



World Health Organization

Berkeley Model
United Nations



LXIII
SIXTY-THIRD SESSION

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Regulation of Antibiotic and Drug Administration

Topic Background

People have been self-medicating in a multitude of ways for as long as history can tell. While technological advancements in medicine have improved and saved billions of lives, they have also introduced new challenges. When they are not created, tested, and used properly, many drugs can have detrimental effects on the health of their users.

The origins of documented drug regulation can be traced back to 1240 AD, when Frederick II of Sicily demanded that all apothecaries use the same processes to create all remedies. This order is considered by many to have given rise to *Pharmacopoeias* - books containing the information necessary to identify medicinal compounds - which are still used today. The origins of pharmaceutical inspection can be traced back to England in 1540 when the *Apothecaries Wares, Drugs and Stuffs Act* designated four officers as inspectors of "Apothecary Wares, Drugs and Stuffs."

The regulation we see today arose in response to the significant increase in drug research and related developments that occurred post-World War II. Scientific advances in chemistry and human physiology in the late 1800s - combined with an increased motivation for advancement after the war - led to a rapid increase in pharmaceutical research and development that necessitated regulation. The importance of quality regulation became recognized on an international level when forty-six different countries were affected by the thalidomide disaster. Thalidomide was a sedative developed in West Germany that was sold internationally and eventually resulted in tens of thousands of babies being born with phocomelia and other deformities.

Today, drugs are regulated on a national level by national regulatory authorities (NRAs). NRAs are responsible for monitoring the quality of all medicinal products on the market. Specific licensing is required for manufacturing, distributing, exporting, and advertising. Manufacturers, wholesalers, and dispensers are all subject to NRA surveillance. Because of catastrophes like the thalidomide disaster, NRAs are also responsible for collecting data on adverse reactions of all medicines.

While thoroughness is key to ensure *safety, efficacy, and quality* - three characteristics that are considered requirements for good NRA practices - it is also important for NRAs to be efficient. When drugs are not accessible and affordable, smuggling becomes more prevalent; smuggled drugs tend to be very low in quality and are oftentimes used illegally. This involves appropriate and uncorrupt relationships between the NRA, law enforcement, customs, etc. With the internet becoming more and more universally accessible, it is also important for the NRA to monitor e-commerce to control illegal sales, especially of counterfeit drugs, which can be extremely dangerous.

The World Health Organization also recommended in a 2003 publication that NRAs closely monitor advertisements and other promotions to ensure that medical professionals and the general public are well-informed on proper use, and that they evaluate their own progress periodically to assess whether or not corrective action is needed to maintain adequate regulation.

In recent decades, generic medicines have become increasingly more popular, typically because they tend to be more affordable than brand-name alternatives. Therefore, successful DRAs have had to develop specific protocol focused on generic medicine to ensure that it is identical in active ingredients, strength, form, quality, purity, and is biologically equivalent to the brand-name drug.



Past International Involvement and Attempted Solutions

The World Health Organization has made efforts to contribute to drug regulation by developing international norms and guidelines for member nations to adopt, and providing training to help nations implement such guidelines.

One example of a WHO attempt to standardize drug regulation is resolution WHA3.11, which, which was adopted by the WHO in 1950 to initiate the International Nonproprietary Name (INN) system. The INN system was eventually implemented in 1953, and is made up of thousands of designated names for active pharmaceutical ingredients, so that medical professionals and researchers are better able to investigate what a medicine consists of. Prior to the introduction of the INN system, chemical names and complex formulas were used to describe ingredients, making it difficult for doctors to know what they were even prescribing. The list of ingredients included in the INN continues to grow each year.

The WHO also hosts The International Pharmacopoeia (Ph. Int.), which has no legal status but is available for member states to adopt and adapt to their own national legislation. The first edition was published in 1951 and included all medicines made and sold around the world. In 1975, the WHO amended the Ph. Int. to focus on the WHO Model List of Essential Medicines, which serves as a guide for national essential medicine lists. Today, the Ph. Int. is even more specifically focused on drugs related to WHO programmes and/or of significant public health importance, such as those used to treat HIV/AIDS, malaria, and tuberculosis. The Ph. Int. also focuses on drugs designated by the Medicines Prequalification Programme, which is a UN programme that prequalifies sources of active ingredients and quality control laboratories through thorough inspection to increase availability of crucial pharmaceuticals.

