COMBATING COUNTERFEIT DRUGS: A CONCEPT PAPER FOR AN INTERNATIONAL FRAMEWORK CONVENTION AND RELATED STRATEGIES

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EXECUTIVE SUMMARY

INTRODUCTION

Counterfeit drugs are a global public health problem causing death, disability and injury affecting adults and children. No country is free of this problem, which plagues developing and developed countries alike. Based on mounting evidence, national measures alone appear to be insufficient appear to address the international nature and scope of the problem of counterfeit drugs and the growing expertise and sophistication of those that produce and market them. By this concept paper the WHO seeks to launch discussions on whether an international framework convention for combating counterfeit drugs is desirable to address the international dimensions of the problem and to further normative guidelines on national standards to combat counterfeit drugs.

DEFINITION OF A COUNTERFEIT DRUG

The WHO in conjunction with the pharmaceutical industry and drug regulators has developed the following definition of a counterfeit drug:

> *"a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."*

The terms drug, medicine, pharmaceutical product and pharmaceutical in English generally are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic or therapeutic use. Despite the consensus this working WHO definition of a counterfeit drug represents, the definitions used in practice by and/or based on the laws of different countries differ enough to create problems in the collection of data and the implementation of measures to combat counterfeit drugs.

THE NATURE AND SCOPE OF THE PROBLEM OF COUNTERFEIT DRUGS

How counterfeit drugs are a public health problem is clear. They are made either without any active ingredient or insufficient quantities or with the addition of some toxic substance such that the counterfeit drug has no or has a decreased therapeutic, diagnostic or prophylactic value. With little or no active ingredient a person does not receive all the therapeutic, diagnostic or prophylactic benefit and will either not recover or will have a delayed recovery. Toxic ingredients of course can poison humans at times with fatal results. With regard to infectious diseases, the primary source of the burden of disease in the developing and least developed countries, counterfeit drugs lead to the selection of drug resistant pathogens, increased morbidity, mortality and a significant economic burden on developing regions of the world.

The WHO began to document the global nature of the problem by collecting data on counterfeit drugs as early in 1982 as have other countries and researchers. Recent country estimates on the percent the total pharmaceutical market that counterfeit drugs represent ranged from 50% in Pakistan, 40% in Laos and Nigeria, 30% India, 17% Argentina and Cambodia, 13% China, 10% Columbia, Philippines, and Russia, and 1% for Vietnam. These unacceptably high levels of counterfeit drugs confirm that national measures are insufficient.

International and National Efforts to Address the Problem

The quality of pharmaceuticals has been a concern of WHO since its inception in 1946. International consideration of the problem of counterfeit drugs was first undertaken in a 1958 conference of Experts on the Rational Use of Drugs. Data collection and the task of informing governments about the nature and extent of the problem were begun as a result. A number of subsequent workshops, training, and two country studies have been conducted and national guidelines for the development of measures to combat counterfeit medicines have been published.

Member states have been active in fashioning measures to combat counterfeit drugs. This paper describes what the United States, Nigeria, India, China and the Philippines have undertaken very recently which include increasing the penalties and sanctions for counterfeiting, developing extensive public information campaigns, model laws for pharmaceutical wholesalers, and other measures.

Why is an International Framework Convention Necessary?

An international framework is necessary to combat counterfeit goods for three main reasons.

The first reason is that national measures currently in place are insufficient to meet the all the challenges counterfeit drugs present.

►In many countries there is no drug regulatory authority at all and in those where one exists, it is either inadequate to regulate drugs generally and/or does not have the power to apply measures to suppress the factors that lead to counterfeiting. A framework convention can establish norms for both the substance of national measures and the manner of their implementation.

The second main reason favoring a framework convention is that trade in counterfeit medicines is a global activity as well as domestic and thus has international dimensions.

►The global trade in medicines and the opening of borders to international trade has encouraged the free movement of drugs but has also facilitated counterfeiters. Moreover, counterfeit bulk ingredients, starting materials, active pharmaceutical

ingredients and excipients trade internationally. These transactions too must be regulated by an international framework to avoid tragedies.

The third reason for a framework convention is based on the nature and scope of such international agreements.

► The word "convention" is broadly understood as synonymous with "treaty", "pact", "protocol", "covenant", and "international agreement" among other designations, which do not control the nature and scope of the obligations contained therein. A framework convention offers the benefit of an incremental approach to law making, can establish a system of governance, and encourages both cognitive and political consensus. Most important, the process by which framework conventions are developed can include substantial input by industry, consumers, and other stakeholders, the views and expertise of which are particularly important for a comprehensive treatment of counterfeit drugs.

►A framework convention approach allows States to proceed in a systematic manner, with out waiting for consensus to emerge on all issues, facts and response measures to the subject of interest. The parent convention establishes fundamental rules and principles, which provide a basis for a coherent and coordinated approach whereas protocols or subsidiary agreements elaborate on specific issues referenced in the parent document.

►The history of other framework conventions has shown that this type of agreement permits flexibility to achieve an agreement in the face of uncertainty and lack of consensus. The use of the framework convention approach is familiar to most countries particularly those that have participated in the negotiation of the Framework Convention on Tobacco Control and members of the World Trade Organization.

►A treaty can be viewed as the first formal institutional step on the road to consolidating a multilateral regime on the control of counterfeit drugs. A framework convention can be a key element of an overall global strategy to stem the unacceptable risks of harm and death and burden of disease associated with exposure to counterfeit drugs.

THE PURPOSE AND FORMAT OF THIS PAPER

This paper sets forth some possible elements of a proposed WHO framework convention to combat counterfeit drugs. This paper is not intended to be a comprehensive treatment of each element of a framework convention or a draft of one. Section Three lists numerous possible elements that can be included. These are drawn from WHO guidelines and other treaties and sources. Rather than detail possible elements in this Executive Summary, a Discussion Worksheet has been developed as a quick reference and partial summary. The order and contents of the Worksheet mirror the contents of Section Three so that further details of the suggestions and background information can be located. The Discussion Worksheet can be found at the end of this document.

SECTION ONE: BACKGROUND

INTRODUCTION

Counterfeit drugs are a global public health problem causing death, disability and injury affecting adults and children. No country is free of this problem, which plagues developing and developed countries alike. Nor is the problem of counterfeiting unique to the modern age, indeed it is an old phenomenon. What is unique about this problem today is the international nature and scope of the problem of counterfeit drugs and the growing expertise and sophistication of those that produce and market them. This paper is presented for the purpose of discussion of the concept of an international framework convention to combat the problem.

