**Medication Safety, Human Rights and the Pharmaceutical Industry**

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The term ‘essential medicines’ first appeared in the 1970s in the context of the WHO and is now defined as medicines that ‘satisfy the priority health care needs of the population.’[[1]](#footnote-1) This definition intends that essential medicines should be ‘available within a national context at all times, in all adequate amounts, in the appropriate dosage forms and with the assured quality and at an affordable price for individuals and the community.’[[2]](#footnote-2)

The ever-increasing use of (essential) medicines in Low- & Middle Income Countries (LMICs) however, also introduced increased health risks due to improper handling, prescribing, dispensing, administration and patient use. Research [[3]](#footnote-3)[[4]](#footnote-4) (although only sparsely available) and common sense make it very likely that having physiologically (very) active products available in a country without the corresponding and crucial safety barriers, like for example, adequate legislation and policy, state enforcement power, quality and quantity of Health Care Practitioners (HCP’s), professional health care IT-tools, inter HCP communication, can seriously endanger the health status of the general public. As a simple (pharmaceutical) example; HIV/TB medication is distributed widely through Global Fund programs, but is known to give many interactions with other medicines. Is that taken into account when prescribing, distributing or using the other medication?

This problem has been recognized internationally and the WHO has taken up an active role the last twenty years, for example in promoting national pharmacovigilance (PV) centres, relevant legislation and policy development and creating an international PV network. In its definition on Pharmacovigilance[[5]](#footnote-5) the WHO states: ‘Pharmacovigilance is the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other medication-related problem’. The WHO has further stressed the importance of this particular issue in its 2014 publication titled ‘Reporting and learning systems for medication errors: the role of pharmacovigilance centres’; and more recently at the 69th WHA (2016) side event: ‘Addressing the Global Challenge of Medication Safety to Improve Patient Safety and Quality of Care’.

Historically the pharmacovigilance focus has been especially on the adverse effects of medication, while far less so on the last part of the WHO definition ‘… any other medication-related problem’. In this article the term ‘Medication Safety’ is used instead of pharmacovigilance as it includes all health risks related to the (global) use of medication and as such is much clearer to the general public. Medication Safety focuses on all of the aspects (including besides the HCPs, also policy, legislation, health system-analysis, stakeholders, culture) concerning the goal of minimizing health risks originating from the global use of medicines.

The provision of and access to essential medicines is protected by international (human rights) law, most obviously in the framework of the human right to health. The right to health is codified in a number of international instruments, most notably article 12 of the 1966 International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 12.1 ICESCR recognises the ‘right of everyone to the enjoyment of the highest attainable standard of physical and mental health’, including ‘the prevention, treatment and control of epidemic, endemic, occupational and other diseases’ and ‘the creation of conditions which would assure to all medical service and medical attention in the event of sickness’. Today the use of medicines is an essential and indispensable part of the treatment of disease.

The ICESCR is an international agreement and as such creates obligations for states party to the Covenant under international law. Article 2.1 ICESCR states that each state party undertakes to take steps, individually and through international assistance and cooperation, to the maximum of its available resource to progressively realise the rights enshrined in the Covenant, including the right to health.

The international Committee on Economic Social and Cultural Rights – a treaty body consisting of independent experts set up to monitor state compliance with the ICESCR – in its General Comment No. 14 on the Right to the Highest Attainable Standard of Health affirms that essential medicines are not only a component of the right to health but, in fact, considered part of its so-called ‘minimum core content’, referring to those elements of a human right without which the right would be devoid of any meaning or relevance.[[6]](#footnote-6) It further finds that the right to health, in all its forms, needs to meet the four interrelated and essential AAAQ-requirements of *availability*, *accessibility*, *acceptability* and *quality*.[[7]](#footnote-7) These criteria therefore also apply to the provision and use of essential medicines. Consequently, essential medicines have to be available in sufficient quantity within the state party, physically and economically accessible to everyone without discrimination, respectful of medical ethics and culturally appropriate and, finally, scientifically and medically appropriate and of good quality.

The Committee finds that, like all human rights, the right to health imposes three types of obligations on state parties – to *respect*, *protect* and *fulfil*.[[8]](#footnote-8) Consequently, state parties must respect the right to health by abstaining from interfering with it, fulfil the right to health by actively working towards the full realisation of the right, and protect the right to health by preventing third parties from interfering with it. It is, therefore, the primary responsibility of the state to regulate the pharmaceutical industry, for example, by legislating and enforcing safety and quality regulations with regard to the manufacturing and use of medicines. In that regard, the Committee has stated that ‘while only states are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society – […] as well as the private business sector – have responsibilities regarding the realization of the right to health.’[[9]](#footnote-9)

The process of globalisation over the past decades shows that non-state actors such as transnational corporations play an increasingly important role both internationally, but also at the national and local levels. This has given rise to a debate about the roles and responsibilities of such actors with regard to human rights. International human rights standards have traditionally been the responsibility of states. However, the increasing (global) power, reach and impact of big business and concern over human rights violations relating to business led to an international effort to identify and clarify human rights responsibilities of businesses.

