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Germany's contribution to the United Nations Secretary-General's High-Level Panel on Access to Medicines

ONLINE SUBMISSION

Section 1: Abstract

Briefly describe your contribution:

TEXT:

Access to medicines is a core element of health systems and has been central to Germany's activities in development cooperation. Germany contributes the following three approaches:

Local pharmaceutical manufacturing: One of the main approaches of the German Government for better access to medicines in developing countries is the support of local pharmaceutical manufacturing. Capacity building in the area of Good Manufacturing Practices (GMP) at the level of the manufacturers and regulatory strengthening are a crucial element. Having the appropriate skill sets available is essential in making local manufacturing effective. At the level of the national regime of intellectual property, our partner countries are advised on how to implement the TRIPS Agreement in a manner supportive of the protection of public health. Access to medicines touches many policy areas, which is why German development cooperation puts an emphasis on policy coherence both in its own strategy as well as in the partner countries.

Leveraging private investments – The Global Health Investment Fund: The Global Health Investment Fund (GHIF) is an innovative instrument to leverage private investments helping to bring about significant improvements in the treatment and prevention of disease.

Cooperation between patent holders and users – WIPO's Re:Search project: The project has demonstrated that intellectual property does not present an obstacle to research and development of pharmaceuticals, vaccines, and diagnostic tools for neglected tropical diseases, malaria, and tuberculosis.

The Federal Republic of Germany welcomes the opportunity to address comments to the High Level Panel on Access to Medicines. Access to medicines is a complex topic which involves a multitude of facets. Germany would like to underline that intellectual property is a driver of innovation for new medicines and new uses for medicines. Consequently, the discussion on international healthcare policies should not be limited to questions of patent law.

Section 2: CALL FOR CONTRIBUTIONS

SUBMISSION OF YOUR CONTRIBUTION

Please ensure that your contribution takes into consideration the criteria as outlined in the Call for Contributions, including: 1) Impact on remedying policy incoherence, 2) Impact on public health, 3) Impact on human rights, and 4) Implementation.

TEXT:

The Federal Republic of Germany believes it can make a valuable contribution to the High Level Panel by presenting three approaches which are being implemented:

Local pharmaceutical manufacturing, financing investments in research and development through the Global Health Investment Fund and fostering the cooperation between patent holders and users through WIPO's Re:Search project. The three approaches make clear that access to medicines is a very complex topic which involves a multitude of facets. **An exclusive focus on patent rights issues is too narrow.** The Federal Republic of Germany does not share the basic assumption of the call for contributions that there is a "misalignment between the rights of inventors, international human rights, law, trade rules and public health where it impedes the innovation of and access to health technologies". Consequently, the discussion on international healthcare policies should not be limited to questions of patent law.

1. Germany's approach for better access to safe and affordable medicines: Local pharmaceutical manufacturing

Health has been a focus of German development cooperation for decades. Health is a human right and a necessary condition for social, economic and political development and stability. Governments are obliged to respect, protect and guarantee the right to health. Germany provides intensive support to its partner countries in fulfilling this obligation. Global health issues are closely connected to and interwoven with other policy fields such as social development, trade, intellectual property or human rights. Taking this into account, Germany recognizes the need for coherent cross-sectoral solutions to improve health worldwide. Adopted in 2013, the Federal Government's strategy paper "Global Health Policy – Taking Joint Action – Embracing Responsibility" guides Germany's approach to making a coherent and active contribution.

Access to medicines is a core element of health systems and has been central to Germany's activities in the development of our partner countries' health sectors. Their lives could have potentially been saved or extended with access to treatment. Germany works on improving access to essential medicines by taking into account all four dimensions of access: Medicines must be available in sufficient quantity, they must be physically and financially accessible to all groups of the population, medicines have to be medically and culturally acceptable and finally also of good quality (OHCHR, 2008).

One of the main approaches of the German Government for better access to medicines in developing countries is the support of local pharmaceutical manufacturing. Well aligned with health policy, the benefits of local pharmaceutical production cut across the four dimensions of access. There is evidence that local manufacturing can improve affordability, cater better to local health needs and create distribution networks that especially target the needs of poor consumers in rural areas (WHO, 2011a). Bangladesh, for instance, was highly successful in achieving public health targets by strongly supporting the development of local pharmaceutical manufacturing. In the

