



IMPROVING THE REGISTRATION OF MEDICINES IN AFRICA

A NOTE FROM THE AMERICAN PHARMACEUTICAL GROUP

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The World Health Organisation has estimated that

“one-third of WHO Member States have no medicines regulatory authority, or at best very limited capacity for regulation of the pharmaceutical market. Regulatory gaps are common, with the informal sector for medicines supply often neglected.” (WHO Medicines Strategy 2004-07).

The consequences are very serious for patients and for the efficient supply of safe medicines:

- Regulators themselves are often poorly qualified and may only duplicate work being carried out by their neighbours
- There is a greater use of substandard or counterfeit medicines which may cause damage to health, treatment failure or death
- Treatment with ineffective medicines leads to the emergence of anti-microbial resistance
- Understaffed systems inevitably mean delays in developing countries licensing a new medicine. This is done following the issuing of a Certificate of Pharmaceutical Product from the source country.

One solution is the harmonization of drug registration by internationally regarded authorities. This would:

- Improve the implementation of regulatory requirements and standards by manufacturers and distributors
- Enable manufacturers to supply effective drugs more rapidly.

These standards have been broadly achieved in the western world. Since 1990, the International Conference on Harmonization (ICH) has compiled documents to harmonize drug registration submissions in the 17 countries in the US, Europe and Japan. The ICH focus was originally on new chemical entities and biotechnology products, but the process has only just begun to influence requirements in non-ICH countries.

There has been some movements in Africa:

- The 19 member countries of the Common Market for Eastern and Southern Africa (COMESA) have undertaken to harmonize drug registration procedures, and afford each other mutual recognition of drugs registered in the common market
- The 15 members countries of the Southern African Development Community (SADC) are also making moves towards harmonization.

However, progress is very slow, and the SADC in particular is seen by many as weak and under-funded.

The loss of qualified staff responsible for registration, even in South Africa, is a major, inhibiting factor.

Pre-qualification

In parallel to COMESA and SADC, the WHO has established a consensus on the product standards to be met by suppliers in order to gain pre-qualification status. This system has been expanded to include a pre-qualification process for TB and malaria medicines and their supplies. However, this is not always a substitute for national registration procedures.

More importantly, there is concern that the quality of medicines might be lowered to expand the pre-qualification list.

Recommendations

We recommend that the Department for International Development organises a stakeholder Conference with DFID, clinicians, selected registration agencies and NGOs, and the pharmaceutical industry. The Conference would assess the situation for licence registration in Africa and help develop policies to encourage much quicker and comprehensive harmonization.

We recommend that the Conference also examines the case for mutual recognition of EMEA and FDA licences, and how national concerns in Africa could be accommodated.

We recommend that any decisions uphold in full the need for high quality medicines and do not sacrifice quality for quick, but counter-productive, gains.

This area is well within the capabilities of the UK Government, with its extensive experience of patents and its contacts in Africa, and its good working relations with the WHO, NGOs and the pharmaceutical industry.

About the American Pharmaceutical Group (APG)

The APG represents all the major American pharmaceutical companies which are also based in the UK. The Group believes that basic healthcare should be independent of where people live. About two billion people, one-third of the world's population, do not have access to essential healthcare services and medicine, because they live in poor countries.

APG member companies are committed to enhancing access to medicines in Low Income Countries (LICs) in Africa through a variety of measures, including:

- Research and development of new medicines for diseases disproportionately affecting developing countries.
- Humanitarian programmes, product donations and product access programmes that provide medicines at significant discounts, or at no profit levels.
- Capacity building programmes, ranging from local health care professional skills development, to technology transfers going to companies based in LICs.

Together, these individual programmes improve and extend the lives of millions of the world's most disadvantaged people.

The members of the APG already make a real difference to the quality of healthcare and lives around the world through a variety of individual initiatives and philanthropic programmes. These are set out in the APG brochure "Access to Medicines" (see).

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