There are different definitions of counterfeit drugs, several of which will be explored in this paper. At the outset however, a basic definition of a counterfeit is presented in order to establish the focus of this concept paper. It is clear that what is common to counterfeit drugs no matter what the definition in law or in common parlance is an understanding of three elements captured by a basic dictionary definition. These elements are that the counterfeit is a forgery; a copy or imitation, is made without authority or right, and with a view to deceive or defraud, by the act of passing the copy or thing forged for that which is original or genuine.[1] When the word counterfeit is used in the adjective form with the noun drug, a counterfeit drug is an imitation of something else with intent to deceive.[2]

THE NATURE AND SCOPE OF THE PROBLEM OF COUNTERFEIT DRUGS

How counterfeit drugs are a public health problem is clear. They are made either without any active ingredient or insufficient quantities or with the addition of some toxic substance such that the counterfeit drug has no or has a decreased therapeutic, diagnostic or prophylactic value. With little or no active ingredient a person does not receive all the therapeutic, diagnostic or prophylactic benefit and will either not recover or will have a delayed recovery. In studies to determine the quantities of counterfeit anti-malarial drugs circulating in five countries, the consequences of sub-therapeutic doses and the development of drug resistance have been well documented. [3] If made with a toxic substance, a counterfeit drug has the capacity to poison or kill a human, as was the case with death of children in Haiti where the drug manufacturer had used a component material that was counterfeit and lethal to humans.[4] The evidence is also growing that the sale of counterfeit drugs and other products is being used to finance terrorism and worse yet, counterfeit drugs can become a vector for terror activities.[5]

In the case of a counterfeit drug, the contents of which does bear full equivalence to an original but has forged labeling, there is also danger. This is so because forged labeling does not meet good manufacturing practice (GMP) standards that represent a global consensus on how drugs should be manufactured to ensure safety, efficacy and quality. Clearly if the label is forged, the identity of the manufacturer is unlikely to be indicated with accuracy eliminating any opportunity for a consumer to contact the

manufacturer. Numerous media, government and industry reports provide other examples of the public health consequences of counterfeit drugs including unwanted pregnancies from counterfeit birth control pills made from table flour. [6]

With regard to infectious diseases, the primary source of the burden of disease in the developing and least developed countries, counterfeit drugs present a particular set of public health problems aptly described as follows:

> "The effect of either inadequate drug formulation or content leads to a sub-therapeutic dose and the development of drug resistance of infectious agents. The consequences of this are obvious; (1) relatively cheap drugs will become ineffective; (2) the loss of such drugs will require new drugs development, which will be more expensive and will further disadvantage patients in the developing countries; (3) selection of drug resistant pathogens will lead to increased morbidity, mortality and a significant economic burden on developing regions of the world." [7]

Another frightening risk of counterfeit drugs is that with the increased mobility of persons, so will be the transmission of drug resistant strains of diseases from country to country and within regions.

Several estimates and indices unquestionably document that the problem is real, is extensive and global, although an exact quantitative description of the scope of the problem of counterfeit drugs cannot be made at this time. The World Health Organization (WHO) began to document the global nature of the problem by collecting data on counterfeit drugs as early in 1982. It established the Counterfeit Drug Database and continues to enhance and refine it. Standardized case report forms are available. The data to date indicates confirms that counterfeit drugs are a global problem and that the problem is more severe in developing countries.

In a compilation of reports and/or studies on cases of substandard and counterfeit drugs published between 1997-2003 regarding USAID assisted countries, the breakdown on the number of reports is 9 from African countries and the region of sub-Saharan Africa, 11 from Asia and the Near East, 4 from Europe and Eurasia, and 7 from Latin America. [8] Country estimates compiled on the percent the total pharmaceutical market that counterfeit drugs represent ranged from 50% in Pakistan, 40% in Laos and Nigeria, 30% India,[9] 17% Argentina and Cambodia, 13% China, 10% Columbia, Philippines, and Russia, and 1% for Vietnam.[10] One study determined that as much as 38% of artesunate in Southeast Asia is counterfeit.[11] Other studies report the number of deaths, which can be very high due to counterfeit drugs such as perhaps the most well known concerning 2500 deaths in Niger in 1995 from a counterfeit meningitis vaccination.[12]

Counterfeit drugs are of course substandard. Other studies measure the incidence of substandard drugs without differentiating for counterfeit status. Studies measure the per cent of available drugs that do not meet minimum GMP standards, or do not possess

the proper quantity of active ingredients, for example, 31% of anti-TB drugs in Botswana are substandard, [13] contain a toxic ingredient or do not contain any active ingredient.

Counterfeit goods are an unrecognized public health problem particularly in the area of injury morbidity and mortality and represent 5-7% of all products worldwide.[14] Drugs are one of the types of counterfeit goods most commonly counterfeited globally along with food, alcohol, tobacco and consumer products and which have the most potential to cause human harm. Counterfeit drugs are a separate and distinct problem due to the nature of their use and are part of the problem of substandard drugs. Customs seizure data from the US and EU indicate that the quantities of seized counterfeit drugs are increasing, suggesting that the problem is increasing in magnitude.[15]

National estimates of the quantities circulating worldwide describe unacceptable conditions by any standard and offer at least one other opportunity to quantitatively analyze the public health problem of counterfeit drugs. Take for example the estimate that 30% of the drugs in India are counterfeit. Could we not therefore conclude that 30% of India's burden of disease is due to counterfeit drugs? As a chilling estimate, one would hope that this simple equation is wholly in error, but clearly when the rate of counterfeiting of a national drug supply is so high one cannot conclude otherwise than a substantial per cent of the burden of disease has no other explanation.

INTERNATIONAL AND NATIONAL EFFORTS TO ADDRESS THE PROBLEM

Fortunately neither the WHO nor member States have waited for precise statistical quantifications of the problem of counterfeit drugs before taking appropriate actions. Nonetheless, despite these efforts, the quantity of counterfeit drugs circulating in the market place appears to be increasing and in many countries as indicated, the rates are unacceptably high. This section will review some of the efforts that have been made at national and international level to address the problem.

