

# NON-TARIFF MEASURES AND THE FIGHT AGAINST MALARIA

## OBSTACLES TO TRADE IN ANTI- MALARIAL COMMODITIES





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Paper focusing on specific non-tariff measures (NTMs) that could negatively affect the affordability and accessibility of anti-malarial commodities - introduces non-tariff measures and other obstacles to trade; present the results of a business-perception survey, conducted by ITC, on NTMs faced by importers and exporters of anti-malarial commodities (medicines for treating/preventing of malaria, diagnostic tests, mosquito nets, insecticides for indoor residual spraying, and pumps for spraying indoor insecticides).

Descriptors: **Non-Tariff Measures, Trade Barriers, Pharmaceuticals, Medicaments, Medical supplies, Nets, Insecticides, Pumps.**

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English

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## Abbreviations

Unless otherwise specified, all references to dollars (\$) are to United States dollars.

The following abbreviations are used:

ACT	artemisinin-based combination therapies
AED-ARTS	Academy for Educational Development – Applied Research and Technical Services, LLC
HS	Harmonized Commodity Description and Coding System
ITC	International Trade Centre
NTB	non-tariff barrier
NTM	non-tariff measure
WHO	World Health Organization
WTO	World Trade Organization



## Executive summary

Malaria can be prevented and treated. Nevertheless, it is one of the most critical and deadly diseases affecting the developing world. In the fight to eradicate malaria, improving access to anti-malarial commodities such as mosquito nets and anti-malarial medicines is a key concern. To the extent that these commodities are imported, prices depend, among others, on the import process and its related costs. While information about customs duties is available, very little is known about the specific non-tariff measures (NTMs) that could negatively affect the affordability and accessibility of anti-malarial commodities for the most vulnerable populations.

To address this information gap, the International Trade Centre (ITC) conducted a business-perception survey on NTMs faced by importers and exporters of anti-malarial commodities. Building upon ITC's large-scale business perception survey on NTMs and other barriers to trade, this survey was undertaken for the Malaria Taxes and Tariffs Advocacy Project (M-TAP) in collaboration with the Academy of Educational Development – Applied Research and Technical Services, LLC (AED-ARTS). A total of 59 companies and institutions trading anti-malarial commodities were contacted; 31 companies based in eight different countries and all importing into or exporting to malaria-endemic countries completed in-depth telephone interviews.

The survey results show that a significant number of measures applied by malaria-endemic countries are perceived as hindering trade, thus hampering the supply and increasing the price of anti-malarial commodities. In total, about two-thirds of survey respondents indicated problems related to non-tariff measures, with a noteworthy similarity of problems experienced by respondents independent from the product's final destination. In particular, importers and exporters of anti-malarial medicines and, to a lesser extent, mosquito nets are affected by challenging NTMs. In contrast, surveyed entities reported fewer problems related to importing or exporting insecticides, spray pumps and rapid diagnostic tests.

Measures that assess conformity of products, including product registration, inspection requirements and testing, were mentioned most frequently as being burdensome. This indicated that importers and exporters have difficulties in *demonstrating* compliance with technical requirements imposed by importing countries rather than difficulties in *complying* with these requirements themselves. Other NTM cases relate to charges and taxes, non-technical inspection at customs and government procurement.

With the exception of taxes, the non-tariff measures themselves were not perceived as problematic but difficulties were reported to be linked to procedural obstacles, i.e. conditions outside the regulation or measure itself that complicate (or render impossible) compliance with an NTM. As such, nearly half of the NTMs were perceived as burdensome because of delays in administrative procedures. In addition, unusually high fees (e.g. related to product registration) were mentioned, followed by lack of transparency and the necessity of informal payments.

Among the obstacles to trade captured by the survey other than burdensome non-tariff measures, exchange rate fluctuations and transportation cost were reported to have a significant effect on the prices of the traded products for the final consumers.

The survey results underline the need to tackle non-tariff barriers to trade, along with tariffs, if governments wish to improve access to anti-malarial commodities effectively, particularly for their most vulnerable populations.



## 1. Introduction

Malaria can be prevented and treated. Nevertheless, it is one of the most critical and deadly diseases affecting the developing world. This mismatch has led to a number of international commitments and declarations with respect to fighting malaria, amongst them, both from the year 2000, the Abuja Declaration and the Millennium Development Goals (see boxes).

In the fight to eradicate the disease, improving access to anti-malarial commodities such as mosquito nets and anti-malarial medicines is a key concern. At the same time as donations and public provision of anti-malarial commodities play an important role, ensuring affordable prices of those products provided through the private sector, can significantly contribute to the affected population's enhanced access to these goods.

To the extent that anti-malarial commodities are imported, prices depend, among others, on the import process and its related costs. Many countries still impose customs duties on these products and studies have shown that measures and procedures applied at the border of importing countries are hampering access to anti-malarial commodities.<sup>1</sup> While information about customs duties is available,<sup>2</sup> very little is known about the specific non-tariff measures (NTMs) that could negatively affect the affordability and accessibility of anti-malarial commodities for the most vulnerable populations.

To address this information gap, the International Trade Centre (ITC), an agency of the United Nations and the World Trade Organization (WTO), conducted a business-perception survey on NTMs faced by importers and exporters of anti-malarial commodities. This survey was done for the Malaria Taxes and Tariffs Advocacy Project (M-TAP) of the Academy of Educational Development – Applied Research and Technical Services, LLC (AED-ARTS) and complements an analysis of tariffs levied on and tariff revenues obtained from anti-malarial commodities, which was undertaken as part of the same project.<sup>3</sup> For the survey, the following five product groups were considered:

- 1) Medicines for preventing or treating malaria (including artemisinin-based combination therapies)
- 2) Diagnostic tests (including rapid diagnostic test kits)
- 3) Mosquito nets (including long-lasting insecticide-treated nets)
- 4) Insecticides (in particular those for indoor residual spraying)
- 5) Appliances for applying insecticides (i.e. pumps for spraying indoor insecticides)

### Abuja Declaration

'...[By signing the Declaration, the African leaders] committed themselves to an intensive effort to halve the malaria mortality for Africa's people by 2010...'

### Millennium Development Goal 6

Combat HIV/Aids, malaria and other diseases

#### Target C

Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases

### Millennium Development Goal 8

Develop a global partnership for development

#### Target E

In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries

<sup>1</sup> See e.g. Bate, R., R. Tren and J. Urbach, *Still Taxed to Death: An Analysis of Taxes and Tariffs on Medicines, Vaccines, and Medical Devices*, AEI-Brookings Joint Center for Regulatory Studies, Working Paper, 2005.

<sup>2</sup> The web-based application Market Access Map for example, a market analysis tool developed by the International Trade Centre to enhance the transparency of market access, contains customs tariffs (import duties) and other measures applied by 187 importing countries and territories to products from 239 countries and territories. Most favoured nation and preferential applied import tariff rates are shown for products at the most detailed national tariff line level. More information about this and other tools at [www.intracen.org/marketanalysis](http://www.intracen.org/marketanalysis).

<sup>3</sup> International Trade Centre, *Taxing health - the relevance of tariff revenue from anti-malarial commodities in selected countries*, ITC technical paper, 2011.

This paper is structured as follows: the remainder of section 1 introduces non-tariff measures and other obstacles to trade and presents the NTM classification and methodology underlying this paper. Sections 2 and 3 present the survey results, section 4 concludes.

