Specifications for prepackaging antimalarial medicines

Report of a WHO technical consultation

World Health Organization

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Abbreviations

ACT	artemisinin-based combination therapy
alu strip	aluminium strip
combination pack	combination pack – blister pack containing two different medicines
DRA	drug regulatory authority
EDM	Essential Drugs and Medicines Policy (WHO department)
GMP	good manufacturing practice
IEC	information, education and communication
INN	international nonproprietary name
PVC	polyvinyl chloride
PVDC	polyvinylidene chloride
RBM	Roll Back Malaria
TDR	UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases

Glossary

The definitions given below were endorsed by the participants of the technical consultation. They apply specifically to the terms used in these guidelines; the terms may have different meanings in other contexts.

blister packing Packing tablets into a sealed primary packaging of aluminium or polyvinyl chloride (PVC) or polyvinylidene chloride (PVDC).

combination pack A blister pack containing two different medicines.

course The number of doses for one curative treatment based on the specific age and/or weight groups of the patient.

dose The number of tablets (or capsules or other solid form) taken or recommended to be taken at one given time, based on the age and/ or weight of the patient.

prepackaging Blister packing of a course of treatment into a sealed primary packaging ofaluminium or PVC or PVDC, the treatment being composed of individual doses in easily recognizable subunits.

primary packaging The packaging that is in direct physical contact with the tablet(s) or capsule(s) that constitute one dose.

product The prepackaged antimalarial medicine comprising the dose form unit(s), the primary packaging, the secondary packaging and the package insert (patient/prescriber information leaflet).

secondary packaging The outer packaging of a treatment course, containing the primary packages with the separate doses.

unit form The individual tablet (or capsule or other solid form) with its specific active ingredient and excipients.

1. Introduction

A WHO Technical Consultation on Specifications for Prepackaging Antimalarial Medicines was held in Geneva, Switzerland, from 2 to 4 September 2003. The participants are listed in Annex 1.

Early diagnosis and prompt treatment with effective antimalarial medicines is the only lifesaving intervention for people afflicted with malaria. The effectiveness of treatment with antimalarial medicines is, however, threatened by the growing resistance of falciparum malaria to chloroquine and sulfadoxine–pyrimethamine, which were once effective against the disease.

As part of a global strategy to delay the rapid development of the parasite's resistance to antimalarial medicines and to enhance the efficacy of treatment with antimalarial medicines, the World Health Organization (WHO) recommends that antimalarial medicines should always be used in combination, preferably with an artemisinin partner – a treatment known as artemisinin-based combination therapy (ACT). The Roll Back Malaria (RBM) global initiative has set a target of reducing malaria mortality by 50% by 2010, and the early diagnosis and prompt treatment of the disease with effective antimalarial medicines are fundamental components of this strategy.

Even in settings where effective treatment policies are in place, patients' non-adherence to the prescribed therapeutic dose and to treatment schedules poses a serious challenge to effective disease management. The prepackaging of treatment courses that are stratified into age or weight groups has greatly contributed towards enhancing the rational use of medicines (*1*). Prepackaged treatment courses are of particular importance in the treatment of malaria, as the disease is commonly managed without contact with a health worker. The strategy of prepackaging treatment courses has even greater relevance to combination therapy for the treatment of malaria, which requires that the individual medicines are co-packaged in a user-friendly way to optimize their use (*2*).

Antimalarial combination medicines are relatively new products with which many manufacturers, regulatory authorities and health-care professionals have limited experience. It is expected that, as the demand for artemisinin-based combination therapies increases, there will be a corresponding increase in the generic sources of these medicines. An overview of existing combination therapies shows that an array of products is already on the market in Africa and Asia, although such products conform to varying standards with regard to their packaging and the patient information provided.

These changes have made it essential to establish minimum required standards for the prepackaging of antimalarial medicines. The main objective of these guidelines is to assist ministries of health and malaria control programmes in their assessment of different prepackaged antimalarial products. The guidelines will, however, also provide guidance to manufacturers in meeting the basic requirements for prepackaging antimalarial medicines. They are not intended to replace the standard guidelines on packaging for pharmaceutical products, published as an annex to the thirty-sixth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (*3*).

