

ABSTRACTED SCIENTIFIC CONTENT

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Generics and off-patent biologicals for cancer treatment in developing countries

Cancer represents a significant, and growing, burden on health-care systems around the world. Population growth and ageing will increase the number of new cancer cases in the coming years [1].

Furthermore, cancer is becoming a more widely recognized health issue in developing countries. The understandable focus on infectious diseases, such as human immunodeficiency virus (HIV), tuberculosis (TB) and malaria, has meant that an increasing burden of non-communicable diseases (NCDs), notably cancer, now needs urgent attention [2]. Generics and biosimilars offer a lower-cost approach to treatment, but these drugs raise challenges of their own.

Cancer is a growing problem across Africa and other low-income regions, where resources for treatment and prevention can be pitiful and sometimes non-existent. A United Nations high-level summit on NCDs was held in New York, USA, in 2011 [3] to address the issues. As a result, it became clear that the complexities of cancer care require more focused and dedicated attention if progress is to be achieved quickly, especially in low-income regions such as Africa.

From the outset, there are problems with the collection of data – in countries preoccupied with the challenges presented by HIV, TB and malaria, there may be no cancer registries, few treatment facilities, a lack of cancer awareness and a lack of screening and diagnostic facilities.

Aside from this issue of scant information on the challenge ahead, the issue of cost plays a significant role in cancer care in developing countries. The cost of medicines can be a barrier to effective treatment in countries where patients with little money often have to pay for their own cancer care. Generics and biosimilars could offer a sizeable reduction in cost, but these drugs are hit by many of the same issues as cancer treatment overall.

Regulation of all medicines, including generics and off-patent biologicals, is variable across developing countries. Sometimes medicines are not regulated at all. This is particularly dangerous in the case of generics and biosimilars, where patients and prescribers need assurance that these products are equivalent to the more expensive brand-name drugs [4].

Dr Alex Dodoo at the University of Ghana Medical School in Accra, Ghana, and co-authors have examined the role of generics and off-patent biologicals in low-income countries using Ghana as an example. Dodoo et al. discuss the options available to developing countries and healthcare facilities, and make recommendations for proper regulation of generic and off-patent biological oncology medicines while calling for special quality and safety monitoring of these products and a rigorous examination of their effectiveness in real-life settings. There is very little safety monitoring of generic oncology medicines. The temperature that medicines may be stored at in tropical countries is a particular – but often overlooked – concern.

The average cost of the most common generics used in Ghana is several times lower than that of branded products. Some branded products are six or more times the cost of generics. The cost

comparison for Ghana applies equally to most of sub-Saharan Africa. The situation is even worse in countries where the supply chain is weaker. In fact, Ghana is, according to Dodoo et al., widely held to be among the 'better performing' countries. Only South Africa fares better, with its improved human, technical and financial resources [5, 6]. Other countries are far worse. With huge differences in price between branded and generic drugs the case for generics is clear. The case for off-patent biologicals in developing countries is less clear, since these products are more expensive and demand is low.

The downsides of generics and off-patent biologicals in developing countries are related to quality control. Where there is any question over the integrity of the product or the circulation of counterfeit or substandard products, the branded product obviously looks like a far safer option. There are many generics manufacturers, so faking oncology products is a growing problem. There are an estimated 1,000 manufacturers in generic oncology medicines in India alone, with only slightly lower numbers in China.

Importantly, argue Dodoo et al., there are not yet any World Health Organization (WHO) prequalified products for oncology medicines. It is left to national agencies or individual hospitals and pharmacies to source oncology medicines. For this reason, there is no impetus for generics manufacturers to seek WHO prequalification.

The authors agree that generic and off-patent biological medicines in developing countries, appropriately priced and quality controlled, have an obvious role to play in the management of established cancer. The availability of these medicines must be widely publicized, with a particular focus on potentially curable cancers [7].

There is also a need for the development of treatment guidelines for low-income countries [7]. Most countries still use cancer treatment guidelines drawn up by the major professional societies, which recommend therapy with what the authors call 'very expensive branded medicines which are stratospherically out of the reach of cancer patients in low-income countries.'

Dodoo et al. argue that now is the time to establish therapeutic guidelines developed by and aimed at cancer health professionals and their patients, to provide cost-effective solutions for cancer care in low-income countries. They also call on WHO to consider generic and biosimilar medicines in its medicines prequalification scheme.

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