

# Executive Summary

Medicines and pharmaceutical treatments are today manufactured, sold, distributed and dispensed across the globe. Complex and interlinked supply and demand chains mean manufacturers, distributors, wholesalers, pharmacists, healthcare professionals and patients all make up a global network of producers, sellers and consumers of pharmaceuticals. The globalisation of the health care sector and the free movement of its goods and services has had enormous benefits: for example, patients can now access medicines that were in the past either not produced locally or far too expensive to import and access.

However, the globalisation of pharmaceutical markets and production has also increased the spread and prevalence of medicines which are unsafe. Broadly speaking, unsafe medicines can be divided up into two categories: counterfeit medicines and substandard medicines. Counterfeit medicines are defined by the WHO as being 'deliberately and fraudulently mislabelled with respect to identity and/or source'.<sup>1</sup> Substandard pharmaceuticals, on the other hand, are those which have been legally authorised for manufacturing and, more often than not, approved for market and sale by a national or regional Drug Regulatory Authority (DRA) but which do not meet the required quality or safety requirements for that particular drug or treatment.

This paper has attempted to show, firstly, just how serious a threat substandard and counterfeited medicines are to public health and, secondly, to discuss how the regulations of the production, sale and use of medicines can have an impact on the availability of these dangerous drugs. The paper began by examining the very nature of medical and pharmaceutical regulations: Why are they necessary? What are the concepts and ideas drug regulations are based on? And what are some of the essential best practices? It then moved on to examining how drug regulations have been designed in a number of countries (China, India, Brazil, Argentina and Turkey) which have experienced problems with substandard and counterfeited drugs. By examining each country separately it was found that because they all faced different sets of challenges, drug regulators and policymakers had responded to them differently. In some cases this had led to positive results; in other instances the results were less encouraging. The paper's final section provided some concrete examples of the lethal effects counterfeiting and substandard drugs can have on public health and how bad, non-existent or un-enforced regulations can play a serious part in this process.

The evidence from this paper's sample of China, India, Brazil, Argentina and Turkey shows that while the problems of substandard medicines and counterfeiting are widespread they also affects countries differently. The specific problems each individual country has to grapple with, depends on the legislative, regulatory, cultural, and socio-economic policies and make-up of that country. As such

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<sup>1</sup> WHO, *The World Medicines Situation*, (Geneva 2004), p. 34-35

there are no easy or quick fixes. Some problems can be addressed relatively easily, while others require hard thinking, large resources, and national – or even international – coordination.

The paper made the following policy recommendations which were divided into two categories: general recommendations valid for all countries, and some country-specific recommendations.

### General Policy Recommendations

<ul style="list-style-type: none"><li>- Recognise the problem. Governments in all countries (and across the world) must acknowledge the extent to which the production of substandard drugs and counterfeiting is a real threat to public health and safety. This is the first step towards action.</li></ul>
<ul style="list-style-type: none"><li>- There must be a better understanding at the regulatory, policy and public level of the differences between substandard and counterfeited drugs. While the effects of the two are often similar – detrimental and sometimes lethal health outcomes to patients – their causes are not always the same. Counterfeiting is the deliberate production of illegal, unsanctioned and mostly harmful medicines. Substandard drugs, by contrast, can be produced, sold and distributed by completely legitimate and authorised entities who are often unaware of their product being (or becoming) substandard.</li></ul>

### Country-Specific Policy Recommendations

<ul style="list-style-type: none"><li>- <b>China:</b> China must do better at implementing its existing regulatory framework. While resources for the SFDA have been increased and there is improvement in national and international coordination, Chinese regulators and policymakers must make enforcement a greater priority.</li></ul>
<ul style="list-style-type: none"><li>- <b>India:</b> Indian drug regulations are highly disparate, inefficient and not well-enforced. Regulations should be streamlined and a clear regulatory framework and source of authority should be established. The current split between central and provincial functions does not foster efficiency or effectiveness. The resulting provincial and regional differences of rules, regulations and enforcement are at the heart of India's difficulties with substandard and counterfeited medicines.</li></ul>
<ul style="list-style-type: none"><li>- <b>Brazil:</b> Like China, Brazil's enforcement mechanisms and authorities need to be strengthened. Legislation introduced in 2003 to effectively outlaw similars by 2015 is a step in the right direction, but the long time frame leaves many potentially dangerous drugs in circulation.</li></ul>
<ul style="list-style-type: none"><li>- <b>Argentina:</b> Unlike Brazil, Argentina has not addressed the existence of non-bioequivalence tested similars and should do so. ANMAT should also introduce a more comprehensive system of pharmacovigilance which increases the burden of reporting onto health professionals.</li></ul>
<ul style="list-style-type: none"><li>- <b>Turkey:</b> Regulations of pharmacists and pharmacovigilance must be improved and implemented more effectively on the ground.</li></ul>