HCCRI XII STUDY GUIDE

WORLD HEALTH ORGANISATION

THE ETHICAL CONSIDERATIONS AND PRODUCTION OF PHARMACEUTICALS

WELCOME LETTER

Dear delegates,

Welcome to the World Health Organisation (WHO) at HCCRI 2023! Introducing to you the Dais of WHO, Anqi, Celesta and Yao Chen. We are extremely excited to meet all of you and look forward to two days of fruitful debate. During the conference, you will be engaging in intense debate as you learn about global affairs and international collaboration.

The WHO will be focusing on the ethical considerations and production of pharmaceuticals. Rapid urbanisation and climate change have increased the rate at which infectious diseases are emerging, with one example being the COVID-19 pandemic. The growing demand for the pharmaceutical industry requires pertinent issues within the industry to be addressed, such as the ethics of research and development, the affordability and accessibility of medicines and the need for increased regulation of the market. As each delegate represents a different country, you will have to be careful to maintain your country's stance while using negotiation skills in the process of debate to collaborate with others. During debate, delegates will have to exercise their judgement to strike a balance between personal gain and public interest.

WELCOME LETTER

We hope this will be a very exciting and fruitful experience for all of you, and that you have some key takeaways from this experience, be it to have better equipped you with knowledge of current affairs or to have encouraged you to further your journey into MUN. We look forward to meeting all of you and facilitating your active participation!

Best regards,
Anqi, Celesta, Yao Chen
Dais of the World Health Organisation (WHO)
Hwa Chong Conflict Resolution and Inquiry 2023

DAIS INTRODUCTION

HEAD CHAIR: MA ANQI

Anqi is a Year 5 SMTP-GATE (she has no idea why the name) student from HCI who takes the not-so-unique subject combination of BCME (she does believe in biology supremacy). Despite being a science student all her life, she often finds herself taking more interest in humanities. Anqi lacked appreciation for coffee until this year, when it proved indispensable for her endurance in class. When she is not engrossed in her biology and economics notes, she strives to either catch up on her sleep or fulfill other commitments she has taken up (at the expense of her sleep).

With HCCRI being her last few MUN conferences (retiremun is a myth), she hopes delegates will have a fruitful and rewarding time at HCCRI.

DAIS INTRODUCTION

DEPUTY CHAIR: CELESTA RUDOVA YONG

Celesta is a JC2 student who is obsessed with Romance languages. Her toxic traits include: thinking that she can guess and understand complete Spanish/Italian sentences simply because she takes H2 French and ELL (this has a 50% success rate), and believing in the sunk cost fallacy, enough to invest in $8 drinks just to "focus better when studying". If anyone has Spanish notes that she can peruse while slowly sipping an overpriced drink, she would really appreciate it.

She hopes that delegates will have a fun time debating in HCCRI!

DEPUTY CHAIR: YU YAO CHEN

Being a JC2 this year, Yao Chen can be often found in the library, with a flask of hot tea for companionship/consumption. Taking BCMELL, he suffers from sleep deprivation, compensated by his passion/addiction for his tea collection. With his deep interest in the Humanities and Current Affairs (and unceasingly questioning his choice of subjects), he has joined HCCRI 2023 to broaden his horizons, and hopes dels can do the same, but most importantly have a blast of a time.

I. COUNCIL INTRODUCTION

The World Health Organisation (WHO) was established on the 7th of April 1948, now celebrated as World Health Day. Originally composed of 53 member states, WHO has grown into one of the United Nations' (UN) foremost specialised agencies, responsible for maintaining global public health. Chief among its successes are the eradication of smallpox, near-eradication of polio, and most recently, the overseeing of development for the Ebola vaccine. [1]

The WHO is governed by the World Health Assembly, has the ability to approve an aspirational budget and to elect the WHO's director general. WHO's director general serves for a 5 year term and is responsible for raising most of the organisation's funds from donor countries.

Underpinning WHO's mandate are the International Health Regulations (IHR), a legally binding agreement involving 196 countries, with the aim of preventing or controlling global health threats. The IHR includes legal frameworks for monitoring and evaluating a country's health security. It also safeguards the rights of travellers specifically protecting the use of personal information, preventing discrimination and ensuring informed consent. By agreeing to the IHR, countries can benefit from WHO's technical assistance, advice, and help in securing funding to meet the IHR's obligations.[2]

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[1] World Health Organization. (n.d.). *World Health Organization (WHO)*. World Health Organization. https://www.who.int/

[2] Wagle, K. (2021, June 6). What is International Health Regulations (IHR)? everything explained!. Public Health Notes. https://www.publichealthnotes.com/what-is-international-health-regulation-ihr/#What_is_International_Health_Regulations_IHR

II. INTRODUCTION TO TOPIC

With the increased rate at which infectious diseases are emerging — due to factors such as climate change and rapid urbanisation — there is a growing need for the expansion of the pharmaceuticals sector, especially through researching and developing new medicines.[3] Despite the implementation of policies meant to ensure the safety, efficacy and quality of pharmaceuticals, ethical considerations pertaining to pharmaceutical research and development, and issues regarding the production of pharmaceuticals continue to plague countries.[4] At the same time, other concerns such as the affordability and accessibility of medicines, as well as the need to regulate the market need to be addressed, for the sustained expansion of the pharmaceutical industry.