1980s the country faced a health crisis over high medicines cost. After a successful support program for local production, prices had dropped by more than 50% in real terms in the early 2000s (Amin & Sonobe, 2013). Moreover, the existence of pharmaceutical production is associated with technological, industrial, intellectual, organizational and research-related capabilities (Mackintosh et al., 2014) that are paramount to tackling LDCs' health care needs. Similarly, there is a body of literature on examples from South-East Asia of knowledge spillover and increased local innovation capacity due to local pharmaceutical manufacturing (WHO, 2011b). Local production can thus be a building block to *“[s]upport the research and development of vaccines and medicines for the communicable and noncommunicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all”* as target 3.b of SDG 3 (“Ensure healthy lives and promote well-being for all at all ages”) is phrased. Moreover, local pharmaceutical manufacturing is a prime tool for ensuring coherence between public health, human rights and trade rules. Recognizing the need for local manufacturing capacities in order to ensure coherence between intellectual property rights and access to medicines Germany has supported local production of medicines since 2006. Germany puts special emphasis on following a coherent approach by taking into account all aspects of local manufacturing, from quality assurance to capacity building and policy advice on intellectual property rights and policy coherence.

Quality standards are of paramount importance for the manufacturing of safe pharmaceuticals. Therefore capacity building in the area of Good Manufacturing Practices (GMP) at the level of the manufacturers and regulatory strengthening are crucial elements of Germany's approach. With regard to local manufacturing there are two main arguments for putting quality of medicines at the centre: There are considerable public health risks from substandard, spurious, falsely labelled, falsified and counterfeit (SSFFC) medical products. According to the WHO, “they affect every region of the world, and medicines from all major therapeutic categories have been reported, including vaccines and diagnostics. They harm patients and undermine confidence in medical products, healthcare professionals and health systems.” (WHO, 2016) Adhering to international quality standards like WHO GMP is a crucial prerequisite for local producers to be able to compete with international drug companies and to win international tenders. With this in mind, Germany has supported projects that enable local manufacturers to reach GMP standards and local regulatory bodies to oversee these processes. For example, the Federal Government works with the United Nations Industrial Development Organisation (UNIDO) and the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) to improve the competitiveness of Kenyan pharmaceutical manufacturers in producing quality medicines by developing and rolling out a roadmap to achieve Good Manufacturing Practices. 34 companies are currently part of the process and are investing in upgrading their technology and production facilities. In addition, the Federal Government through the National Metrology Institute (PTB) helps to build a quality infrastructure in the East African Community that can ensure consumer protection and support producers in quality assurance.

Having the appropriate skill sets available is essential in making local manufacturing effective. Companies need industrial pharmacists, chemists, or engineers to compete in a high-skilled industry like pharmaceuticals. Once the pharmaceuticals are produced, they need to reach the patients to improve access. This step demands skilled health workers, which is why, in a pilot project at the Kilimanjaro School of Pharmacy in Tanzania, a curriculum for dispensers is being developed and implemented. There are also multiple projects that aim to improve education in professions required for manufacturing, especially with regards to applied skills. For example, the University of Ghana School of Pharmacy is working on a PharmTech Masters Programme, advised by Chulalongkorn University in

Thailand and in cooperation with a Ghanaian pharmaceutical company. In Ghana, the Federal Government has also supported the National Vocational Training Institute to pilot a vocational training programme for pharmaceutical technicians in order to improve maintenance processes in the factory. Likewise, pharmaceutical manufacturers in the East African Community and local universities have initiated joint preparatory programmes for industry internships.

At the level of the national regime of intellectual property, our partner countries are advised on how to implement the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in a manner supportive of the protection of public health. The Federal Republic of Germany would like to underline that intellectual property is a driver of innovation for new medicines and new uses for medicines. Research-based pharmaceutical manufacturers need effective legal protection for technical inventions not only as an essential precondition for their economic success but also as a basis for future R&D activities. Continued R&D activities, however, are not only in the interest of the manufacturers, but also of patients around the world and thereby of the public at large. Sufficient pharmaceutical production capacity in developing countries is important. The existence of the flexibilities of the TRIPS Agreement is an incentive for companies to invest in local manufacturing of essential medicines. The exemption of Least Developed Countries (LDCs) from having to provide for the protection of pharmaceutical patents which has recently been extended until 2033 creates an incentive for investors to invest in the generics industry in LDCs and thereby build their technological capabilities. Since 2005, Germany has been supporting developing countries and especially LDCs through capacity building on how to implement the TRIPS Agreement in accordance with public interest objectives such as access to medicines. Members of government institutions, parliamentary structures, patent offices, representatives of the judiciary as well as civil society learned about the potential uses of the TRIPS flexibilities in facilitating access to medicines and enhancing generic competition and thereby lowering medicine prices. Through the United Nations Conference on Trade and Development (UNCTAD), GIZ, South Centre and UNIDO, introductory training was in many cases accompanied by policy advice on how to build a legal framework that encourages innovation, technology transfer and access to medicines without violating intellectual property rights. Alumni of capacity building measures can today network and discuss policy and legal approaches to access to medicines and the promotion of innovation on the Global Academy for Innovation and Access platform (www.gafia.info).

