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IFMSA Policy Proposal Trade and Health

Proposed by MEDSAR-Rwanda and IFMSA-Pakistan

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Policy Statement

Introduction:

Global trade and health are inextricably connected. Access to medicines, food security, transport of infectious agents, trade based migration, sale of harmful products like cigarettes, alcohol and sugar-sweetened food products and economic impacts on health systems are just some of the many areas of health that are affected. All areas of life have positive and/or negative impacts on health and all areas of life are impacted by trade; these are often referred to as the commercial determinants of health.

IFMSA position:

The commercial determinants of health have an incalculable impact on patient outcomes and population health. A 'health in all policies' approach must be used to ensure that profits and private interests are not put ahead of health in trade and policy deliberations. Governments should work with all sectors to support businesses and jobs whilst ensuring their operations don't negatively impact public health. Inter-governmental organizations should facilitate fair negotiation of trade details to ensure equitable access to health products to protect the global population.

Call to Action:

Therefore, the IFMSA calls on:

WHO Member States

1. Implement a 'Health in All Policies' approach to governance that reviews all new and existing policies' impact on health and seeks to remove or mitigate any negative impacts
2. Work in conjunction with relevant intergovernmental organization (i.e. World Trade Organization) rules to ensure fair trading practices and uphold international law surrounding trade and health
3. Adhere to World Health Organization guidance surrounding access to medicines
4. Provide sufficient financial resources for medical education and oppose any trade agreements that increase the commercialisation of the medical education sector
5. Reduce trade tariffs and seek free trade agreements to strengthen diplomatic ties in order to prevent conflict and subsequent negative health impacts
6. Adhere to International Health Regulation law surrounding borders and trade in health emergencies
7. Ensure multinational corporations based in their country do not impact citizens' health in another member state
8. Agree to only climate-friendly trade agreements and policies, acknowledging the links between trade, climate change and health



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9. Ensure public services such as health are excluded from free trade agreements except in the instance of trading health related goods. Services must be excluded to ensure equitable access.
10. Implement ethical procurement policies in healthcare organisations
11. Consider the consequences of trade initiatives on the source country, ensuring steps are taken to improve inequities in wealth distribution thus improving the health divide in developing countries

World Health Organization to:

1. Seek to update the International Health Regulations to work in conjunction with updated global trade laws and practices
2. Facilitate agreements between member states to increase access to medicines, vaccines, diagnostics and other health products
3. Work with other intergovernmental organizations to facilitate global agreements that protect health whilst allowing trade
4. Facilitate the improvement and approval of TRIPS flexibilities in public health emergencies to rapidly increase access to essential medicines, vaccines and other health products

IFMSA National Member Organizations and Medical Students:

1. Advocate for their governments to implement the Health in All Policies approach
2. Advocate for their governments to implement the calls to action made in this policy
3. Raise public and peer awareness of the links between trade and health
4. Raise public awareness of tactics used by multinational corporations to increase consumption of their products and exploitation of disparities between countries domestic trading laws
5. Advocate for ethical procurement in healthcare organisations, clearly stating the standards expected from organisations in the supply chain and the effective communication of this to the people with a role in upholding these principles.
6. Advocate for open and transparent trade agreement negotiations with meaningful and equitable opportunities for stakeholder participation



Position Paper

Background information:

Trade law is constantly updated, and new trade agreements negotiated and implemented, especially in this time of globalisation. Trade and health are inextricably connected, and issues caused by trade practices often arise without being foreseen. It is difficult to create policy that addresses all issues with all trade agreements but in this policy document we detail common themes and general issues of trade governance and trade processes.

Discussion:

Food Industry

The food and agriculture industry are key when assessing the relationship between food and health. As agriculture employs 1 in 3 of the world's workers and 60% of child labourers work in agriculture (1), it is important not to overlook the effect that this industry has on health, not only that of the consumer, but also of the workers. Inappropriate use of pesticides, for example, can be hazardous to both human and animal health (1); and child labour, with the subsequent loss of educational opportunities and improvement of socioeconomic status, has adverse effects on children's development and wellbeing (2).