In countries where resources are limited, the prevalence of counterfeit medicines is growing. Where regulatory systems are less developed, offshore companies and bank accounts are often involved as a conduit for ill-gotten funds raised through the sale of counterfeit medicines.[5] As the issues of ethics and the production of pharmaceuticals are relevant to the global economy, it is vital for countries to convene and find common ground, such that the negative impact of illicit activities is minimised and those who are in dire need of pharmaceuticals have access to them.

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[3] Baker, R.E., Mahmud, A.S., Miller, I.F. et al. (2022). *Infectious disease in an era of global change.* Nat Rev Microbiol 20, 193–205. https://doi.org/10.1038/s41579-021-00639-z

[4] Argawal, N. B., & Karwa, M. (2018). *Pharmaceuticals regulation*. Pharmaceuticals Regulation in India. https://www.sciencedirect.com/topics/pharmacology-toxicology-and-pharmaceutical-science/pharmaceuticals-regulation

[5] World Health Organization. (2017, November 28). *1 in 10 medical products in developing countries is substandard or falsified*. World Health Organization. https://www.who.int/news/item/28-11-2017-1-in-10-medical-products-in-developing-countries-is-substandard-or-falsified

II. INTRODUCTION TO TOPIC

The World Health Organisation (WHO) strives to provide universal pharmaceutical access while impeding the proliferation of products with severe side effects. From the testing of pharmaceutical drugs and their affordability, to the necessary regulations to be imposed, there remains a multitude of aspects to the issue of ethical considerations and the production of pharmaceuticals which await discussion.

III. BACKGROUND INFORMATION

The development of pharmaceutical drugs to treat illnesses and diseases can be traced all the way to the Medieval Ages, when herbs were used for medicinal purposes. Notable development started in the early 20th century, when the discovery and mass-production of drugs and vaccines led the pharmaceutical industry a step closer to what it is now. Drugs like penicillin and insulin were discovered, which was followed by the significant life expectancy of patients across many regions. However, as drugs were often sold without testing, concerns regarding the safety of drugs arose. This encouraged the establishment of regulatory organisations globally to ensure safe drugs and industrial regulation. The US Food and Drug Administration (FDA), which was established in the 1930s, made drug testing compulsory before it could be approved for sale.[6] Similar organisations include the European Medicines Agency (EMA), founded in 1995 which regulates and oversees pharmaceutical products in the European Union.[7]

In the 1970s to 1980s, concerns about the affordability of drugs emerged. The WHO created the Model List of Essential Medicines in 1977 to aid countries in developing their own list of essential medicines, which are those that fulfil the top medical demands of a population, such as antiviral medicines and anaesthetics.[8] They should always be available in working healthcare systems, in appropriate dosage forms, of guaranteed quality and at prices both healthcare systems and individuals can afford.[9] By 2016, more than 155 countries had developed local lists of essential medicines based on the WHO's model list.[10] In 1981, the World Health Organization established the Action Programme on Essential Drugs to support countries to implement national drug policies and to work towards the rational use of drugs.[11]

III. BACKGROUND INFORMATION

Today, there remain problems regarding the pharmaceutical industry which are yet to be resolved. The lack of resources in developing countries, for instance, prevents them from being able to commence boosting pharmaceutical productions all over the world, save for a few key areas in developed countries. According to the United Nations, developing countries need help to build their capacity to produce essential medical products, which include vaccines and antibiotics.[12]

The WHO has been continuously playing a vital role in promoting the development of the pharmaceutical industry over the years. With globalisation and urbanisation, the pharmaceutical industry has grown, but its development also comes with issues to be solved. The regulation and safe use of drugs, the ethical concerns of human and animal testing, the affordability of drugs and the accessibility of drugs in LDCs are all rising issues in today's world.

[6] FDA. (2018, June 29). FDA History. U.S. Food and Drug Administration. https://www.fda.gov/about-fda/fda-history

[7] Ema. (2022, August 5). European Medicines Agency. https://www.ema.europa.eu/en

[8] World Health Organization. (n.d.). *WHO Model Lists of Essential Medicines.* World Health Organization. https://www.who.int/groups/expert-committee-on-selection-and-use-of-essential-medicines/essential-medicines-lists

[9] World Health Organization. (2021, September 30). *WHO model list of essential medicines - 22nd list, 2021.* World Health Organization. https://www.who.int/publications/i/item/WHO-MHP-HPS-EML-2021.02

[10] World Health Organization. (2010, December 2). *The WHO Essential Medicines List (EML): 30th anniversary.* WHO. https://web.archive.org/web/20140527003625/http://www.who.int/medicines/events/fs/en/

[11] World Health Assembly, 37. (1984). *Action programme on essential drugs and vaccines*. World Health Organization. https://apps.who.int/iris/handle/10665/161032

[12] *Covid-19 heightens need for pharmaceutical production in poor countries.* UNCTAD. (2020, May 27). https://unctad.org/news/covid-19-heightens-need-pharmaceutical-production-poor-countries

IV. KEY DEFINITIONS

Bullwhip effect: A supply chain phenomenon which happens when a marginal fluctuation in demand at the retail level causes larger supply fluctuations and problems on supplier, manufacturer, wholesale, distributor and retail levels.[13]

Patent: An exclusive right, lasting for a set period of time, officially and legally granted for an invention.[14]