The quality of pharmaceuticals has been a concern of WHO since its inception in 1946. Article 2 of the WHO Constitution establishes its obligation to set standards which has been implemented with regard to drugs by the Quality Assurance Program. It has the responsibility of setting norms, developing guidelines and advising WHO Member States on issues related to quality assurance of pharmaceutical preparations in national and international markets, with particular emphasis on generic products. Combating and preventing counterfeit drugs is an essential component of ensuring the quality of pharmaceuticals in national and international markets.

International consideration of the problem of counterfeit drugs was first undertaken in a 1958 conference of Experts on the Rational Use of Drugs. Data collection and the task of informing governments about the nature and extent of the problem were begun as a result. In 1988, programs were initiated for the prevention and detection of the import, export and smuggling of counterfeit drugs in accordance with

World Health Assembly resolution WHA41.16. Subsequently, the first multidisciplinary international meeting was jointly organized by WHO and IFPMA in 1992, which settled a working definition of a counterfeit drug, still in use by the WHO today, and participants made commitments to solve the problem.

In 1994, pursuant to WHA47.13, a program to assist member States to ensure the quality of drug supply was launched and with assistance from Japan, the MDP-DAP Joint Project began. To date this effort has included an assessment of the scale and problem of counterfeit drugs, the development of simple tests to detect counterfeits, the education and training of drug inspectors and analysts, the formulation of national guidelines to combat counterfeit drugs, and a 1997 workshop that made recommendations for action at the international and national levels. A number of subsequent workshops, training, and two country studies have been conducted and national guidelines for the development of measures to combat counterfeit medicines have been published.[16]

By this concept paper on an international framework convention for combating counterfeit drugs, WHO seeks to launch serious discussions and negotiations to address the international dimensions of the problem and to establish normative guidelines on national standards to combat counterfeit drugs. This paper will be presented at both the pre-ICDRA workshop and at the 11th ICDRA meeting in February 2004.[17]

Member States have been active in fashioning measures to combat counterfeit drugs. This paper will describe what the United States, Nigeria, India and the Philippines have undertaken.

In July 2003, the US Food and Drug Administration (FDA) commenced a major initiative to protect American consumers from counterfeit drugs. A Counterfeit Drug Task Force was established by Commissioner Mark McClellan, which was mandated to develop recommendations for achieving four goals: (1) to prevent the introduction of counterfeit drugs, (2) facilitating the identification of counterfeit drugs, (3) minimizing the risk and exposure of consumers, and (4) avoiding the addition of unnecessary costs on the prescription drug distribution system, or unnecessary restrictions on lower-cost sources of drugs. The Task Force held a hearing in October to receive comments on its Interim Report issued just before the hearing. [18] A final report is expected in early 2004.

Preliminary recommendations for measures at the international level include that (1) American stakeholders should consider working with foreign stakeholders to better coordinate their anti-counterfeiting efforts, (2) the strengthening of international cooperation in law enforcement efforts, (3) the identification of counterfeit products, (4) use of anti-counterfeiting technologies and (5) education of stakeholders and consumers; and (6) the development of global standards for (a) the packaging of final dosage forms and active pharmaceutical ingredients, (b) the use of tamper evident packaging, (c) product pedigrees, (d) the use of anti-counterfeiting measures, and (e) the use of track/trace technologies.

The US based National Association of Boards of Pharmacy (NABP) has proposed model legislation for the regulation of wholesalers as a means to combat and prevent counterfeit drugs from entering the drug supply as part of a model States pharmacy act.[19] In addition to pharmacy boards from within the US, boards or pharmaceutical organizations from Australia, Canada, South Africa, Puerto Rico, Virgin Islands New Zealand contributed to the final model. Florida has taken the lead within the US to combat counterfeit drugs by enacting Senate Bill 2312, which details to wholesalers registration and pedigree requirements, and imposes sanctions. The model also includes guidelines for disciplinary actions,

Nigeria has posted an excellent web site with information and messages on counterfeit foods and drugs.[20] The site has a definition of a fake and is full of information useful for consumers, pharmacists and others, including lists of registered products, identified fakes, blacklisted companies, banned substances, and has information and downloadable forms on how to report a fake product. It informs the public about the concerted effort by the drug regulatory authority to combat counterfeit drugs. The Director General was honored by The President Chief Aremu Olusegun Obasanjo for her work to combat counterfeit drugs.

In August 2003 a special committee established in India in January 2003 with the objective of taking speedy action against the menace of spurious drugs, sub-standard drugs and for the detection of violations under public health laws recommended stiffer penalties for violating India's drug laws. As a result, in December 2003 the death penalty was approved for the sale or manufacture of fake medicines that cause grievous harm or death and the minimum prison term increased from five to ten years.[21] The committee also recommended improvements to the nation's drug regulatory infrastructure including a central drug administration to control the licensing of all drugs rather than the current system of States licensing, greater surveillance, laboratory improvements, increasing the number of drug inspectors.

Philippines in 1996, a special law on counterfeit drugs came into force in the Philippines. It includes requirements for random sampling and monitoring of the drug quality in pharmacies and hospitals and raising penalties for offenders from six months to life imprisonment along with a hefty US$ 25, 000 fine. "We need cooperation with WHO", said Mrs. Nazarita Lanuza, Head of the Food and Drug Bureau in the Philippines. "This fight is a cooperative undertaking. We cannot do it alone."

China now has implemented measures permit authorities to reward informants of cases of production or sale of counterfeit drugs up to 50,000 Yuan ($US6,048). In addition, the States Food and Drugs Administration will investigate allegations of fake medicine production.[22]

DEFINITION OF A COUNTERFEIT DRUG

The WHO has developed the following definition of a counterfeit drug:

"a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging."

The terms drug, medicine, pharmaceutical product and pharmaceutical in English generally are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic or therapeutic use. A drug is a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.[23]

Despite the consensus this working WHO definition of a counterfeit drug represents, the definitions used in practice by and/or based on the laws of different countries differ enough to create problems in the collection of data and the implementation of measures to combat counterfeit drugs. There may also be different elements in the definition depending on whether an inquiry flows from a public health discussion or from a case of infringement of an intellectual property right. For example, the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property defines counterfeit trademark goods in the provisions on enforcement therein as follows,

"counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;"[24]

This definition reflects a prevailing view that trademarks are most often counterfeited and are what border inspectors such as customs officials rely upon to survey and detect counterfeits under national intellectual property seizure and health and safety regulatory enforcement procedures. Counterfeit drugs would not generally be identified at borders by an analysis of their composition. Rather the labeling, packaging and regulatory certification documents would be the basis for denial of entry and customs intellectual property seizures. Nonetheless, counterfeit drugs fall within this definition, which shall be important for any provisions on seizure and destruction in a convention on combating counterfeit drugs.