The WHO also organizes the International Conference of Drug Regulatory Authorities (ICDRA) every other year (since 1980) to provide a platform for regulatory agents from around the world to collaborate, share ideas and procedures, and determine priorities for international regulation. It was at the ICDRA in 1989 that talks revealed the need for harmonization of regulations, leading to the formation of the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). The ICH is made up of regulatory authorities and pharmaceutical experts from Europe, Japan, and the United States. More specifically, the ICH consists of the European Commission; the European Federation of Pharmaceutical Industries and Associations; the Ministry of Health, Labour, and Welfare; the Japan Pharmaceutical Manufacturers Association; the Food and Drug Administration; and the Pharmaceutical Research and Manufacturers of America. The ICH focuses on innovative medical techniques and creates relevant requirements as technology evolves.

Overall the World Health Organization has made notable effort to increase harmonization among nations and establish an international consensus on standards in order to increase competition and lower prices without sacrificing quality. Unfortunately, a lack of resources and uncorrupt law enforcement in many regions has made it very difficult to regulate the pharmaceutical industry without interference from illegal sales. In addition, there is still a large grey area regarding standards in situations like those involving distribution by humanitarian workers because there is a significant amount of variation between national policies, with international standards acting as suggestions.



Case Study

Sudan

In Sudan, humanitarian aid and the distribution of pharmaceuticals are regulated by the National Health Policy, which was updated in 2007. This policy is an official guideline for medicine donations, and the pharmaceutical policy implementation is monitored and assessed by the General Directorate of Pharmacy. The Ministry of Labor and Human Resources Development is responsible for overseeing the National Good governance Policy, and while there is a formal code of conduct for public officials, the Sudan Medical Council is responsible for handling the actions of both departments. Coordination between the General Directorate and the Ministry of Labor and Human Resources Development is ideally maintained so as to prevent conflict of interest issues within the area of pharmaceutical affairs. However since Sudan is not a member of the World Trade Organization, patenting laws are not applicable or available. This subsequently limits the abilities of all parties involved to establish cohesive policies regarding drug regulation, especially in the field of humanitarian aid.

In Sudan, the leading causes of mortality in hospitals and clinics are malaria and pneumonia. Since the government only allocates around \$3.7 million U.S. dollars per year for health, a large percentage of the population is reliant on humanitarian aid and non-governmental organizations that establish accessible clinics. When such organizations choose to provide certain pharmaceuticals that are not overseen by health services in the immediate area, it can result in misuse and further harm. In conflict zones such as Sudan, humanitarian workers often air drop food and medicine into refugee camps. When refugees are unfamiliar with specific drugs and their proper application, they may resort to taking improper doses on their own and developing further sickness. While there are agencies within Sudan that operate for the sole purpose of preventing such situations, their oversight may be limited to the clinics and facilities that are established by the government.

Questions to Consider

1. Who is responsible for determining a standard of quality for drugs and antibiotics? Should this be an international standard?
2. Who is responsible for ensuring adequate quality and proper use when drugs are being provided by humanitarian workers?
3. Who should be held accountable for increased illness, side effects, or death due to bad quality or misuse?
4. Should there be an international standard of drug regulation, which includes application and distribution? Or would this be too limiting to nations that do not have the resources to meet such standards and are already reliant on NGOs and other forms of foreign aid?



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Treatment of Disabilities in Developing Nations

Topic Background

The World Health Organization defines ‘disability’ as “an umbrella term, covering impairments, activity limitations, and participation restrictions” and about fifteen percent of the world’s population can be categorized as ‘disabled’ under this definition (Disabilities). The International Classification of Functioning, Disability and Health describes disability as the “interaction between individuals with a health condition [...] and personal and environmental factors,” like lack of sufficient infrastructure and social supports (Disability and health). The treatment of disabilities is a World Health concern because disabled people have the same, if not more health needs as everyone else, but they oftentimes experience more barriers to access. In many nations, quality health care is difficult to come by for all citizens, and providers are oftentimes very limited in knowledge, time, and resources. Disabled people face even more challenges due to lack of awareness, proper diagnosis, and access to or existence of adequate treatment or accommodations in their respective nations.

