Médecins Sans Frontières – Campaign for Access to Essential Medicines
May 2009

PUT PATIENTS' SAFETY FIRST

MSF briefing paper on the quality of medicines

Identifying the greater problem

Like all other actors in the field of public health, Médecins Sans Frontières (MSF) teams are faced with the problem of medicines that do not meet World Health Organization (WHO) standards for quality.

The problems of quality of medicines are linked to two main causes: substandard medicines on the one hand and fake medicines on the other. Substandard medicines are genuine drugs produced by originator and generic manufacturers, which do not meet the quality standards set for them. Fake medicines, often called counterfeit medicines include those manufactured with criminal intent, by deliberately and fraudulently mislabelling drugs, giving a false representation of identity and/or source, so that people will think they are legitimate medicines. Products from both originator and generic manufacturers can be faked.

MSF's experience, gleaned from our projects and evaluations in over 70 countries, indicates very clearly that substandard medicines are widespread and represent by far a greater public health problem than is recognised in current debates.[1]

Ensuring medicines meet quality standards

There is an urgent need for improving access to medicines which are in line with WHO standards for quality, efficacy and safety. The focus of attention must be on the detection and removal of poor quality medicines, whether they are fake or genuine, while at the same time putting adequate measures in place to ensure legitimate manufacturers improve the quality of their pharmaceutical production.

Improving standards of practice at all stages of the supply chain is vital. Quality issues affect both Northern and Southern producers, effective systems of regulation thus need to be applied to all. Some developing countries have limited capacities and other constraints; long-term technical assistance may be needed where national capacity is considered insufficent after assessment and evaluation of current outcomes.

WHO's Prequalification Programme (WHO PQ) is a benchmark for the identification of quality essential medicines and has significantly improved access to quality HIV/AIDS, tuberculosis and malaria medicines over the past years. A key factor of success has been that

[1] J.-M. Caudron, N. Ford, M. Henkens, C. Mace, R. Kiddell-Monroe and J. Pinel. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. Trop Med and Int Health, Vol. 13 no 8 pp 1062-1072 August 2008. Available from: http://www.msfaccess.org/fileadmin/user_upload/key-publication/Trop_Med_and_Int_Health_vol_13_Substandard%20Meds.pdf

financial support to national programmes has been dependent on purchasing medicines respecting clear quality assurance criteria. In this the WHO PQ Programme played an important role, providing guidance to purchasers on the quality of medicines, and thereby creating a positive market dynamic where manufacturers strive to reach WHO standards in order to comply with procurement policies.

The lessons learnt from this success need to be applied to other essential medicines. Unfortunately, the majority of donors today do not have sufficient quality assurance criteria that ensure all medicines are purchased based on WHO guidelines. This gives a wrong signal to manufacturers by removing the incentive to comply with WHO norms and standards, and ultimately endangers patients' health in countries where the regulatory system remains weak.

There is no one-size-fits-all solution. It is clear from the wide range of actors and their interests that there is no single course of action that will be sufficient to significantly tackle the problems posed by substandard medicines.

MSF has identified some actions that could serve as a starting point to improve the situation. These actions have been outlined in a recent publication.[2]

Confusion stemming from use of the term "counterfeit"

Lately, the majority of international attention and action is directed at 'counterfeits'. This trend now poses substantial problems - recent examples have shown how the public health concerns raised by fake drugs can be misused to create considerable risks for access to genuine medicines.

Discussions on 'counterfeits' routinely create confusion and conflate issues relating to quality, fraud and intellectual property rights. Multiple definitions have been proposed for what is included under the term 'counterfeit medicine'. From a public health perspective, a big concern is that the deliberate and fraudulent copying of the logo or brand of a legitimate drug, whether originator or generic, is done to disguise the fact the contents have been faked and may contain toxic ingredients or incorrect amounts of ingredients.

However, the use of the term has been diverted, to focus not on health concerns but rather on commercial interests. This is of concern for two reasons:

- Firstly, it promotes the wrong or inadequate responses to address public health concerns - fighting against trademark infringements and preventing generic logos from being similar to originator logos will not stop the danger of poor quality fake medicines in circulation.
- Secondly, excessively broad definitions of the term 'counterfeit' can be misused. In cases where the term is used to mean all forms of copying, it can in fact raise barriers to access to lawful generic medicines.

The recent misuse of the term 'counterfeit' has been seen in two areas – patents and trademarks.

