

**Human Rights Council****Twenty-third session**

Agenda item 3

**Promotion and protection of all human rights, civil,
political, economic, social and cultural rights,
including the right to development****Report of the Special Rapporteur on the right of
everyone to the enjoyment of the highest
attainable standard of physical and mental health,
Anand Grover, on access to medicines ****Summary*

The present report identifies and analyses challenges and good practices with respect to access to medicines in the context of the right-to-health framework. Full realization of access to medicines requires the fulfilment of key elements of availability, accessibility, acceptability and quality. The report therefore utilizes these key elements in examining national and international determinants of access to medicines.

In the first section of the report, the Special Rapporteur reviews the international legal framework as it applies to access to medicines. In the second section, he identifies key determinants of access to medicines and discusses challenges and good practices with respect to each aspect. The substantive issues outlined in this section include: local production of medicines, price regulations, medicines lists, procurement, distribution, rational and appropriate use and quality of medicines. The Special Rapporteur concludes the report with specific recommendations for promoting access to medicines in accordance with the framework of the right to health.

* Late submission.

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I. Introduction

1. In its resolution 17/14, the Human Rights Council requested the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health to prepare a study on existing challenges and good practices with regard to access to medicines in the context of the right to health, ways to overcome them and good practices. Taking into account previous reports of the Special Rapporteur and his predecessor on various aspects of access to medicines,¹ he deemed it appropriate not to deal with issues related to intellectual property in the present report. This report therefore focuses on other important issues that determine access to medicines, including essential medicines,² local production of medicines, procurement, distribution, quality control and appropriate use of medicines.

2. In the preparation of this report, the Special Rapporteur carried out consultations with a variety of stakeholders, including Member States, international organizations, civil society, pharmaceutical companies and other experts. He considered responses generated from consultative questionnaires, which were distributed to the stakeholders and also made publicly available on the Internet. The Special Rapporteur is grateful for the overwhelming interest shown by States, international organizations and civil society in responding to the questionnaires. It is however regrettable that only a few responses were received from the 40 pharmaceutical companies to which the questionnaire was sent. The Special Rapporteur also held consultations in Belgium (Brussels), the United Kingdom (London, through his assistants), Brazil (Brasilia and Sao Paolo), Uganda (Kampala) and the United States (Washington, DC), where he met with government agencies, pharmaceutical companies and associations, civil society representatives and other experts. Information from these visits also fed into the report.

II. International legal framework

3. Access to medicines is an integral component of the right to health, as enunciated under article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR).³ The Committee on Economic, Social and Cultural Rights in its interpretation of the normative content of article 12 issued its general comment No. 14 (2000) on the right to the highest attainable standard of health, which provides that all health services, goods and facilities, including medicines, should be made available, accessible, acceptable and of good quality.⁴ While several aspects of the right to health are understood to be progressively realizable, certain core obligations cast immediate obligations on States, including the provision of essential medicines to all persons in a non-discriminatory manner.⁵

4. The right-to-health framework sets out key elements that should be fulfilled by States to ensure access to medicines. First, medicines should be made available in sufficient

¹ A/HRC/17/43, A/65/255, A/HRC/11/12 and A/63/263.

² While essential medicines are selected nationally, internationally they are defined within the framework of the World Health Organization (WHO) Model Lists of Essential Medicines.

³ The 2001 Declaration of Commitment on HIV/AIDS and the Doha Declaration on the TRIPS agreement and public health also recognize access to medicines as instrumental to the full realization of the right to health.

⁴ E/C.12/2000/4, para. 12.

⁵ *Ibid.*, para. 43(d).

quantities within a country to meet the needs of the people. In fulfilling this obligation States should select essential medicines that reflect the priority diseases in the population, procure them in sufficient quantities and ensure their availability in all public health facilities. Second, medicines should be accessible in terms of economic affordability and physical distance from where the population lives on the basis principle of non-discrimination. Third, medicines should be determined to be culturally and ethically acceptable to the population. Finally, States also have the obligation to put in place strong regulatory mechanisms and transparent processes which ensure the quality, safety and efficacy of medicines.⁶

5. Furthermore, States have the obligation to respect, protect and fulfil the right to health, including access to medicines.⁷ The duty to respect extends to the obligation of States to refrain, *inter alia*, from denying or limiting equal access for all persons, including vulnerable groups, to all health services, including medicines. The duty to protect requires a State to ensure that third parties do not obstruct the enjoyment of the right to health. For example, a State should ensure that privatization of the health sector and the supply of medicines by private companies does not constitute a threat to the availability, accessibility, acceptability of quality medicines. The duty to protect also extends to the regulation of the marketing and sale of safe and good quality medicines by third parties. Finally, the duty to fulfil necessitates that States take positive measures that enable and assist individuals and communities to enjoy the right to health and give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation. In this context and as part of States' immediate obligations to take deliberate, concrete and targeted steps towards the full realization of the right to health, States should adopt a national health policy with a detailed national plan of action aimed at ensuring access to medicines.