Trade liberalisation has led to changes in food availability and increases in both imports and exports of food, as well as in prices (7).

- Increases in imports have allowed countries with insufficient domestic production to reach or become closer to food adequacy (7). Relative availability of food has also changed, by making certain products available, or decreasing the availability of a product through the increase of a substitute, as was the case with Pacific Islands and the increased consumption of imported high-fat meat and consequent decrease in traditional root crops (7, 8).
- Trade liberalisation has resulted in a reduction in prices for animal products, which has driven an increase in their consumption in LMICs - improving protein intake and contributing to the alleviation of undernutrition (11). It has also reduced the cost associated with energy-dense foods (7), resulting in a greater prevalence of obesity and overweight among those of lower socioeconomic status (2, 9). The nutrition transition that accompanies economic development results in a high burden of NCDs (10,11). This is illustrated by the Pacific Islands, where the low-cost of imported fatty meats, described as dumping of low-quality products (7, 8, 11, 12), lead to high consumption and is considered a contributing factor to the high prevalence of NCDs (8). The incentivising of exports that often occurs under trade liberalisation has resulted in a favouring of these more profitable crops over domestic traditional crops, shifting alimentary patterns, often towards more processed foods and animal products (11).

Subsidising healthier foods, such as fruit and vegetables, is largely viewed as a complementary measure to the taxation of unhealthy foods. The WHO Global Strategy on Diet, Physical Activity and Health (2004) recognises that fiscal measures are powerful means to effect consumption patterns and promote healthy dietary choices. These kinds of measures can also be used to protect food security and as part of a broader agricultural policy. However, countries wishing to implement specific subsidies for agricultural and food products must ensure that the subsidy does not discriminate, deliberately or inadvertently, against imports compared to domestic products. States with higher bound tariff rates enjoy a greater scope for subsidisation. Alternatively, tariffs for healthful products can be reduced, while maintaining bound tariffs for unhealthy products. Countries should feel empowered to implement non-discriminatory food subsidisation measures, which are viewed as largely compatible with current international trade law structures. Some countries, such as some small island states, may need to encourage local production of healthy foods because of the difficulties of



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importation. In these cases, States can implement production subsidies to promote domestic production.

NCDs are increasing in prevalence and are the commonest cause of death worldwide (3). Within NCDs, cardiovascular disease is the commonest cause of death (3). The WHO hinges their prevention of NCDs on tackling tobacco use, harmful use of alcohol, obesity, unhealthy diet and insufficient physical activity, excessive salt intake and on improving oral health (4).

Obesity and overweight in particular have risen to such an extent that they cause more deaths than undernutrition (5), and the cause of this problem is two-pronged - a result of the increase in consumption of energy-dense foods, and a decrease in physical activity and uptake of a sedentary lifestyle (5,6).

Tobacco and Alcohol

The threats to health of tobacco and alcohol use are well-known, while the factors underlying the global increase in tobacco and alcohol use, especially in lower income countries, are not well understood and largely underestimated. There is evidence that trade and investment liberalisation over the last few decades have stimulated consumption and increased the rates of tobacco use above modelled rates had markets not been opened (1). The reasons for the link between increased market access and increased domestic tobacco and alcohol use are multifactorial; and include lower tariffs, the increased availability of established foreign brands (including in previously tobacco-free markets), altered competitive conditions resulting in lower prices, and more aggressive marketing and advertising, including to new population groups, especially women and children (1). Tobacco and alcohol measures interact with trade law slightly differently, although many themes are common for both. Fiscal policies, such as tariffs, taxation and other price measures, fall under the remit of the General Agreement on Tariffs and Trade (GATT), while non-tariff barriers to trade, such as packaging and labelling measures, are examined under the TBT agreement. Similarly, measures affecting cross-border advertising and retail services for tobacco and alcohol may be found to violate the GATS agreement if the measure is deemed an unjustifiable and disguised restriction on trade, despite being necessary to protect human health (14,16). However, some specific public health measures for tobacco and alcohol interact differently with international trade law. For example, the plain packaging of tobacco products, a policy that is becoming increasingly popular globally, is primarily discussed under the TRIPS agreement because the prohibition of the use of tobacco trademarks on cigarette packages affects the trademarks rightfully owned by tobacco companies.