The reliability of the WHO Counterfeit Drug Database and any newly proposed global database that aggregates national statistics is jeopardized by differing national definitions of reporting countries and will make law enforcement and cooperation across national borders more difficult particularly when counterfeit drugs that meet one country's definition do not meet that of another. Moreover, in the literature on counterfeit drugs and products, there is much confusion between the words counterfeit, fake, illicit, and substandard so that it often impossible to determine whether a report is referring to an actual or suspected counterfeit or a substandard product that may or may not be counterfeit in the intellectual property legal sense. The lack of uniformity in the definition will also create difficulties for researchers who are attempting to quantify the

problem and determine if interventions are effective and reduce the effectiveness of media and government reports which for example convey alerts to the public about counterfeit drugs in circulation.

A review of some of the differences in national definitions demonstrates this point further. In Nigeria, a 1999 Miscellaneous Provisions Decree adds to the WHO definition the concept that a counterfeit drug is one that is not registered or one that does not contain required safety warnings, directions for use or warnings regarding consumption by children.[25] The additional elements found in the Nigerian definition of a counterfeit drug are often found in the consumer product safety or fair trade laws of a country as they are in the US and elsewhere. The failure to add safety warnings, instructions for use and other elements of the Nigerian law places products that fit the WHO definition along with those that do not, thus creating impediments to accurate quantitative measurement and data comparisons with other countries.

Under Nigerian law counterfeit and fake drugs are defined as follows

> *"a) any product which is not what it purports to be; or b) any drug or drug product which is coloured, coated powdered or polished that the damage is concealed or which is made to appear to be better or of greater therapeutic value than it really is, which is not labelled in the prescribed manner or which label or containers or any thing accompanying the drug bears any Statement, design or device which makes a false claim for the drug or which is false or misleading; or c) any drug or drug product whose container is so made, formed or filled as to be misleading; o rd) any drug product whose label does not bear adequate direction for use and such adequate warning against use in those pathological conditions or by children where its use may be dangerous to health or against unsafe usage or methods or duration of use; or e) any drug product which is not registered by the agency in accordance with the provisions of the Food, Drugs and Related Products Decree 1993, as amended."*

In comparison the definition from Pakistan's Manual of Drug Laws is *"a drug, the label or outer packing of which is an imitation of, resembles or so resembles as to be calculated to deceive the label or outer packing of a drug manufacturer" conforms* more closely to the WHO definition.

Under the United States Federal Food, Drug and Cosmetics Act the definition of a counterfeit drug relies on the labelling and packaging aspect of a counterfeit. The US definition is as follows:

> "*a drug which, or the container or labelling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint, of device or any likeness thereof, of a drug manufacturer, processor, packer, or distributor, other than, the person or persons who in fact manufactured, processed, packed, or distributed such drug and which thereby falsely purports or is represented to*

be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer, or distributor."

Under the definition used in the Philippines, unregistered imported drug products are counterfeit as are genuine containers refilled by unauthorized persons. The Republic Act No. 82036 from the Philippines defines counterfeit drugs in a manner similar to the WHO by focusing on the composition and second on the labeling as follows:

"...medicinal products with correct ingredients but not in the amounts as provided there under, wrong ingredients, without active ingredients, with insufficient quantity of active ingredients, which results in the reduction of the drug's safety, efficacy, quality, strength or purity, a counterfeit drug is deliberately and fraudulently mislabeled with respect to identity and/or source or with fake packaging, and can apply to both branded and generic products.

SECTION TWO: THE INTERNATIONAL FRAMEWORK CONVENTION

WHY IS AN INTERNATIONAL FRAMEWORK CONVENTION NECESSARY?

An international framework is necessary to combat counterfeit goods for three main reasons, the first two of which are directly related to what is known about the problem of counterfeit drugs and the third related to the process of and nature of a framework convention approach.

The first reason is that national measures currently in place are insufficient to meet the all the challenges counterfeit drugs present.

In many countries there is no drug regulatory authority at all and in those where one exists, it is either inadequate to regulate drugs generally and/or does not have the power to apply measures to suppress the factors that lead to counterfeiting. A framework convention can establish norms for both the substance of national measures and the manner of their implementation. A variety of factors described in detail elsewhere account for why medicines are counterfeited.[26] To demonstrate what a framework convention can offer that a national practice does not, some of the key factors will be reviewed here.

Regulation: Trade in counterfeit medicines occurs in most if not all countries, appears to be more prevalent in countries with weak drug regulatory control and enforcement systems which permit unregulated markets to continue. Lack of regulation is one of the reasons why basic medicines can be scarce and/or their supply erratic or where drug prices are high or there are significant price differentials. An international framework can provide the minimum standards for drug regulation and enforcement. It is true that many of these can be the subjects of national laws, however, in more than one half of the countries of the world no drug regulatory or consumer product safety authority is in place. As such, a framework convention can establish norms to guide national laws.

Political will, resources and public health policy: The lack of political will to combat the problem often equates to an economic or other policy such as a military one that trumps pharmaceutical and public health policy. As a result, the attention and resources available for drug regulatory activities are inadequate and skilled personnel lacking. This reality is in the face of evidence that skilled personnel and a regulatory scheme capable of enforcement are essential measures to combat counterfeit drugs.[27]

A framework convention focuses political will in the direction of the problem and by virtue of participation in a negotiation process, government officials are influenced by global opinion in addition to that of their constituents who may be too weak to influence national policy and practice. Corruption and conflict of interest have also been cited as reasons why counterfeiting is prevalent in certain countries. A framework convention can include terms modeled on other conventions, which focus on corruption and bribery. An example is the Organization for Economic Cooperation and Development (OECD) 1997 Convention on Combating Bribery of Foreign Public

Officials in International Transactions, elements of which can be incorporated directly or by reference into a framework.