6. While States have the primary responsibility for enhancing access to medicines, it is a shared responsibility in which numerous national and international actors have a role to play. In its general comment No. 3 (1990) on the nature of States parties' obligations, the Committee on Economic, Social and Cultural Rights also stressed the obligation of States to take steps, individually and through international assistance and cooperation, especially economic and technical, towards the full realization of the rights recognized in the Covenant, including the right to health. Moreover, in the spirit of Articles 55 and 56 of the Charter of the United Nations, articles 2(1) and 23 of the Covenant, as well as the Alma-Ata Declaration on Primary Health Care, States should recognize the essential role of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health. According to the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines,⁸ pharmaceutical companies should integrate human rights, including the right to health, into their strategies, policies, programmes, projects and activities.

III. Determinants of access

7. Market-oriented approaches to medicines in a highly competitive global marketplace often project issues related to access to medicines as a matter of profit rather than a public

⁶ *Ibid.*, para. 12.

⁷ *Ibid.*, paras. 34-37.

⁸ A/63/263.

health concern.⁹ While it is understandable that private pharmaceutical companies should follow such an approach, there is a growing need for States to balance that market-driven perspective by positioning access to medicines in the right-to-health framework. There is thus the need to shift the dominant market-oriented paradigm on access to medicines towards a right-to-health paradigm and reaffirm that access to affordable and quality medicines and medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central elements of the enjoyment of the right to health.

8. Ensuring access to medicines also requires a functioning health system that encapsulates the key elements of the right to health: availability, accessibility, acceptability and quality. As part of the State obligation to fulfil the right to health¹⁰ and with a view to the progressive realization of access to affordable and quality medicines,¹¹ the Special Rapporteur urges States to adopt a detailed national plan of action on medicines. The plan of action should be backed by a strong political will and commitment that prioritizes access to medicines within the public health budget and allocates resources accordingly. This is particularly pertinent in the context of the current global economic crisis, where some States are increasingly taking retrogressive measures such as reducing spending on health by reducing national health budgets.¹² The Special Rapporteur stresses that States have the burden of proving that deliberately retrogressive measures have been introduced after careful consideration of all alternatives and that they are justified under full use of the State party's maximum available resources.¹³

9. National plans should also include principles of non-discrimination, transparency and participation. Participation of all stakeholders, including vulnerable groups, in health-related decision-making is the cornerstone of the right-to-health framework. Participation provides individuals with an opportunity whereby they can advance their health rights. It is through participation and empowerment that individuals, patient groups and communities can claim their right to health and achieve improvements in accessing such essential medicines.

10. Based on the submissions received from various stakeholders and following numerous consultations, the Special Rapporteur considers, henceforth, the main determinants of access to medicines in the context of the right to health.

A. Local production

11. An efficient and functional health system is crucial to ensure the availability of medicines, particularly essential medicines, in sufficient quantities, at all times and in all public health facilities. Under the right-to-health framework, States have an immediate obligation to take legal and administrative measures to ensure that access to essential medicines for their populations is secured by all available means. However, a third of the world's population, living mainly in developing countries, still do not have regular access

⁹ Patrice Trouiller et al, "Drugs for neglected diseases: a failure of the market and a public health failure?", *Tropical Medicine and International Health*, vol. 6, No. 11 (November 2001), pp. 945-951, p. 946.

¹⁰ E/C.12/2000/4, para. 36.

¹¹ *Ibid.*, para. 31.

¹² Philipa Mladovsky et al, *Health policy responses to the financial crisis in Europe* (WHO and European Observatory on Health Systems and Policies, 2012), pp. 38-70.