Pharmaceutical drugs: Substances used to prevent or cure a disease or ailment or to alleviate its symptoms.[15]

Supply chain: The network of all individuals, organisations, resources, activities and technology involved in the creation and sale of a product.[16]

[13] Daniel, D. (2023, January 30). *Bullwhip Effect*. ERP. https://www.techtarget.com/searcherp/definition/bullwhip-effect

[14] *World Intellectual Property Organisation.* (n.d.). Patents. WIPO. https://www.wipo.int/patents/en/

[15] Chen, J. (2022, December 22). *What is a drug? Definition in Pharmeceuticals and How They Work.* Investopedia. https://www.investopedia.com/terms/d/drug.asp

[16] Lutkevich, B. (2021, June 2). *What is a supply chain? - definition, models and best practices.* WhatIs.com. https://www.techtarget.com/whatis/definition/supply-chain

V. SCOPE OF DEBATE

RESEARCH AND DEVELOPMENT OF PHARMACEUTICAL DRUGS

HUMAN TESTING

Pharmaceutical drugs need to undergo clinical trials involving human testing before they can be approved for wider use and brought to the market.[17] Clinical trials are an essential step in the discovery and development of new drugs and are mandatory in most countries. However, human testing poses certain risks to the test subjects, hence necessitating a clearer definition of its ethical boundaries. The WHO has a set of guidelines regarding the ethical considerations of research involving human testing, delegates can discuss, with reference to the Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants, a set of common policies that can be implemented, on the monitoring and proper conduct of human testing.[18]

[17] Center for Drug Evaluation and Research. (2014, June 11). *Inside clinical trials: Testing Medical Products in people.* U.S. Food and Drug Administration. https://www.fda.gov/drugs/information-consumers-and-patients-drugs/inside-clinical-trials-testing-medical-products-people

[18] National Institutes of Health. (2011). *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants.* U.S. National Library of Medicine. https://www.nlm.nih.gov/

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PRIVACY AND DATA SECURITY

Another concern is the protection of data and privacy of participants. The data collected from participants are often shared by research institutes for transparency and more efficient research conducted in the future to be able to use these data, meaning these data are stored in large-scale databases. There first needs to be a way to monitor the data shared has been acknowledged and given consent to by participants, and that the confidential information of individuals such as their names, gender and address are. The cybersecurity of these databases will also need to be improved to protect the privacy and data of participants. How can countries improve the data security of these institutes to maintain the privacy and security of research participants? This calls for regional and international collaboration; governments can encourage the sharing of data between international research institutes and build a centralised database to contain the information with the cybersecurity of such databases strengthened by all participating nations. However, such frameworks will only be effective with the strong enforcement of regulations and mutual trust between the members.

V. SCOPE OF DEBATE

ANIMAL TESTING

RELEVANCE OF ANIMAL TESTING

While animal testing has been done in pharmaceutical testing historically, scientists are questioning the relevance of animal testing today as the results do not accurately predict the outcomes in humans. Some scientists believe animal testing does not lead to medical advances and even prolongs the search for effective cures due to the misleading results. Clinical trials are unsuccessful for 92% of potential pharmaceutical drugs that were proven safe and efficient by animal testing.[19]

Moreover, animal testing causes extreme suffering to test subjects both physically and emotionally. Animal rights activists believe that animals are thinking and feeling creatures, and by conducting experiments on them without their consent is going against animal rights. Some countries have banned cosmetics animal testing, including the EU, India, Israel, Norway, Iceland, Switzerland, Australia, Colombia, Mexico, New Zealand, South Korea, Taiwan, Turkey, Guatemala and the UK[20]; but this does not extend to pharmaceutical testing– while changes in U.S. law have no longer required potential pharmaceutical drugs to undergo animal testing before human trials it is still mandatory for a majority of other countries.

[19] World Health Organization. (2011, September 29). *Standards and operational guidance for Ethics Review of health-related research with human participants.* World Health Organization. https://www.who.int/publications/i/item/9789241502948

[20] Cosmetics animal testing FAQ. The Humane Society of the United States. (n.d.). https://www.humanesociety.org/resources/cosmetics-animal-testing-faq

V. SCOPE OF DEBATE

Detractors to banning animal testing say that some animals are biologically similar to humans and are susceptible to the same illnesses, by allowing scientists to observe the effect of potential pharmaceutical drugs on animals before testing them on humans, lowering the risk of exposing human participants to health risks. Some countries have banned cosmetics animal testing, including the EU, India, Israel, Norway, Iceland, Switzerland, Australia, Colombia, Mexico, New Zealand, South Korea, Taiwan, Turkey, Guatemala and the UK; but this does not extend to pharmaceutical testing– while changes in U.S. law have no longer required potential pharmaceutical drugs to undergo animal testing before human trials it is still mandatory for a majority of other countries. Detractors to banning animal testing say that some animals are biologically similar to humans and are susceptible to the same illnesses[21], by allowing scientists to observe the effect of potential pharmaceutical drugs on animals before testing them on humans, lowering the risk of exposing human participants to health risks.