Penal Codes: Substantive penal codes criminalizing counterfeiting and imposing harsh sanctions for their violation can be a deterrent to criminal behavior. In countries that harshly sanction certain behaviors such as driving while intoxicated, rates of such behavior are reduced. Generally, since counterfeiting is also a violation of property rights, many countries do provide for liability in the case of infringement. However, this liability is private to the property rights holder and bears no direct benefit to society or to an injured consumer. Counterfeit drugs also pose a threat to the public's health and safety such that criminalizing this behavior is appropriate. Unless the judiciary is authorized to impose harsh sentences of both monetary penalties and imprisonment, counterfeiters bear little or no personal consequences for their actions.

In most countries, there is no substantive crime associated with counterfeiting or a process whereby the judiciary or the States prosecutor can be informed of the case in order to institute criminal proceedings. Clearly if a counterfeit drug causes a death whether directly by some toxic reaction or indirectly because a patient does not receive the therapeutic benefit of the intended drug, a murder has taken place. And if a counterfeit drug does not cause death, but illness or delayed healing there is an injury in the legal sense that can be seen as the result of an intention to harm and should be criminalized as an assault and/or battery or other crime. A framework convention can detail substantive crimes and sanctions for counterfeiting which can be codified by parties.

Cooperation: Cooperation between the branches of law enforcement, regulatory authorities, police, customs services and the judiciary is essential to solving the problem of counterfeit drugs. Cooperation should include the timely and appropriate exchange of information and the harmonization of measures to prevent the spread of counterfeit medicines. For cooperation to occur, law is often necessary to empower law enforcement officials and the judiciary. Domestic cooperation is often a fact under national law, but not so internationally. Various aspects of criminal procedure must be the subjects of international law before cooperation is required or permissible.

Ultimately at the national and international level, governments, law enforcement agencies, heath professionals, the pharmaceutical industry, importers, distributors, consumer organizations and all stakeholders should adopt a shared responsibility in the fight against counterfeit drugs. Combating counterfeit drugs requires the participation of the public and all the stakeholders. No one solution is enough.

The second main reason favoring a framework convention is that trade in counterfeit medicines is a global activity as well as domestic and thus has international dimensions.

The global trade in medicines and the opening of borders to international trade has encouraged the free movement of drugs but has also facilitated counterfeiters. Moreover, counterfeit bulk ingredients, starting materials, active pharmaceutical

ingredients and excipients trade internationally. These transactions too must be regulated by an international framework to avoid tragedies such as in Haiti.[28]

The fact is that the venues of legal international trade are also used for counterfeiting. Counterfeit drug trade often moves through several intermediaries, or through and within free trade zones or free ports where can be re-labeled or re-packed and which are not under the jurisdiction of the drug regulatory authority. Also, exporting countries do not control drugs destined for export nor does the drug regulatory authority have oversight over imported drugs destined for re-export. These many avenues for trade present unlimited opportunities for counterfeiters and limited opportunities for national governments to comprehensively combat the problem.

Criminals who counterfeit drugs do not limit their activity to one country. Ultimately greed and the potential for profit primarily motivate the criminals who trade in counterfeits. Once counterfeiters are blocked by local efforts, they quickly move to where they can operate without interruption. National legislation does not reach beyond national borders, thus cooperation between countries, especially trading partners becomes essential to combat counterfeiting. Measures to address the factors that lie beyond the reach of national legislation can be advanced through the creation and implementation of a treaty.

The third reason for a framework convention is based on the nature and scope of such international agreements.

The term "framework convention" does not have a technical meaning in international law.[29] In contrast, the word "convention" is broadly understood as synonymous with "treaty", "pact", "protocol", "covenant", and "international agreement" among other designations, which do not control the nature and scope of the obligations contained therein.[30] The definition of the term treaty may have special meaning under national constitutions however, such as is the case under the US Constitution. There is no single style or length for a framework convention.

A framework convention offers the benefit of an incremental approach to law making, can establish a system of governance, and encourages cognitive, normative and political consensus.[31] Moreover, reliance on provisions common to framework conventions such as the requirement of national reports or the creation of a secretariat aids in the reduction of uncertainty about what a convention should contain. Discussion forums and the negotiation process focus international public opinion and build momentum. Most important, the process by which framework conventions are developed can include substantial input by industry, consumers, and other stakeholders, the views and expertise of which are particularly important for a comprehensive treatment of counterfeit drugs.

A framework convention approach allows States to proceed in a systematic manner, with out waiting for consensus to emerge on all issues, facts and response measures to the subject of interest. The parent convention establishes fundamental rules and principles, which provide a basis for a coherent and coordinated approach whereas protocols or subsidiary agreements elaborate on specific issues referenced in the parent

document. Often a protocol deals with complex issues requiring negotiation by a group of specialists or the issue is controversial and requires more discussion than basic principles do and/or protocols can be developed when the science and understanding of the problem is advanced to clarify appropriate interventions. There is no requirement to annex protocols in order to achieve a convention. Protocols can be developed concurrently or consecutively.

The history of other framework conventions has shown that this type of agreement permits flexibility to achieve an agreement in the face of uncertainty and lack of consensus. Examples of other conventions that were achieved despite a lack of agreement at the outset on the right approach include the recent Framework Convention on Tobacco Control, the Convention on Biological Diversity and the Framework Convention on Climate Control.[32] While it may be more typical to use a framework convention approach where there is less consensus at the outset, even where this is not the case a framework convention is appropriate.

Various approaches to the nature and scope of a framework convention have been taken. A convention can provide for minimum or maximum standards or for the replacement of nonexistent, inadequate or incipient legislation at the national level. Alternatively, a convention can encompass strategies that are only amenable to international cooperation by establishing obligations of a transnational nature. A foundation for international cooperation on wide number of issues can also be created. Moreover, both of these approaches can be included in a convention. The need to negotiate separate bilateral or regional arrangements can be reduced or eliminated by a convention, which covers issues that are common to all parties, leaving to other approaches the issues specific to regions or neighboring countries.

The use of the framework convention approach is familiar to most countries particularly those that have participated in the negotiation of the Framework Convention on Tobacco Control. Those who are members of the World Trade Organization are also familiar with global standards for the regulation of international trade and in implementing the obligations for national laws as established by the Marrakech Agreements.[33]

It is also true that the convention process is a substantial undertaking and is resource intensive. Various members of each government must participate for the process to proceed. Certainly if other measures were successful in combating the problem of counterfeit drugs, these would be most welcome. In view of history and the current data, this seems unlikely however.