¹³ E/C.12/2000/4, para. 32; Committee on Economic, Social and Cultural Rights general comment No. 3 (1990), para. 9; International Covenant on Economic, Social and Cultural Rights, art. 2.

to essential medicines.¹⁴ During the period 2001-2009, the average availability of essential medicines in public health facilities was only 42 per cent and in private sector facilities was 64 per cent.¹⁵ For chronic conditions, most of which require life-long access to medicines, the availability in public and private sectors was even poorer, at 36 per cent and 55 per cent respectively.¹⁶ Despite momentous gains in the past decade, only 8 million out of 14.8 million people living with HIV globally receive necessary treatment.¹⁷

12. Inadequate prioritization of health, insufficient resources and poor governance has increased the inability of governments to finance efficient health systems that enhance access to medicines, consequently increasing their dependence on out-of-pocket payments and international donor funding.¹⁸ Even where international donors like the United States President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to fight AIDS, Tuberculosis and Malaria have stepped in to fill this gap, they have only managed to reach a portion, though significant, of those who need these medicines due to limited budgets.

13. There are wide disparities between the global burden of disease and the global consumption of medicines. For example, in 2004, South-East Asia and Africa accounted for 54 per cent of the global burden of disease predominantly caused by communicable diseases.¹⁹ However the geographical breakdown (by main markets) of sales of new medicines launched during the period 2004-2008 indicates that North America, Europe and Japan accounted for 95 per cent of the sales, while Africa and Asia, representing more than two-thirds of the world population, only accounted for 5 per cent of the market.²⁰ During this period 90 per cent of the global production of medicines was also concentrated in the developed regions of the world.²¹

14. Manufacturing capacities in developing countries are limited to countries such as China, India, Brazil, South Africa, Thailand, Kenya, the Syrian Arab Republic and Egypt. Even in the developed world, large innovator multinational companies are concentrated in a small number of countries such as Switzerland, the United Kingdom, the United States, Germany, France and Japan. The Special Rapporteur recognizes that while factors such as inefficient procurement and poor distribution practices²² do determine the availability of medicines in a country, it may still be politically and strategically important for developing countries to ensure the security of access to medicines for their populations through local production.

15. Investing in local production as a long-term strategy holds the promise of improving medicines security in developing countries. Fulfilling this goal would require, inter alia, a coherent policy framework that explicitly links local production to improved access to

¹⁴ WHO, *The World Medicines Situation 2011: Access to Essential Medicines as part of the right to health* (Geneva, 2011), p. 1.

¹⁵ United Nations, Millennium Development Goal 8, *The Global Partnership for Development: Time to Deliver*, *MDG Gap Task Force Report 2011*, p. 51.

¹⁶ *Ibid.*, p. 52.

¹⁷ UNAIDS World AIDS Day Report 2012, p. 6.

¹⁸ A/67/302, para. 2.

¹⁹ WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* (2012), p. 25.

²⁰ European Federation of Pharmaceutical Industries and Associations, "The Pharmaceutical Industry in Figures", Key data, 2009 update, p. 3. Available at [http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA%20in%20Figures%202009-20080612-009-EN-v1%20\(1\)_0.pdf](http://www.efpia.eu/sites/www.efpia.eu/files/EFPIA%20in%20Figures%202009-20080612-009-EN-v1%20(1)_0.pdf)

²¹ WHO, *The World Medicines Situation* (2004), p. 3.

²² *MDG Gap Task Force Report 2011* (see Note 16 above), p. 51.

medicines²³ and is backed by strong political commitment. The Special Rapporteur notes with satisfaction that in this respect a regional plan of action was drawn up for local production of essential medicines aiming to promote access to medicines in the east African region by the East African Community.²⁴

16. There are, however, several challenges that need to be addressed in order to ensure sustainability of local production of essential medicines. In the short term, the pressures of reaching economies of scale and countering price competition from importers can mean higher prices for locally produced medicines.²⁵ This results in a greater burden on the public health budgets of developing countries.

17. Lack of data on the price difference between locally produced and imported medicines is also a drawback in promoting local production.²⁶ To help determine the affordability of locally produced medicines in the long term, States should also collect disaggregated data on the prices of imported medicines in comparison to locally produced medicines.

