Access to Affordable Medicines and the HIV/AIDS Pandemic: Facing a New Challenge in International Security Law

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While not traditionally an issue in international security law, consensus is emerging that HIV/AIDS is one of the major security threats of the twenty-first century. In three parts, this paper attempts to map this threat and point to possible ways forward. Part 1 highlights what makes HIV/AIDS a security issue and, more particularly, an issue of international security. This relates to HIV prevalence in armed forces and peacekeeping missions as well as to recognition of these factors by the Security Council. In light of the recognition of the HIV/AIDS pandemic as a challenge for international security, Part 2 focuses on responses developed at the World Trade Organization (WTO) and the European Union (EU) with regard to one important aspect: access to medicines. The paper juxtaposes two legal instruments: the WTO Decision on compulsory licensing for countries without manufacturing capacity in the pharmaceutical sector, and the EU Regulation on import prohibition of differentially priced medicines. Part 3 puts these initiatives into the international security perspective and assesses whether they provide adequate means to face this challenge. It is argued that a combination of strategies that both reinforce governments and provide incentives to private companies may be a promising way forward. Part 4 provides some concluding remarks and points to future developments.

1. HIV/AIDS as a Security Issue

Just a brief update on the scale of the problem: figures from December 2003 indicate that an estimated 38 million people live with HIV/AIDS globally, and that 2.9 million people died in 2003 alone.² This makes AIDS the most globalized epidemic in history. Due to its extraordinary extent and impact, it needs to be dealt with both as an emergency and a long-term development issue.³ Sub-Saharan Africa is still the region worst affected, but there are also diverse HIV

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See generally: Altman, 'AIDS and Security', 17 *International Relations* (2003) 417; S. Elbe, *Strategic Implications of HIV/AIDS*, Adelphi Paper 357 (2003); Heinecken, 'HIV/AIDS, the military and the impact on national and international security', 32 *Society in transition* (2001) 120; International Crisis Group, *HIV/AIDS as a Security Issue*, ICG Issues Report (2001), available at http://www.icg.org//library/documents/report_archive/ A400321_19062001.pdf; Singer, 'AIDS and International Security', 44 *Survival* (2002) 145; Spectar, 'The Olde Order Crumbleth: HIV-Pestilence as a Security Issue & New Thinking About Core Concepts in International Affairs', 13 *Ind. Int'l & Comp. L. Rev* (2003) 481; UNAIDS, 'Fact Sheet No. 1: HIV/AIDS and Security' (2003). See also the activities and projects reported in: UNAIDS Office on AIDS, Security and Humanitarian Response (SHR), 3rd *Quarterly Report* 2004 (2004), available at http://www.unaids.org/en/in+focus/hiv_aids_security

⁺and+humanitarian+response.asp.

² UNAIDS, 2004 Report on the global AIDS epidemic, UNAIDS/04.16E (2004).

³ *Ibid.*, 13.

epidemics under way in Eastern Europe and Central Asia, including in a number of countries considered key to international stability such as the Russian Federation or Ukraine.⁴

It is increasingly recognized that the scale of the epidemic makes HIV/AIDS much more than a public health problem. It is both an issue under the traditional meaning of security as threats to defense of the state, with those threats emanating from other states, and under the newer concept of "human security" as coined by the UNDP Human Development Report 1994. The report stresses that security, at its most basic level, is personal and people-centered. The epidemic reduces life expectancy by decades, deepens poverty and devastates individuals, families and communities. But its impact goes beyond the personal suffering and loss. In the countries worst affected, HIV/AIDS has the effect of destabilizing society and the state by destroying structures of governance that ensure human security. High HIV/AIDS prevalence can exacerbate a variety of economic, political and social tensions and threatens political stability. Therefore, AIDS is a personal, economic and communal security issue.