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[2] J.-M. Caudron, N. Ford, M. Henkens, C. Mace, R. Kiddell-Monroe and J. Pinel. Substandard medicines in resource-poor settings: a problem that can no longer be ignored. Trop Med and Int Health, Vol. 13 no 8 pp 1062-1072 August 2008. Available from: http://www.msfaccess.org/fileadmin/user_upload/key-publication/Trop_Med_and_Int_Health_vol_13_Substandard%20Meds.pdf

Patents
Patent disputes and legitimate generics must not be confused with fake drugs. This has been recognised by numerous stakeholders, including the IFPMA.[3] Whether a drug infringes a patent is an entirely separate matter from whether a drug is unsafe.

Yet there have been two recent examples of such confusion, which threaten access to medicines.

The first concerns the Kenyan Anti-Counterfeit Act adopted in December 2008 and a similar bill currently under consideration in Uganda, which contain excessively broad definitions of what constitutes a 'counterfeit' product by potentially including legally-manufactured generics. As such, legally manufactured and/or imported generic medicines of approved quality may be erroneously interpreted as 'counterfeits' because of the provisions of this Act.[4]

The second surrounds the customs regulations in the EU, originally introduced to combat trademark infringments, but which have since been expanded to cover other intellectual property infringements, including patent infringements. Serious concerns have arisen in recent months about the potential impact on access to medicines resulting from the 'detentions' of generic medicines in transit in the Netherlands from India to Brazil, and from India to Nigeria (procured by international drug purchasing agency UNITAID), on the grounds of patent infringement in the EU. The logistical operations of MSF and other humanitarian agencies, which consolidate procurement supplies in the EU en route to other countries, could also be harmed by customs officials' enforcement of this type of regulation.

Trademarks
'Counterfeit trademark goods' is a term legally-defined in the TRIPS Agreement.[5] Here, the TRIPS Agreement is designed to protect the trademark owner from commercial or financial loss due to its brand or logo being copied when, for example, another legitimate manufacturer uses a similar sounding name or logo to market genuine drugs.

The act is indeed a form of copying - but the focus of the concern is mostly commercial. Regulatory agencies make sure that the name or look of a drug is not confusing for patients. However, trademark disputes can go much further. For example, two manufacturers of legitimate and registered drugs may fight in court over a similar sounding name or logo. This is a 'counterfeit' issue under the TRIPS Agreement – but it is not a health issue.

Conclusions and recommendations

The persistence of unclear thinking and misdirected action is putting at risk international efforts to ensure access to adequate quality, safe and affordable medicines as part of the right

[3] www.who.int/entity/impact/resources/IMPACTthirdgeneralmeeting_%20report.pdf
[4] See MSF briefing document – Fatal Confusion: How Kenya's 2008 Anti-Counterfeit Bill Endangers Access to Medicines, October 2008. Available from: http://www.msfaccess.org/resources/key-publications/key-publication-detail/?tx_ttnews%5Btt_news%5D=1497&cHash=fa92956fc1
[5] "Counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

to health. There is a need to improve the evidence base on availability and problems of both fake and substandard medicines based on clear definitions and transparency.

Substandard medicines:

- More political will is needed at national and international level to recognize the burden of substandard medicines and its public health implications as a priority for action, and to commit to implementing appropriate actions for improving standards of practice at all stages of the supply chain.

- Donors and drug purchasers should make sure that medicines bought on behalf of developing countries meet WHO norms and standards.

- WHO should identify the most adequate actions to improve the situation in the short and long term, together with partners, and to assist member states to improve their practices.

Fake medicines:

- WHO needs to acknowledge that the public health concerns about fake medicines have been hijacked to promote trade and commercial issues and not solely prevent public health problems . While health professionals may know what they mean when they use such terms, this understanding is not shared. The term 'counterfeit' itself has thus become a problem.

- WHO should quickly lead an independent, member-state-driven process that reviews whether this term can still be used, provided further clarification is given, or whether new term or terms must be used in order to unequivocally distinguish public health concerns from commercial issues.

- WHO must provide guidance on appropriate measures that drug regulatory agencies can take to tackle fake drugs. The process for establishing such guidance must be independent . If external stakeholders are consulted there must be clear conflict of interest rules. Any solutions must be subject to independent review and must be tested for their effectiveness in resource-poor settings before being endorsed. The solutions must be tested to ensure they do not create barriers to generic competition and should specifically include safeguards from the misuse or over-reach of these solutions.

- WHO also needs to strongly speak out against legislation or other measures that throw up harmful barriers to the trade in and availability of legitimate generic medicines. All actors involved in drawing up policies to fight fake medicines must clearly justify that the recommended measures address health problems and not those that simply are commercial disputes between companies.

- Quality drugs at affordable prices: Trade in fake medicines is encouraged when quality affordable medicines are not available. One effective measure to combat this trade is to ensure the availability of quality drugs at affordable prices. If people had systematic access to affordable, effective medicines of assured quality, those engaging in fraudulent activities would have very little space to operate.