18. In complying with their obligation to ensure availability of medicines, States may consider the following policy options to develop an enabling environment that promotes the growth of local pharmaceutical industry: (i) levying taxes on imports of medicines that can be locally produced, except for active pharmaceutical ingredients which are generally not imported; (ii) providing subsidies;²⁷ (iii) tax incentives; (iv) guaranteed government procurement to local manufacturers; and (v) a regulatory framework to increase local competitiveness. As highlighted during the Special Rapporteur's consultations, local production of medicines has indirect benefits, such as (i) promoting transfer of technology (ii) providing employment and capacity-building of local people through training programmes for local pharmacists (ii) microbiologists and technicians, and (iii) setting up local institutes of higher education and contributing to capacity-building of the regulatory agencies. Thus, opting for local generic production should be weighed and balanced against a number of benefits, including strategic security in medicines supply, which would be achieved in the long run as opposed to the higher prices in the short run.

19. States should also take advantage of flexibilities under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). The 2001 Doha Declaration on TRIPS and Public Health reaffirms these flexibilities in support of World Trade Organization (WTO) members' right to protect public health and to promote access to medicines for all. Furthermore, paragraph 6(i) of the Decision of the General Council of 30 August 2003, under the Doha Declaration on TRIPS and Public Health, specifically allows least-developed countries (LDCs), more than half of whom are party to a regional trade agreement, to produce medicines locally in the public health interest, irrespective of patents on medicines, with the intention of making medicines more affordable by increasing economies of scale through regional sales.

²³ United Nations, *Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A series of case studies* by the UNCTAD Secretariat (2011), p. 14.

²⁴ East African Community Regional Pharmaceutical Manufacturing Plan of Action (2012-2016).

²⁵ WHO, *Increasing Access to Vaccines Through Technology Transfer and Local Production* (2011), p. 24.

²⁶ WHO, *Local Production for Access to Medical Products: Developing a framework to improve Public Health* (2011), p. 47.

²⁷ Lorraine Hawkins, "Competition Policy", Working Paper 4, Review Series on Pharmaceutical Pricing Policies and Interventions, WHO/Health Action International (HAI) Project on Medicines Prices and Availability (2011), p. 26.

B. Pricing

20. According to the right-to-health framework, medicines should be economically accessible to all sectors of the population. Medicines should therefore be priced in a fair and equitable manner and be affordable so as to not disproportionately burden poorer households. This is an even greater problem in developing countries, where up to two-thirds of expenditure on medicines is individually financed through out-of-pocket payments.²⁸ Such payments are primarily responsible for catastrophic health expenditures, annually pushing approximately 100 million people, mostly in developing countries, into poverty.²⁹ Ensuring affordable and equitable pricing of essential medicines is therefore a key determinant of access to medicines in most developing countries.

1. Price control

21. States have a legal obligation under the right to health to ensure that production of essential medicines by the private sector does not threaten affordability and accessibility of medicines. Market monopoly or market domination combined with insufficiently competitive forces in the market to ensure efficient prices can result in monopolistic pricing leading to high cost of medicines. Hence, price regulation becomes critical.³⁰ In some countries, however, the term “price control” has acquired a negative connotation,³¹ including that it affects revenue-induced innovation for pharmaceutical companies.³² In developed countries, where a substantial proportion of the population is covered by health insurance schemes, governments frequently apply price control mechanisms as part of the overall strategy to contain costs. The absence of price controls in developing countries causes grave problems if private-sector monopoly over manufacture and distribution of vital medicines remains unregulated. Such unfettered monopoly can lead to profit-maximizing pricing. In developing countries with high income-inequality it would mean that access to medicines is only affordable to the wealthy. States that inadequately use price controls to ensure affordability of medicines would fail in their obligation to use all available resources, including regulatory powers, to promote the right to health.

22. States which responded to the Special Rapporteur’s survey reported on the use of price control mechanisms to promote affordability of medicines, particularly essential medicines. Accordingly, external reference pricing (ERP), therapeutic reference pricing (TRP), as well as the regulation of manufacturers’ selling price and distributor’s mark-ups, have been applied as the most common methods for setting a ceiling price for medicines. States also reported the use of competition law as the preferred indirect price control mechanism. Tax incentives to manufacturers, wholesalers and retailers and government subsidies to manufactures were indicated as other methods of indirect control used by States to control prices of medicines.

23. According to the respondent States, ERP is the primary method used by regulatory bodies to set a retail price above which medicines cannot be sold to consumers. Under ERP,

²⁸ WHO, *The World Medicines Situation 2011: Medicine Expenditures, 3rd Edition* (2011), p. 7.

