

Statement on Agenda item 13.7: Substandard/spurious/false-labelled/falsified/counterfeit medical products

I am making this statement on behalf of CMC Churches Action for Health and other like-minded public interest non-governmental organizations.

We believe that every individual has a right to access safe, quality and efficacious medicine and steps do need to be taken to ensure the safety, quality and efficacy of medicines.

In this regard we would like to raise a three points:

First, a critical component of addressing the problem of proliferation of compromised medicines is ensuring the availability of medicines at affordable prices as prompt and wide availability of medicines at affordable prices eliminates the incentive for engaging in the business of compromised medicines. We believe that this issue has not been given sufficient attention as a solution to dealing with compromised medicines and urge member states to agree to bold solutions to deal with “high prices” of medicines, as without adequately resolving this problem we are unlikely to satisfactorily resolve the problem of compromised medicines

Second, we are of the view that in order to effectively address the issue of compromised medicines, we need to be focused on strengthening national drug regulatory systems.

We would like to highlight a recent study by WHO of the regulatory systems of 26 sub-saharan African countries which concluded that “On the whole, countries did not have the capacity to control the quality, safety and efficacy of the medicines circulating on their markets or passing through their territories. Regulatory capacity should be built urgently in African countries”.

In this context we are increasingly concerned with initiatives that have lost sight of the need to work on strengthening drug regulatory capacity and that are instead diverting scarce resources to “quick fixes” such as strengthening enforcement agencies, technology that will do very little in protecting public health in the long term.

We urge member states to once again refocus their attention to addressing the two root causes of proliferation of compromised medicines that we have raised.

Thirdly, we also urge member states to take decisions on this matter guided by concrete and reliable evidence. Presently all sorts of statistics are bandied about on the extent of the problem of “counterfeit medicines”. However it is a fact that these statistics are largely from industry groups and simply cannot be supported.

Due to the confusion over the term “counterfeit”, it is also common for statistics to conflate the problem of substandard medicines with infringements of intellectual property.

We are of the view that obtaining reliable evidence based on well-defined and transparent methodology on the extent and nature of the problem is important to have a better understanding of the problem and to enable development of suitable solutions.

We support the renewal of the working group and urge the working group to take up issues mentioned above when they meet again.