While the treatment of disabled people in developing nations is a world health concern, it is also important to take into account the economic and social concerns that are involved. In many places, disabled people face significant amounts of discrimination, and the lack of awareness about this conditions in developing nations only exacerbates these issues.

Disabled people can also have a harder time accessing the already-limited health care that is available to them for several reasons. First, mental or physical handicaps prohibit many disabled people from accessing public transportation, and in many places this type of infrastructure is not even in place. In addition, economic barriers that make it especially difficult for them to afford necessary care, since the care that disabled people require tends to be more specialized, less available, and more expensive.

Past International Involvement and Attempted Solutions

Over the past seventy years, people with disabilities have become increasingly active in seeking representation and protection from the United Nations. Prior to the 1970s, disabled people were typically segregated in special schools and medical care facilities. While the disabled continue to require care that is unique to their respective handicaps, experts in disabilities research advocate inclusion whenever possible.

Rehabilitation of the disabled was first discussed extensively at the Geneva Conference in 1950, attended by the International Labour Organization (ILO), the World Health Organization (WHO), the United Nations Educational, Scientific and Cultural Organization (UNESCO), the International Refugee Organization, (IRO) and the United Nations International Children Emergency Fund (UNICEF). In 1969, the General Assembly addressed similar issues pertaining to rehabilitation and adopted the Declaration on Social Progress and Development; Article 19 of the declaration addresses the health, social security, and social welfare services for all persons, focusing on the rehabilitation of the mentally and physically disabled so as to facilitate their integration into society.

In 1976, the General Assembly adopted a stronger position that focuses on the human rights of people with disabilities, and recommended that all nations consider the Declaration on the Rights of Disabled Persons when formulating policies and programs. At this time, the GA also declared 1981 as International Year for Disabled Persons. The biggest outcome of the Year for the Disabled Persons was the creation of the World Programme of Action Concerning Disabled Persons, which was adopted by the General Assembly the following year.



In 1993, the GA adopted the Standard Rules on the Equalization of Opportunities for Persons. This is a reflection of the aforementioned theory that disabled people should be integrated in society in order to ensure equal opportunities for all. The adoption of this document eventually led to the 2006 adoption of the United Nations Convention on the Rights of Persons with Disabilities (CRPD), which was the first human rights treaty of the millennium. This is significant because all parties to the convention are required to ensure the full employment and legal treatment of all disabled people.

Case Studies

The Groningen Protocol

The Groningen Protocol was adopted in the Netherlands in 2004, and condones the euthanasia of children under the age of 12 given that certain circumstances are met. The child must be facing hopeless and unbearable suffering, have the consent of their parents to terminate life, obtain a medical consultation and approval, and receive careful execution during the termination. Between 1997 and 2004, there were 22 reported cases of termination. All cases involved newborns with spinal bifida and hydrocephalus, conditions in which the spinal cord is surrounded by a fluid-filled sac and portions of the brain remain unfused. Individuals living with these conditions face physical complications, neurological challenges and typically require multidisciplinary teams to help them transition into adulthood.

Spina bifida is classified and treated differently around the world. In the United States, it is recognized as a “birth defect” which “causes moderate to severe disabilities.” While there are varying levels of spina bifida that are recognized as a disability, individuals still face restrictions when seeking to obtain Social Security Disability claims. The semantics of the definition regarding certain birth defects as “disabilities” affects the ability of individuals to seek certain medical attention and rights. In the case of the Groningen Protocol, individuals that do not meet certain levels of spina bifida would be restricted from seeking termination. In these cases, the individual with the disability is prevented from determining their own level of “hopeless and unbearable suffering.” Addressing the definition and rights of individuals living with disabilities will apply to many situations around the world, in which topics such as termination and assistance claims are under question.

Questions to Consider

1. What are some of the most prevalent disabilities in your nation and how are they being addressed? (i.e. autism is very prevalent in the US and there is a significant amount of discussion surrounding research and awareness)
2. What policies does your nation have in place to protect disabled people and who specifically is protected by those policies?
3. What conflicting cultural and/or religious beliefs that are somewhat prevalent in your nation might affect or disagree with national policy?



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