The TRIPS agreement provides tobacco companies with the right to register their trademarks, but arguably not the right to use them (29). Plain packaging represents a prohibition on use of the trademark, and not the acquisition of the trademark by the government, and the measure arguably does not qualify as one of the special requirements on trademark use that are prohibited by the Agreement, which would make plain packaging permissible under trade law. This is the view that was taken by the WTO panel in a dispute lodged against Australia following the announcement of its plain packaging law in 2011 (29). A specific example for alcohol would be the prohibition of "alcopops", where contents that make these beverages more attractive to young people, would qualify as an additive and thus fall under the SPS agreement. The SPS Agreement is slightly different from the GATT, which applies mainly to fiscal policies, because it requires that all measures are determined to be necessary, using scientific evidence, which may not always be available when a country decides to implement a novel measure (31). Furthermore, measures assessed under the SPS Agreement need a thorough risk assessment, which may lead to regulatory chill in governments with less in-house capacity for legal defence. In summary, trade liberalisation and resultant increased market access has greatly contributed to global increases of tobacco and alcohol use in epidemic proportions. In spite of this, public health measures with the regulatory objective to decrease the use of tobacco and alcohol within the population may face a legal challenge under existing instruments of international trade law, both those agreements held by the World Trade Organisation and various regional and bilateral free trade agreements (13).



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Governments must be able to argue that their measures are necessary to protect human health, and that there are no other measures they could alternatively use that would be less restrictive to trade (29). Other tobacco and alcohol control policies should be seen as complementary rather than alternative, because these complex risk factors for non-communicable disease are best tackled with a multi-pronged approach (16).

Trade Governance: WTO

The World Trade Organisation (WTO) is an international organisation concerned with rules pertaining to trade among nations. Its primary aim is to reduce obstacles to free trade by facilitating negotiations between member states (14). With 164 member states, the majority of the world's population falls under trade regulations and laws established by the WTO, it is important to consider the impact of their legislation in a health care context, particularly with attention paid to the impact of trade liberalisation at the very core of the institution's purpose (14)(15).

Whilst the expansion of free markets and increasing volumes of trade have been proven to generate economic surplus, the globalisation and subsequent marketisation of health care represents a serious risk to the concept of universal, publicly funded health care as outlined by the WHO (16)(17). To ensure that the maximum portion of the population is able to access quality and universal health care, the 2008 commission by the WHO recommends "The commission advocates the financing of health-care systems through general taxation or mandatory universal insurance. The evidence is compellingly in favour of publicly funded health care systems" (17). Furthermore, another potential hindrance of greater trade liberalisation in the global health care sector, as desired for by the WTO, is the possibility of a "brain drain", whereby skilled professionals become in shortage in the developing world as they move elsewhere for higher living conditions; this results in a less equitable health care system (18).

In the past there have been collaborations between the WTO and WHO, including the TRIPS agreement, which has previously been criticised as it has been thought to reduce pharmaceutical availability in nations by enforcing stricter patent protection, thus disallowing more affordable, slightly modified alternatives (19). Despite this, not all actions taken by the WTO pertaining to health are detrimental. New foreign investment opportunities in health care may result in the creation of previously unavailable resources and there is sufficient literature to confirm that increasing free trade has led to reductions in poverty (18).

Trade Governance: TRIPS

The Agreement on Trade -Related Aspects of Intellectual Property Rights (TRIPS) is the legal framework for intellectual property rights agreed to by all member states of the WTO. It lays down the minimum standards of protection and regulation each member state has to give to the intellectual property of any national of any other member state of the WTO. This is achieved by covering the basic principles by which intellectual property is to be regulated, the minimum standards of protection expected, how this can be enforced, how to settle disputes and guidance on transitional arrangements for new members (29). It was the first multilateral agreement on intellectual property rights, having been negotiated during the Uruguay Round in 1994 (29).

