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Council for Trade-Related Aspects of Intellectual Property Rights

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INTELLECTUAL PROPERTY AND THE PUBLIC INTEREST: R&D COSTS AND PRICING OF MEDICINES AND HEALTH TECHNOLOGIES

COMMUNICATION FROM SOUTH AFRICA

The following communication, dated 3 October 2019, is circulated at the request of the delegation of South Africa.

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1. This topic is a continuation of a sustained debate regarding the intersection between intellectual property and public interest. Public interest is a central component of the of the TRIPS Agreement, which recognizes underlying public policy objectives of national systems for the protection of intellectual property. The protection and enforcement of intellectual property rights is not an end in itself. Article 7 of the TRIPS Agreement recognizes that intellectual property rights must contribute to the promotion of technological innovation and the transfer and dissemination of technology to the advantage of all stakeholders, including the users of technological knowledge and in a manner conducive to social and economic welfare.

2. In September 2015, 193 Member States of the United Nations adopted the 2030 Agenda for Sustainable Development (2030 Agenda). This agenda includes Sustainable Development Goal (SDG) 3 that aims to ensure healthy lives and promote the well-being of all people of all ages.

3. The WTO is central to achieving the 2030 Agenda for Sustainable Development Goals (SDGs), which sets targets to be achieved by 2030 in areas such as poverty reduction. Trade has proven to be an engine for development and poverty reduction by boosting growth, particularly in developing countries. Target 3.b underscores the importance of support for R&D of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries. The Doha Declaration on the TRIPS Agreement and Public Health affirms the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health and, in particular, provide access to affordable medicines and medical technologies for all.

4. The Doha Declaration on the TRIPS Agreement and Public Health recognizes both the importance of intellectual property for the development of new medicines and concerns that intellectual property rights affect medicine pricing.

5. The UN Secretary General's High-level Panel on Access to Medicines[1] observed the following: *"The rules governing human rights, trade and public health exist in separate but overlapping spheres; their implementation rests at different levels. An important factor behind the incoherence between trade, intellectual property laws, human rights and public health lies in the different accountability mechanisms and uneven levels of transparency.*" It further observes that transparency is a core component of good governance, especially where civil society and patient groups rely on transparency of information. Transparency, as further stated, can also ensure fairness during negotiations that take place between biomedical companies and procurement organizations.[2]

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[1] Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting innovation and access to health technologies (September 2016) at p. 33.

[2] Ibid.

6. In this context, Members of the WTO must commit to the full use of the flexibilities in the TRIPS Agreement to increase access to affordable, safe, effective and quality medicines, noting that, *inter alia*, intellectual property rights are important incentives in the development of new health products.

7. The current model of medical innovation is ill-equipped to respond to the increasing emergence of infectious diseases, the unprecedented explosion of NCDs and neglected tropical diseases. For developing and least developed countries (increasingly developed countries raise similar concerns) affected by inadequate funding for R&D and access to health technologies and medicines continue to struggle to ensure access to affordable medicine for their citizens. Prevailing high prices of medical technologies and medicines have been subject of much debate in the recent past.[3]

8. The Seventeenth World Health Assembly of the World Health Organization (WHO) passed Resolution WHA70.12 on 31 May 2019 noting the increasing costs to health systems and patients of the introduction of new pharmaceutical products for cancer treatment in recent years. The WHO Assembly requested the Director General to prepare a comprehensive technical report to the Executive Board at its 144th session that examines pricing approaches, including transparency, and their impact on availability and affordability of medicines for the prevention and treatment of cancer.

9. Many WTO Members have implemented national or regional medicines policies to guide and coordinate context-specific actions towards achieving long-term goals for the pharmaceutical sector and health sector in general. A preponderant component of such frameworks deals with pricing policies. Taking into account the broader health system and economic objectives of such frameworks, a balance is often sought between an optimal pricing policy to promote the availability and affordability of quality, safe and effective medicines as well as financial sustainability. Transparency is a central component that informs decision-making models within such national frameworks, hence adequate disclosure of price information is required. Pricing policies of private companies remain opaque and may differ from one company to another which makes it difficult for governments and other procurement institutions to accurately gauge prices of medical health technologies and pharmaceutical products.