Although statistical data is scarce, armed forces frequently have high rates of HIV, going beyond the levels found among the civilian population. While these high rates may not directly inspire or foreclose the outbreak of armed conflict, they pose difficult challenges, particularly for African militaries. HIV/AIDS contributes to an environment in which individuals, communities and nations are more vulnerable to conflict. The social dynamics of conflict, and even of post-conflict rehabilitation, result in greatly increased potentials for the spread of HIV/AIDS, as populations are destabilized and armies move across new territories. Therefore, HIV/AIDS and conflict pose two fundamental and negatively reinforcing threats to the lives of millions and to the stability and security of African nations, in particular. HIV/AIDS not only contributes to international security challenges, but also undermines the international capacity to resolve conflicts. This is because high levels of HIV infection experienced among militaries also translate to peacekeeping personnel. Therefore, peacekeepers may be both at risk of being infected with HIV/AIDS on mission and be a source of infection among local populations. In turn, this may reduce a state's willingness to participate in peacekeeping operations or make states reluctant to host missions.

These factors have led to a wider recognition of the security dimension of HIV/AIDS, particularly by relevant UN bodies. During its 4172nd meeting in July 2000, the Security Council

⁴ *Ibid.*, 30-34; 35-36.

⁵ UNDP, Human Development Report (1994), 22 et seqq.

⁶ UNAIDS, *supra* note 2, 41 *et segg*.

⁷ See S. Elbe, *supra* note 1, 49-57 and UNAIDS, *supra* note 1.

⁸ S. Elbe, *supra* note 1, 59-61.

⁹ International Crisis Group, *supra* note 1, 4 *et segg*.

¹⁰ S. Elbe, *supra* note 1, 17-21; Heinecken, *supra* note 1, 121 *et seqq*.; International Crisis Group, *HIV/AIDS as a Security Issue in Africa: Lessons from Uganda*, ICG Issues Report No. 3 (2004) 1-2, available at http://www.icg.org//library/documents/issues/ 03___lessons_from_uganda.pdf.

¹¹ S. Elbe, *supra* note 1, 23 *et seqq*.

¹² International Crisis Group, *supra* note 1, 2.

¹³ UNAIDS, 'Fact Sheet No. 2: HIV/AIDS and Conflict' (2003); UNAIDS, *supra* note 2, 175 *et seqq*.

¹⁴ International Crisis Group, *supra* note 10, 17-18.

¹⁵ See S. Elbe, *supra* note 1, 39-44; Spectar, *supra* note 1, 491-492.

unanimously adopted its first health-only resolution. ¹⁶ Resolution 1308/2000 recognized that the spread of HIV/AIDS can have a uniquely devastating impact on all sectors and levels of society and that the HIV/AIDS pandemic is exacerbated by conditions of violence and instability. The Security Council stressed that "the HIV/AIDS pandemic, if unchecked, may pose a risk to stability and security". ¹⁷ Thereby, it endorsed the broader concept of security as outlined above.

2. Access to Medicines: Responses developed at the WTO and the EU¹⁸

The multi-faceted challenges posed by the AIDS pandemic require an equally multi-faceted response at various levels and across subject areas. It has been pointed out that Resolution 1308/2000 significantly increased the level of international cooperation and coordination regarding global health. During the UN General Assembly Special Session on HIV/AIDS in June 2001, the UN Declaration of Commitment on HIV/AIDS was unanimously adopted. With regard to the security dimension, Resolution 1308/2000 led to the creation of the UNAIDS Office on AIDS, Security and Humanitarian Response (SHR) which covers international security, including international peacekeepers, national security including national uniformed services such as armed forces and civil defense personnel, and humanitarian response, focusing on vulnerable populations affected by conflict. ²¹

While other contributions have pointed to steps taken within the UN system and to national and non-governmental efforts, this paper links the security dimension to two initiatives that attempt to ensure access to affordable medicines. Support for this approach can be found in Resolution 1308/2000, where the Security Council expressed "keen interest in additional discussion among relevant United Nations bodies, Member States, industry and other relevant organizations to make progress, *inter alia*, on the question of access to treatment and care, and on prevention". Even though full response clearly involves more than just providing antiretroviral treatment, there is a conceivable link between access to medicines and security, as lack of treatment may create political tensions as well as additional potential for conflict. The system of the providing and the providing and the system of the providing and the providing and the system of the providing and t

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¹⁶ SC Res. 1308 (2000). On the role of the US in the adoption of the Resolution, see Spectar, *supra* note 1, 515 *et segg*.