²⁹ WHO, *The World Health Report, Health Systems Financing: The path to universal coverage* (2010), p. 8.

³⁰ Jaime Espin et al, “External Reference Pricing”, Working Paper 1, Review Series on Pharmaceutical Pricing Policies and Interventions (2011), p. 1.

³¹ U.S. Department of Commerce International Trade Administration, *Pharmaceutical Price Controls in OECD Countries: Implications for U.S. Consumers, Pricing, Research and Development, and Innovation* (2004), p. 3.

³² Neeraj Sood et al, “The Effect of Regulation on Pharmaceutical Revenues: Experience in Nineteen countries”, RAND Corporation, published by Health Affairs (2008), pp. w125-w137, p. w136.

the price of a specific medicine in one or several countries is used as a benchmark to set or negotiate the price of medicines in a given country. Regrettably, some developing countries select developed countries, with higher medicines prices, as reference countries, resulting in substantially higher medicines prices. For example, in 23 developing countries, public sector prices for generic medicines were 1.9 to 3.7 times higher than even the international reference price (calculated at the median price of multi-sourced medicines offered to developing countries by different suppliers) and for originator brands, 5.3 to 20.5 times the international reference price.³³ To secure the lowest price for medicines and enhance affordable and equitable access to essential medicines, purchasing States should therefore select reference countries whose level of economic development is similar to theirs.³⁴ If States use high-price countries for referencing, they should adjust the benchmark price to the levels of local income per capita when setting prices.

24. The Special Rapporteur was informed that pharmaceutical companies adopt various methods to reduce price transparency in order to work around any loss incurred from ERP. They introduce their products in high-price markets first, to be used as reference countries, thus maximizing the price. Additionally, transparency is reduced when companies list high prices in a country while granting discounts and rebates on the condition of confidentiality.³⁵

25. Under the right to health, access to information includes providing consumers with information on the prices of medicines. This has been a good practice adopted in some States, which require by law that the maximum retail price of medicines be printed on medicine packages.³⁶

26. About half of the surveyed States use TRP to set the ceiling price of medicines. TRP is applied generally in developed countries, where the reimbursement price of a medicine is fixed at the average or lowest price of other drugs in its therapeutic class that are available on the internal market. Manufacturers may price their medicines at a higher level and if the patient decides to purchase a medicine which is not covered by the reimbursement limit, they will have to pay the difference. States informed the Special Rapporteur that they offered alternatives to companies to set their prices below that limit, thus avoiding the extra cost to the patient. TRP allows doctors and patients to select the lowest price medicine from a range of alternatives within a therapeutic group, improving consumer awareness about options available and thereby helps increase transparency in the market.

27. States also exercise other forms of direct regulation through cost-based pricing, which is based on actual costs of production, a profit margin and a percentage, fixed or regressive, towards distributors' mark-ups. Determining actual costs of production, however, requires reliable and documented evidence of actual local costs of production, which is difficult to obtain given the global dimension of pharmaceutical production. Alternative methods to determine costs of production have included proxies, for example tax paid on manufacturing costs through excise returns and customs duties on landed costs of active pharmaceutical ingredients (APIs).³⁷ Transparency in providing costs of production is important to ensuring fair pricing of medicines, while allowing for a profit

³³ Alexandra Cameron et al, "Medicines Prices, Availability and Affordability", in *The World Medicines Situation 2011* (World Health Organization, 2011), pp. 5-6.

³⁴ A/HRC/20/15/Add.2, p. 12.

³⁵ Jaime Espin et al, "External Reference Pricing" (see Note 33 above), p. 22.

³⁶ WHO, "Public-Private Roles in the Pharmaceutical Sector: Implications for equitable access and rational drug use", *Health Economics and Drugs Series, No. 005* (1997), pp. 61-62.

³⁷ Sakthivel Selvaraj and Habib Hasan Farooqui, "India: Draft Drug Policy 2011: Legitimising Unaffordable Medicine Prices?", *Economic and Political Weekly*, vol. XLVII, No. 46 (2012), pp. 13-17, p. 14.

margin that sustains the industry. However, accounting manipulations, use of transfer pricing by companies, and corruption in government agencies pose additional challenges to ensuring a transparent system of cost-based pricing.

