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THE KENYAN ANTI-COUNTERFEIT REGULATIONS 2010

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The Anti Counterfeit Regulations 2010 (the "Regulations") were published subsequent to the Anti-Counterfeit Act of 2008 (the "Act") under legal notice no. 126/2010 on 27th August 2010and come into force with immediate effect.

The Act's main positive advantage is that it establishes an Agency which will co-ordinate the fight against counterfeits across Kenya in an efficient and simple manner. The publication of the Regulations has now provided a mechanism for IP rights owners to use the Act to enforce their rights. Under the Regulations, Intellectual Property (IP) Right Owners can now submit particulars of their IP rights to the Anti-Counterfeit Agency (the "Agency") who will maintain a database of such particulars. This will enable the Agency to actively investigate and eliminate suspected counterfeit practices in Kenya. The Regulations also permit affected persons through their agents to report suspected counterfeit goods to the Agency, whose inspectors are empowered to search, seize and assess any breaches of the affected persons IP Rights.

The Pharmaceutical industry is among the key areas likely to be significantly affected by the Regulations. While on the one hand these Regulations will help protect Kenyan consumers against potentially harmful counterfeit medicines, on the other hand, the laws as drafted may be interpreted in a manner which may work as a barrier to the availability of cheaper generic medicines that currently serve as a lifeline to a majority of the low income generating members of the country's population. In determining the likely stance the Agency will take, it is vital to appreciate the definitions of what constitutes a counterfeit medicine under the Act and whether that definition could be reasonably interpreted to extend application to generic medicines.

In our analysis of the Act we note that it provides that the act of "Counterfeiting" means, in relation to medicine, taking the following actions without the authority of the owner of the intellectual property right subsisting in Kenya or elsewhere in respect of protected goods:

"The deliberate and fraudulent mislabelling of medicine with respect to identity or source, whether or not such products have correct ingredients, wrong ingredients, have sufficient active ingredients or have fake packaging."

The law goes further to define 'Counterfeit goods' under Section 2 of the Act to mean goods that are the result of counterfeiting and include any means used for purposes of counterfeiting.

Generic medicines are made using similar or sufficient active and correct ingredients as those used by the innovator company's medicine and are sold under a brand which is different from the innovator company's brand for the particular medicine. They are equivalent versions of the originator medicine and provide the same quality safety and efficacy as the original brand name product having undergone strict scrutiny before they are licensed and given market approval by the relevant national medicines authority. They are not counterfeit medicines.

That said, an analytical interpretation of the above provision of the Act would mean that it is possible that generic medicines may be labelled as counterfeit medicines. In addition, counterfeiting may apply to both branded and generic medicines. Counterfeit products may include products with the correct ingredients or the wrong ingredients, lacking active ingredients, with incorrect quantities of active ingredients, or with fake packaging. Therefore this provision does not give similar treatment to generic medicines as it does to the original innovator's medicines creating an unhealthy market in terms of competition.

The above scenario has been the subject of litigation in the Kenyan High Court in the case of Patricia Asero Ochieng', Maurine Atieno and Joseph Munyi versus The Republic (High Court Civil Suit No. 409 of 2009). In this case, the Petitioners filed a Petition seeking declarations that their fundamental rights under Sections 70 and 71 of the Kenyan Constitution were likely to be infringed with the implementation of the Act arguing that it limited access to affordable and essential drugs including HIV/AIDS generic drugs and that consequently the enforcement of the Act would infringe their constitutional rights. After finding that the Petitioners had sufficiently demonstrated that the Petition is not frivolous and discloses an arguable case with chances of success, the learned judge granted an injunction staying the application and enforcement of Section 2, 32 and 34 of the Act as relates to the importation of generic drugs and medication and an injunction in the interim restraining the Anti-Counterfeit Agency from enforcing the same sections of the Act relating to the importation of generic drugs and medication pending the hearing and determination of the suit.

It is our view that, the Act needs to be amended to define counterfeiting of medicines as has been defined by the WHO; *"The deliberate and fraudulent mislabelling of medicine with respect to identity or source."*

In light of the above, and as we await a final conclusion of the pending case in the High Court, it will be interesting to monitor the Agency's stance towards producers and distributors of generic

medicines as this will mark out the parameters that will be involved in the fight against counterfeit medicines.

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