[21]Stanford Medicine. (n.d.). *Why Animal Research?*. Animal Research at Stanford. https://med.stanford.edu/animalresearch/why-animal-research.html

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Recent developments have made it possible for pharmaceutical testing to be accurate and animal free. Non-animal research methods like organs-on-chips technology (microchips mimicking how organs' functions are affected by pharmaceutical and computer modelling) have proven to show more reliable and accurate results than animal testing. However, supporters of animal testing point out that there are limitations of technology and their ability to reflect potential results to pharmaceutical drugs.[22] The development of technology and Artificial Intelligence in the research and medical fields has made it possible for us to reduce our reliance on animal testing. This reduces unnecessary suffering of animals and resolves the ethical concern of animals being involved in research without giving consent. The WHO may want to explore the possibility of gradually reducing the significance animal testing has on pharmaceutical research, as well as advancements in technology that allows animal testing to be completely banned. However, countries which use animal testing more commonly like China, Japan and Canada may find it difficult to limit animal testing in their countries. Delegates will have to find ways to negotiate and make compromises to encourage the development of science and technology while reducing the use of animal testing in research.

[22] Ma, C., Peng, Y., Li, H., & Chen, W. (2021). Organ-on-a-Chip: A New Paradigm for Drug Development. *Trends in pharmacological sciences*, 42(2), 119–133. https://doi.org/10.1016/j.tips.2020.11.009

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ACCESSIBILITY OF DRUGS

LEGAL COMPLIANCE

The Addis Ababa Action Agenda in 2015 reaffirmed the need for World Trade Organisation (WTO) members to contribute to Trade-Related Aspects of Intellectual Property Rights (TRIPS).[23] TRIPS is supposed to allow generic pharmaceutical producers to use patented technology for the production of cheaper, generic versions of pharmaceuticals.[24] However, one of TRIPS biggest limitations is that its flexibility has not been incorporated by many developing countries into their legal legislation due to lacking legal expertise.[25] One international incident regarding TRIPS was over AIDS drugs in Africa. Patent protections which originated from TRIPS were responsible for higher drug costs for public health in Africa, but TRIPS was not revised. Rather, an interpretive statement, the Doha Declaration was issued by the WTO. The Doha Declaration stated that TRIPS should not prevent states from intervening to solve public health issues and allowed for compulsory

[23] United Nations. (2015, July 27). *Addis Ababa Action Agenda of the Third International Conference on Financing for Development.* Third International Conference. https://www.un.org/esa/ffd/wp-content/uploads/2015/08/AAAA_Outcome.pdf

[24] United Nations. (n.d.). *Access to affordable medicines*. United Nations: Inter-agency Task Force on Financing for Development. https://developmentfinance.un.org/access-affordable-medicines

[25] Musungu, S. (2011, December 21). *"The use of flexibilities in trips by developing countries: Can they promote access to medicines?"* Commission on Intellectual Property Rights, Innovation and Public Health. https://web.archive.org/web/20131031151841/http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/index.html

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licensing, allowing African health officials during the AIDS crisis to use such patents without seeking permission, though there is some compensation to the patent holder. Afterwards, developed nations such as the US attempted to minimise the Doha Declaration's effectiveness.[26] This happened as a result of the Doha Declaration commitment to improving development without import barriers for developing countries. However, some countries such as China and India began exporting far more medicine than importing, competing with wealthier countries. When these countries asked for China/India to roll back their import barriers to allow for foreign competition, they refused. Hence the Doha Declaration fell apart due to opposition from the Western and Eastern blocs.[27]

In addition, regulatory agencies take a long time to approve drugs for sale in new markets. Even in developed countries with greater access to manpower and resources, such approvals can take up to 18 months on average.[28] For agencies in developing countries, this process is even

[26] Timmermann, C. A., & Belt, H. van den. (2013, January 1). *Intellectual property and global health: From Corporate Social Responsibility to the access to knowledge movement*. Intellectual Property and Global Health: From Corporate Social Responsibility to the Access to Knowledge Movement. https://library.wur.nl/WebQuery/wurpubs/438139

[27] The Editorial Board. (2016, January 1). *Global Trade After the Failure of the Doha Round*. The New York Times: Opinion. https://www.nytimes.com/2016/01/01/opinion/global-trade-after-the-failure-of-the-doha-round.html#:~:text=In%20recent%20years%2C%20it%20became,able%20to%20make%20fundamental%20concessions

[28] Nationwide Children's Hospital. (2021, January 7). *What does it take to get a medication approved through the FDA?*. Nationwide Children's. https://www.nationwidechildrens.org/family-resources-education/700childrens/2018/03/what-does-it-take-to-get-a-drug-approved-through-the-fda

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longer, especially due to insufficient manpower and resources. This process occurs despite generics generally being of equivalent quality to their branded counterparts.[29] Dealing with such legal red tape costs large sums of money and time.[30] This makes the provision of affordable pharmaceutical drugs in developing countries more difficult, given that manufacturers may increase prices to offset legal costs, or elect not to offer their drugs in these countries.

Developed countries with advanced pharmaceutical industries, in regions where the pharmaceutical market is highly concentrated, such as the United States and a number of countries in the European Union (EU), can help less developed countries with the attainment of such drugs. Nonetheless, these countries may be reluctant to play a part in expanding the pharmaceutical industry of other countries, for practical reasons such as protecting their own local establishments, by enabling people from around the world to be limited to purchasing the products of their country, or simply because they do not feel any moral obligation to do so. Delegates will have to find a method of balancing between increasing accessibility to drugs in a timely manner, while still maintaining safety/efficacy standards for generics.

