PHARMACEUTICAL REGULATION AND LEGISLATION

- The role of pharmaceuticals has become more prominent on international agendas as health indicators have been increasingly linked with a country’s successful development.
- In addition, the legal and economic issues that surround pharmaceuticals have become more complex and politicized because of the increase in global trade.

- the use of ineffective, poor-quality or harmful medicines can result in therapeutic failure, exacebration of the disease, resistance to medicines and sometimes death.
- It also undermines confidence in health systems, health professionals, pharmaceutical manufacturers and distributors. To protect public health, governments need to approve comprehensive laws and regulations and to establish effective national regulatory authorities to ensure that the manufacture, trade and use of medicines are regulated approprietally and that the public has access to accurate information on medicines.

Differences

- Laws today are usually written in fairly general terms to meet present and possibly future needs. Laws usually have language that enables the government to issue regulations based on the law. Passing new laws may require a lengthy process with the country's legislative branch giving final approval.
- Regulations can be passed more rapidly and simply than laws, sometimes requiring, for example, only the approval of a single government minister on the advice of experts.
- They can also be altered more easily. After approval, a regulation has the same power as the law itself.
- Guidelines, which do not carry the force of law, can be more easily modified and updated.

- Pharmaceuticals involve many parties, including patients, doctors, overhealth workers, sales representatives and manufacturers. The field also involves important risks: people can suffer and die not only from a lack of medicines, but also from drugs that are impure, wrongly prescribed or used incorrectly. Thus, it is easy to see why laws and regulations are needed. However, some argue that medicines-like many other commodities-should be subject only to the control of ultimate user.
- Additionally, informal controls are insufficient: sales of worthless remedies- the firm action may be needed to stop it
- However, the Internet presents new challenges in controlling deceitful drug promotion.

- Counterfeiting, also, has been on the rise in developed and developing countries. U.S. customs officials, for example, report that pharmaceuticals are one of the fastest-growing categories of counterfeit goods coming into the country illegally.
- The approach to pharmaceutical regulation should not be simply punitive: rules creating a positive situation tend to be more effective. Finally, law and regulations are effective only to extent that they meet society’s needs.

GLOBALIZATION AND HARMONIZATION

- Laws and regulations evolve within countrie over time, but in recent years the trend has been toward the globalization of pharmaceutical issues, which affect national legislation. This globalization, exemplified through changes in international trade, patent protection and pricing, has resulted in a number of initiatives that must be considered by countries developing pharmaceutical regulations:
- 1. TRIPS Agreement. the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) of the WTO has greatly affected pharmaceutical regulation. TRIPS is an attmpt to reduce gaps in the way intellectual property rights are protected around the world and to bring them under common international rules

- However, the implication of the agreement's provision on patients caused concerns in developing countries. In response to those concerns, at the Doha Conference in 2001, WTO members adopted a special affirmation-known as Doha Declaration- on issues related to TRIPS and public health.
- The declaration affirms that the TRIPS Agreement should be implemented in ways that protect public health and promote access to medicines.
- Driven by the increase of global trade in pharmaceutical products and the subsequent complexity of technical regulations related to medicine safety and quality, several initiatives have been established to promote the harmonization of international pharmaceutical guidelines and regulations by intergovernmental organizations at regional and interregional level

International Conference on Drug Regulatory Authorities

Organized by WHO, ICDRA provides officials from the drug regulatory authorities from all WHO member states with a forum to work on strengthening cooperation and collaboration. Held since 190, the annual conferences promote the exchange of information and provide a platform to develop international consensus on pharmaceutical regulation. The conferences are a unique forum that assemble all drug regulatory authorities, regardless of their organization stage of development. The ICDRA has been instrumental in guiding regulatory authorities on how the harmonization of regulation can improve the safety, efficacy and quality of medicines.

International Conference of Harmonization

- The International Conference of Harmonization of Technical Requirements for Registration of Pharmaceutical for Human use (ICH) is a project that brings together the regulatory authorities and experts from the pharmaceutical industry in Europe, U.S. and Japan to discuss scientific and technical aspects of product registration.
- The purpose is to promote harmonization in the application of technical guidelines and requirements for new product registration in order to reduce the duplication of and to facilitate the evaluation of testing carried out during the research and development of new medicines.

- Harmonization conserves resources and increases the availability of new medicines, while maintaining regulatory obligations to safeguard the products. Although intended for new products, ICH guidelines are also used to register existing products. The guidelines, formally produced by and for ICH member countries, reflect the technical capabilities of their well-developed regulatory agencies and pharmaceutical industries.
- Thus, other countries should consider their local situations before trying to apply ICH guidelines. However, ICH guidelines do end up affecting all countries, particularly as they relate to the quality specifications of medicinal products, including generic medicines requirements for which vary considerably across coutries.