### **1.1. Non-tariff measures and other obstacles to trade**

In recent years, an increasing number of international trade rules and standards have been developed to regulate and facilitate trade, which is considered key for countries' economic and social development. In parallel, the trade arena has seen a proliferation of regional and bilateral trade agreements that, like multilateral trade negotiations, seek to reduce tariffs among others.

While customs duties have been declining over the years to an unprecedented low level today, new trade measures have gained prominence and become increasingly problematic for importing and exporting companies, especially in developing countries. Anti-malarial commodities have not been exempt from these new measures.

NTMs can induce obstacles to trade that are less visible and more complex than tariffs. They refer to a wide range of measures other than import duties, such as technical regulations, product standards, and quotas. It is important to note that non-tariff *measures* are not automatically non-tariff *barriers* (NTBs). The former can very well have no impact at all on trade and is as such a neutral concept, while the latter implies a negative impact. This report aims to identify these *burdensome* NTMs (i.e. non-tariff barriers), but also procedural obstacles, which are problems linked to conditions outside the regulation or measure itself that complicate (or render impossible) the compliance with an NTM. For example, to import a product it may be necessary to have a specific certification (NTM); however, the certification authority or testing laboratory can be excessively costly, slow in response or be located too far away (procedural obstacles related to the NTM).

In addition to burdensome NTMs and procedural obstacles, problems related to the more general business environment (such as infrastructure) are discussed to the extent that they arise during the survey.

This document uses the term '*obstacles to trade*' for all types of obstacles other than tariffs experienced by companies, including NTBs, procedural obstacles and bottlenecks related to the business environment. By definition, companies can experience obstacles to trade in their home country, in trading partner countries but also in transit countries.

As a final note, it is important to recall that NTMs can of course be introduced for legitimate reasons, such as to protect human, animal and plant health, but they can also be misused as an instrument of protection. In this context, it should be noted that the NTM survey and this paper do not attempt to categorise NTMs as legitimate or illegitimate.

### **1.2. The non-tariff measure classification for trade in goods**

A new international taxonomy of NTMs was prepared by a group of technical experts from eight international organizations: the Food and Agriculture Organization of the United Nations (FAO), the International Monetary Fund (IMF), ITC, the Organisation for Economic Co-operation and Development (OECD), the United Nations Conference on Trade and Development (UNCTAD), the United Nations Industrial Development Organization (UNIDO), the World Bank and the World Trade Organization (WTO), and was finalized for adoption in November 2009. This classification is used to collect, classify, analyse and disseminate information on NTMs received from official sources (government regulations), and for working with perception-based data.<sup>4</sup> The NTMs discussed in this paper are classified according to a slightly adapted and simplified version of this classification, which takes into account insights obtained by ITC during a test phase of large-scale NTM surveys. The NTM classification differentiates measures according to 16 chapters (from A to I, see box). The different types of procedural obstacles that can be experienced when attempting to comply with an NTM are listed in table 1.

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<sup>4</sup> Cited with slight modifications from International Trade Centre, *Market Access, Transparency and Fairness in Global Trade: Export Impact for Good 2010* (2010), Box 5, pp. 43-44. Available online at: <http://www.intracen.org/publications> (accessed in May 2011).

**Table 1: List of procedural obstacles to comply with NTMs, and other obstacles to trade**

<b>A. Administrative burdens</b>	A1. Large number of different documents
	A2. Documentation is difficult to fill out
	A3. Difficulties with translating documents from or into other languages
	A4. Large number of checks (e.g. inspections, checkpoints weigh bridges )
	A5. Numerous administrative windows/organizations involved
<b>B. Information and transparency issues</b>	B1. Information is not adequately published and disseminated
	B2. No due notice for changes in procedure
	B3. Regulations change frequently
	B4. Requirements and processes differ from information published
<b>C. Inconsistent or discriminatory behaviour of officials</b>	C1. Inconsistent classification of products
	C2. Other inconsistent or arbitrary behaviour of officials
<b>D. Time constraints</b>	D1. Delay in administrative procedures
	D2. Delay during transportation
	D3. Deadlines set for completing requirements are too short
<b>E. Payment</b>	E1. Unusually high fees and charges
	E2. Informal payment (e.g. bribes)
	E3. Need to hire a local customs agent to get shipment unblocked
<b>F. Infrastructural challenges</b>	F1. Limited or inappropriate facilities (e.g. storage, cooling, testing, fumigation)
	F2. Inaccessible or limited transportation system (e.g. poor roads, road blocks)
	F3. Technological constraints (e.g. information and communications technologies)
<b>G. Security</b>	G1. Low security level for persons and goods
<b>H. Legal constraints</b>	H1. No advance binding ruling procedure
	H2. No dispute settlement procedure
	H3. No recourse to independent appeal procedure
	H4. Poor intellectual property rights protection (e.g. breach of copyright, patents, trademarks, etc.)
	H5. Lack of recognition (e.g. of national certificates)
<b>I. Other</b>	I1. Other obstacles

**Box: Classification of non-tariff measures**

- A.** Technical regulations
- B.** Conformity assessment
- C.** Pre-shipment inspection and other formalities applied by the importing country
- D.** Charges, taxes and other para-tariff measures
- E.** Quantity control measures (e.g. licences, quotas, prohibitions)
- F.** Finance measures
- G.** Price control measures
- H.** Anti-competitive measures
- I.** Trade-related investment measures
- J.** Distribution restrictions
- K.** Restriction of post-sales services
- L.** Subsidies
- M.** Government procurement restrictions
- N.** Intellectual property
- O.** Rules of origin
- P.** Export-related measures

**Chapter A** on technical regulations refers to product-related requirements that are legally binding and set by the country where the product is exported (or imported into). Technical regulations define the product characteristics, technical specifications or the production processes and post-production treatment, and also include the applicable administrative provisions with which compliance is mandatory.

**Chapter B** on conformity assessment refers to technical procedures such as testing, inspection, certification and traceability, which confirm and control that the product fulfils the requirements laid down in the technical regulations.

**Chapter C** on pre-shipment inspection and other (customs) formalities refers to the practice of checking, consigning, monitoring and controlling shipment of goods before or at entry into the destination country. Inspections and quarantine are examples.

**Chapter D** on charges, taxes and other para-tariff measures refers to measures, other than tariffs, that increase the cost of imports in a similar manner, i.e. by a fixed percentage or by a fixed amount.

**Chapter E** on quantity control measures includes measures restraining the quantity of imports of any particular good, from all sources or from specified sources of supply, either through restrictive licensing, fixing of a predetermined quota or through prohibitions.

**Chapter F** on finance measures refers to measures that are intended to regulate the access to and cost of foreign exchange for imports and to define the terms of payment.

**Chapter G** on price control measures includes measures implemented to control prices of imported articles in order to: support the domestic price of certain products when the import price of these goods is lower; establish the domestic price of certain products because of price fluctuation in domestic markets, or price instability in a foreign market; and counteract the damage resulting from the occurrence of 'unfair' foreign trade practices.

**Chapter H** on anti-competitive measures refers to measures that are intended to grant exclusive or special preferences or privileges to a limited group of economic operators (e.g. certain producers or exporters).

**Chapter I** on trade-related investment measures covers measures that restrict investment by requesting local content, or requesting that investment be related to export to balance imports.