The Doha Declaration in 2001 clarified how TRIPS should impact on public health, as a response to concerns raised about its potential impact on access to medicines, particularly in LMICs (2). The main focus was on emphasising that the TRIPS Council is responsible for assisting countries with limited production capabilities, and highlighted that "does not and should not prevent member governments from acting to protect public health" (30)

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The WHO on TRIPS from “WHO Trade and Health / Towards Building a National Strategy”:

The TRIPS Agreement requires WTO Members to grant patents in all fields of technology. This means that all WTO Members will eventually be required to make patent protection available for pharmaceutical subject matter inventions. Developing countries that did not provide pharmaceutical patent protection when the TRIPS Agreement entered into force in 1995 had the option of delaying protection for a 10-year period (TRIPS Art. 65), but this transition arrangement ended on January 1, 2005,¹ and developing countries that have newly acceded to the WTO have not been accorded new transitional extensions.

Least-developed country (LDC) Members of the WTO were initially accorded an 11-year transition period to implement the TRIPS Agreement (Article 66.1). This transition period has been extended twice, first until 1 July 2013,² later until 1 July 2021.³ In parallel, LDCs benefit from a specific transition period that authorizes them not to adopt or enforce pharmaceutical patent protection and data protection,⁴ nor to extend exclusive marketing rights (EMRs),⁵ until 1 January 2016. Because the general extension until 1 July 2021 for TRIPS implementation by LDCs does not prevent them from “rolling back” existing IP protections that may have been granted,⁶ it appears that a renewal of the specific pharmaceutical-related extension that will otherwise expire on 1 January 2016 is not needed to authorize LDCs to continue to disapply pharmaceutical patent protection, data protection and the EMRs (Article 70.9) provision of TRIPS. Nonetheless, LDCs might decide to seek such a specific extension to avoid any doubts on this issue.

The early experience of developing countries with implementation of the TRIPS Agreement was problematic. South Africa confronted challenges by developed-country governments and multinational pharmaceutical enterprises following adoption of public health legislation in 1997. South Africa prevailed, but by the end of this episode the TRIPS Agreement was widely perceived as an obstacle to addressing public health problems. Members of WTO reacted to this by recognizing the importance of allowing governments to pursue flexible policies with respect to the protection of public health, which recognition was expressed in the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

The Doha Declaration was followed in 2003 by the adoption of a “waiver decision”⁸ that facilitated the export of pharmaceutical products under compulsory licence. In 2005 the General Council of the WTO adopted a Protocol Amending the TRIPS Agreement which, once accepted by a sufficient number of Members, will formally transform the 2003 waiver into a part of the TRIPS Agreement.¹⁰ As of 2014, the Protocol had not yet been accepted by a sufficient number of Members to bring it into force, but the waiver decision remains in effect. Despite the Doha Declaration and associated events, the political situation with respect to access to medicines has remained difficult. Throughout 2007–2008 Brazil and Thailand came under pressure from multinational industries and supporting governments for having issued compulsory licenses. India has seen its 2005 pharmaceutical patent law, and subsequent administrative and judicial decisions applying it, harshly criticized by the multinational pharmaceutical industry as well as right-holder groups such as the US Chamber of Commerce. India's grant in 2011 of a compulsory license on an important anti-cancer drug benefitted a substantial group of patients needing treatment, but this grant also garnered significant criticism from right-holder interest groups. While India's patent law, patent office and court decisions are consistent with the TRIPS Agreement, foreign industry groups argue they reflect problematic policy. India, on its side, has reaffirmed a strong stance in favour of protecting the public health of its population despite the criticism from foreign industry groups.

TRIPS-Plus:

“TRIPS-plus” is a non-technical term that is used to refer to intellectual property rules that extend the scope of covered subject matter or provide higher levels of protection than is required by the TRIPS Agreement. While TRIPS-plus is often used in reference to bilateral and regional free trade (and economic partnership) agreements (FTAs and EPAs), TRIPS-plus rules are also part of multilateral agreements and may be found in national legislation (35).