The key issues that need to be addressed in establishing minimum standards for prepackaging antimalarial medicines are:

- ensuring product quality by blister packing in compliance with good manufacturing practice (GMP) requirements, with emphasis on the shelf-life of the finished products;
- providing adequate information that is presented in the right format to enhance ease of use and adherence to therapy by patients and providers. Clear information is particularly important when medicines are used by mothers and other caregivers whose literacy is limited, particularly with regard to medicines supplied outside the public sector;
- meeting the challenges to in-country distribution and regulatory processes and other aspects of the health structure to provide scope for improving end-users' access to effective antimalarial medicines.

Thus, in view of this recognition of the role of prepackaged antimalarial medicines, the RBM department of WHO convened a technical consultation with the following objectives:

- to define minimum technical specifications for the blister prepackaging of antimalarial medicines;
- to define minimum requirements for product labelling, product information inserts, and information, education and communication (IEC) materials for prepackaged antimalarial medicines;
- to elaborate and review the regulatory requirements for registering antimalarial medicines as co-packaged and/or prepackaged products;
- to highlight issues related to improved access (good distribution, storage and other drug management processes) for end-users in relation to "course of treatment" packaging.

The technical consultation took the form of presentations of prepared papers, followed by plenary and group discussions, on the basis of which specific conclusions were reached and recommendations were made. The proceedings of the meeting and working papers form the basis of this report.

2. Background

In most malaria-endemic countries, antimalarial treatment and the use of antimalarial medicines have a number of characteristics, which are summarized below.

2.1 Treatment-seeking behaviour and the rational use of medicines

When health-care centres are several kilometres from villages, communities or homes, the management of fevers at home is the norm in most malaria-endemic regions (*4, 5*). Even in areas where health-care facilities are easily accessible, the inability of patients to pay for medicines and a perceived absence of medicines in the public sector have contributed to the non-use of these facilities. Self-administered treatments using medicines bought from local shops or pharmacies are often inappropriate, in relation to both the choice of antimalarial medicine and its dosage (*4*).

The failure of formal and informal providers to supply effective instructions for the patient contributes to the problems of inappropriate use of antimalarial medicines. Also, the use of antimalarial medicines is often guided by the concept of treating symptoms rather than that of treating the disease. Many caregivers have a low level of literacy, which exacerbates the problems posed by the patient's inability to read and understand written instructions.

2.2 Quality of antimalarial medicines

Data from a recent survey conducted by the WHO Department of Essential Drugs and Medicines Policy (EDM) indicate that significant problems are associated with substandard antimalarial products circulating through the medicine-distribution chains in the African region. These substandard products appear to be the result of non-compliance on the part of manufacturers with GMP guidelines for the production of antimalarial medicines (*6*).

2.3 Cost of antimalarial treatment

The cost of medicines represents a large proportion of the total cost of antimalarial treatment. On the basis of current evidence, it has been estimated that household expenditures on malaria treatment range between US$ 0.39 and US$ 3.84 per person (*7*). New ACTs cost between 10 and 20 times more than current monotherapies and would significantly add to the expenditure on malaria at household level, with the added risk of inappropriate treatment due to non-affordability of the complete course of treatment.

2.4 Capacity development

Adherence to the correct course of treatment is low; yet effective training modules for health workers, pharmacists and dispensers in the public sector and for shopkeepers and pharmacists in the private sector are few and little used. Model courses such as the *Health workers for change* training programme for health workers in the public sector, and the model shopkeeper training programme in Kilifi District, Kenya, are still being used only in pilot or relatively small-scale projects, and little effort has been made to scale up these models.

2.5 Regulatory requirements for labelling

Inserts in medicine packs are designed to provide information for health professionals, not for the clients and end-users. Clear regulations apply to the information that must be included on the inserts of medicine packs. However, the information required by the regulatory authority to be provided for the client is limited to written instructions concerning the dose and the treatment regimen, and the possible side-effects. This information is usually given in very small print, and is expressed in technical language. Currently, limited account is taken of the client's need to understand the instructions in the inserts. Regulatory authorities normally focus their efforts on product control and restrictions rather than on improving access to antimalarial medicines and facilitating their effective use by end-users.

A number of prepackaged antimalarial products are already on the market. The varying standards to which the packs and the product information have been produced, and hence their variable quality, underline the need to establish minimum standards for use by ministries of health and drug regulatory authorities (DRAs) in their assessment of the quality of these prepackaged antimalarial medicines.

3. Technical specifications for prepackaging antimalarial medicines in compliance with good manufacturing practice requirements

The quality of the packaging of pharmaceutical products plays a very important role in the quality of such products. It must:

- protect against all adverse external influences that can alter the properties of the product, e.g. moisture, light, oxygen and temperature variations;
- protect against biological contamination;
- protect against physical damage;
- be compatible with the dosage form;
- carry the correct information and identification of the product.