**Chapter J** on distribution restrictions refers to restrictive measures related to internal distribution of imported products.

**Chapter K** on restriction on post-sales services refers to measures restricting the provision of post-sales service in the importing country by producers of exported goods.

**Chapter L** on subsidies includes measures related to domestic support provided by a government or government body to producers, such as direct or potential transfer of funds (e.g., grants, loans, equity infusions), payments to a funding mechanism and income or price support.

**Chapter M** on government procurement restrictions refers to measures controlling the purchase of goods by government agencies, generally by preferring national providers.

**Chapter N** on intellectual property refers to measures related to intellectual property rights in trade. Intellectual property legislation covers patents, trademarks, industrial designs, lay-out designs of integrated circuits, copyright, geographical indications and trade secrets.

**Chapter O** on rules of origin covers laws, regulations and administrative determinations of general application applied by the government of importing countries to determine the country of origin of goods.

**Chapter P** on export-related measures encompasses all measures that countries apply to their exports. It includes export taxes, export quotas or export prohibitions, among others. This chapter has to be used when the measure is applied by the exporting country, i.e., when certain documentation has to be granted by the home country's customs, which is not required by the importing partner. (All the other chapters (A to O) refer to measures that countries apply to their imports.)

**Source:** ITC NTM survey classification booklet for interviewers (2010).



### 1.3. The non-tariff measure survey on anti-malarial commodities

The survey underlying this paper builds on ITC's large-scale business perception survey on NTMs and other barriers to trade, which was developed for in-depth national studies aimed at identifying at product, sector and partner country levels the predominant obstacles to trade that a country's exporting and importing companies experience in their daily operations. These large-scale surveys were tested in seven pilot countries throughout 2008 and 2009. At the time of writing, surveys were completed or ongoing for a total of ten countries, with another nine planned for 2011.

While the large-scale NTM surveys focus on one country at a time and cover all export sectors, the survey adapted for this study looked at importers and exporters from several different countries and of anti-malarial commodities only. The selection criterion for companies was that they had to either import into or export to a malaria-endemic country. Given the complexity of obtaining a comprehensive list of entities trading anti-malarial commodities and due to severe time constraints, ITC relied on a contact list provided by the Academy for Educational Development (AED) that included 38 importing and 21 exporting companies.

**Table 2: Number of surveyed importing and exporting companies / institutions, by country**

Importers: 29 (25*)	Exporters: 6
Benin: 1	Denmark: 1
Cambodia: 7 (6*)	Nigeria: 1
Nigeria: 7 (4*)	South Africa: 1
South Africa: 3	Switzerland: 2
Uganda: 11	United States: 1

\* Four companies abandoned the interview before completion. In brackets the number of companies / institutions without counting these four entities.

In total 35 companies and institutions participated in the phone interviews: 29 importers and 6 exporters of anti-malarial commodities (see country distribution in table 2). The institutions interviewed included two governmental agencies, four non-governmental/international organizations, and 29 private companies. Four importers (one governmental agency and three private companies) abandoned the interview before completion. Table 3 lists for each type of anti-malarial commodity the number of importers (or exporters) of these products (with several companies having more than one type of anti-malarial commodity in their portfolios).

**Table 3: Number of companies/institutions per product group**

Product group	Number of companies / institutions
Medicine	17
Diagnostic tests	12
Mosquito nets	18
Insecticides	16
Appliances	12

**Note:** An importer or exporter can trade more than one type of product.  
Total number of companies/institutions: 31.

Given the number and the method for selecting the interviewed exporters and importers and given the lack of information on the total number of companies trading anti-malarial commodities with malaria endemic countries, the survey results should be treated as anecdotal evidence rather than results that are representative for the studied countries or would allow generalization across malaria endemic countries. Nevertheless, the results allow important insights into obstacles other than tariffs faced by importers and exporters when trading anti-malarial commodities.

### **1.3.1. Implementation**

The malaria NTM survey was conducted through in-depth telephone interviews with the objective of (a) identifying companies that experienced non-tariff obstacles to trade and (b) capturing at the product level and by partner country which exact NTMs were challenging for the importing/exporting entity and why. The interviews lasted between 35 and 45 minutes and were performed by an ITC technical officer with experience in NTM classification and survey analysis. The interviews were conducted at ITC facilities in Geneva, Switzerland between 15 June and 13 July 2010.

The questionnaire used for the interviews (see appendix) consists of three parts. The first part covers some basic characteristics of the entity (e.g. type of the company / institution), the products imported or exported, and establishes whether or not burdensome NTMs and procedural obstacles were experienced over the past 12 months. Where this is the case, each problem is recorded in detail during the second part of the interview. The interviewer helped respondents identify the relevant government-imposed regulations, affected products (6-digit level of the Harmonized System), the partner country exporting or importing these products, and the country applying the regulation (i.e. home, partner or transit country). The last part of the questionnaire contains three questions on the importer's (or exporter's) business operations.

Each burdensome measure (regulation) is classified according to the NTM classification described in the previous section. The questionnaire captures not only the type of burdensome NTMs, but also procedural obstacles linked to it, the place where the obstacle is experienced, and the agencies involved, if any.

The NTM survey is confidential which is key to ensuring the greatest degree of participation, integrity and confidence in the data's quality.

### **1.3.2. Survey data analysis**

The analysis of results is based on 'cases'. Each case consists of one NTM (a government-mandated regulation), one company and product affected by this NTM, and one partner country applying the reported NTM. For example, if one company reports three products, each of them affected by the same NTM applied by a given partner country, the results would include 3 cases. If one product is affected by two NTMs in the same partner country, this would result in 2 cases. Similarly, if two different companies report a problem with respect to the same product, partner country and NTM, it would be counted as two cases. Linked to each 'NTM case' is, where applicable, the procedural obstacle (or obstacles) reported by the surveyed entities.

The next two sections present the survey results. First is a general overview of the reported NTMs and their related obstacles. Subsequently, the most frequently reported NTMs are discussed alongside the specific challenges faced by respondents when complying with these NTMs. Section 3 then discusses the results obtained with regard to other issues affecting anti-malarial commodity affordability and accessibility that survey respondents raised during the in-depth interview process.