28. In contrast to cost-based pricing, market-based pricing fixes the maximum retail price through an “average” formula for all brands in a therapeutic category that have a specific market share. Market-based pricing therefore tends to cap the price of medicines at the middle range between the highest and lowest price, making medicines more expensive in comparison to cost-based pricing.³⁸

29. In some States, the use of health insurance schemes to reimburse patients the cost of essential medicines is common and vital to ensuring access to affordable medicines for people. This is done through the subsidizing of prescription medicines, usually from a preferred list of medicines, with patients making a co-payment for the medicines and the State bearing the remaining cost. The Special Rapporteur notes that the trade policies of some countries are pushing trade partners to establish judicial or administrative forums to determine when a reimbursement price unlawfully restricts the “value” of a patent on a medicine, thereby restraining the listing of such a medicine on the reimbursement schemes. At best, compelling governments to establish such forums is a waste of crucial administrative resources that could be spent delivering health goods and services. The Special Rapporteur therefore advises States to guard against trade interests prevailing over primary and immediate obligations to ensure access to affordable medicines.

2. Mark-ups

30. Prices of medicines are also affected by high add-on costs. Distribution mark-ups can represent over 40 per cent of the price ultimately paid on medicines by consumers.³⁹ States tend to regulate mark-ups in the distribution chain through varied incentives or disincentives for wholesalers, retailers, public sector, private sector and suppliers in general to ensure continuity of the supply chain and access for consumers. Most developing countries use fixed percentages to regulate mark-ups throughout the distribution chain. While this method can reduce the price of specific medicines, it may also encourage the sale of higher-priced medicines rather than low-cost generic ones. To address this shortcoming, some developing and many developed countries use regressive mark-ups: the higher the cost of the product, the lower the mark-up it attracts. Some States do not apply mark-ups to medicines on the essential medicines list, or reimbursable lists, or if they do, they apply mark-ups differentially based on whether it is a branded medicine or a generic.⁴⁰

31. States which responded to the Special Rapporteur’s survey also recommended, as a good practice in reducing medicine prices, the regulation of the price at which manufacturers can sell medicines to intermediaries along with the regulation of distribution mark-ups in the supply chain. In this context, the Special Rapporteur urges States to assess the impact of distribution mark-up regulations on medicine prices while maintaining the viability of different actors in the supply chain to ensure security of the medicines supply chain.

³⁸ Selvaraj and Farooqui, “India: Draft Drug Policy 2011: Legitimising Unaffordable Medicine Prices?” (see Note 40 above), p. 1.

³⁹ A. H. Rietveld and F. M. Haaijer-Ruskamp, “Policy options for cost-containment of pharmaceuticals”, *International Journal of Risk and Safety in Medicine*, vol. 15 (2002), pp. 29-54.

⁴⁰ Douglas Ball, “The Regulation of Mark-ups in the Pharmaceutical Supply Chain”, Working Paper 3, Review Series on Pharmaceutical Pricing Policies and Interventions, WHO/HAI Project on Medicine Prices and Availability (2011), pp. 11, 13, 14 and 21.

3. Tariffs

32. Imported medicines usually exact a tariff in the country of import which is normally added onto the cost of a medicine. Half of the surveyed States indicated that a tariff or levy is imposed on imported medicines. Tariffs are indeed applied to finished pharmaceutical products in 38 per cent of countries and to APIs in 41 per cent.⁴¹ The States, however, reported having differential policies with respect to import tariffs levied on such specific medicines as antibiotics, antiretrovirals (ARVs), cancer drugs and vaccines, which is a positive practice and can help reduce the prices of these life-saving medicines.

33. At the same time, for 92 per cent of all States, tariffs contribute less than 0.1 per cent of their gross domestic product and hence hold little economic value.⁴² However to promote local production States may consider the strategic value of tariffs on particular medicines. For instance, tariffs on imported finished products that are already manufactured locally have a stronger economic and social basis in promoting local production. The Special Rapporteur therefore encourages States to revise tariff policies in light of the lack of evidence of their economic value to State revenues, whilst allowing for tariffs that incentivize local production.