A treaty can be viewed as the first formal institutional step on the road to consolidating a multilateral regime on the control of counterfeit drugs. A framework convention can be a key element of an overall global strategy to stem the unacceptable risks of harm and death and burden of disease associated with exposure to counterfeit drugs. The right to health is further strengthened by nations working towards combating counterfeit drugs and by establishing global standards for drug regulation.

The next section of this paper presents possible key elements of a framework convention with suggestions on the parameters of each. This paper is not intended to be a comprehensive treatment of each element of a framework convention or a draft of a convention. The elements typical of framework conventions have been extensively described elsewhere therefore only a brief description of each and explanatory material is included in this paper.[34] Last, a Worksheet for Discussion is presented as a quick reference and partial summary for the convenience of the reader. It is in a format that mirrors Section Three for easy reference.

SECTION THREE: POSSIBLE KEY ELEMENTS OF A FRAMEWORK CONVENTION AND EXPLANATORY MATERIAL

I. PREAMBLE: OBJECTIVE (S), PRINCIPLES AND DEFINITIONS

Box 1: Preamble. Objective(s), Principles and Definitions

These introductory provisions set forth the convention's basic objectives and principles guiding its development. The process of determining the objectives and principles help to build consensus among prospective parties. If the objectives are drawn too narrowly, certain issues may be excluded from the convention or any future protocols. These do not determine which measures should be taken. Instead, this question is the essence of the negotiations.

The preamble provides the context for interpretation of a convention and can vary in length and content. It can include the objectives and principles or these can be separate sections.

A. Objectives and principles could include for example,

1. To protect public health and to prevent and combat counterfeit drugs at national, regional and global levels through the measures provided in this convention and protocols.

2. To formulate a common and coordinated approach towards the elimination of counterfeit drugs, and the development of common definitions, information sources and tools.

3. To create a basic duty to eliminate or combat counterfeit drugs at national, regional and global levels through the measures in the treaty.

4. To promote cooperation among Parties to more effectively address various aspects of counterfeit drugs having an international dimension.

5. To recognize that counterfeiting is a crime which is a legitimate subject of international law, is a violation of a duty of persons to refrain from activity that can cause harm to others and for which universal jurisdiction should apply such that a counterfeiter can be prosecuted by any country that captures him or her.

B. Definitions

Often the terms to be defined in a convention are identified during the process of negotiations rather than at the beginning of the process. However, since there are words and terms that are likely to be essential to the overall process, some are listed here with working definitions that may be the basis for discussion.

1. Drug: medicine, drug pharmaceutical product and pharmaceutical are used interchangeably to refer to medicinal products intended for prophylactic, diagnostic or therapeutic use. It may be desirable to consider devices in this convention.

2. Counterfeit drug: The WHO has developed the following definition: "a medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.

3. Generic, branded, patented, substandard, adverse drug event, traditional medicine are other vocabulary that may be desirable to be defined.

4. The definition of a counterfeit drug may include counterfeit traditional medicine.

II. General Obligations of Parties to the Framework

Box 2: General Obligations

A framework convention often contains general obligations. Specific commitments are often placed in protocols or annexes, however there is no prohibition against including specific obligations in the parent document or any section thereof. Most framework conventions contain obligations on national measures, education, training, raising public awareness, general cooperation, exchange of information, monitoring, and scientific cooperation. There is no single way to draft the obligations or any other section of a convention. Each convention can be tailored to address the topic of concern.

In the case of counterfeit drugs, there is some consensus on the nature of the problem and how to combat it. Accordingly, there are no suggestions in this paper as to which topics should be in the convention or treated in a protocol, rather all are placed in this outline. Their final location is the subject of negotiations. The placement of topics under certain categories, a paragraph or subject heading is not intended to direct their ultimate location. Rather their location is merely a means to place some order to the overall list of subjects of possible provisions in a framework convention.

A. National measures to implement the objectives and principles of this convention

Parties may be obligated to undertake the following legal, administrative, and other measures in order to strengthen the drug regulatory and public health authority and thereby combat counterfeit drugs.

1. Establish national laws and policies to protect public health, including the establishment and/or strengthening of the ministry of health, a consumer product safety and drug regulatory authority.

2. Establish and/or strengthen their drug regulatory authorities (DRA) with responsibility for the registration and inspection of locally manufactured and imported medicines and other measures which meet minimum international standards such as those recommended in WHO/EDM/QSM/99.1. Place responsibility for the protection of public health by ensuring that an adequate supply of safe, effective drugs is accessible, affordable and available to meet the essential medicine needs of its citizens given the morbidity and mortality characteristics of the Party.

3. Establish a national office or appoint a senior level officer within the drug regulatory authority with responsibility for the prevention and combat of counterfeit drugs, to ensure the enforcement of national laws and to coordinate with other government authorities with responsibility for counterfeit products other than drugs and that potential to harm humans when consumed or used. This appointment may have sole responsibility or be combined with other functions, such as Quality, or office of criminal enforcement or elsewhere.

4. Establish national laws which meet minimum standards established in this convention to effectively regulate the manufacture, trade, distribution and sale of medicines, including post market surveillance and obligating manufacturers to report adverse events whether of genuine products or those of the manufacturer that are counterfeited and other measures to be determined.

5. Establish a code of good practice for drug regulatory authorities and standard operating procedures and guidelines for the inspection of suspected counterfeits. This section or a later one on technical assistance could include the use of improved test methods and current technology.

6. Adopt the definition of a counterfeit drug into national civil and criminal law.

7. Enforce compliance with good manufacturing practices.

B. National measures to assure the quality of the drug supply can include:

1. Establish chain of custody, licensing and document requirements for all materials used in the production of drugs and for all persons involved in the production, manufacture, or distribution of drugs.

2. Require tracking methodology for consigned or donated drugs and for those sold.

3. Apply technology to the problem of counterfeit drugs such as authentication, forensic analysis, bar coding, and other methods to identify authorized drugs and as

a means to identify counterfeit drugs. This may be suitable for a protocol, which can be changed, in a shorter time in order for the terms of the convention to stay concurrent with changes in technology.

4. Provide adequate training and powers of enforcement against counterfeits should be given to personnel from drug regulatory authorities, the judiciary, customs and police.