This section sets out the recommendations on the minimum technical specifications for prepackaging antimalarial medicines. In addition to fulfilling the functions of packaging listed above, prepackaging should ensure that:

- all the doses of a course of treatment are packaged together in a blister pack, and
- the individual doses are in easily recognizable subunits.

In addition, the manufacture of such products should follow the WHO guidelines for GMP for pharmaceutical products *(8)*.

3.1 Prepackaging procedures and processes in compliance with GMP requirements

Key issues in the blister packaging of medicines:

- locality of the plant and packing facility;
- selection of packaging materials;
- packaging process;
- quality control;
- staff and training.

3.1.1 Locality of the plant and packaging facility

Recommendations in the event that a new packaging facility is required

- The locality of the plant should conform to the WHO guidelines for GMP for pharmaceutical products *(8)*, and should in particular allow for environmental control in all areas where the products are exposed to the atmosphere (humidity).

- Select a semiautomatic packaging machine that complies with the specifications contained in the WHO guidelines for GMP for pharmaceutical products *(8)* and that is simple to operate and relatively slow (20–60 blisters per minute). The speed of the blistering process has implications for the quality of the finished product. The speed of production depends on the sophistication of the machine, the expertise of the machine operators and the complexity of the pack. The co-packaging of tablets of different shapes and sizes in the same blister requires special modifications to the machine and a greater expertise on the part of the machine operators and thus influences the speed of production.

3.1.2 Selection of packaging materials

- Select packaging materials that are suitable for the type of product to be blistered (e.g. select coloured polyvinyl chloride (PVC)/polyvinylidene (PVDC) foil for antimalarial medicines that are sensitive to light and humidity).
- Design a user-friendly blister, i.e. one treatment course per blister, with easily identifiable dose subunits.
- Design aluminium foil to facilitate understanding of its functional mechanism and ease of administration.
- Storage and quarantine regulations applying to raw materials and finished products must follow the GMP guidelines *(8)*.
- For blistering, purchase only bulk products: DO NOT DEFOIL.
- Aim to expose the tablet compounds to the atmosphere for the shortest possible time.

Given the link between the quality of a pharmaceutical product and the quality of packaging, pharmaceutical packaging materials and systems must be subject, in principle, to the same quality assurance requirements as pharmaceutical products.

There are, at present, no standard procedures or machines to detect the minimum quality of the aluminium foil, and there are large variations in the quality of the aluminium foil. The stability of the packaged product is significantly better preserved when the packaging material employed is PVC or PVCD; however, these materials are more costly than aluminium strip packaging. Note that aluminium–aluminium strip packaging is not suitable for most products that are co-packaged since these products need to be visually identifiable either by size, colour or shape.

- The two main components of packaging are:
  - the lidding material;
  - the forming film.

- The lidding material is a laminate of:
  - a barrier layer (e.g. aluminium foil), with
  - a print primer on one side, and
  - a sealing agent on the other side (in contact with the dosage form and the forming film).
- The forming film may be a single film, a coated film or a laminate.
- A leak (or seal integrity) test must be part of in-process quality control.

3.1.3 Packaging process

- Factors that can cause degradation of the packaged medicines include:
  - sensitivity of the product to light and moisture;
  - loss of solvent;
  - exposure to reactive gases, e.g. oxygen;
  - absorption of water vapour;
  - microbial contamination.

Protection from exposure to light

- Light-resistant primary packaging for light-sensitive products can be achieved only by:
  - an opaque or amber-coloured container, PVC or aluminium–aluminium strip for blisters;
  - an opaque secondary packaging component; however, the products are often exposed when opaque secondary packaging has been removed.

The packaging must be tested using the *United States Pharmacopoeia* test for light transmission

Protection from water vapour and reactive gases

- Solid oral dosage forms generally need protection from water vapour.
- Water vapour or reactive gases (e.g. oxygen) may penetrate a container closure system by:
  - passing through the surface of a permeable container;
  - diffusing past a seal.

  (Note: plastic containers are susceptible to both of the above.)
- A seal integrity test must be performed during validation and stability testing, and as part of in-process quality control.

Safety aspect

- Packaging components should not leach harmful or undesirable amounts of substances to which the patient will be exposed during treatment.