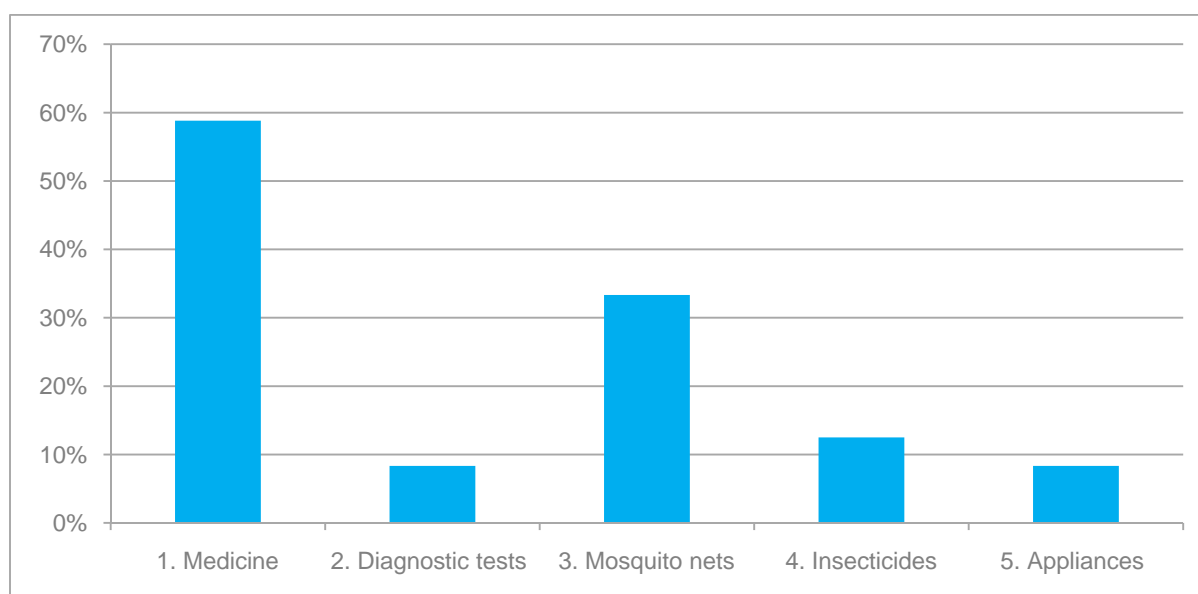
## 2. Reported non-tariff measures and related procedural obstacles

### 2.1. Affected companies or institutions, and product groups

Of the 31 respondents who completed the interview, about two-thirds – 18 private companies and one governmental agency – indicated problems related to non-tariff measures; in addition, one company mentioned only problems related to the general business environment. Interestingly, no non-governmental organizations (NGO) or international organizations interviewed reported on burdensome NTMs or other obstacles to trade. This could be because these organizations benefit from a special status and simplified importing procedures.

In total, 21 cases were reported: 10 for medicine, 1 for diagnostic tests, 6 for mosquito nets, and 2 each for insecticides and appliances for applying insecticides (see also figure 1 where these numbers are expressed as a percentage of all entities in the sample trading each type of anti-malarial commodity). Pharmaceutical products and mosquito nets seem most affected by regulations perceived as problematic: nearly 60% of respondents active in importing or exporting anti-malarial medicine and more than 30% of those trading mosquito nets mention problems related to NTMs. This may be due to stricter product quality requirements, in particular for anti-malarial medicine, but also due to each entity's trade value and volume of these goods; interviewees principally reported challenges for the main anti-malarial commodity they trade. In contrast, diagnostic tests, insecticides and spray pumps seem less affected by problematic non-tariff measures.

**Figure 1: Share of respondents reporting burdensome NTMs, by product group (as % of all interviewed entities trading this type of product)**

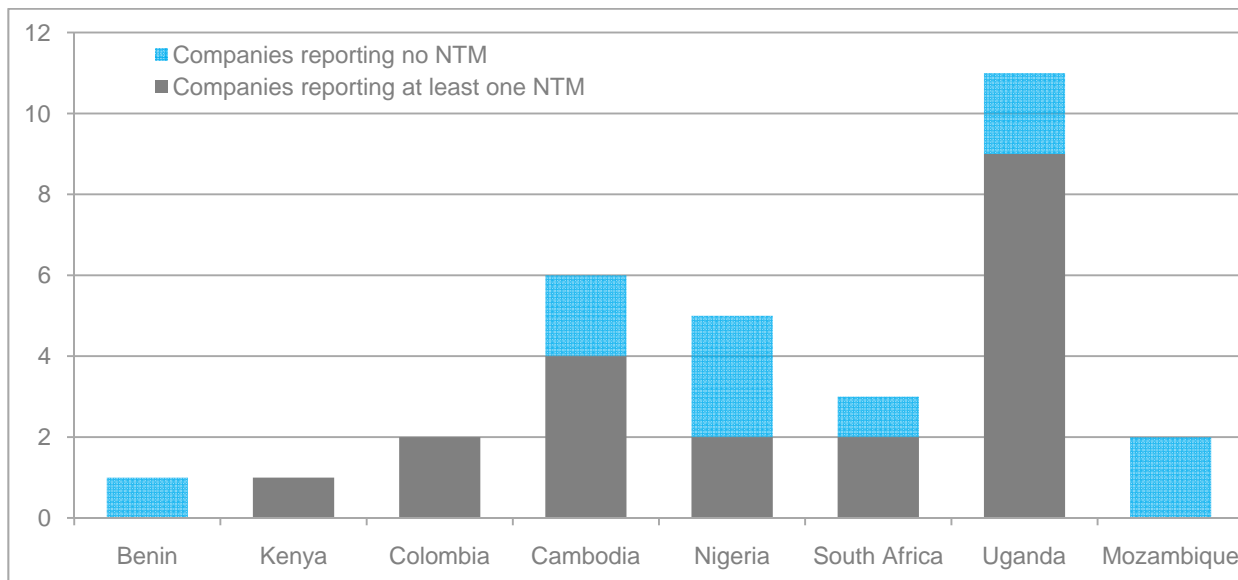


**Note:** Total number of companies/institutions trading malaria medicine: 17; diagnostic tests: 12; mosquito nets: 18; insecticides: 16; appliances for applying insecticides: 12 (see table 3).

Figure 2 disaggregates by country of destination (i.e. the home country for importers and partner country for exporters) the number of respondents, distinguishing between those that report at least one burdensome NTM (grey part of the bar) and those who indicate no problems at all (blue). With the exception of Benin, where the only importer interviewed (an NGO) did not mention any non-tariff barrier, and Mozambique, for which two exporting companies reported no problems, burdensome NTMs are reported for all countries of destination for anti-malarial commodities in the sample. As a note of caution and as indicated earlier, the sample size and selection do not allow inferences about the actual incidence of burdensome NTMs and other obstacles to trade in the respective countries.

Per NTM case, between one and three procedural obstacles were mentioned for a total of 31. When asked whether the reported problems had an impact on the product availability in the market, the majority of respondents (70%) said that the problems caused a delay in product accessibility to the affected population and all but one stated that the burdensome measure affected the price of the concerned product.

**Figure 2: Number of respondents, by country of destination of the traded product (home country for importers, partner country for exporters)**