¹⁷ SC Res. 1308 (2000), 2.

¹⁸ This part draws on ideas developed in my doctoral thesis, K. Gamharter, *Access to Affordable Medicines – Developing Responses under the TRIPS Agreement and EC Law* (2004).

¹⁹ Spectar, *supra* note 1, 528.

²⁰ 'Declaration of Commitment on HIV/AIDS', GA Res. 2/S-26, 2 August 2001.

See http://www.unaids.org/EN/in+focus/hiv_aids_security+and+humanitarian+response.asp. For SHR's most recent activities, see UNAIDS Office on AIDS, Security and Humanitarian Response (SHR), *supra* note 1.

²²Altman, *supra* note 1, 424 *et seqq*.; International Crisis Group, *supra* note 1, 23 *et seqq*.; Spectar, *supra* note 1, 530.

²³SC Res. 1308 (2000) (on the narrowness of the language in comparison with the rest of the resolution, see Spectar, *supra* note 1, 517-518). See also the recommendations made by the International Crisis Group, *supra* note 1, suggesting that the pharmaceutical industry should take all steps necessary to increase access to essential drugs and antiretroviral therapies, should support developing country use of compulsory licensing and parallel importing consistent with TRIPS and should work with the UN and the international community to establish the mechanisms needed for procurement of essential drugs and HIV therapies at the best possible level of pricing (iv).

²⁴ International Crisis Group, *supra* note 10, 10-11.

²⁵ See S. Elbe, *supra* note 1, 35 and 51-52.

Both the WTO and the EU have actively pursued initiatives aimed at ensuring access to affordable medicines, particularly needed in the case of HIV/AIDS. These initiatives cannot be viewed in isolation, ²⁶ but they are highlighted here to demonstrate how the challenge of HIV/AIDS has led to closely related activities across institutional borders. The debate on access to medicines in relation to the WTO, and specifically the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), was initiated during the "Special discussion on Intellectual Property and Access to Medicines" in June 2001. ²⁷ Even though the discussion covered a broader range of issues related to public health and intellectual property, the HIV/AIDS pandemic clearly triggered these efforts. ²⁸

At the Doha Ministerial Conference, the debate culminated in the adoption of the "Doha Declaration on the TRIPS Agreement and Public Health". In the Doha Declaration, WTO Members stressed that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." Besides affirming existing flexibilities in the TRIPS Agreement to achieve these goals, the Declaration also led to the adoption of a new legal instrument aimed at ensuring access to medicines in countries with insufficient or no manufacturing capacities in the pharmaceutical sector.

Decision WT/L/540³¹ establishes a mechanism aimed at allowing Members with insufficient or no manufacturing capacity in the pharmaceutical sector to make effective use of compulsory licensing. The goal of this mechanism is to overcome the limitation of Art 31(f) TRIPS Agreement, requiring that a compulsory licence must be granted "predominantly" for the supply of the domestic market. This provision had raised concerns that with full TRIPS implementation by 2005, ³² countries without domestic manufacturing capacity for medicines would no longer be in a position to purchase lower-priced medicines in order to import them under a compulsory licence. ³³ The new system established at the WTO level essentially requires the granting of two compulsory licences, one in the exporting and one in the importing Member. The Decision establishes various limiting conditions, including that only the amount necessary to meet the needs in the importing Member may be produced and that it must be exported in its entirety. If these conditions are met, the requirement to issue a compulsory licence predominantly for the supply of the domestic market is waived on a case-by-case basis. ³⁴ Given appropriate

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²⁶ For an overview of the global movement to scale up access to HIV treatment, see UNAIDS, *supra* note 2, 101 *et seqq*.

²⁷ 'Special discussion on Intellectual Property and Access to Medicines', IP/C/M/31, 10 June 2001.