Potential problems resulting from the packaging material used

- Loss of potency of the active ingredient by:
  - absorption or adsorption of the active ingredient;
  - degradation of the active ingredient induced by a chemical entity leached from a packaging component.
- Reduction in concentration of an excipient due to absorption, adsorption or degradation induced by reaction with a leached substance.
- Discolouration of either the dosage form or the packaging component.
- Increase in brittleness of the packaging component.

3.1.4 Quality control

- Apply and maintain in-process controls every 15 minutes, and complete batch documentation.
- Ensure that the finished product receives its own batch number and expiry date.
- Ensure that the expiry date is defined as the earliest expiry date of any of the active components in the product.

3.1.5 Staff and training

- Train staff to comply with the specific GMP requirements for procedures relating to hygiene, quality control and documentation, as set out in the WHO guidelines *(8)*.

4. Regulatory requirements

Pharmaceutical products need to meet adequate safety, quality and efficacy criteria. This requires a quality assurance system or programme.

Note that prepackaged blisters of antimalarial medicines need to meet the national regulatory requirements.

The structure, provisions and prerequisites for regulatory control, the operating activities of DRAs, and a review of applications for marketing authorization of multisource (generic) pharmaceutical products are contained in the WHO guidelines on marketing authorization of pharmaceutical products with special reference to multisource (generic) products *(9)*.

Key issues: When choosing a manufacturer to prepackage antimalarial medicines, consider the following:

- compliance with GMP and licensing status of the manufacturing facility;
- definition of a "product";
- scheduling;
- labelling.

4.1 Compliance with GMP and licensing status of the manufacturing facility

The criteria used for licensing a manufacturing facility for the prepackaging of antimalarial medicines must be based on the facility's compliance with GMP. This is part of the quality assurance process and ensures:

- consistency in production and quality control, so that
- products conform to prescribed quality standards and meet legal requirements.

Components of good manufacturing practice

A facility meeting GMP requirements conforms to the following prescribed standards:

- manufacturing processes are clearly defined (through batch manufacturing records and batch packaging records);
- critical processes are validated;

- all facilities are provided with:
  – qualified and trained personnel
  – adequate premises and space
  – suitable equipment and services
  – correct materials, containers and labels
  – approved procedures and instructions
  – suitable storage and transport
  – adequate facilities, materials and personnel for quality control
  – clearly written instructions;
- records are maintained in order to track compliance with standard operating procedures and the product master file, and can be easily retrieved;
- there is a proper storage and distribution system to ensure traceability of batches;
- there is a recall policy;
- a system exists for handling complaints.

4.2 Definition of a "product"

- The product is specific to a manufacturer and a manufacturing site and is produced in compliance with a set of specifications.
- Any change either produces a new product or constitutes a major or a minor variation.
- Major or minor changes may require regulatory approval (*9*).
- Two separate products packed together in one pack (strip or pack) become ONE NEW PRODUCT that is different from the constituent products.
- Changing the manufacturer of the registered product may constitute a MAJOR change.

Generic versus new product

- Generic = pharmaceutical and therapeutic equivalence (multisource interchangeable product).
- The introduction of a new non-official strength may require clinical data to be approved by regulatory authorities.
- The formulation of established medicines as a fixed-dose combination may require clinical data to be provided, especially in order to demonstrate bioequivalence.
- Accelerated stability studies may enable the drug regulatory authority to approve the product, subject to real-time stability data being provided when these are available for old-established products which are co-packaged in new strengths.

4.3 Scheduling

In many countries, the antimalarial treatment policy requires that the first-line medicine should be readily available to the public.

- An antimalarial medicine that is scheduled as a prescription-only medicine may require rescheduling as either a general sales or an over-the-counter medicine if it becomes first-line treatment.

Considerations when scheduling:

- antimalarial treatment policy;
- safety and side-effect profile of product;
- product packaging and presentation – course of treatment packs; patient-friendly, usable information;
- patient awareness and compliance: easy for patients to use correctly.

Minimum stability requirements

- Number of batches: at least three.
- Nature of batches: at least pilot batches.
- Nature of packaging: same as that proposed for marketing (blister pack + combo pack).
- Type of study: accelerated (temperature = 45 °C, with relative humidity = 75% for 3 to 6 months) and/or real-time, long-term studies (room temperature with relative humidity of 65%).
- Analytical methods: stability indication, with reference to release and shelf-life specifications.
- Storage condition and duration of testing.
- Shelf-life: maximum 24 months for new products with no real-time stability data or longer if this duration is supported by real-time, long-term studies (*9*).