Access to medicines touches many policy areas, which is why German development cooperation puts an emphasis on policy coherence both in its own strategy as well as in the partner countries. For local manufacturing to be able to contribute to improving access to medicines, an enabling and coherent policy framework is essential. Industrial and health policy need to share a common focus on improving access to essential products. A successful case can be found in Brazil, where the Ministry of Health reduced local producers' risk of innovation and investment in essential medicines by using public procurement guarantees and thus creating a market (Aragao, Guimaraes & Loureiro, 2014). Only if policy-makers from different departments share a common goal of improving access to medicines, policies can create synergies. A WHO (2011a) study has found that countries with the most advanced local production of medicines were also among those with the best policy coherence. That is why Germany puts an emphasis on this aspect. In the East African Community, German cooperation has strongly supported the development of a coherent "Regional Pharmaceutical Manufacturing Plan of Action" and the set-up of an inclusive steering structure at the regional as well as the national levels, integrating stakeholders from Ministries of Industry, Trade, Health, private sector players, civil society representatives and policy-makers from the EAC Secretariat. Stakeholders in the EAC have reported that coordination between the different interest groups has improved, especially for the development of new policy initiatives with regards to access to medicines and local production. In order to assess policy coherence for access to medicines in the EAC, but also

in Vietnam and Thailand, the Federal Government has partnered with GIZ and UNCTAD to analyse existing policies in the partner countries on their contribution to the wider goal of access to medicines. Resulting from this exercise, a policy guideline will be published in 2016 that shall enable countries to align their policies on access to medicines. When all stakeholders act in concert for better access to medicines there is potential to strategically select essential medical products for local production, for pricing of locally produced products that governments and people can afford, for strict compliance to quality standards by the manufacturers, for health security, i.e. an uninterrupted supply of essential medicines as well as for innovation for development of formulations that are more suitable for local conditions.

So far, Germany has invested over 100 million EUR in support of local pharmaceutical manufacturing in developing countries. In the last few years the market for medicines in developing countries has grown strongly. In Africa alone, the size of the pharmaceutical market five-folded between 2000 and 2012 (McKinsey, 2015), with generics expanding even faster than branded products. Local manufacturers benefit from that development and mostly report increasing sales, but also an increasing diversity in marketed products. Recently, local producers have attempted to expand their product range and to offer affordable medicines for increasingly prevalent noncommunicable diseases, such as diabetes. However, in order to strengthen the position of local manufacturing and increase its effectiveness for improving access to medicines, more needs to be done especially with regard to companies' competitiveness. Only then will local manufacturing bear the fruits of reaching more people by achieving better economies of scale and thereby offering its products at competitive prices. With more donor engagement partners could expand the scope of investment in improving the quality standards of local manufacturers which hinder many to access wider markets. The same would enable local pharmaceutical companies to export to other countries, potentially improving access to medicines in countries without own manufacturing capacities or opening larger procurement markets for regional blocs. Once again, policy coordination is of utmost importance in order to retain the local industry's interest in its local markets. The Indian generics industry's tendency of reorientation away from markets in Africa and towards more lucrative markets e. g. in Europe is precisely one of the reasons why it is so important to develop self-sufficient pharmaceutical industries in African countries. Similarly, the donor community could raise efforts to bring local manufacturing and local academia closer together optimizing the skill sets for the pharmaceutical industry and at the same time stimulating research on local drug needs. Technology transfer and strengthening research and development capacity would greatly enhance the absorption capacity for new technologies and adapting medical technologies to local needs.

Germany is convinced that investments in local pharmaceutical manufacturing are an effective way to improve access to medicines in the long run and to simultaneously ensure coherence between public health, human rights and trade rules. Strengthening regulatory systems and research capacity will also provide better conditions for clinical trials in developing countries, lowering precisely those costs that innovators otherwise need to recoup through exclusive marketing rights conferred by patents.

2. Leveraging private Investments: The Global Health Investment Fund (GHIF)

The Global Health Investment Fund (GHIF) is a \$108 million social impact investment fund designed to provide financing to advance the development of drugs, vaccines, diagnostics and other interventions against diseases that disproportionately burden low-income countries.

The GHIF is a private investment fund structured by JPMorgan Chase & Co., the Bill & Melinda Gates Foundation and Lion's Head Global Partners, which received anchor support from Grand Challenges Canada, the German Ministry for Economic Cooperation and Development, the Swedish International Development Cooperation Agency and the Children's Investment Fund Foundation.