**Note:** Total number of respondents: 31.

## 2.2. Major problems

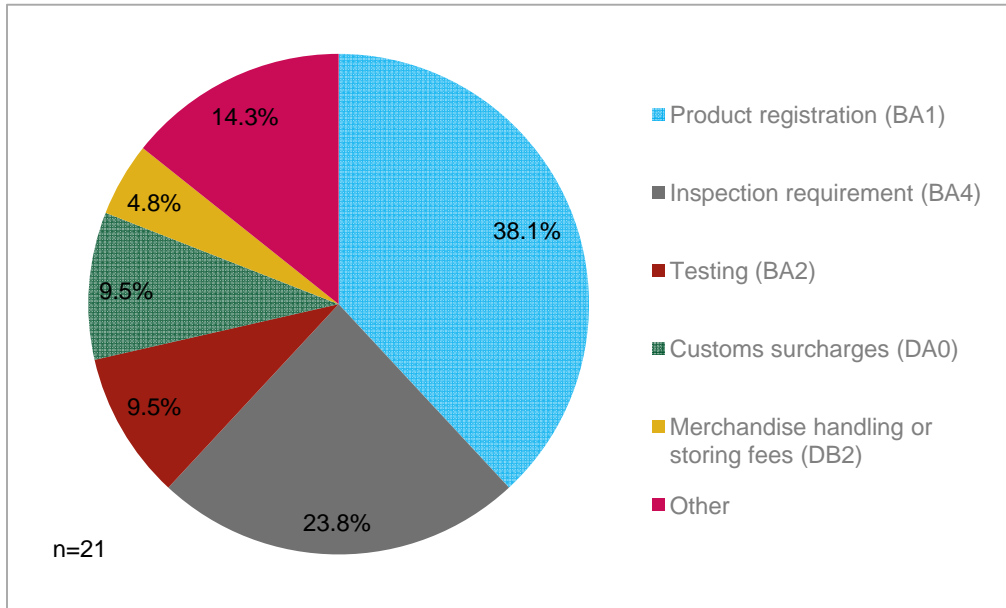
The non-tariff measures perceived by survey respondents as most challenging when trading anti-malarial commodities are shown in figure 3. More than one-third of reported NTM cases (8 of 21) are related to product registration in the importing country. Inspection requirements were mentioned as burdensome in five cases, while measures related to product testing were perceived as challenging in two cases. These first three categories, combined responsible for over 70% of reported cases, all belong to chapter B of the NTM classification containing the group of measures that regulate the conformity assessment of products, i.e. technical procedures such as testing, inspection, certification and traceability that confirm and control that the product fulfils the requirements laid down in technical regulations.<sup>5</sup> This indicates that importers and exporters have difficulties *demonstrating compliance* with technical requirements imposed by importing countries rather than difficulties *complying* with these requirements themselves - interestingly, only one case refers to technical regulations (summarized in figure 3 in the category 'other').

In total, three NTM cases relate to charges and taxes (chapter D of the NTM classification), of which two cases concerned customs surcharges and one merchandise handling or storing fees. Other burdensome NTMs mentioned included non-technical inspection at customs and issues related to government procurement.

In the case of importers, all regulations or bottlenecks reported referred to their home country or a transit country. In the case of exporters (e.g. Denmark or South Africa), they referred to the partner country.

<sup>5</sup> Definition from the ITC NTM survey classification booklet for interviewers (2010).

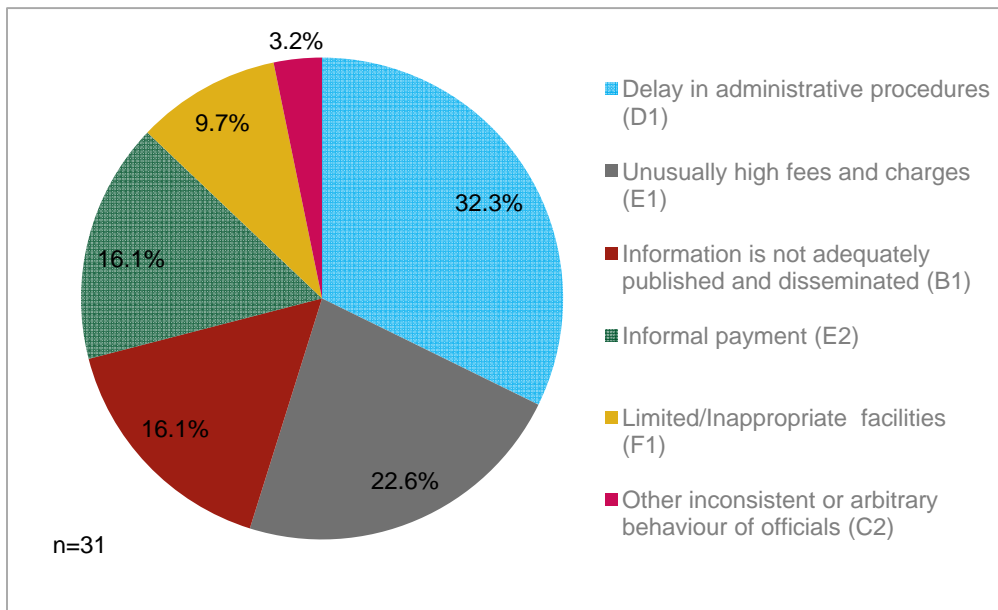
**Figure 3: Non-tariff measures reported as problematic**



**Note:** In brackets the classification code for the respective NTM (see also box 1 for a list of chapters of the NTM classification).

Figure 4 summarizes the procedural obstacles that were experienced by respondents with respect to the non-tariff measures mentioned above. Per NTM, up to three procedural obstacles were reported for a total of 31 for the 21 non-tariff measures. Nearly half of the NTMs were perceived as burdensome because of delays in administrative procedures (10 cases, i.e. 32.1% of all procedural obstacles reported). In seven cases (22.6% of all procedural obstacles), unusually high fees and charges were mentioned, followed by lack of transparency and the necessity of informal payments (five cases each, 16.1%). The most frequently mentioned NTMs and the related procedural obstacles are reviewed in detail in the next section.

**Figure 4: Procedural obstacles related to the burdensome NTMs reported**



**Note:** In brackets the classification code for the respective procedural obstacle (see also table 1).

### 2.2.1. Product registration

- 38.1% of reported NTM cases (8 of 21) concern product registration.
- In five of these eight cases (62.5%), problems related to product registration caused delays in product accessibility to the population.
- In all cases, problems related to product registration had a negative impact on the price charged for the product.

The survey indicates that for respondents, the process of product registration was the most troublesome regulation with which to comply: 38.1% of all NTMs reported in the survey referred to product registration. If a company wants to import anti-malarial commodities it has to register the specific product with the local authorities, usually the ministry of health. Subsequently, the product is usually certified according to national health regulations and an import licence is issued for the specific product that can then be legally imported. Importers of anti-malaria medicine turn out to be especially affected by problems arising in the product registration process. The main procedural obstacles reported with respect to product registration match the most frequently mentioned obstacles displayed in figure 4: delays in administrative procedures, charges and informal payments, and issues of transparency. These are discussed in more detail below.

Many enterprises importing anti-malarial commodities mentioned that the initial registration process was the most challenging; for example, respondents experienced problems when applying for the required product registration documents, such as the import licences. The most pressing issue seems to be **administrative delays**, which were mentioned in five of the eight cases related to product registration. More generally, respondents reported that they had to wait for several months or even up to one year before they received the documents necessary to start importing the anti-malarial commodity. Importers reported that even when all the documents required for the import licence were submitted to the issuing agency (in most cases, the national drug regulation authority), it could take several months to get the certificate or even only an update on the current status of the issuing process. According to some importers, this is due to lack of trained officials, understaffed issuing agencies and general institutional inefficiency. The interviewees also mention that although they can anticipate the adverse conditions that they often face with regard to shipment (especially landlocked countries) and customs formalities, the insecurity about when they will receive the necessary import documentation makes business planning and punctual delivery of anti-malarial commodities to the customer very challenging. As an importer of ACTs stated, *'product registration takes a long time (up to 6 months), with irregularities, which makes it difficult to plan easily.'*

Another major concern mentioned was payments related to product registration, including **fees and informal payments**. Several importing companies reported that the 'verification fee' applied by a national

'In the registration process, the national drug authority required additional testing, apart from officially acknowledged testing labs, so that officials can be sent overseas to "inspect" the facilities, which they take as a free holiday.'

drug authority was 2% of the commodity import value. The fee was perceived as a significant cost as their anti-malarial commodities were valued at several million US dollars. Furthermore, high registration and verification fees also seem to open the door to informal payments and corruption: one responding enterprise importing ACTs reported that *'ministry of health officials have to be bribed to let products pass.'* Similarly, an exporter of mosquito nets reported that the importing country's *'government unexpectedly applied*

*fees for environmental licence testing although we know that products are not actually being tested,'* and that governments often consider product registration fees as an additional source of income (rather than a measure to cover administrative costs). Another respondent estimated that unofficial charges for licences, permits and clearance amounted to about 6%-7% of import value – a significant share in the total shipment value that is passed on to the final consumer.