In 2005 the United Nations Human Rights Commission mandated John Ruggie, as Special Representative of the Secretary-General, to undertake this task. The result was that in 2011 the United Nations Human Rights Council unanimously endorsed the UN Guiding Principles on Business and Human Rights (or also the ‘Ruggie Principles’).[[10]](#footnote-10) At the same time a parallel development was taking place with regard to pharmaceutical corporations initiated by Paul Hunt, the first UN Special Rapporteur on the Right to Health. He argued that safeguarding access to medicines was a ‘shared responsibility’ between public and private actors and that the pharmaceutical industry had an ‘indispensable role to play’.[[11]](#footnote-11) A set of draft Guidelines for Pharmaceutical Corporations in Relation to Access to Medicines (or also the ‘Hunt Guidelines’) was released in 2007 for public comment and finally submitted to the UN General Assembly in 2008.[[12]](#footnote-12)

Both the Ruggie Principles and the Hunt Guidelines reaffirm the primary responsibility of the state to protect human rights, also from violations by business. But in addition they recognise that companies, next to complying with national laws, have a baseline responsibility to respect human rights, meaning not to infringe on the rights of others. Besides this responsibility to respect, the Hunt Guidelines also recognise that pharmaceutical companies might have additional responsibilities beyond this baseline. These are often closely connected to the state duty to protect.

When it comes to access to medicines, much focus has been put on the pharmaceutical industry and their input on this issue; see for example the ‘Access to Medication Index’,[[13]](#footnote-13) in which the positive actions of different pharmaceutical companies are rated. In light of the right to health, and the Hunt Guidelines, we argue that the pharmaceutical industry has a responsibility to act upon the issue of Medication Safety. And not just from a mere technical product quality point of view, but by taking a systematic approach in which the industry accepts its role as a system player for whom other system players’ activities and results have a big impact on the individual therapeutic result. In the end, medication is a (potentially dangerous) tool in reaching a desired health goal, in which numerous stakeholders have their positions, responsibilities and goals.

As a first step, the pharmaceutical industry should acknowledge and accept its role and responsibility both from a human rights, as well as a moral point of view. The second step could be to jointly start up integrated and structural discussions with organisations like the WHO, national Patient Safety Organisations and entities like the GIMS foundation, to find out how to address the global issue of Medication Safety systematically, mutually and effectively. A multi-party and multi-disciplinary ‘Medication Safety Taskforce’ under guidance of the WHO should be the initial objective. According to the GIMS foundation state/country oriented items which should be addressed are: national research into the theme, medicine regulation and legislation, pharmaceutical policy, academia, training of HCP’s, available or desired professional health care ICT-tools, marketing guidelines, culture, advocacy on the theme, etc.

This article advocates that the right to health and access to (essential) medicines, and the subsequent issue of health risks originating from the global use of medicines, entail obligations and responsibilities for state parties as well as for the pharmaceutical industry. Consequently, the pharmaceutical industry, as a system player and according to the Hunt Guidelines, should take up this responsibility and shift to a real action modus so as to protect patients and consumers from non-desired and avoidable health effects of its products wherever in the medication-system the health risk may occur. If structural results fail to get realised by the industry in a reasonable time frame, state parties could follow the road of legislative measures in order to enforce industry.

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1. WHO, ‘WHO Policy Perspectives on Medicines. Issue No. 4: The Selection of Essential Medicines’ (June 2002) p 1 <http://apps.who.int/iris/bitstream/10665/67375/1/WHO\_EDM\_2002.2.pdf> accessed 24 April 2016. See also the website of the WHO <www.who.int/medicines/services/essmedicines\_def/en> accessed 24 April 2016. [↑](#footnote-ref-1)
2. Ibid p 2. [↑](#footnote-ref-2)
3. Management Sciences for Health 2012, MDS-3, ‘Managing Access to Medicines and Health Technologies’, Chapter 35. [↑](#footnote-ref-3)
4. Sten Olson, Shanti N Pal & Alex Dodoo (2015) Pharmacovigilance in resource-limited countries, Expert Review of Clinical Pharmacology, 8:4, 449-460. [↑](#footnote-ref-4)
5. WHO; ‘The importance of Pharmacovigilance’, Geneva (2002) [↑](#footnote-ref-5)
6. CteeESCR, ’General Comment 3 on the Nature of States Parties’ Obligations’ (14 December 1990) UN Doc E/1991/23, para 10; CteeESCR, ‘General Comment 14 on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health’ (11 August 2000) UN Doc E/C.12/2000/4, para 43. [↑](#footnote-ref-6)
7. CteeESCR, ‘General Comment 14’ (2000), para 12. [↑](#footnote-ref-7)
8. CteeESCR, ‘General Comment 14’ (2000), para 33. [↑](#footnote-ref-8)
9. CteeESCR, ‘General Comment 14’ (2000), para 42. [↑](#footnote-ref-9)
10. UNHRC, ‘Resolution 17/4 on Human Rights and Transnational Corporations and other Business Enterprises’ (6 July 2011) UN Doc A/HRC/RES/17/4. [↑](#footnote-ref-10)
11. UNGA, ‘Report by the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health’ (13 September 2006) UN Doc A/61/338, para 82. [↑](#footnote-ref-11)
12. UNGA, ‘Report by the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health’ (11 August 2008) UN Doc A/63/263, para 19 and further. [↑](#footnote-ref-12)
13. See for more information the website of the AtM Index at <www.accesstomedicineindex.org/> last accessed 13 June 2016. [↑](#footnote-ref-13)