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TRIPS-plus provisions have raised concerns among a number of affected stakeholder groups, including in the area of information technologies, but for present purposes refer to provisions that affect the scope or duration of intellectual property protection for pharmaceuticals and related products. Patents establish rights to exclude third parties from making, using, selling, offering for sale and importing (for these purposes) medicines for a limited term. They provide the basis for pricing at above “competitive market” prices, and in doing so limit affordability and access to newer treatments (31). Requirements to provide periods of marketing exclusivity based on submission of data to regulatory authorities likewise limit the introduction of generic medicines (35). Other forms of intellectual property, such as trademark and copyright, may also influence affordability and access (31). When TRIPS-plus requirements are introduced regarding these forms of intellectual property, they enhance the ability of patent and other IP right holders to limit competition (35). From the standpoint of affordability and access to medicines, TRIPS-plus rules must be approached with caution. Patents, in particular, are thought to encourage innovation and the development of new medicines, and this is not to suggest that patent protection as such is detrimental from a public health standpoint (32). The policy objective is to properly balance the innovation-encouraging aspects of patent protection with the need for access and affordability. The proper balance may be different for different countries and regions.

Such TRIPS-plus marketing exclusivity requirements potentially have serious consequences with respect to the introduction of generic products in national markets. In the first place, the introduction of a fixed term of marketing exclusivity is nowhere mandated in the TRIPS Agreement, but a number of bilateral or regional agreements, notably those to which the United States or the European Free Trade Association are parties, incorporate minimum terms that may sometimes be extended based on submission of supplementary clinical data (35). In some ongoing regional trade agreement negotiations demands are being made to provide extended periods of marketing exclusivity for originator biological medicines that may substantially delay the introduction of generic biologicals.

Second, a number of bilateral and regional agreements subtly extend the scope. As pharmaceutical companies often use minor changes in technology (such as slight changes in chemical structure that produce similar results in the body) to promote newer medicines to both doctors and patients, a patent on a minor change may effectively extend the marketing exclusivity enjoyed by the patent holder in a given therapeutic class (36).

One of the most important TRIPS-plus issues associated with bilateral and regional trade agreements involves the treatment of clinical data submitted in connection with government approval of pharmaceutical products. Article 39.3 of the TRIPS Agreement requires WTO Members to protect against “unfair commercial use” of undisclosed clinical data submitted to the government with respect to new chemical entities in the pharmaceutical sector. WTO rules leave substantial discretion to Members regarding how to implement this obligation (37).

The net result of all these requirements may be to significantly reduce the prospects for registration of generic versions of originator pharmaceutical products. At the same time, policy-makers should take into account that there should be some incentive to register originator products for the local market, whether that incentive is directed towards the originator or a generic provider. If the generic provider is unable to locally provide the clinical data that was relied on for an initial registration abroad, there needs to be some local mechanism for assuring that drug regulatory approval is based on sound criteria

Marketisation of healthcare

The dominance of capitalist market structures in western society and increasingly so elsewhere (20), arguably makes it inevitable that elements of this economic ideology should permeate to all industries including health care. Marketisation, in the context of health care, refers to the implementation of policy that enables the creation of markets, buyer-seller-relationships and elements of privatisation to provide care (21). Despite the reduced burden on public sector spending, measures taken to marketize the health sector may result in greater income and subsequent health inequalities within and across societies. (21)(22).



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Potential consequences of health care marketisation are most evident in the United States whereby numerous insurance companies compete for customers who are dependent on their product for health care coverage, not the government as observed in other western regimes such as Great Britain (23). Potential inefficiencies of an increasingly marketized global health market can be extrapolated from the inefficiencies of the USA, which records much poorer health outcomes compared to other high-income countries (28) despite spending the most on health care (29). The emergence of a two-tiered system of public and private with inequitable movements of personnel and resources is a real threat to equitable access to health care in systems globally that continue to commercialise (31). Furthermore, commercialisation such as this is found to not only reduce access but also result in the introduction of out-of-pocket payments; a detriment to health care equity in LMIC (31). To combat the inequitable distribution of resources and money observed globally, the WHO recommends well-financed public health sectors - not private or mixed health care markets (29).