- WHO, with its observer status on the ICH steering committee is expected to act as a link between ICH and non- ICH countries and to disseminate information to non-ICH countries. The ICH has also established a Global Cooperation Group that promotes ICH guidelines by acting as an information resourse for nonmembers.

Drafting and revising pharmaceutical legislation and regulations

Regulatory authorities are continually faced with new issues-such as globalization and extension of free trade-while increased responsibilities from the market expansion and the sophistication and new categories of products place heavy demands on regulatory systems.

As a first step before drafting any new law, it is important to inventory the laws and regulations already in force. Even if no general drug law exists, pieces of legislation are likely to touch on the field-for example, laws on narcotics and licensing and responsibilities of pharmacists.

An out-of date general drug law may exist that should be replaced rather than merely amended.

- Determining the extent to which existing laws and regulations contribute to attaining and the national policy objectives is essential, because concepts of pharmaceutical policy are modern, legislation more than 20 years old may not be relevant-starting over may be simpler.
- In countries with a long history of regulation, laws on pharmacists and the registration of medicines as well as regulation on prices and costs are likely to be separate, because they came into being at different times. In starting afresh, however, and particularly if the laws on these matters are outdated or incomplete, it may be easier to pull together all relevant elements in single law.

- Ideally, the task of writing and revising the law should be entrusted to a group of legal and health experts who are familiar with all the issues, but not all countries can assemble such a group. Rather than solving the problem by copying laws from abroad, countries with limited expertise can obtain assistance from international and bilateral agencies to draft new pharmaceutical legislation that meets the country's own needs.
- International and regional meeting of drug regulatory authorities also provide opportunities for learning how to approach the problem and identifying expert colleagues who can be called on for advice.

- At all stages of the process it s important to discuss early drafts of the law with all interested parties, including the health professions, trade and industry groups, other concerned government departments and consumer groups. The greater the consensus, the greater is the chance that a law will be passed and will work in practice.
- When the law is approved, regulations are developed to guide the implementation of the law. Regulations can be modified more easily than laws as the local situation evolves. When a regulation is revised, it is important to research and take into account what other laws will be affected by the revision.
- Declaring that a revision nullifies all previous laws and regulations in conflict, without makin sure what those previous laws cover, can result in confusion.

Basic elements of pharmaceutical legislation

A well-defined set of elements constitutes the initial requirements for s strong and comprehensive national pharmaceutical law. These elements, though basic, are sufficiently wide and varied in their scope to meet most of the objectives of a national pharmaceutical policy.:

General provisions

Control of availability and marketing

Drug control administration

Powers of enforcement

Repeal and transitional provisions

Key provisions of national pharmaceutical legislation

Because a consumer cannot independently asses the safety, efficacy, or quality of pharmaceuticals, these products are universally recognized as being different from ordinary items of commerce, handling by specially trained health professionals. These requirements make pharmaceutical subject to numerous controls at all the levels. Legal authority is granted to regulate their manufacture, distribution, marketing, prescribing, labeling, dispensing and pricing.

- An effective national pharmaceutical law is a primary means of ensuring that pharmaceutical policy goals are achieved while the unique character of pharmaceutical products, personnel and facilities is preserved. The law may specify what products can legally be imported-for example, those included on the national medicines list and processing a WHO type certificate of quality- and which individuals are legally qualified to prescribe and dispense them, thus promoting certain national pharmaceutical policies.
- Likewise, control of the manufacture, storage, distribution and sale of pharmaceutical products enables a government to better ensure complience with national policy of having essential medicines of appropriate quality, safety and efficacy available for their intended purposes.

- The processes of licensing and registration can grant authorization only to those personnel, products and facilities that conform to the national pharmaceutical law. For example, the counterfeit medicines or dangerous medicines can be taken off the market and sanctions can be taken against those responsible for introducing them illegally.
- In addition, countries that host clinical trials to test new medicines should incorporate regulations on how the studies should be conducted, including an application process that explains the purpose and protocol of the intended research and the creation of an ethics committee to approve and monitor any study protocol that includes human participants.
- For countries needing assistance in this area, WHO publishes guidelines on good clinical practices.

- The promulgation of regulations, the collection of licensing and registration fees, and the enforcement of the national law and its regulations are legally delegated to an agency- usually called the national drug regulatory authority-headed by director who is responsible to a cabinet-level person, such as minister of health.

- Regulatory authority should be vested with legal powers to:
- - issue, vary and revoke licenses for pharmaceutical products on grounds of quality, safety and efficacy.
- - ensure the safe and effective use of each product by controlling through the terms of the licence, the content of all labeling and the channels through which the product may legitimately be supplied.
- - inspect and license all manufacturing premises, importing agents, wholesalers, distributors, independent pharmacies