

## ONLINE AVAILABILITY OF REGULATORY DOCUMENTS AND SAFETY INFORMATION

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### BACKGROUND

The objective of the African Medicines Regulatory Harmonisation Programme (AMRH) is to establish and improve standards and requirements related to the regulation of and access to safe, high-quality medicines. The Internet as the greatest source of information nowadays, it is important that stakeholders have online access to regulatory information, and that safety information can be reported and accessed online.

### AIM

To investigate the free accessibility of regulatory documents on drug regulatory authorities' (DRAs) websites; further to assess the type of documents available, and the possibility for ADR reporting online; and to delineate gaps and provide recommendations for regulatory measures.

### METHOD

A random list of thirty countries to be screened was generated, complemented with 9 remaining countries analyzed by NEPAD (New Partnership for African Development) in 2010. A checklist to collect data from each DRA for analysis was developed based on information from RRFA (regulatory resources for Africa), WHO and NEPAD.

### RESULTS

Documents on application for registration are online accessible in 34% of the countries, pharmacovigilance documents in 29%. 26% provide ADR reporting online, and 18% publish online safety warnings. Some countries have limited or no online information. A list of registered products is accessible in 24%; 1 country provides summaries of product characteristics.

### CONCLUSION

Most countries don't have regulatory information accessible online, although more countries than in 2010 provide this information. In countries with online information, application is enhanced and safety information easily accessed and reported.

### RECOMMENDATIONS

To enhance registration of medicines, authorities should provide online information and forms on behalf of the pharmaceutical companies. For the safe use of medicinal products, ADR reporting online should be possible. We propose to assess in collaboration with RRFA, NEPAD and WHO all African countries. Based