[29] Center for Drug Evaluation and Research. (n.d.). *Generic Drugs: Questions & Answers*. U.S. Food and Drug Administration. https://www.fda.gov/drugs/frequently-asked-questions-popular-topics/generic-drugs-questions-answers

[30] *Reducing the red tape around supply chains – Third way*. (n.d.). Third Way. https://www.thirdway.org/report/reducing-the-red-tape-around-supply-chains

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SUPPLY CHAIN ISSUES

In setting up supply chains in developing countries, there are numerous issues. Firstly, there are high risks faced by Just-in-time procurement (JIT), which is often utilised by the pharmaceutical industry. In short, JIT is a strategy used to produce goods only when needed, reducing storage costs and redundancy. JIT is particularly useful for developing countries, as JIT improves the quality of medicines, as many drugs cannot be stored for extended durations. JIT also reduces inventory space requirements, helping save on storage costs over the long term.[31] However, transportation costs prohibit JIT from being further utilised in developing countries, as JIT necessitates a higher volume of deliveries. Reducing inventory space would require more deliveries, which decreases efficiency, and increases delivery costs. Some countries have tried to reduce transportation costs, such as Rwanda, which utilises drones to transport blood products, though the current system is small in scale and may not work for drugs that require constant refrigeration.[32]

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[31] *Using the just in time method helped this indian hospital reduce waste and save cost*. (n.d.). hospitalmanagementasia.com. https://www.hospitalmanagementasia.com/tech-innovation/using-the-just-in-time-method-helped-this-indian-hospital-reduce-waste-save-cost/

[32] Nast, C. (2022, April 21). *Drones have transformed blood delivery in Rwanda*. WIRED. https://www.wired.com/story/drones-have-transformed-blood-delivery-in-rwanda/

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Additionally, pharmaceutical producers and distributors suffer from an inability to easily identify potential disruptive events in the supply chain.[33] For many pharmaceuticals, small temperature deviations can ruin an entire shipment– but as industry practice records data passively (i.e. logs data after arrival) instead of in real time, most companies cannot respond quickly enough to rectify any problems. More than a quarter of pharmaceutical firms have experienced damaged or lost inventory, mainly due to a lack of full visibility into their supply chains.[34] A transition to active data loggers, however, is difficult to achieve, as these active data loggers are limited by high costs.[35] Without access to data, supply chains will be vulnerable to the *bullwhip effect*. This effect occurs due to overstocking following initial shortages and causes instability amongst manufacturers and suppliers. In the pharmaceutical industry, due to the pervasive impacts of the *bullwhip effect*, even a minute change in temperature or pressure could potentially affect an entire batch of drugs, especially during shipping. Therefore, countries must work hand in hand to develop supply chains, such as mitigating the *bullwhip effect*.

[33] *Five critical challenges facing Pharma supply chains.* (n.d.). https://www.supplychainbrain.com/articles/34798-five-critical-challenges-facing-pharma-supply-chains

[34] *Top challenges facing Pharma supply chains.* (2022, June 30). ParkourSC. https://www.parkoursc.com/top-challenges-facing-pharma-supply-chains/

[35] SensoScientific. (2022, April 20). *Evolution of data loggers to continuous monitoring*. https://www.sensoscientific.com/evolution-of-data-loggers-to-continuous-monitoring/

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SUPPORT FROM PHARMACEUTICAL FIRMS

The only stakeholders who can realistically set up production of pharmaceuticals in developing countries are pharmaceutical companies. This is mainly due to their research and development expertise and capabilities. It is unfeasible for health agencies of less developed countries to develop/manufacture products to meet local demands. Obstacles include lacking knowledge, manpower and resources.[36] In light of this, there has been some progress in getting pharmaceutical firms to develop R&D/production facilities in developing countries, for diseases such as malaria, HIV/AIDS and tuberculosis.

The three primary methods these pharmaceutical firms use to further access are voluntary licensing, equitable pricing, and drug donations. Voluntary licensing involves agreements with generic manufacturers to supply patented drugs more cost effectively than the patent holder, while equitable pricing consists of bundles of medicines that target key diseases. These bundles are priced at around $1 monthly in developing countries. However, a majority of these efforts are concentrated around certain disease areas, and with only 5 companies (GlaxoSmithKline, Novartis, Sanofi, Merck, and Johnson and Johnson) doing a majority of the work. This causes large amounts of volatility, as one of these companies changing their focus would greatly disrupt global health efforts.[37] In order to solve this issue, delegates should attempt to reduce volatility or raise support for company subsidised pharmaceuticals.