Globally, increased trade liberalisation through the introduction of mechanisms such as Free Trade Agreements (FTAs) and Trade Blocs could threaten universal health care due to an increased emphasis on market access and profitability rather than comprehensive patient care, a reality where patients are treated based on these factors rather than need is a threat (26). Evidenced already in the 10/90 gap which illustrates that only 10% of spending of health research is targeted at alleviating conditions that comprise 90% of the global burden of disease (32). The mismatch in health care spending is a direct result in a greater value placed on profit rather than equity, as evidenced particularly in the pharmaceutical companies globally, disproportionately affecting LMIC where counterfeit medications are often resorted to as affordable alternatives (31). Furthermore, the creation of FTAs and similar agreements is detrimental to nations not a part of the agreement, creating possibilities for increased pharmaceutical prices and a degradation public services and health regulation (27). Agreements that provide patent protection such as TRIPS have only exacerbated the market power of large pharma and reduced equitable access to medicines (31).

While there is much evidence that the increased wealth associated with trade liberalisation and free markets promotes greater health outcomes, several subsequent inequities need to be managed accordingly (30). A marketisation of health care may indeed result in a less equitable distribution of health care resources, knowledge and skills that could be detrimental to the sustainable goal outlined by the WHO for universal health access for all (32).

Ethical Trade

Ethical trade refers to the steps taken by purchasing organisations, such as healthcare institutions, to improve the pay and working conditions of the people involved in the supply of goods and services. This involves the entire supply chain – from material planning, fulfilment, procurement, manufacturers, distributors and retailers (33)(34).

Consequently, it is important to work collaboratively with each firm of the supply chain to improve worker access to the fundamental right to a safe working environment, pay at least the minimum wage and permit the formation of trade unions (35). Indeed, this also includes abiding by the Fundamental Conventions outlined in the Declaration on Fundamental Principles and Rights at Work, adopted by the International Labour Standards (ILO). The ILO is the UN agency accountable for encouraging workers' rights and welfare, and creating fundamental conventions emphasising the abolishment of forced labour (debt bondage, trafficking and slavery), child labour and discrimination in the workplace (36)(37). Further, the UN Global Compact is a non-binding pact encouraging the prioritisation of sustainability in trade and hence a push towards global corporate social responsibility; in alignment with the Sustainable Development Goals (38).

Globally, health services spend in excess of billions every year in the procurement of goods and services for use in the health sector. This growing trade market for commodities in health is significantly affected by the market switch towards globalisation, whereby, in order to cut costs, production of medical equipment is being outsourced to emerging markets (35). Paradoxically, it is often the case that goods and services purchased by healthcare organisations, actually harm health elsewhere, as they fail to protect basic labour rights. This is through the narrow focus on a growth-led



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economy resulting in increased inequities in wealth distribution, thus fuelling the health divide in developing countries. In lieu of cost minimisation initiatives, global competition has led to diminished labour standards, reduction of wages, dire working condition and even child labour – affecting the most defenceless of society (39).

Nevertheless, the United Nations Conference on Trade and Development (UNCTAD) is a permanent intergovernmental body established to support developing countries in getting access to the benefits of a globalised economy and using trade as a conduit for sustainable development (36). Pioneers in enacting ethical trade initiatives include the UK's National Health Service (NHS) Purchasing and Supply Agency (NHS PASA), who have launched the Ethical Procurement for Health guidance document to ensure the ethical manufacturing of goods purchased (35)(41). It is important to note that ethical procurement does not necessarily mean purchase of more expensive goods, nor compromise on quality(42)(43).

Ultimately, since the levels of spending are so vast in healthcare, the medical community has a lot of leverage over its suppliers and hence has the capacity to make a significantly positive impact upon global trade; and consequently global health.

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