The case of an unexpected fee for an environmental license leads to another problem experienced by importers and exporters regarding product registration: **the lack of clear and transparent information** about the registration process and requirements. Respondents discussed frequent changes in the registration process that are not sufficiently communicated, thus causing additional delays. The problems range from new documents requested (such as the abovementioned environmental licence) to new registration or implementation procedures. For example, an exporter reported that in order to sell long-lasting treated mosquito nets to a government's national malaria programme they needed to conduct field trials to start the registration process, although the product was recommended by the WHO Pesticide Evaluation Scheme. Despite the WHO recommendation, authorities did not allow registration of this product because the mosquito nets had an ingredient considered to be toxic. This example shows the need for more transparency in product-specific import requirements and better accessibility to this information and related documentation for importing and exporting companies.

The abovementioned problems pose considerable challenges for importers and exporters with respect to planning and timely delivery of anti-malarial commodities. More than half of respondents who reported product registration as problematic stated that these difficulties caused significant delays of more than four weeks and adversely affected the accessibility of the anti-malarial commodity for the local population. In addition, all respondents indicated that these problems had a negative impact on the price charged for the traded product.

### 2.2.2. Inspection requirements and testing

- 33.3% of reported NTM cases (7 of 21) concern testing and inspection requirements.
- In six of these seven cases (86%), problems related to testing and inspection requirements caused delays in the product accessibility to the population.
- In all cases, problems related to testing and inspection requirements were reported to have a negative impact on the price charged for the product.

Behind product registration, inspection requirements and testing were the non-tariff measures most frequently mentioned as hampering the importing process of anti-malarial commodities in destination countries. These are conformity assessment measures through which importers or exporters have to prove their product complies with established requirements in the importing country before being able to access local markets. In other words, it is not the technical regulation (such as requirements regarding active ingredients or the production process) itself that poses the problem, but the process of showing that imported products comply with them. Only entities trading medicines and mosquito nets mentioned inspection requirements and testing as burdensome NTMs.

Similar to the initial product registration process, testing and inspection was perceived as an obstacle primarily because of the time delays experienced. Whereas product registration is usually done before the product leaves the country of manufacturing or export, testing and inspection take place at the importing country's border, with potentially considerable implications for the efficiency (and predictability) of product delivery.

The most common reason cited by the interviewees for **delays at customs** was the high traffic of arrivals at the port of the importing country. As one mosquito net importer noted, the *'inspection process at customs takes too long as*

*'The inspection process at customs takes too long as the port is often congested.'*

*'There are not enough local testing facilities; product samples need to be sent to foreign testing laboratories.'*

*the port is often congested, especially the port Tin Can Island in Lagos.'* Other concerns mentioned by importers were insufficient training of customs officials, insufficient staff members to process import requests efficiently and high levels of bureaucracy. Some importers of quinine injections also reported that the clearing process was not well organized, that there were inadequate testing facilities and obsolete technology, and that the procedures

and delays experienced in many instances depended on the individual clearing agents. Overall, six of seven institutions that reported testing and inspection as challenging stated that problems related to these measures caused delays, of usually between one and six weeks, in anti-malarial product accessibility to the population.

Respondents also mentioned that delays create a loophole for **informal payments** as this becomes a means for 'accelerating' the time-consuming testing and inspection procedures, even when anti-malarial commodities are imported as part of a national anti-malaria programme. It is therefore not surprising that all respondents who reported difficulties in complying with testing and inspection requirements stated that these problems lead to higher product prices. Several respondents remarked in this context that when commodities are destined for national health campaigns, given the limited public anti-malaria budget available from the affected country or the donor organization, this price increase means that fewer than foreseen (and necessary) supplies of the anti-malarial commodities are available.

### 2.2.3. Charges and taxes

- 14.3% of reported NTM cases (3 of 21) concern charges and taxes.
- In all cases, problems related to customs and service charges had a negative impact on the product's end-price.

Charges and taxes are measures other than customs duties that increase the cost of imports at the border. They can take the form of a fixed percentage levied on the total value of the merchandise, or of a specific amount levied on the basis of volume or weight. In the survey, customs surcharges and service charges in the form of merchandise handling and storing fees were mentioned.<sup>6</sup> As these fees are in most cases applied independently from the product type, it is not surprising that the three cases reported concern three different products: mosquito nets, medicine and diagnostic tests.

The charges and taxes are the only examples of non-tariff measures mentioned by respondents in this particular survey which in itself were already perceived as a problem, rather than being a problem because of related procedural obstacles. Generally the rates were considered too high with reported fees ranging from 5%-10% of shipment value. Interviewees questioned the logic of imposing such charges and fees, in particular on potentially life-saving medicines and mosquito nets.

Nevertheless, important procedural obstacles were also linked to these measures, mainly concerning transparency and bribery. Respondents mentioned being unsure what these taxes were used for or whether they were official at all (e.g. a 'withholding' tax for rapid malaria diagnostic tests) and that customs officials charged informal taxes to importers, offering to circumvent even higher official taxes.

## 3. Other factors influencing the price of anti-malarial commodities

In addition to requesting information specifically on restrictions and regulations (NTMs) and their related obstacles to trade, the survey included questions about other issues affecting importers' or exporters' operations that could hamper access to anti-malarial commodities for the importing countries' populations. The interviewees were asked to specify in particular additional factors that impacted the price of the product in the importing country. These could be related to the product's country of origin, the transit country (or countries) as well as the destination country.

Sixty-five percent (65%) of the companies facing obstacles to trade (13 of 20, all private sector) reported on additional factors affecting their prices. These other factors are discussed in the next section in declining order of frequency with which they were mentioned.

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<sup>6</sup> Customs surcharges are an ad hoc trade policy instrument to raise fiscal revenue or to protect domestic industry, while service charges are fees imposed for inspections, quarantines or other services provided by the customs authorities (e.g. storing fees).



### 3.1. Exchange rate

Among the other factors affecting anti-malarial commodity prices, problems linked to the fluctuation of exchange rates, usually between US dollars and the local currency, was the leading point mentioned (11 cases). Many interviewed companies reported that products priced in US dollars became relatively more expensive in recent months. Where anti-malarial commodities are not purchased directly by the local population but by the national health department or an international donor, price increases tend to decrease the quantities purchased as the allocated budget usually stays fixed.

### 3.2. Transportation

For 10 respondents, transportation problems were reported to adversely impact prices of anti-malarial products. The main concerns raised were inaccessible and limited transportation systems (such as poor roads, road blocks and slow or unreliable trains) and transport costs in general, in particular for air-freight.