[36] *Generic medicine manufacturers.* (n.d.). Access To Medicine Foundation | Access to Medicine Foundation. https://accesstomedicinefoundation.org/sectors-and-research/generic-medicine-manufacturers

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INADEQUATE DIGITAL SYSTEMS

Digital health care systems, which encompass mobile health applications, online health and medical records, as well as personalised medicines, are implemented in order to improve the monitoring of pharmaceutical drug usage.[38] Information regarding the personal medical needs of different patients are commonly registered and stored in systems which vary from hospital to hospital, leading to complications when it comes to the sharing of information across health care organisations and countries. The main issues this causes are the lack of monitoring of pharmaceuticals, owing to the incomplete digitalisation of the healthcare sector, are the increased risks in diagnosis, which worsens the problem of overprescription, and the delay in time taken to assist a patient, which is most definitely not ideal in the medical field.[39]

[37] Nawrat, A. (2020, January 17). *Stop ignoring the two billion: Pharma and access to medicine*. Pharmaceutical Technology. https://www.pharmaceutical-technology.com/features/access-to-medicine-pharma/

[38] *What is digital health (digital healthcare) and why is it important?* (2021, March 11). Health IT. https://www.techtarget.com/searchhealthit/definition/digital-health-digital-healthcare#:~:text=Under%20its%20umbrella%2C%20digital%20health,as%20well%20as%20personalized%20medicine

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Consequently, this problem is exacerbated in less developed countries, which may not have systems as complete and advanced in their health institutions, preventing progress from being made in terms of ensuring the safety of patients and the quality of medical care. A number of developing countries, especially those in conflict zones such as Yemen and Syria, do not have a system of universal healthcare in place at all, let alone a working digital system. This impedes the advancement of pharmaceutical drugs, regardless of whether developed countries are willing to support the increased accessibility of such medicines in the region.[40] Due to these countries potentially being prone to conflict and violence, the people living there likely need the pharmaceutical resources most, yet the dysfunctional "healthcare systems" currently in place do not cater to their severe needs.

[39] *Challenges faced by health professionals in obtaining correct medication information in the absence of a shared digital medication list.* (n.d.). PubMed Central (PMC). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8006028/

[40] Expatriate Healthcare. (2022, November 15). What countries have free healthcare? Expatriate Group. https://www.expatriatehealthcare.com/what-countries-have-free-healthcare/#:~:text=However%2C%20some%20people%20cannot%20afford,%2C%20Iran%2C%20and%20South%20Africa

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REGULATION OF PHARMACEUTICAL DRUGS

DIFFERENT USES OF PHARMACEUTICAL DRUGS

Certain drugs are used for purely medical reasons, but they also have the potential to be abused as people turn to the usage of those very drugs for recreational purposes. A full ban of these pharmaceutical drugs, though effective in regulation, undermines their medicinal value, and disables those who require them from having perhaps the sole available chance at treatment they have. For instance, opioids, present in medications such as OxyContin, Vicodin and morphine, are prescribed by doctors to alleviate severe pain.[41] Yet, despite its proven medicinal benefits, this pharmaceutical drug has been banned in a number of countries, due to its highly addictive nature caused by the triggering of endorphin release.[42]

The banning of pharmaceutical drugs has always been argued to be able to bring crime rates down too[43], but countries with full bans on may want to reevaluate their regulations, by considering if the trade-off between people having less access to the essential medicine they need for treatment in order to survive and the social implications of having people becoming addicted is worth the ban, particularly for medicines which contain the addictive THC.

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[41] *Opioid basics.* (2022, October 7). Centers for Disease Control and Prevention. https://www.cdc.gov/opioids/basics/index.html#:~:text=Opioids%20are%20a%20class%20of%20drugs%20used%20to%20reduce%20pain.&text=Prescription%20opioids%20can%20be%20prescribed

[42] Am I vulnerable to opioid addiction? (2022, April 12). Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/prescription-drug-abuse/in-depth/how-opioid-addiction-occurs/art-20360372#:~:text=Doctors%20define%20drug%20addiction%20as,reward%20centers%20in%20your%20brain

[43] Legalization of illicit drugs. (n.d.). C G A. https://cga.ct.gov/PS94/rpt%5Colr%5Chtm/94-R-1089.htm

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The view that countries should allow for the safe use of drugs, by differentiating if they are used for medical or recreational purposes, is supported by the United States, which has a lucrative pharmaceutical market. Pharmaceutical drugs are commonly used in pain relief medicines, such as opioids — whose family heroin is a part of — sleeping pills and stimulant medicines to treat ADHD and narcolepsy. Nevertheless, these drugs also serve recreational purposes when a consumer crosses the fine line between dependence and addiction, and this is an issue which needs addressing.[44]

DECRIMINALISATION OF DRUGS

While others such as Czechia, the Netherlands, Portugal and Switzerland have worked on decriminalising their usage[45], with Portugal being the first to do so in 2001[46], others have put laws in place to ensure the safety and efficacy of pharmaceutical drugs, with possible recreational purposes, in the market.[47] These include Japan, Singapore, Germany and most other European countries who are in favour of having a full ban on recreational drugs, to ease the monitoring of their usage and to have the ability of introducing new regulations as soon as possible, where necessary. Nonetheless, this stability reinforced by regulations may come with drawbacks, hence the controversies and differences in laws amongst countries.

