

GOVERNANCE

BASEL INSTITUTE ON GOVERNANCE

Conference «Access to Life-Saving Medication – Innovative Solutions» | September 7 2006 | UBS Training- and Conference Center Basel

Industrialised countries vs. developing regions - two markets, two rules? A regulator's view

Dr Petra Dörr, Head International Affairs, Swissmedic, Swiss Agency for Therapeutic Products

The presentation will look at the role of a drug regulatory authority (DRA) in general which should basically be the same in all countries. A functioning regulatory system - the availability and implementation of medicines legislation (national law and regulations as well as technical guidelines, which mostly are established based on international standards) is one of the pre-requisites for ensuring access to essential or life-saving medicines.

Differences can be realised in what concerns the issues related to access to medicines in industrialised countries vs. developing regions. As an example, rapid access to new medicines is a concern in industrialised countries, whereas developing regions sometimes struggle to ensure access to essential medicines.

The presentation will highlight some of these issues. What can regulators do to address them? Most of the activities in this area require a strong involvement of WHO - supported by the member states' competent authorities. International cooperation is key as well transparency of information. The International Conference of Drug Regulatory Authorities (ICDRA), as an example, is a forum under the auspices of WHO for DRAs to promote exchange of information and collaborative approaches – also related to access of medicines. Great efforts are also undertaken with regard to harmonisation of requirements for drug registration. Regional initiatives as well as global approaches in this area will be introduced.