10. Pricing strategies are based on determinants such as, *inter alia* the cost of R&D, costs of production or financial returns to incentivize future R&D programmes. The true costs of R&D for pharmaceuticals are often unknown and highly variable, while the contribution made by public and non-profit-making sectors towards the R&D of medicines is not always accounted for. The marginal production costs of medicines are relatively small compared to their market prices while a significant proportion of this expenditure might be for marketing and promotional activities, which are costs not related to the development of the product.

11. Companies in the health technology sector, including pharmaceutical and bio-similar market, achieve market dominance through various means, including the protection of intellectual property that keeps generic or biosimilar competition out of the market for varying periods of time depending on the jurisdiction. Patents on new molecules, new combinations, variations of existing molecules, and patents on minor variations of an existing product tend to consolidate existing market positions and may lead to *de facto* monopolies or differentiated oligopolies.

12. In any given system, pricing strategies of pharmaceutical companies and healthcare providers that hold monopolist positions are always welfare reducing. In order to maximize its profit a monopolist would supply at a quantity lower and at a higher price than what would maximize societal welfare. This would cause a transfer of welfare from consumers to the monopolist, as well as a loss of overall economic efficiency for the society. The *WTO, WIPO and WHO Report on IP and Public Health (Trilateral Study)* notes the following: "*One of the main arguments put forward by industry with respect to the need for strict protection of IPRs is the high cost of R&D for new medical*

[3] Jonathan D. Campbell & Zoltán Kaló (2018) Fair global drug pricing, Expert Review of Pharmacoeconomics & Outcomes Research, 18:6, 581-583, DOI: 10.1080/14737167.2018.1524296 https://doi.org/10.1080/14737167.2018.1524296.

products… [T]here are, however, few sources of data available that enable the true costs of medical research to be assessed."[4]

13. The sponsor of this communication calls on Members to share their experiences of how TRIPS flexibilities have been used to address high prices and barriers to access to medical technologies and medicines in order to achieve public health and related national objectives. In the past the impact of competition and anti-trust laws on access to medicines was explored in IP/C/W/643. The issue of abuse of IP rights remains relevant in the context of the application of national and regional norms to ensure cheaper and more effective access to medical technologies and medicine. Policies that influence the pricing of health technologies or the appropriate rewards for successful research outcomes can be better evaluated when there is reliable, transparent and sufficiently detailed data on the costs of R&D inputs (including information on the role of public funding and subsidies), the medical benefits and added therapeutic value of products.

Guiding questions:

- What are the TRIPS flexibilities adopted by Members in their Patent laws to ensure availability of patented medicines at reasonable prices?
- What are Members experiences with escalating prices of patented medicines and what are the policy responses implemented to address this trend through the use of TRIPS flexibilities?
- What approaches have Members implemented regarding price regulation of patented medicines such as a combination of cost-based pricing, value-based pricing, reference pricing, and/or through tendering and negotiation, and regulating mark-up levels? If any of these approaches have been used, what are the results and challenges that Members face to ensure compliance and disclosure of necessary information or their effect on the prices of medicines?
- What measures have Members implemented to enhance the publicly available information on the costs of manufacturing of medicines, vaccines and health technologies, in particular information on grants, tax credits or any other public sector subsidies and incentives relating to the initial regulatory approval and annually on the subsequent development of a product or procedure?
- Can Members share their experiences to improve the transparency of the patent landscape of medical technologies to ensure that no barriers are created to generic competition through sharing complete and up to date information?

[4] WHO/WIPO/WTO *Promoting Access to Medical Technologies and Innovation. Intersections between Public Health, Intellectual Property and Trade*. Geneva 2012, p. 107 http://www.who.int/phi/promoting_access_medical_innovation/en/.