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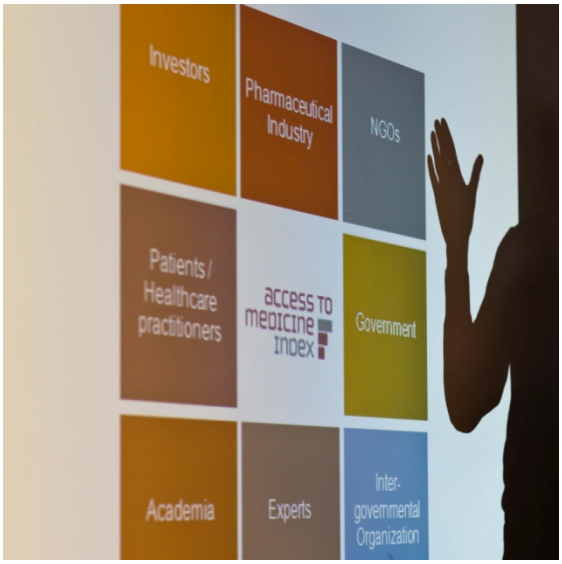

AXIS 3 SUMMARY

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DAY 3 - AXIS 3

« REGULATION OF THE PHARMACEUTICALS SECTOR »

THEME FOR THE DAY

Day 3 of the Medical Theme Days was devoted to the « regulation of the pharmaceuticals sector ».

This general theme was subdivided into one prerequisite and three specific subjects:

- Prerequisite: Good governance...
- Subject 1: Experience of reinforcing the technical capacities of National Pharmaceutical Regulatory Authorities
- Subject 2: Difficulties and limits effecting National Pharmaceutical Regulatory Authorities - Experiences of harmonising policies, procedures and regulation at the sub regional level.
- Subject 3: Pharmacovigilance: goals and resources to be applied

The results of Day 3 can be summarised as follows:

GOOD GOVERNANCE

Corruption is one of the most serious obstacles to achieving a system's goals: the corruptors are at least as guilty as the people corrupted.

Any system must clearly rest on intangible principles of good governance and on suitable and transparent procedures, thus enabling proper functioning of services and systematically reducing possibilities of corruption. With respect to regulatory bodies with which we are presently concerned, that must be based upon a political will supported at the national level, without which the principles of good governance cannot be applied and suitable procedures cannot be put into effect.

A number of years ago, the WHO set up a programme for strengthening pharmaceutical governance in low and middle income countries. This programme is initially based upon voluntary commitment by countries, which is then developed in three stages:

- Stage 1: Reporting (diagnostic, assessment of transparency framework);
- Stage 2: Setting up (definition) of a national framework for good pharmaceutical governance;

- Stage 3: Support for applying the programme.

The promotion of good governance for pharmaceuticals, based on discipline and values and as carried out with the support of the World Health Organisation, is to be encouraged. It provides an important basis for the effectiveness of procurement systems and for the effectiveness of all steps towards strengthening regulation of the pharmaceutical sector, in which « transparent » National Pharmaceutical Regulatory Authorities play a necessary role.

STRENGTHENING NATIONAL PHARMACEUTICAL REGULATORY AUTHORITIES

The National Medicines Control Authority is the corner stone of the pharmaceutical system. In the light of assessments carried out by the WHO, the majority of National Regulatory Authorities are not functional.. Only 20% of the NRAs in 193 member states of the WHO are considered as mature. Strengthening of the NRAs is therefore primordial. Our discussions have shown the areas requiring reinforcement:

- Technical training;
- Legislation et Regulation;
- Resources released;
- Recognition of the role of the DPM;
- Remuneration;
- Knowledge recruitment both at the national and the international level;
- Political marketing to gain commitment from politicians;
- International collaboration;
- Functioning (Certification schema)

Our endeavours have also shown that, for historical reasons, the situation of French speaking countries in Africa is very different from that of English speaking countries, where the regulatory authorities are generally clearly better organised and more functional (usually taking the form nowadays of Agencies).

Since the conference is French speaking, our discussions have concerned the problems of strengthening NRAs in French speaking African countries.

FINANCING NRAS

The Agency model (on the basis of the example of Zimbabwe), involving a structure which is more independent in its operations and management, helps to free up and make available the financial resources required for this strengthening.

It is however important to diversify sources of finance. The AFMPS (Belgian Federal agency for medicines and health products) has shared its experience: the financing of monitoring the Belgian market comes from dues and industrial taxes but also from a charge on the price of each pack of medicines.

HARMONISATION

Taking into account the importance of the part played by the National Pharmaceutical Regulatory Authorities and the insufficiency of the resources available to them, the necessity for pooling appears to be self evident. Prior to any pooling, harmonisation of guidelines and quality standards is indispensable. This must be accomplished at the international level. This international dimension to quality moreover helps to strengthen the independence of each national structure, which must ensure its compliance with supranational standards.

The legal and operational framework for the National Pharmaceutical Regulatory Authorities must be clearly defined and there must be a clearly signalled political will to adhere to harmonisation processes.

The benefits of harmonisation should be identified for each country: some authorities could refuse to harmonise since it could have economic consequences (i.e., a reduction or cessation of local production if that production is not consistent with the standards as defined at sub regional level). It is therefore important to keep in mind possible consequences for the parties (local industries, patents) when approaching questions of harmonisation.

In any event, harmonising has little real interest if a vertical carve up of tasks is envisaged in the long term. The work load could for example be shared out within a sub region or a system of mutual recognition could be set up. The latter goal would nevertheless be difficult to reach and is a very long term project if one refers to the setting up of a system of mutual recognition between the regulatory authorities of the EU/Switzerland/Australia and Japan, but excluding the USA.