

Executive Summary

Early last year the Stockholm Network published a paper entitled Keeping Medicines Safe which looked at the spread of substandard medicines. The paper formed part of our Patient Safety Series which puts patients' wellbeing and better quality of care at the heart of all our policy recommendations. In the paper, the serious threat to public health posed by substandards was highlighted and the regulations used in the approval, manufacture, sale and use of medicines were examined.

In particular, the paper focused on five countries, Argentina, Brazil, China, India and Turkey, all of which form part of a general grouping described as "emerging markets". The task of this paper is to develop further the findings explored in the previous paper, in particular by broadening the scope of our research to include four additional markets: Egypt, Peru, Russia and Thailand. The importance of these countries relates to the growth in their domestic pharmaceutical markets and in their role in the trade of pharmaceuticals internationally. As a result, they will form an important supplement to what has already been explored in the previous paper. In studying these four additional countries, the purpose of this paper will be to explore the problems that substandards may pose and the effectiveness of regulation designed to prevent such medicines from entering the market.

At present, there is a somewhat blurry distinction between the terms "substandard" and "counterfeit" in regards to pharmaceuticals. The tendency to group substandards and counterfeit medicines collectively is based on a belief among policymakers that a strategy to tackle counterfeits will inevitably prevent substandards from spreading as well. This is because the existence of both substandards and counterfeits can be indicative of the same or similar problems of ineffective drug regulation and enforcement. Therefore, coordinated action is rightly aimed at encouraging more rigorous regulatory control of medicines and enforcement by national DRAs in the developing world. Yet, these are often focused on preventing and detecting counterfeit medicines, which whilst substandard, do not account for all harmful pharmaceuticals that may be in the healthcare system. To complement this, more action is now needed to encourage countries to establish standards that ensure products meet the necessary, internationally accepted criteria of quality, safety and efficacy, which substandard manufacturers would be unable to meet.

The four countries studied in this paper all have flaws in how they regulate against substandard medicines reaching the market. The proof is in the scale of inferior products that are consumed within their healthcare

systems today. The reasons why these countries suffer from high incidences of substandard medicines vary, yet there are a few common themes that present themselves in all four countries:

- Ineffective legal and regulatory frameworks;
- Ongoing gaps between the "text book" legislation and practices on the ground; and
- Lack of transparency, rule of law and even exposure to corruption.

Each country in this study has a great deal of work to do if it wants to rid its public health system of substandard and counterfeit medicines. Specifically, the following policy recommendations should be taken into consideration:

In **Egypt**, recent political developments should push for the implementation of fresh legislation aimed at dealing specifically with those manufacturers which produce inferior pharmaceutical products before instigating reforms to expand healthcare coverage. In addition, there needs to be a substantially increase in the level of enforcement, as well as a greater degree of compliance with international organisations, such as the World Health Organisation, that are taking action against producers of substandards in Egypt.

In **Peru**, there needs to be a greater emphasis on public awareness of the problem of substandard medicines and on enforcing regulations on the manufacturers, in line with internationally-recognised standards, with tough, prohibitive sanctions on those that fail to comply

In **Russia**, new legislation that imposes GMP standards on domestic companies should be implemented rigorously with tough penalties for those who do not comply. On top of this, Russia should look to introduce greater transparency in pharmaceutical decision-making and tougher penalties for manufacturers and producers of substandards and counterfeits.

In **Thailand**, modern legislation is needed to replace the archaic laws currently governing pharmaceuticals. Standards requirements should be introduced for all companies supplying pharmaceuticals in the healthcare system and the relationship between the GPO and the Thai healthcare system needs to be reformed to allow for greater transparency and accountability.