaria private sector strategy.

Furthermore, WHO could use its convening power to facilitate discussions among all national stakeholders (e.g., Ministry of Health, NRA, Medical Council, Pharmacy Council, drugstore owners' industry association, etc.).

Resourcing

When budgets are set and donor funding is sought, initiatives to support the private sector (e.g., the CPM for ACTs) can get crowded out by other public health projects. Countries need guidance on the best way to prioritize funding needs in order to ensure that private sector initiatives receive the level of resources appropriate for delivering quality case management.

Negative test results

There is an urgent need for recommendations on the correct protocol for PMRs to follow in the event of a negative test. Such recommendations should recognize the pressures on PMRs, both financially and from patients/caregivers, to provide treatment even in the event of a negative mRDT result, rather than referring the patient to a public health facility.

Affordability

Key barriers to the proper implementation of the Test, Treat and Track strategy in the private sector are how to make the package affordable to caregivers/patients and how to promote testing before treatment. WHO should carry out more work at the global and regional level to identify approaches to overcome these barriers.

Promoting innovation

There is still a need for improved diagnostic tools that can distinguish between malaria and other causes of fever and that are appropriate for the private sector context.[12] In addition, there is a need for data capture tools (e.g., through mHealth technologies) that can be used in the private sector to allow it to play a full role in national surveillance systems. Countries would welcome WHO's continued support and advocacy for work on these innovations.

Technology transfer

WHO should support technology transfer to promote local manufacturing of ACTs and mRDTs so as to increase the supplier base and, by increasing competition, drive down prices.

[12] FIND has a disease programme looking at this (see https://www.finddx.org/mal-fev/).

Key Requests

- **Advocacy:** Advocate for the importance of the private sector in order to ensure that quality case management is available to all, as an essential component of achieving UHC.
- **Support and guidance**: Provide support to governments (including sharing best practice) on how best to engage the private sector in terms of:
    - facilitating cross-sectoral coordination through country-based forums;
    - making investment decisions for improving access to malaria case management in the private sector in relation to other health priorities.
- **Quality case management:**
    - Provide guidance on how to assess the quality of care in the private sector, not just the quality of health products.
    - Ensure continued promotion of appropriate use of malaria diagnostics in order to deliver quality care for febrile illnesses in malaria-endemic countries.
    - Make recommendations on the correct protocols to follow in the event of a negative mRDT, acknowledging the actual pressures on the ground.
- **Affordability:** Based on a range of business models/pricing strategies, make recommendations on how quality case management can be made affordable to patients, while ensuring a reasonable return to private health care providers.
- **Innovation:** Develop innovative systems and incentives to promote reporting from the private sector and to integrate the sector into national surveillance systems.
- **Local manufacturing:** Support technology transfer in malaria-endemic countries in order to increase local production of ACTs and mRDTs that meet the quality requirements needed for procurement with international funds.

Ideally, this guidance should be brought together into a **Roadmap** (similar to the TB Roadmap) for integrating the private sector into national strategies to improve malaria case management. This guidance should provide direction to ministries of health and other national agencies on how best to engage with the private sector, especially PMRs, to deliver proper diagnosis and treatment, and contribute to surveillance and routine reporting of malaria.

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Annex 1: List of meeting pre-reads

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Annex 3: Agenda

Wednesday 1 May 2019		
9:00 - 9:15	Welcome and opening remarks	P. Alonso
9:15 - 9:30	Objectives of the meeting	A. Bosman
Session 1 – What is known on malaria case management in the private sector		
9:30 - 9:45	Results from DHS/MIS surveys in high-burden countries	J. Aponte
9:45 - 10:20	Review of evidence on improving malaria case management by private-sector providers	C. Goodman & T. Visser
10:20 - 11:00	Discussion	
11:20 - 12:20	ACTwatch, AMFm/CPM, ADDO programme & Unitaid RDT project Panellists: S. Poyer, C. Goodman, E. Shekalaghe & N. Charman	R. Orford (moderator)
12:20 - 13:00	Discussion	
Session 2 – Laws, regulations and policies influencing malaria case management in the health sector		
14:00 - 14:40	Survey tool and comparative analysis of policies and regulations that affect malaria case management in the private sector in Chad, DRC, Ghana, Kenya, Nigeria, United Republic of Tanzania and Uganda	T. Visser
14:40 - 15:30	Discussion	
16:00 - 16:20	WHO assessment of national regulatory authorities	H.B. Sillo
16:20 - 16:50	Market survey in Kenya, Nigeria, United Republic of Tanzania and Uganda following interruption of Global Fund Co-Payment Mechanism (CPM) in 2018	A. Woolsey J. Tibenderana
16:50 - 17:10	WHO surveys of spurious, falsified and substandard antimalarial medicines	M. Deats
17:10 - 17:30	IQVIA market intelligence	D. Batra
17:30 - 18:15	Discussion	
Thursday 2 May 2018		
Session 3 – Relevant lessons learned by other public health programmes		
8:30 - 9:20	Tuberculosis programme for public–private mix to improve case management in private sector	H.M. Dias A. Tarimo
9:20 - 10:10	Family-planning and IMCI experience by SHOPS Plus project for improving case management in the private sector	S. Callahan J.A. Yobo
10:10 - 10:40	Discussion	

Session 4 – Experience of private companies in priming the market in malaria-endemic countries

11:00 - 12:00	Perspectives from manufacturers of prequalified antimalarial medicines and RDTs on priming the market in malaria-endemic countries	Panel session
12:00 - 12:15	Perspectives from FLBs of prequalified antimalarial medicines and RDTs on priming the market in malaria-endemic countries	T. Visser
12:15 - 13:00	Discussion	

Session 5 - A strategic framework for engaging the private sector in malaria case management

14:00 - 14:15	Introduction to the working groups	J. Cunningham
14:15 - 16:00	Working groups (Salle D, D13014, D23015 and other)	
16:30 - 18:00	Working groups, continued (Salle D, D13014, D23015 and other)	
Friday 3 May 2019		
8:30 - 10:30	Working groups, continued (Salle D, D13014, D23016 and other)	
11:00 - 13:00	Presentation of working groups and discussion	Working groups
14:00 - 15:30	Consensus-building on core elements and format of a roadmap to improve malaria case management in the private sector	Chairperson
16:00 - 16:30	Summary of points of agreement	Rapporteur
16:30 - 16:45	Proposed next steps	A. Bosman
16:45 - 17:00	Closing remarks	P. Alonso

Annex 4: Templates used in country breakout sessions

Prioritized Diagnosis Production to Use (P2U) Matrix

	Market Function	RDT Manufacturers	Importers	Wholesalers	Providers	Clients / Consumers
Core Functions	Product					
	Price					
	Place					
	Promotion					
Supporting Functions	Information					
	Coordination					
	Guidance					
	Quality Assurance					
	Financing					
	Labour					
Rules Functions	Policy					
	Regulation					
	Taxes and Tariffs					

Tool 1: Where are we now?

Adapted from: Population Services International (2018). *The Keystone Design Framework Manual.*

Future Vision for Sustainability of High-Quality Private Sector Case Management Market (Who does, who pays?)

			Current State		5 Years (2024)		
Market Function (e.g. Product, Price, Place, Promotion, Information, etc.)	Current Constraint	Long-term vision for the function	Who does?	Who pays?	Who does?	Who pays?	Why?

Adapted from: The Springfield Centre (2015). *The operational guide for making markets works for the poor (M4P) approach.*