5. Use the WHO Certificate Scheme on the Quality of Pharmaceutical Products Moving in International Commerce and coordinate and harmonize the Certificate Scheme with international trade standards and customs for the documentation of goods in international trade, such as those published by the International Chamber of Commerce and the World Trade Organization.

6. Initiate widespread use of screening tests for the detection of counterfeits.

7. Establish quality control laboratories with adequate equipment and trained personnel.

8. Harmonize or streamline the registration of imported drugs.

C. Education, training and public awareness:

These common and non-controversial features of a framework can be achieved through a variety of measures and can include:

1. Promote and encourage the understanding and importance of counterfeit drugs as a public health problem using the media, educational programs.

2. Provide training to scientific, technical, medical and managerial personnel.

3. Provide judicial and law enforcement particularly for cases of intellectual property rights infringement in which new and more severe penalties such as confiscation, destruction and referral for criminal prosecution may be imposed as a result of the convention.

D. Offences and Sanctions:

It appears that in many countries, substantive criminal law does not adequately address counterfeiting and particularly when a counterfeit causes human injury or death. Further, there is no reference in TRIPS provisions on remedies for infringement for additional sanctions in the case of human injury or death or potential therefore. Thus, the parties may find it desirable to include provisions on offenses and sanctions along the following lines.

1. Establish as a criminal offenses under its domestic law:

a. The production, manufacture, preparation, sale, offering, offering for sale, distribution, delivery on any terms, importation or exportation of any counterfeit drug.
b. The manufacture, transport, or distribution of equipment, materials or components used in the production of counterfeit drugs;
c. Participation in, association or conspiracy to commit, attempts to commit and the aiding, abetting, facilitating, and counseling in the commission of any offenses described in the convention.
d. Make the intent to counterfeit an element of the crime, which may be inferred from the facts and circumstances.
e. Make the fraudulent labeling of a counterfeit drug or the trading of fraudulent labels a crime.

2. Sanctions for the commission of the offenses established in accordance with the treaty can include

a. Imprisonment, pecuniary sanctions, confiscation, and destruction without compensation of any kind. The severity of the sanction may increase depending on whether actual human harm or death occurs and sanctions can be made mandatory.
b. Where necessary the provisions of the treaty can supplement and further define the rights of the judiciary under national intellectual property laws as defined by TRIPS Articles 41-49. Accordingly in the event of human harm or death, the judiciary may be mandated to order confiscation and destruction of counterfeit drugs and that in addition to the civil remedies pursuant to intellectual property laws, the courts may refer cases to the prosecutor for criminal action.
c. Pecuniary sanctions can extend to the identification and seizure of bank records and accounts, proceeds of the crime, property, or other instrumentalities for the purpose of eventual confiscation.

3. National criminal procedures may include provisions on extradition, mutual legal assistance in the investigation, prosecution and judicial proceedings in relation to criminal offenses established in the treaty, and the transfer of proceedings.

4. Other topics related to offenses and sanctions can include provisions on a statute of limitations, release and parole of persons convicted of these crimes, limitations on discretionary powers relating to the prosecution of these crimes, no limitation on the exercise of criminal jurisdiction under domestic law and rights of bona fide third parties.

III. OTHER ISSUES FOR A FRAMEWORK CONVENTION

Box 3: Other issues for a framework convention

The following suggestions are based on WHO guidance materials and previous conference recommendations to combat counterfeit goods. The sections include exchange of information and provision of technical support, international cooperation between the parties, research, development and scientific cooperation, and international trade dimensions. This is not an exhaustive list.

A. Exchange of information and provision of technical support.

1. Record keeping in relation to all medicines being sold and tracking systems that may include a computerized system for the monitoring of all drugs. All Parties to the convention shall have access to the computerized system, which shall be managed to provide alerts and surveillance, to track the movement of counterfeit drugs, and to integrate data from other databases such as intellectual property seizure programs.

2. Cooperate in the exchange of information and skills relevant to meeting the objectives of this treaty. Each party to include in its national program measures to assist other Parties to meet the objectives of this treaty.

3. Establish a technical body to assist the Parties in undertaking effective cooperation and exchange of information and skills, and to determine guidelines for common statistical approaches to facilitate comparability of data gathered, considering existing surveillance systems, to assist regulatory authorities to improve screening and testing of local and imported drugs.

4. Countries with experience in combating counterfeit drugs should provide assistance to others for training in areas related to quality control, drug detection and enforcement.

B. International Cooperation between the parties

2. Parties shall cooperate to identify, monitor, and prosecute persons, organizations, and companies involved in counterfeit drugs and in their investigation, prosecution and judicial proceedings.

3. Cooperate between the different organizations required to implement the obligations of the treaty.

4. Partnerships should be established between health professionals, importers, industry and local authorities to combat counterfeits.

5. Countries in the same region should work towards the harmonization of their marketing authorization procedures.

6. Recognizing that the strategies and measures that this convention determines may also be applied with success to counterfeit products other than drugs, particularly when such products are used or consumed by humans. Cooperate and coordinate with efforts to combat counterfeit products other than drugs in order to avoid duplication and to enhance the ability of law enforcement to conduct its work with regard to all counterfeit products.

C. Research and Development and scientific cooperation

1. Each party shall support as appropriate national and international programs, networks, or organizations aimed at defining, conducting, assessing, and financing research and data collection minimizing duplication of effort.

2. Monitor and collect data on counterfeit drugs and the harms caused to humans;

D. International Trade Dimensions

1. Given that counterfeit drugs and their components are part of international trade, it may be desirable to qualify their treatment by countries under certain other treaties, such as the WTO Agreement on Sanitary and Phytosanitary Measures. The treaty can declare that it would not be a violation of international trade rules for a party to unilaterally ban the imports of counterfeit drugs, excipients, starting materials, active pharmaceutical ingredients, bulk chemicals intended for pharmaceutical manufacture or to ban their import from countries that are either not in compliance with this convention or that are not Parties or from where the Secretariat finds/reports counterfeit drugs are exported. For achieving the intent of this provision, the parties may consider requiring the Secretariat or other subsidiary body to maintain a database of known drug counterfeiters, their country origin and in which they do business and other data appropriate to implement this provision.

2. In addition, there are other aspects of international trade which can be scrutinized in order to determine what aspects are appropriate for treatment in this convention such as regulating means of transport, or establishing standards and requirements for commercial documents, the labeling of exports, measures applicable to free trade zones, the use of the mails, the Internet sale of drugs, and anti-diversion.