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5. Specifications for package labelling, package inserts and information, education and communication materials accompanying the product

The contents of prepackaged courses of treatment must include:

1. Blister pack(s) (primary pack)
2. Package insert: mandatory regulatory information
3. Package insert: for consumers: instructions/information prepared by qualified IEC personnel
4. Secondary pack

5.1 Labelling of primary pack (blister pack)

- Minimum requirements for labelling of the primary pack (regulatory):

  – name of the product;

  – international nonproprietary name (INN) and the strength of the active ingredient;

  – dose instructions;

  – batch number and expiry date;

  – the manufacturer's identification.

- The expiry date of the combination pack should be defined as the earliest expiry date of any of the active components in the product.

5.2 Package insert (regulatory)

The present regulatory minimum specification requires that there should be a package insert for prescribers. The minimum requirements for regulatory approval of the package insert are:

- the INN of each active ingredient;
- indications of the product;
- the name and address of the manufacturer (*9*).

5.3 Labelling of secondary pack

The specifications and regulatory requirements for the labelling of secondary packs are contained in the WHO guidelines on marketing authorization of pharmaceutical products with special reference to multisource (generic) products (*9*).

5.4 Information, education and communication materials for prepackaged antimalarial medicines

General considerations: what end-users should know when taking antimalarial medicines

This section highlights recommendations on the minimum general information and concepts that should be communicated to the consumer of the product.

- **Information**

  – Malaria is a curable disease.

  – The earlier you treat it with the right medicine the better.

  – Completing the whole course of treatment is important.

  – If you do not complete the treatment, the malaria is not cured.

  – People need to use the right dosage for their age and weight.

  – If you become sicker during or after completion of the treatment, see a trained health worker.

  – If the child vomits, give the unit dose to replace the one which is lost.

- **Concepts**

  – Malaria is caused by a parasite

  – The longer the parasite is in the body, the more chance there is that it can kill.

  – The full treatment is needed to kill all the parasites; if the treatment is not completed, malaria will come back.

  – Bigger and older children require higher dosage levels.

  – Other diseases may coexist with malaria, or the parasite may be resistant to the medicine.

Regulations governing the information provided on the product label and inserts have focused on satisfying the requirements of drug regulators, and not on satisfying the users' needs. It is important to keep the consumers in mind when designing the packs. One of the main objectives of prepackaging is to improve compliance with and adherence to treatment. To achieve this,

local cultural issues and preferences need to be taken into account. It is necessary to "identify with the customer" and develop instructions from this perspective. The present regulatory minimum specification requires that there should be a package insert for prescribers. It is recommended that there are two inserts: one for the prescriber and one for the consumer, as most antimalarial medicines are now intended for household use and are being sold over the counter. More information is needed for the consumer, and that information should be clear, simple and concise.

The aim of supporting IEC materials for prepackaged medicines is to assist consumers to use medicines correctly. Consumers need to understand how medicines should be taken, and the implications of taking a full course and of NOT taking a full course (i.e. WHY a full course should be taken). Field testing has shown that complicated pharmaceutical concepts are not understood, but that consumers can often understand simple illustrations with a clear message.

Studies have also shown that, although prepackaging improves adherence to treatment, an accompanying IEC strategy is needed to achieve the desired goal. Even though the majority of consumers may understand instructions that are presented clearly, such clarity does not by itself ensure adherence. Consumers need to change their behaviour so that instead of merely treating the symptoms, i.e. treating fever and not taking the full course, they cure the disease by taking the full course. Good IEC materials, designed for interactive use, inspire providers to explain clearly, and enhance consumers' understanding and adherence.

5.4.1 Labelling of primary pack (blister pack)

In addition to the information the provision of which is a mandatory regulatory requirement (e.g. identification of source, dosage of ingredients, etc.), the following information should be included in the labelling of the primary pack:

- This is a medicine for fever/malaria.
- Differentiate dosage between days (e.g. day 1, 2, 3 ...).
- Finish all tablets for a complete cure.
- Differentiate blister pack according to age groups and/or weight by colour and/or other symbols.

5.4.2 Package insert for the customer

The wording should be factual and patient-friendly. Minimum information required:

- Name, dosage form, strength and pack size of product.
- This is a medicine for fever/malaria.
- Malaria is a curable disease. It is caused by mosquitoes that carry parasites.
- The earlier you treat malaria with the correct medicine the better (the longer the parasite is in the body, the greater the chance that it can kill).
- People need to use the correct dosage for their age and weight.
- Finish all tablets for a complete cure.