²⁸ For further references, see K. Gamharter, *supra* note 18, 122.

²⁹ WT/MIN(01)/DEC/2, 20 November 2001. For detailed information on the Doha Declaration, see K. Gamharter, *supra* note 18, 133 *et seqq*.

³⁰ WT/MIN(01)/DEC/2, para 4.

³¹ 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health', WT/L/540, 2 September 2003.

³² On transition periods in the TRIPS Agreement, see, for example, K. Gamharter, *supra* note 18, 104 *et segg*.

For a comprehensive presentation of this problem as addressed in para 6 of the Doha Declaration (*supra* note 29), see K. Gamharter, *supra* note 18, 162 *et seqq*.

³⁴ WT/L/540, *supra* note 31, para 2. For a detailed analysis of the established procedure, see K. Gamharter, *supra* note 18, 238 *et seqq*.

implementing legislation both in potential exporting and importing WTO Member countries, this should provide a framework to ensure that countries without pharmaceutical manufacturing capacity can purchase antiretroviral medicines.

In contrast, the target strategy pursued by the EU to enhance access to medicines has been to encourage differential pricing.³⁵ Differential pricing refers to the adaptation of prices charged by the seller to the purchasing power of governments and households in different countries.³⁶ In the case of medicines, this strategy aims to reconcile increased affordability for consumers with the creation of sufficient incentives for pharmaceutical research & development. Underlying economic theory suggests that pharmaceutical prices should be inversely related to price sensitivity in each market, thus leading to an adaptation of prices to the purchasing power of governments and households in different countries and lower prices in the markets of developing countries. However, a crucial prerequisite for differential pricing to work is the possibility of effective market segmentation.

In order to encourage differential pricing, EU Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines was passed.³⁷ The Regulation aims to encourage pharmaceutical manufacturers to make pharmaceutical products available at heavily reduced prices in significantly increased volumes by preventing re-importation into the EU. 38 It covers pharmaceutical products used in the prevention, diagnosis and treatment of HIV/AIDS³⁹ that are exported to a country of destination listed in Annex II (76 least-developed countries and low-income countries). For these products, the Regulation establishes mandatory price calculations, requiring either that the price be not more than 25% of the weighted average exfactory price charged by a manufacturer in OECD markets for the same product or must be the manufacturer's direct production cost plus maximum 15%. 40 If a medicine fulfills these requirements, the Regulation provides a voluntary registration system.⁴¹ In order to facilitate recognition of the products registered under the system, a permanent logo set out in Annex V to the Regulation has to be affixed.⁴² The importation of medicines approved by the Commission and registered under the system into the EU is prohibited.⁴³ This should prevent the diversion of differentially priced products to high-income markets and thus encourage a supply of affordable medicines. The significance of this legal instrument, particularly in relation to HIV/AIDS, has

³⁵ For the evolution of EU policy in this regard, see K. Gamharter, *supra* note 18, 247 *et seqq*.

³⁶ On this and the following, see, for example, World Health Organization and World Trade Organization, 'Differential Pricing and the Financing of Essential Drugs', in B. Granville (ed), *The Economics of Essential Medicines* (2002) 209.

³⁷ Council Regulation 953/2003 to avoid trade diversion into the European Union of certain key medicines, OJ 2003 L 135/5. For more in-depth scrutiny, see K. Gamharter, *supra* note 18, 252 *et seqq*.

³⁸ Regulation 953/2003, *supra* note 37, recitals 6-7.

³⁹ Also covered are products related to malaria and tuberculosis, including opportunistic diseases (Regulation 953/2003, *supra* note 37, Art 1(2)(a) and Annex IV).

⁴⁰ Regulation 953/2003, *supra* note 37, Art 3.

⁴¹ *Ibid.*, Art 4.

⁴² *Ibid.*, Art 7.

