



## AIDE-MEMOIRE

### Strengthening National Regulatory Authorities

*The overall objective of a National Regulatory Authority (NRA) for medical products is to ensure that all medicines (drugs, vaccines, blood products and other biologicals) and medical devices are of assured quality, safety and efficacy and are accompanied by appropriate information to promote their rational use.*

NRAs need to be competent, independent, with strong political backing and have clear authority to enforce established regulations. They also need to interact closely with medical and scientific institutions and civil society organizations representing health care users and professionals.

All countries require an NRA. In countries with production facilities the NRA must exercise all critical control functions. These are:

- Licensing (of products, manufacturers and distributors)
- Laboratory testing and lot release (where required)
- Inspections of manufacturing sites and distribution facilities
- Control of clinical trials
- Control of advertising and promotion
- Post marketing surveillance of quality and safety

Experience gained from national regulatory systems worldwide indicates that many countries face challenges in fully implementing effective regulation. Therefore NRAs may not be able to guarantee the necessary quality, safety and efficacy of marketed products and the availability of appropriate information for use.

To achieve effective regulation, national authorities need to identify areas of weakness, define priorities, plan and implement corrective measures. Special attention must be given to adopting appropriate regulations, providing needs-oriented training, and obtaining sound technical advice. Over the last thirty years, successful implementation of this approach has had a direct impact on the quality, safety, efficacy and rational use of regulated products in many countries.

#### Words of advice

- **Secure strong political will and commitment, both human and financial, for NRA functions**
- **Assess existing NRA functions regularly**
- **Develop a systematic plan to address identified weaknesses**
- **Implement, monitor and evaluate**



#### Checklist

##### Secure Commitment for:

- political will to support regulation
- adequate funding and human resources
- independent technical decision making

##### Establish solid foundations:

- adequate legislation and regulations
- appropriate mission statement and organizational structure
- sufficient number of qualified and trained staff
- internal quality system
- adequate and sustainable financing
- accountability and transparency

##### Identify weaknesses in:

- licensing of products, manufacturers and distributors
- post-marketing surveillance of quality and safety
- detection and containment of illicit trade and inappropriate promotion
- regular inspection of manufacturing and distribution sites
- control of clinical trials
- laboratory testing and/or lot release for products where required

##### Take corrective measures :

- identify priorities
- assess training needs
- develop action plan
- set time-frame
- secure human and financial resources
- implement, monitor and evaluate results