- The full treatment is needed to kill all the parasites; if the treatment is not completed even when you feel better, malaria will come back.
- If you become sicker during or after completion of the treatment, see a trained health worker.
- If the child vomits, give a tablet to replace the one which is lost.
- Adverse effects, contraindications, precautions and warnings.

If the blister pack is in an individual box, the following information should also be included on that box:

- Identification of a product as a malaria medicine for a specific age and/or weight group – use of colour, symbols, logo, portrayal of fever in the country context.
- How to take the medication.
- State clearly that the prepack constitutes one course for a single malaria attack.
- Finish the x-day course for a complete cure.
- What happens if you do not complete the course/why complete the course.
- Mandatory regulatory information (drug, batch number, expiry date, etc.).

If the blister pack does not have its own individual box, then the above information should be included on the blister pack itself.

5.5 Supporting IEC materials and use of media

- Pictures, symbols and colour enhance communication, but must be tested according to the country context. Cost is a consideration.
- Interpersonal communication to accompany prepacks is most effective, but mass media can also enhance product uptake and use.

Providers must be supplied with supporting educational materials harmonized with the information provided in prepacked medicines. These materials should include teaching aids, posters, information booklets and point-of-sale materials for community health workers, shopkeepers and others.

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Annex 1: List of participants

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[1] All participants completed declaration of interest forms prior to the meeting.

Annex 2: Draft framework to guide analysis of the development and testing of information, education and communication materials for prepackaged antimalarial medicines

Below is the first draft of a framework to be used for guiding the analysis of the process of developing and testing prepackaging designs and other information, education and communication (IEC) materials. The purpose of the framework is to provide a means of collecting examples of the processes followed and of the lessons learnt by countries and groups that have already developed these materials. Such examples will assist other countries by facilitating the process of developing similar designs and materials, enabling them to avoid making the same mistakes that "the pioneers" have made. The collective results obtained by the countries that have already developed and tested prepackaging designs and IEC materials will form the basis of a set of guidelines to be formulated by WHO for developing such materials.

1. Background

- Title of project
- Name of institution
- Who contributed to the development of the IEC materials? (Indicate the professions of the contributors, including the profession of the leader/person in charge.)
- How long did the process take – i.e. from initiating the development of the first version to the production of the final version?
- What was the extent of the budget? Who paid for the project?

2. Medicine pack

Version 1 and subsequent versions of the medicine pack

- How was the first version of the pack developed and on what information was it based? Was any formative research conducted or any other information gathered? If yes, from what group(s) of people was it gathered and by whom? Was any literature used?
- What were the results of the pre-testing: What worked/was understood (by about how many/from which groups), and what did not work/was not understood (by about how many)? How were the insights gained from producing the first version used to produce the next version, and what did this subsequent version look like?
- Show subsequent versions, answering the same questions as above.
- **Final version:** With how many people was the final version tested? (Specify gender and whether individuals or groups.) What percentage of the subjects understood the visuals and the text in the intended way? What made you decide that this should be the final version?

3. Supporting IEC materials and training

- What materials were developed? For whom were they developed? How were they to be used?
- Were the materials pre-tested? If yes – with how many people (specify gender, whether individuals or groups), what were the results, and how were the results used in producing the next version? (Show all subsequent versions, including the final one; explain why this version became final.)
- Was any training undergone by or planned for the group(s) that were to use the materials? How much training did they receive, and who were the trainers?

4. Field testing

- Where were the materials tested (location, type of community)? Why was this location/ type of community chosen?
- With how many and what types of people were the materials tested (males or females, approximate ages, individuals or groups, members of the community, shopkeepers, pharmacists, health workers, others)?

  Note: If the medicine pack and IEC materials were tested separately, please describe the individuals or groups with whom each component was tested.
- Who conducted the testing?
- Did anybody other than the target audience influence the formulation of the text and artwork? If yes – who were they, what was the nature of their input, and how was this used in formulating the subsequent version?

5. Afterthoughts, reflections and lessons learnt

- What has been learnt in the process of carrying out this testing?
- Specifically, what has been learnt about:

  – what people understand (text, visuals, symbols)

  – what people do not understand (text, visuals, symbols)
- What would be done differently if the exercise were to be repeated?
- Would other or additional professionals be involved?
- What has been learnt about testing support materials, and about conducting training to use these materials?
- What advice should be given to others intending to carry out this work?
- Any other comments?

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