The public investors and the Gates foundation partly offset any losses, mitigating the risk for potential investors. In this sense the Fund is an innovative instrument to leverage private investments giving an opportunity to help bring about significant improvements in the treatment and prevention of disease, along with the prospect of a net financial return for investors. The demand for such an instrument from the private investor side is demonstrated by the fact, that the initial goal of attracting 100 Mio USD was exceeded.

Since its inception the GHIF completed its first collaborative funding agreement with a UK-listed company completing in-field clinical testing of its point-of-care PCR platform for diagnosing TB and drug-resistant TB in July 2014. Under the collaborative funding agreement, the company has agreed to make its PCR platform available for sale in developing countries under a pricing framework that reflects the needs of poor patients most at risk of TB (Fitchett et al. 2015).

Additionally the GHIF invested in August 2014 in a South Korean vaccine company to expand the availability and manufacturing capacity of low-cost oral cholera vaccine (OCV) and in a new drug for the treatment of river-blindness (March 2015).

The GHIF is a pilot and could be used as a blueprint for an enhanced approach attracting more private sector financing for global health research and development which is more important than ever to meet the raising need for investments in clinical trials.

3. Cooperation between patent holders and users – WIPO's

Re:Search project

The Federal Republic of Germany would like to remind the Panel of the significant amount of ongoing activities in this area, particularly the work conducted by international organisations such as the WHO, the WTO, and the World Intellectual Property Organization (WIPO). The Federal Republic of Germany welcomes initiatives such as the Re:Search project sponsored by the WIPO; this encourages inventors, respectively patent holders, to cooperate on a voluntary basis with potential users and licensees when it comes to use of intellectual property. The stated objective of Re:Search is to expedite the discovery and development of pharmaceuticals, vaccines, and diagnostic tools for neglected tropical diseases, malaria, and tuberculosis. The project has demonstrated that intellectual property does not present an obstacle to research and development. To deal with those cases where a voluntary reconciliation of interests is not viable or does not take place, thus undermining public welfare, TRIPS allows mandatory licenses to be granted under certain conditions.

Section 3: Reference and bibliography

Please provide your references and bibliography *

Better access to safe and affordable medicines: Local pharmaceutical manufacturing

Amin, N., & Sonobe, T. (2013). *The success of the industrial development policy in the pharmaceutical industry in Bangladesh*. GRIPS Discussion Paper 13-07. Retrieved from: http://www.grips.ac.jp/r-center/en/discussion_papers/13-07/

Aragao, E., Guimaraes, J. M., & Loureiro, S. (2016). The Dissemination of Local Health Innovations: Political Economy Issues in Brazil. In: Wamae, W., Mackintosh, M., Tibandebage, P., Banda, G. (2016). *Making Medicines in Africa. The Political Economy of Industrializing for Local Health*. UK: Palgrave Macmillan

Federal Republic of Germany (2013). *Global Health Policy – Taking Joint Action – Embracing Responsibility*. Retrieved from: http://health.bmz.de/what_we_do/Sector-strategies/shaping-global-health/Globale_Gesundheitspolitik_de.pdf

Mackintosh, M., Tibandebage, P., Banda, G., Wamae, W. (2016). African Industrial Development, Values and Health Care. In: Wamae, W., Mackintosh, M., Tibandebage, P., Banda, G. (2016). *Making Medicines in Africa. The Political Economy of Industrializing for Local Health*. UK: Palgrave Macmillan

McKinsey & Company (2015). *Insights into Pharmaceuticals and Medical Products Africa: A Continent of Opportunity for Pharma and Patients*. Retrieved from: http://www.mckinsey.com/insights/health_systems_and_services/africa_a_continent_of_opportunity_for_pharma_and_patients

Office of the United Nations High Commissioner for Human Rights (2008). *The Right to Health*. Retrieved from

World Health Organization (2011a). *Local Production for Access to Medical Products: Developing a Framework to improve Public Health*. Retrieved from:

World Health Organization (2011b). *Local production and access to medicines in low- and middle-income countries*. Retrieved from:

World Health Organization (2016): *Substandard, Spurious, Falsely labelled, Falsified and Counterfeit (SSFFC) Medical Products*. Retrieved from: <http://www.who.int/medicines/regulation/ssffc/en/>

WTO (2001). *The Declaration on the TRIPS agreement and public health*. Retrieved from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

References to the Global Health Investment Fund

Global Health Investment Fund (2016) <http://www.ghif.com/about/>.

Fitchett, J.R., Fan Li, J., Atun, R. (2015) *Innovative financing for late-stage global health research and development: the Global Health Investment Fund*. Int. Health 2015

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Please tick "YES" if you agree.