[44] *Can medicines be addictive?* (2022, September 3). Trusted Health Advice | healthdirect. https://www.healthdirect.gov.au/medicines-and-addiction

[45] Decriminalization works, but too few countries are taking the bold step. (2020, March 3). UNAIDS. https://www.unaids.org/en/resources/presscentre/featurestories/2020/march/20200303_drugs

[46] Want to win the war on drugs? Portugal might have the answer. (2018, August 1). Time. https://time.com/longform/portugal-drug-use-decriminalization/

[47] Pharmaceuticals regulation an overview. (n.d.). ScienceDirect. https://www.sciencedirect.com/topics/medicine-and-dentistry/pharmaceuticals-regulation

V. SCOPE OF DEBATE

In China, due to the bureaucratic processes accompanying the approval of legal medicinal drug usage, many turn to black markets,[48] or even resort to making their own treatment, as a man by the name of Zhang Zhejun did in order to have a shot at saving his mother from the pains of lung cancer.[49] Others have smuggled painkillers to relieve the symptoms of Covid-19.[50]

On the other hand, countries decriminalising the usage of drugs, especially for pharmaceutical purposes, are of the belief that having strict law enforcement has proven to be ineffective in the past decades, and the constant surveillance needed takes a toll on a country's resources. Switzerland, in particular, saw thousands in the country consuming heroin — an opioid drug made from morphine, with some claiming that it is of therapeutic value — in a bid to combat waves of HIV/AIDS surges despite the law.[51]

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[48] Liang, X. (2022, December 26). *Chinese turn to black market for generic Indian COVID-19 drugs.* South China Morning Post. https://www.scmp.com/news/china/politics/article/3204617/chinese-turn-black-market-generic-indian-covid-19-drugs-surge-sweeps-nation

[49] *In China, desperate patients smuggle drugs. Or make their own.* (Published 2018). (2021, September 15). The New York Times - Breaking News, US News, World News and Videos. https://www.nytimes.com/2018/11/11/business/china-drugs-smuggled-homemade.html

[50] *As COVID-19 ravages China, some seek black market drugs.* (2023, January 16). Time. https://time.com/6247596/covid-china-contraband-treatments/

[51] *Heroin DrugFacts.* (2022, March 22). National Institute on Drug Abuse. https://nida.nih.gov/publications/drugfacts/heroin

V. SCOPE OF DEBATE

Though every country should be able to have their own laws, the fact that these drugs carry medicinal value and are proven to alleviate pain necessitates discussions on the issue of drug regulation. The differences countries have in their protocols and laws regarding the use of pharmaceuticals has led to issues such as smuggling pharmaceutical drugs. Even with patents being handed to pharmaceutical companies, the prices of smuggled drugs with medicinal value — as was the case for AIDS drugs in 2005 — will increase in the black market, making these medical solutions inaccessible to those who need it, especially in less developed countries.[52] As such, countries need to strike a balance between keeping pharmaceutical drugs accessible, and mitigating issues such as overprescription and addiction that would stem as a result of a potential decriminalisation.

[52] Harvard. (2005). *Price discrimination and smuggling of AIDS drugs.* https://core.ac.uk/download/pdf/28932729.pdf

VI. KEY STAKEHOLDERS

COUNTRIES WITH WELL-DEVELOPED PHARMACEUTICAL MARKETS

Countries with well-developed pharmaceutical markets have a high market value and host many multinational pharmaceutical companies. They also have leading biotechnology in the research and development sector of the pharmaceutical industry, playing an important role in global pharmaceutical innovation. However, these countries are often plagued with issues within their own country, such as inequality in healthcare systems and inaccessibility of medicines in rural areas. They also face competition with emerging pharmaceutical markets of developing countries.

Delegates of these countries will have to stay relevant in global markets, collaborate with others to improve the supply chains worldwide while maintaining a lead in the market. It is likely that these countries will come up with solutions which require collaboration and financial aid for developing countries to establish a stable pharmaceutical industry as well as to increase healthcare coverage within their own countries.

VI. KEY STAKEHOLDERS

LESS DEVELOPED COUNTRIES WITH POOR ACCESS TO PHARMACEUTICAL DRUGS

Despite often contributing to the development of new pharmaceuticals through clinical trials, these countries do not see much, if any, benefits from them.[53] There are substantial gaps in market access between developed and developing countries. Even after copyright protection expires and opens the market to generics, generics can actually be more expensive in less developed countries compared to developed countries. This is due to low levels of competition, enabling manufacturers to set up monopolies.[54]

These countries, found mostly within African, Latin American and South Asian societies, tend to be unable to develop or manufacture their own drugs, due to a lack of expertise/knowledge, resources and manpower. These countries also often lack the suitable infrastructure for further development. Delegates of these countries must keep in mind their resource constraints in attempting to set up production/supply lines in their states and secure the proper infrastructure to develop such industries.

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[53] *Clinical trials in Asia: A World Health Organization database study*. (2019). PubMed Central (PMC). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6647899/#:~:text=The%20USA%20accounted%20for%2024,trials%20that%20recruited%20in%20Asia

[54] Poor countries desperately need better access to generic medicines. (2023, February 15). Financial Times. https://www.ft.com/content/99d64932-fd04-488f-9c63-b3646083cbbc

VI. KEY STAKEHOLDERS

COUNTRIES DECRIMINALISING PHARMACEUTICAL DRUGS

These countries, found mostly within the EU and in Western societies, believe that the decriminalisation of drugs is effective in solving pharmaceutical issues internally within the country, and externally. Moreover, decriminalising pharmaceutical drugs would allow precious resources to be diverted for other purposes, instead of having to constantly regulate the flow of drugs in and out of the country, and dedicating a considerable proportion of the justice system to drug-related crimes.[55]

According to UNAIDS, a joint programme of the UN system created to spur global effort to end AIDS as a public health threat by 2030, decriminalising pharmaceutical drugs has indeed benefited some countries, but "too few countries are taking the bold step".[56] [57] A number of countries which have successfully decriminalised pharmaceutical drugs would call for others in the council to do so as well, in order to increase the accessibility of pharmaceutical drugs, and more importantly, to protect the human rights of people around the world by reducing severe penalties, such as the capital punishment. Nevertheless, given the contentious nature of this issue, these countries would have to also consider the fact that different countries have different demographics, which may affect their rules against drug usage.