3. Given that a wealth of information on the movement, origin and nature of counterfeits can be derived from customs intellectual property seizure data, it may be desirable to require customs authorities to maintain a separate category for counterfeit drugs and to report the details of such seizures to the Secretariat for inclusion in any database and alert system that may be established.

IV. OPERATION OF THE FRAMEWORK AND THE CREATION OF INSTITUTIONS

Box 4: Operation of the framework and the creation of institutions:

A framework convention creates the basic institution that will provide ongoing governance and management of the issue area covered by the convention. Existing framework conventions include a range of choices from a skeletal structure such as a conference of the parties to a broader range of institutions including such bodies as a science advisory board, a financial mechanism, a secretariat, an executive body or other subsidiary bodies. The meetings of the parties is in essence the supreme decision making body of a convention, although decisions can also be delegated to an executive body.

A. Secretariat, Conference of the Parties or Other institutions/subsidiary bodies

1. A treaty need not establish a secretariat. Instead, the duties of the secretariat may be assigned to existing organizations. In the case of counterfeit drugs, the WHO Secretariat or UN Office on Drugs and Crime or another newly created institution may be candidates. It has been observed that environmental treaties that did not establish a secretariat have had little effect. [35]

2. All framework conventions establish periodic meetings or conference of the parties, which are normally only open to States and other entities that are parties to the convention. Often relevant intergovernmental organizations and nongovernmental organizations are permitted to observe or otherwise participate as determined in the treaty. The conference of the parties is the means by which the work of the treaty is continued and provides a forum for ongoing negotiations. The tasks and duties of the conference of the parties can be detailed in the convention.

3. The functions of a secretariat which is an independent intergovernmental organization also range widely and include administrative functions of servicing and making arrangements for the meetings of the parties, transmitting reports, coordinating with other international institutions, or more substantive functions such as monitoring, compliance with treaty obligations, managing dispute resolution, and facilitating assistance and guidance to the parties. These can be managed by the secretariat or assigned to separate institutions or to panels, councils, commissions or other subsidiary bodies. Until a separate secretariat is established, the executive head of the organization under whose auspices the convention is proposed and adopted fulfils the secretariat functions.

B. Financial Mechanism

Managing the financial aspects and the resource implications can be resolved by a treaty that includes provisions on the financial mechanisms, or a treaty can be adopted without, but with provisions to establish it after entry into force of the

treaty or some other date. A separate financial mechanism such as a multilateral fund can be established to assist parties and particularly developing countries in implementing the treaty or the function can be managed by the Secretariat. The specifics of financial contributions or assistance can be the subject of a conference of the parties as is the case in the

V. IMPLEMENTATION MECHANISMS

Box: 5 Implementation Procedures

Generally, the section on implementation can include provisions on national reporting, monitoring and evaluation and related provisions such as dispute resolution, liability and compensation and a consultative process by which compliance with the treaty is advanced.

A. National Reporting

1. Establish an obligation to report the measures taken to implement the treaty/protocol to the Secretariat or Conference of the Parties, which ever is established and to do so within (….) of months of the entry into force of the treaty or (….) months before each meeting of the Conference of the Parties.

2. A formula allowing countries to adhere to the treaty and adapt their legislation gradually or provide specific timetables.

3. Each party may be required to furnish information to the Secretariat/Conference of the Parties on the particulars of cases of counterfeit drugs within their jurisdiction including such information as shall be prescribed and in such form as shall be established by the Secretariat. Information such as new trends disclosed by cases, the quantities involved, the names of the persons or organizations which counterfeited the drug in the case reported, the methods employed by such persons and other information as may from time to time be prescribed shall be reported. This information shall be available to all Parties and shall be accessible in written report format, on a web site and in such other forms as may be desirable.

B. Monitoring and Evaluation of Implementation

Often monitoring and evaluation for framework conventions is developed pursuant to protocols however these can also be treated in detail. Methods to achieve monitoring and evaluation can include among others an in depth review by outside experts, or each States is obligated to designate a monitoring authority, or it can be done by the secretariat.

C. Related Provisions

1. Any number of provisions that relate to monitoring implementation can be included such as dispute resolution or imposing liability and compensation for failure to implement.

2. The nature of any dispute resolution provision will depend on how the parties resolve the question of how binding the obligations of the convention shall be. Options include arbitration by consensus, consultation between the parties, a system that is binding on parties or is only so on mutual consent of the parties or by any means acceptable to the parties, conciliation or no dispute resolution at all.

VI. LAW MAKING PROCESS AND FINAL PROVISIONS

Box 6: Law Making Process and Final Clauses

Signature is generally only a first step in a process by which nations are bound to the treaty. The final clauses outline who can sign and other steps that determine when the treaty is in effect.

Law making process and final clauses resolve questions relating to the legal status of the convention, how it is interpreted in relation to other treaties, who can sign, the procedure for protocols, and other final clauses typical of all treaties.

A. Legal Status and Interpretation of the Treaty

1. The convention can provide for whether the obligations within are binding or voluntary and adopt a policy of non-derogation from earlier treaties.

2. The convention can provide how it is to be interpreted in relationship to other international conventions. It can establish its own procedure to resolve conflicts that may arise as between it and other conventions or it can select customary international law as codified in Article 30 of the Vienna Convention. Generally, Article 30 provides that in the event of a conflict between two treaties, which do not contain applicable provisions, the more recent and the more specific shall apply if certain conditions are met.

3. Parties may be permitted to enact stricter national measures than the requirements of the convention.

A. Who may sign and participate in the processes related to the convention

1. A signatory party is generally defined and is one that is eligible to become a party. Generally, parties are limited to governments or specialized governmental agencies such as a regional economic integration organization. In addition, provision can be made to permit non-governmental organizations to participate in any process related to the convention.

2. Often a treaty will designate when it is open for signature and a closing date after which States wishing to join do so by accession.

B. Protocols

Framework conventions set procedures for the adoption of protocols and the requirements for their adoption by parties.

D. Other provisions

Other provisions that are typical in all conventions include ratification, acceptance, approval or act of formal confirmation, accession, entry into force, denunciation, annexes, amendments, authentic texts, and depository, reservations, withdrawal, depository, and authentic texts.

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