⁴³ *Ibid.*, Art 2.1 in conjunction with Art 1.2.a.

been warranted by the fact that the first products registered under the system were medicines used in the treatment of HIV. 44

3. Assessment from a Security Perspective

After outlining the different approaches taken with regard to the question of access to medicines under the WTO and the EU legal system, the final part of this paper provides an assessment of these strategies and attempts to put them into a security perspective. Both the activities at the WTO and within the EU are aimed at the same goal, namely to ensure access to affordable medicines in poor countries. At the WTO, the strategy for reaching this goal has been to strengthen compulsory licensing, whereas the EU has promoted differential pricing.

Compulsory licensing and differential pricing diverge fundamentally. Compulsory licensing aims to create greater room for manoeuvre for states with insufficient manufacturing capacity. It is addressed primarily to the governments of WTO Member countries, and the additional elements of flexibility contained in the Decision WT/L/540 require national implementation. In contrast, differential pricing creates incentives for (private) pharmaceutical companies. By providing enhanced legal security against re-exports of differentially priced products, Regulation 953/2003 attempts to provide an element in an international legal framework conducive to the establishment of a global system of differential prices.

The grant of a compulsory licence is by definition a non-voluntary measure. In contrast, differential pricing is based on voluntary commitments by the pharmaceutical industry. While compulsory licensing applies only where an intellectual property right is granted, differential pricing is not per se related to intellectual property rights. Compulsory licensing benefits the producers of generic medicines, whereas Regulation 953/2003 may be invoked both by research-based and generic producers. 46

On the one hand, advocates of differential pricing argue that such mechanisms may render the granting of compulsory licences unnecessary. On the other hand, only the credible threat of the issuance of a compulsory licence may provide the necessary incentive to engage in differential pricing schemes. Therefore, interlinkages exist between these different strategies. Enhancing legal security for pharmaceutical companies must go hand in hand with the empowerment of states to use compulsory licensing as a fall-back option, even though it should be used with extreme prudence.

However, both legal instruments also provide reason for criticism. Main points of criticism include that the WTO Decision on compulsory licensing is procedurally complicated and that its workability will largely depend on the effectiveness of national implementing

⁴⁴ The medicines' list can be viewed and searched online at http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl.

⁴⁵ Norway and Canada have been the first developed countries to implement Decision WT/L/540, *supra* note 31. For more on national implementation, see K. Gamharter, *supra* note 18, 240-241.

⁴⁶ See also http://trade-info.cec.eu.int/cgi-bin/antitradediversion/index.pl.

⁴⁷ See the European Commission's press release 'Access to medicines: EU clears plan to ensure delivery of cheap medicines to developing countries', IP/03/748, 26 May 2003.

⁴⁸ For further exploration of these interlinkages, see K. Gamharter, *supra* note 18, 266 *et seqq*.

legislation and the coordination of procedures in exporting and importing countries.⁴⁹ In turn, Regulation 953/2003 has a limited scope of potential beneficiary countries, and the mandatory price calculations may be too rigid to promote widespread use.⁵⁰ In addition, to curb trade diversion into the EU market may prove ineffective unless other developed countries follow suit.⁵¹ Lastly, these trade-based approaches face the criticism that the magnitude of the problems can only be faced through a massive increase in international health aid and donor programs.⁵²

As was pointed out above, the challenge created by the HIV/AIDS pandemic requires a multi-faceted response. Clearly, neither of the two legal instruments provides such a response as a stand-alone measure, and both instruments are nothing more than first steps. In order to reduce the security risk created by the scale of the disease, further coordinated action is urgently required. However, despite the criticism, the development of these two legal mechanisms as the result of a closely interrelated political process is exemplary of the creation of a response across institutional borders. It is argued that also from a security point of view, a combination of strategies that both reinforce governments and provide incentives to private companies may be a promising way forward.

Another element linking the debates on HIV/AIDS in the trade and the security context relates to the assessment of Regulation 953/2003 under WTO law. As pointed out, Art 2 of Regulation 953/2003 establishes an import prohibition for differentially priced products into the EU. Under Art XI GATT, import prohibitions or restrictions such as quotas, import licences or other measures other than duties, taxes or other charges are prohibited. Therefore, Art XI prohibits an import ban such as the one established in Regulation 953/2003. As a consequence, the import prohibition would have to fall within the scope of an exception to the GATT in order to be admissible. While justification under Art XX GATT is not dealt with here in detail, 53 the context of this paper raises the question of justification under the security exception contained in Art XXI GATT.