Transportation cost turned out to be especially relevant for companies importing into or exporting to landlocked Uganda, usually having to rely on transit through Kenya. In particular the port of Mombasa was perceived as crowded and causing import delays. One company stated that *'the Mombasa port is too small and congested; also, there are weighbridges and customs controls all the time on the way to Uganda, which slows down the transport.'* As a result, some importers from Uganda use airfreight instead of boats and trucks or trains to guarantee more rapid and reliable transport. However, this usually implies a sharp increase in the transportation cost, which in turn increases the price of the imported anti-malarial commodity. These observations are in line with the results of ITC's large-scale enterprise survey on NTMs for Uganda,<sup>7</sup> that also identified the poor quality of both railways and roads, along with frequent and often unannounced controls, informal payments and insufficient export- and import-related facilities (e.g. cooled storage) as major factors that make the export and import processes more burdensome and costly.

'The overland transport [through the transit country] is slow and burdensome. However, transport by air is expensive.'

The Uganda example illustrates that landlocked developing countries face a double burden, as they do not only depend on the conditions (e.g. customs and infrastructure) *within* the country, but also on those in transit countries, making them particularly dependent on neighbouring states when shipping goods via land.

### 3.3. Tendering process and distribution

An issue that emerged throughout the in-depth interviews concerned the way that anti-malarial commodities, in particular anti-malaria medicine, was purchased and distributed in the destination country. The importing procedure usually starts with the tendering process in which anti-malaria product producers enter an official bidding process to supply national health ministries with the commodities required for health campaigns. Often, this process causes severe delays (up to six months). One exporter of insecticides mentioned that *'in the tendering (bidding) process, governments make last-minute decisions, leaving little time for importers to acquire the necessary anti-malarial commodities, so the goods have to be flown in by plane, which makes them more expensive, potentially resulting in sub-optimal provision of those goods (governments use less materials in campaigns as the budget is fixed and materials are more expensive when transported by air).'*

In addition, it was reported that throughout this legal tendering process, in which companies place a bid to get a mandate to supply anti-malarial products, the receiving country accepts bribes and awards mandates accordingly. For instance, an exporter supplying appliances for indoor spraying of insecticides to public health projects indicated that officials from the ministry of health require 'personal visits to the overseas facilities', mainly located in Japan, before they approve the anti-malarial appliances. Such practices are perceived as unfair, with importers indicating that such requirements do not contribute to allocating limited resources effectively in fighting malaria.

<sup>7</sup> Report forthcoming.

Another concern raised was the lack of official retail prices for anti-malaria medicine in some countries; one ACT importer stated that there was '*no maximum retail price for malaria drugs*', opening the door to higher prices. Similarly, another importer reported that there were '*too many parties involved between the importing company and the final consumer; several parties in between make a profit, pharmacists for example*'. A more direct link between the producing and importing companies and the final consumer was therefore considered helpful for decreasing prices, particularly of medicine.

'Too many parties are involved between the importing company and the final consumer; several parties in between make a profit...'

#### 4. Conclusion

Despite the small sample size, the business-perception survey on obstacles to trading anti-malarial commodities provided a range of insightful observations that characterize the particular challenges that importers and exporters of these goods face in their daily operations. The newly developed NTM classification allowed the analysis of problems related to NTMs in a more structured and globally comparable way than was previously possible. The in-depth phone interview asked for elaboration on statements made, so the survey methodology captured the multifaceted nature of problems related to non-tariff measures and related procedures. In addition, since all survey data is confidential, the more sensitive issues such as bribery were reported frankly and in detail in most cases.

The survey results identify two main areas of concern with respect to non-tariff measures, linked to efficiency and transparency. With respect to the efficiency, survey respondents highlighted important institutional deficiencies, including lack of (sufficiently trained) staff, in serving product registration demands in particular; but also inefficient customs procedures that lead to significant administrative delays. In other words, it is not the procedures and requirements that are perceived as problems but the time-consuming path to complete and fulfil them. In addition, these delays open the door to bribery in exchange for speeding up the importation process. Improving institutional capacities with the view to enhance the general efficiency of administrative procedures, such as product registration or clearing and inspection at customs, could therefore support a smooth importation of anti-malarial commodities.

Second and linked to the above, transparency was a recurring topic during the interviews. Even when procedures are time-consuming and relatively complicated, transparency on the expected administrative processing time can enhance planning and allow better timing of imports. In addition, clear and easily available information, such as on the number and types of documents needed (for product registration or importation), on the testing required and acknowledged testing facilities, and on taxes as well as other charges and fees applied, can significantly reduce uncertainty on the prevailing legislation, limit the scope for corruption and avoid those delays due to wrong or incomplete information (e.g. missing documents).

In addition to problems related to transparency and efficiency, many survey respondents expressed a lack of understanding of taxes and fees applied on anti-malarial commodities imports, in particular medicines and mosquito nets. These charges, which were reported to reach 10% of the import value, were in general perceived as too high (apart from often being suspected to be informal rather than formal taxes) and as detrimental to the final product price.

Among the obstacles to trade other than burdensome non-tariff measures, exchange rate fluctuations and transportation cost were reported to have a significant effect on the final consumer prices of the traded products.

Concerning the different types of anti-malarial commodities, the results suggest that above all medicines and, to a lesser extent, mosquito nets, are affected by challenging non-tariff measures. In contrast, surveyed entities reported fewer problems related to importing or exporting insecticides, spray pumps and rapid diagnostic tests.

The survey results show that a significant number of measures applied by malaria endemic countries are perceived as hindering trade, thus hampering the supply and increasing the price of anti-malarial commodities. The present survey has revealed a noteworthy similarity of problems experienced by the interviewed importers and exporters, independent from the product's final destination. It is therefore safe to

say that trade in anti-malarial commodities is affected by burdensome NTMs and other obstacles to trade across malaria endemic countries. To draw conclusive statements on challenges related to specific product groups and countries, a large-scale survey would be necessary. Thoroughly understanding and addressing NTMs that affect the accessibility of anti-malarial commodities will be indispensable for countries that wish to reach the goal of eradicating malaria. As a consequence, if government authorities aim to improve access to essential life-saving goods effectively, particularly for their most vulnerable populations, they should not only reduce or eliminate tariffs on these commodities, but also tackle the non-tariff barriers to trade.



## Appendix Survey questionnaire

### BASIC INFORMATION

Complete Q1-Q9 before the interview.

Q1. Company location (city): \_\_\_\_\_

Q2. Date of interview: \_\_\_\_\_

Q3. Company's unique number (as indicated in the sample frame): \_\_\_\_\_

Q4. Company name: \_\_\_\_\_

Q5. Type of company or organization (select only one box):

- 1  Producing and importing company  
 2  Agent, broker, forwarding company, transport company  
 3  Agency of an international organization, non-governmental organization (NGO), etc.  
 4  Governmental agency

Q6. Entity in charge of your import process and compliance with customs procedures and other import related regulations:

Multiple answers possible

- 1  Our company itself (our company has import specialist)  
 2  Partner company abroad which exports goods to our company  
 3  Specialized agent/broker/forwarding company  
 4  Other (please specify): \_\_\_\_\_  
 5  I do not know

Q7. Respondent name: \_\_\_\_\_

Q8. Job title/Function: \_\_\_\_\_

Q9. Department: \_\_\_\_\_

### SECTION 1: PRODUCTS IMPORTED

Q1. Does your company import anti-malarial commodities pertaining to one (or more) of the following categories?