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[55] Greer, A. (2021, June 28). *Decriminalizing drug use is a necessary step, but it won't end the opioid overdose crisis.* The Conversation. https://theconversation.com/decriminalizing-drug-use-is-a-necessary-step-but-it-wont-end-the-opioid-overdose-crisis-162497

[56] *About UNAIDS.* (n.d.). UNAIDS. https://www.unaids.org/en/whoweare/about

[57] *Decriminalization works, but too few countries are taking the bold step.* (2020, March 3). UNAIDS. https://www.unaids.org/en/resources/presscentre/featurestories/2020/march/20200303_drugs

VII. POTENTIAL SOLUTIONS

COMMON POLICIES ON SUPPLY CHAIN DISRUPTION

International policies can also be drafted to further cushion the impacts of potential disruptions along the supply chain, especially in times of crisis.[58] Countries can work together to implement frameworks with the purpose of ameliorating access and affordability of pharmaceuticals to areas of violence and conflict. An example of such a policy would be to collectively accede to reducing trade barriers and tariffs amongst the countries involved should the need arise, and people in a certain region are in dire need of pharmaceuticals. This would be especially useful for countries within conflict-prone areas, since the supply of pharmaceuticals rely on a wide global network, in order to maintain its accessibility. The execution of such an international initiative, however, would necessitate countries to agree and be cooperative on setting common standards in terms of trade, such that the policy would not be futile, as this is an issue which affects the global market.

[58] *Five critical challenges facing Pharma supply chains.* (n.d.). SupplyChainBrain. https://www.supplychainbrain.com/articles/34798-five-critical-challenges-facing-pharma-supply-chains

VII. POTENTIAL SOLUTIONS

AGREEING TO BULK PURCHASES AS INTERNATIONAL/REGIONAL ORGANISATIONS

Pharmaceutical companies have large amounts of leverage over individual consumers. Consumers, however, can be represented by their governments. Governments, who represent an entire country's population, have significantly more bargaining power. As such, they are more able to negotiate with pharmaceutical companies for better prices, in addition to buying in bulk for the entire country, thus making these drugs much more affordable for the average consumer. Examples of such systems include the UK's National Health Service which has significantly lower prices for drugs such as insulin, compared to the USA which pays 8.9 times more. A larger scale version of such a system, comprising multiple countries on an international scale, would grant governments greater collective bargaining power to negotiate prices in their favour. This could work similarly to the EU's latest agreement to jointly purchase weapons.[59] However some limitations of this solution are that drugs for rare diseases, known as orphan drugs may be inaccessible to consumers, as governments may not want to purchase large amounts of a drug that few will use. Drugs for diseases such as hereditary angioedema (HAE), amyotrophic lateral sclerosis (ALS), Gaucher's disease, and Huntington's chorea suffer from a lack of financial incentive, due to governments unwilling to buy them, and companies who are forced to price orphan drugs highly to recoup research and development costs.

[59] *EU closer to joint arms-buying to aid Ukraine but hurdles remain.* (2023, March 6). Reuters. https://www.reuters.com/world/europe/eu-closer-joint-arms-buying-aid-ukraine-hurdles-remain-2023-03-06/

VII. POTENTIAL SOLUTIONS

ENHANCED MONITORING

The pharmaceutical industry currently faces the issue of poor regulation and enforcement of law. The WHO Global Surveillance and Monitoring System, which aims to better analyse and prevent substandard and falsified (SF) medical products, currently has measures which allows member states to submit reports of suspected SF medical products which will then be analysed and provided with assistance if necessary. There can be further actions done by this committee. Regular monitoring of research involving human and animal testing should be conducted to ensure the rights of humans are well protected and regulations protecting animal test subjects are followed. The organisation can also oversee the usage of funds given to developing members to set up a stable pharmaceutical market, ensuring the financial assistance is used effectively, as well as the equity and equality of fund distribution process. However because this committee is given access to sensitive information, not all countries will be cooperative. The extent of involvement of the committee will need to be determined. Furthermore, mutual trust and regular monitoring will be required for this solution to be effective.

QUESTIONS A RESOLUTION MUST ANSWER (QARMA)

1. How can more developed countries support less developed ones in producing pharmaceutical drugs?

2. How can human and animal rights be better respected in research?

3. What are the ethical guidelines that should be established to govern the pricing, manufacturing and developing process of pharmaceutical products?

4. To what extent should national policies criminalising pharmaceutical drugs be implemented?

5. In what ways can countries ensure that others would uphold international standards with regards to the ethics and production of pharmaceuticals?

CONCLUSION

Despite various efforts to improve the pharmaceutical industry, there are still many underlying issues yet to be resolved. While countries have made progress, through new animal-friendly laws and the encouragement of technological developments, the lack of coordinated efforts, enforcement of laws and regulation of drug production hinders the efficiency and accessibility of the pharmaceutical industry. At this conference, the issue of ethical concerns regarding human and animal testing, accessibility of drugs and the regulation of pharmaceutical drugs awaits to be debated.

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