



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

Key elements

Government Commitment

Governments must be fully committed to maintaining strong NRAs. To be effective NRAs must have a clear mission, sufficient legal power, an appropriate organizational structure and facilities, an adequate number of qualified, experienced and motivated staff, adequate and sustainable financial resources, and appropriate tools such as standards, procedures and guidelines. Governments should ensure:

- Clear, comprehensive and equitable legislation, including appropriate sanctions for violations
- Firm commitment to implement legislation
- Availability of necessary financial and other resources for exercising NRA functions
- Support for decisions and policies that prioritize public health against any other consideration

To promote strong political commitment NRAs and public-interest groups must raise government awareness on:

- the public-health rationale for regulating medical products
- the dangerous consequences of unsafe, ineffective, substandard and counterfeit products
- the need to implement national policies that give priority to the public-health rather than economic value of medicines.

Organisational structure

To promote effective regulation, governments can:

- assess organization of NRA and re-organize if necessary in order to increase its visibility and its role
- assign the NRA effective legal powers, independence in decision-making, and autonomy to recruit and dismiss staff
- ensure that clear, transparent written procedures are developed for all regulatory functions

If distribution of responsibilities falls among different governmental agencies the Government can:

- ensure that responsibilities of different agencies is based on written regulations
- create co-ordination and information flow systems to support regulatory decision-making at national level
- build a monitoring and evaluation system to assess implementation of relevant legislation, identify shortcomings and their causes, and make timely corrections

Human Resources

Shortage of appropriately qualified and skilled professionals is a problem for many NRAs.

Governments and NRAs can respond by developing a sustainable human resources development plan.

Governments can:

- ensure competitive and attractive salaries for NRA staff
- ensure merit-based staff selection and recruitment policies that attract new recruits
- ensure career structures and incentives are attractive enough to prevent high staff turnover
- improve the knowledge and skills of NRA staff through in-house and external training programmes

NRAs can:

- computerize regulatory processes
- establish stable, transparent collaboration with experts from academia, health care and research institutions, professional associations
- encourage input from civil society
- develop and make use of written procedures
- train staff for multi-skilling
- take advantage of using decisions made by other reliable NRAs to make own decisions
- regularly network and exchange information with other NRAs

Sustainable Financing

Governments can revise their legislation and introduce fee systems or other funding mechanisms that reflect the real costs of all NRA activities.

Provisions for fee reduction or exemption should favour availability of life-saving and priority medicines. NRAs should preferably not be entirely dependent upon fees and financial support should be available from government sources.

Revenues collected should be exclusively used to implement and support regulatory activities. Fees should not negatively influence the work of NRAs and the decision-making process.

An interesting financing model is characterized by a contribution from government budget, a set of fees for the different types of applications and services, and an annual fee for retaining product or company licence validity.

National Regulatory Authorities

Protecting public health
regulate - educate - communicate

Additional information on strengthening National Regulatory Authorities can be found on the World-Wide Web at www.who.int/medicines www.who.int/vaccines-access www.who.int/biologicals www.who.int/bct

Health Technology and Pharmaceuticals, World Health Organization
20 Avenue Appia, CH-1211 Geneva 27, Switzerland
Fax: +41 22 791 2111