Make multiple selections if necessary:

- 1  Malaria medicine (finished formulation)  
 2  Diagnostic tests  
 3  Mosquito net  
 4  Insecticides (indoor insecticides)  
 5  Appliance for application of insecticides (only for spraying indoor insecticides)

If respondent only imports 1 type of product go to Q3. If respondent imports several types of products, ask Q2.

Q2. Which one of the groups that you mentioned is the main group of anti-malarial commodities that your company imports?

If respondent has difficulties identifying the sector, list the groups he mentioned in Q1. Then, select one group only.

- 1  Malaria medicine (finished formulation)  
 2  Diagnostic tests  
 3  Mosquito net  
 4  Insecticides (indoor insecticides)  
 5  Appliance for application of insecticides (only for spraying indoor insecticides)



## SECTION 2: NTM FACED ON MAIN PRODUCTS AND PARTNER COUNTRIES

In the following 10-15 minutes, we would like to learn more about the products and country (or countries) of origin of your imports where you face burdensome measures/obstacles.

In general, products need to comply with a number of rules and regulations. Some of these, however, impose an additional burden, which might involve a delay of shipment, additional costs and suchlike. Burdensome regulations and procedures may concern the entire process: from production to the final consumer. Some examples include: production process and inputs; packaging and transportation; formalities related to border crossing and customs (for example charges, taxes); licenses and quotas, prohibitions; regulations imposing a certain price on your product; anti-dumping duties; advance payment and exchange rates requirements; behind the border restrictions (e.g. requirements to use a certain retailer). They also include inspections, testing and other assessments showing that a product satisfies the requirements as well as certificates of origin to show that the product was de facto produced in the country of origin that is declared.

Could you please tell us, on what product do you face burdensome regulations/procedures?

Case Number: 1	
Q1. Product code:	(HS 6-digit level or national tariff line level): _____
Q2. Product description:	_____
Q3. Product type:	<input type="checkbox"/> Generic <input type="checkbox"/> Patent/Brand
Q4. Partner country:	_____

Q5. Which mode of transport do you use when importing this product? Is it train, truck, boat?

Only one answer (ask for the most common transport used)

- 1  Truck  
 2  Train  
 3  Boat  
 4  Other (please specify): \_\_\_\_\_  
 5  I do not know

Q6. Please describe the regulation that you experience as a barrier and which is very burdensome or very difficult to comply with (it can be a rule, requirement, regulation etc). Please provide as much details as you can.

\_\_\_\_\_

\_\_\_\_\_

Q7. Is it [home country name] or partner country which applies this regulation?

Select only one box:

- 1  The measure is applied by [home country name]  
 2  The measure is applied by the partner country

Q8. Instructions: After the interview you should identify the correct measure code using the booklet 'NTM Survey Classification' and write it here: \_\_\_\_\_

Q9. Do you know when this measure was introduced? If yes, please provide the year

- 1  Yes \_\_\_\_\_ 2.  No

**Q10.** The measure you have just described can be burdensome because of the nature of the measure itself (e.g. ‘prohibition of import’) or because of a related burdensome process or procedure. For example, the measure is a certificate requirement, and the related obstacle is a long waiting period to obtain this certificate. Or the challenge is not experienced in relation to a specific regulation but only to a procedure/process (e.g. ‘my country customs does not accept the HS Code under which I would like to import my product’). Other examples include administrative burdens, such as a lack of information or efficient procedures; inconsistent behaviour of officials; high payments; lack of legal enforcement or recognition. Obstacles can be also related to the business environment, e.g. to infrastructure and facilities, or security. These obstacles can happen in your home country, partner country or transit country.

**Do you experience such obstacles in relation to the measure you just described?**

1  **Yes**    2  **No**

If the answer is ‘Yes’ ask the remaining questions below, if the answer is ‘No’ start a new case.

**Q11. Please specify which procedural obstacle you experience with the described measure. You can mention different problems.** If appropriate, ask for the number of days of delay, number and names of required documents, amount of additional fee etc.

Obstacle 1	Obstacle 2	Obstacle 3
Description: _____ _____ _____ _____	Description: _____ _____ _____ _____	Description: _____ _____ _____ _____
<b>Q12.</b> Nr of days, documents, amount of fee: _____ _____	<b>Q12.</b> Nr of days, documents, amount of fee: _____ _____	<b>Q12.</b> Nr of days, documents, amount of fee: _____ _____
<b>Q13.</b> Name of involved agency/institution: _____ _____	<b>Q13.</b> Name of involved agency/institution: _____ _____	<b>Q13.</b> Name of involved agency/institution: _____ _____
<b>Q14.</b> The problem occurs in (select one box) <input type="checkbox"/> [home country name] <input type="checkbox"/> Partner country <input type="checkbox"/> Transit country, namely _____	<b>Q14.</b> The problem occurs in (select one box) <input type="checkbox"/> [home country name] <input type="checkbox"/> Partner country <input type="checkbox"/> Transit country, namely _____	<b>Q14.</b> The problem occurs in (select one box) <input type="checkbox"/> [home country name] <input type="checkbox"/> Partner country <input type="checkbox"/> Transit country, namely _____

<b>Q15.</b> After the interview, identify the corresponding code for each obstacle:		
Code: _____	Code: _____	Code: _____

**Q16. Please specify any further details related to this case.**

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**Q17. On how many weeks do you estimate that these measures and/or obstacles delay the accessibility of anti-malarial commodities to your country's population? (If not relevant leave empty)**

- 1  1 – 3 weeks  
2  4 – 6 weeks  
3  More than 6 weeks

**Q18. Are these measures and/or obstacles affecting your price of this product?**

- 1  Yes 2  No

**Q19. Are there any other factors affecting your price of this product? What are these and where does it originate?**

Select the country where the problem occurs and indicate the other factors, e.g. currency exchange rate, transport price increase, contract not respected by partner, etc.

- [home country name]: \_\_\_\_\_  
 Partner country \_\_\_\_\_  
 Transit country \_\_\_\_\_  
 No (use this case for: I do not know, there is no other factor)

**Q20. Do you face burdensome regulations/procedures in another product or vis-à-vis another country?**

- 1  Yes 2  No

If the answer is 'Yes', repeat Q1-19 of Section 2; do this for each case. If the answer is 'no', move to Section 3.

### SECTION 3: BUSINESS OPERATIONS

The following questions are about your company. It will not take more than 5 minutes to answer these questions. Please provide only one answer for each question. All questions refer to the current situation (this current year).

**Q1. How many years has your company been in operation? Less than 1 year, less than 5 years, or more than 5 years?**

- 1  Less than 1 year 3  More than 5 years  
2  Between 1 and 5 years 4  I do not know

**Q2. What is the extent of foreign ownership of your company? That is do foreign partner(s) have ownership of your company, and if so, is it less or more than 50% ownership?**

- 1  No foreign ownership  
2  Foreign partner(s) have less than or equal to 50% ownership  
3  Foreign partner(s) have more than 50% ownership  
4  I do not know

**Q3. Does your import passes through transit countries and their customs?**

- 1  Yes  
2  No, because our company imports from neighbouring countries only  
3  No, because our company uses airfreight  
4  Other (please specify): \_\_\_\_\_  
5  I do not know

Thank the interviewed and end the interview.



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