Art XXI(c) GATT provides:

Nothing in this Agreement shall be construed

⁴⁹ Another point of criticism relates to the adoption of the solution in the form of a waiver, arguably undermining the amendment provisions in the WTO Agreement (for details, see K. Gamharter, *supra* note 18, 242 *et seqq*.).

⁵⁰ See K. Gamharter, *supra* note 18, 260-261.

⁵¹ See also IP/03/748, *supra* note 47.

At the international level, such programs notably include the "Global Fund to Fight AIDS, Tuberculosis and Malaria", created in 2002 in order to attract and disburse additional resources to prevent and treat the three targeted diseases in a partnership between governments, civil society, the private sector, and the international community. See The Global Fund to Fight AIDS, Tuberculosis and Malaria, *The Global Fund Annual Report 2003* (2004).

⁵³ For an outline of a possible justification under Art XX GATT, see K. Gamharter, *supra* note 18, 262-263.

The import prohibition is not directly related to IPRs, therefore justification under the parallel provision in Art 73(c) TRIPS Agreement is not pertinent. While the distinct security exceptions contained in Art XXI(a) and Art XXI(b) GATT have received considerable attention in literature, Art XXI(c) is frequently left aside in these analyses. For a compilation of the literature considering Art XXI GATT, see Akande and Williams, 'International Adjudication on National Security Issues: What Role for the WTO?', 43 *Va. J. Int'l L.* (2003) 365 (in note 18).

- (a) to require any contracting party to furnish any information the disclosure of which it considers contrary to its essential security interests; or
- (b) to prevent any contracting party from taking any action which it considers necessary for the protection of its essential security interests
- (i) relating to fissionable materials or the materials from which they are derived;
- (ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;
- (iii) taken in time of war or other emergency in international relations; or
- (c) to prevent any contracting party from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

As outlined above, the Security Council recognized the international security dimension of HIV/AIDS in Resolution 1308/2000. If conditions become worse and adequate response is not provided through other *fora*, it is conceivable that the Security Council will return to this issue and make recommendations for additional steps. If it went so far as to adopt a Resolution recommending that UN Member States enhance supply with medicines at greatly reduced prices in developing countries and that they prevent such differentially priced products from re-entering their territory, measures adopted in pursuance of this recommendation may be justified under Art XXI(c) GATT. Under such circumstances, an import prohibition such as the one established by Regulation 953/2003 could also be justifiable under Art XXI(c).

4. Concluding Remarks

This paper has explored issues at the interface of HIV/AIDS, security and international trade. A health problem of the dimension of the global HIV/AIDS pandemic has inherent security implications. The recognition that HIV/AIDS constitutes a threat to the stability and security of states should be fully reflected in the way countries, particularly in Africa, face the problem. Therefore, HIV/AIDS should be addressed as a priority for security forces as part of a comprehensive, government-wide approach, rather than leaving it to the health sector alone to deal with its impact or prevent its further spread. ⁵⁵

However, the steps to be taken within militaries in order to face the security challenge posed by HIV/AIDS should not only relate to specific measures such as education and prevention programs, but also require the endorsement of governmental contributions to local and international efforts. This arguably includes initiatives such as the ones that were conducted at the WTO and the EU. Endorsement is necessary both from developing and developed countries. While the link between HIV/AIDS and security is now well established, further exploration of the concrete security dimension of HIV/AIDS is still lacking. Efforts to systematically assess this dimension are under way at the UNAIDS Office on AIDS, Security and Humanitarian Response and a comprehensive report on "AIDS and Security" is due to be presented to the Security

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⁵⁵ See also International Crisis Group, *supra* note 10, 17.

⁵⁶ S. Elbe, *supra* note 1, 67-69.