4. Taxes

34. Taxes constitute the third largest component in price add-ons for medicines after the manufacturer's price and distribution mark-ups paid by the consumer.⁴³ At the country level, the tax range for medicines is between 5 and 34 per cent.⁴⁴ These can include State tax, stamp duties, community tax, State excise duties and freight tax. Taxes are applied variably depending on whether a medicine is locally produced or imported and sold in the in the public or private sector.⁴⁵ Almost half of the States surveyed reported that taxes are not levied on medicines. Of those in which they are, some provide exemptions for medicines listed on the national essential medicines lists, donated medicines, antiretroviral drugs, imported generic medicines, cancer and diabetes medicines. The Special Rapporteur encourages States to refrain from taxing medicines, especially essential medicines, and instead consider other ways to generate revenue for health, such as so-called sin taxes – excise taxes levied on socially harmful goods such as tobacco, alcohol and junk foods.⁴⁶

5. Manufacturer's pricing policies

35. Pricing policies of pharmaceutical industries greatly impact the affordability of medicines. Under the right to health, pharmaceutical companies have a shared responsibility to ensure that the prices of their medicines do not put them out of the reach of a majority of the population. Earlier tiered pricing of essential medicines was the norm, whereby essential medicines were sold systematically at a lower price in developing countries as compared to developed countries. Later many multinationals however opted for universal tiered prices. Tiered pricing policies have now re-emerged. Some multinational companies now engage in tiered pricing between and within countries, based

⁴¹ Müge Olcay and Richard Laing, "Pharmaceutical Tariffs: What is their effect on prices, protection of local industry and revenue generation?", prepared for the Commission on Intellectual Property Rights, Innovation and Public Health (2005), p. 35.

⁴² *Ibid.*, pp. 2 and 38.

⁴³ Andrew Creese, "Sales Tax on Medicines, Review Series on Pharmaceutical Pricing Policies and Interventions", Working Paper 5, WHO/HAI Project on Medicines Prices and Availability (2011), p. 13.

⁴⁴ *Ibid.*

⁴⁵ *Ibid.*

⁴⁶ A/67/302, para. 17.

on income levels (equity based pricing), which can be profitable for companies due to increases in volume and attractive to developing countries due to reductions in prices.⁴⁷ In practice, however, tiered pricing has been limited to certain medicines such as ARVs, vaccines and contraceptives.⁴⁸ Moreover, given the lack of guarantee of low prices and the diminished role for government decision-making in such pricing policies, alternatives such as promoting robust market competition have been recommended as good practices with a view to lowering the prices of medicines.⁴⁹

6. Competition law and policies

36. As part of their obligation to ensure affordability of medicines, States employ competition laws to take action against companies that abuse a dominant position in the market. This would include measures against such practices as charging excessive prices, restricting other companies from accessing the market, collusive tender practices, and restrictive agreements.⁵⁰ For example, in 2002, one country's competition commission found that charging excessively high prices for ARVs was an illegal abuse of market dominance.⁵¹

37. During his consultations, the Special Rapporteur learnt that competition law is one of the most commonly used methods to reign in excessively high prices charged by pharmaceutical companies. States should apply competition law to monitoring mergers between generic and brand name pharmaceutical companies, which could potentially block future market competition. Competition law represents an accountability mechanism for legal redress under the right-to-health framework and provides a powerful tool to check wrongful practices by pharmaceutical companies that engage in anticompetitive practices, which can also negatively affect access to medicines.

38. Competition laws that are well formulated and enforced could also counter anticompetitive practices at every stage of the pharmaceutical supply chain.⁵² For example, such laws can address attempts by originator companies to influence suppliers in order to restrict supply of active pharmaceutical ingredients to potential competitors, or prevent agreements between larger pharmaceutical companies from using distribution strategies that reduce wholesaler competition, which would restrict smaller companies' access to the market, adversely impacting on the price of medicines. States should also consider including representatives of civil society groups on the panels of competition authorities, which has been demonstrated to have positive results in reducing the prices of medicines in some States.⁵³

39. Evidence from developed and developing countries shows that competition, including among generic companies, can reduce the prices of essential medicines. In the

⁴⁷ Access to Medicine Foundation, *Access to Medicine Index 2012* (2012), p. 50.

⁴⁸ Prashant Yadav, "Differential Pricing for Pharmaceuticals: Review of current knowledge, new findings and ideas for action" (United Kingdom Department for International Development (DFID), 2010), pp. 5-6.

⁴⁹ Suerie Moon et al, "A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries", *Globalization and Health* (2011), vol. 7, No. 39, p. 9.

⁵⁰ United States Federal Trade Commission, Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012, A Report by the Bureau of Competition (2013). Available at <http://www.ftc.gov/os/2013/01/130117mmareport.pdf>

⁵¹ Sean Flynn, "Using Competition Law to promote access to medicines", *Program on Information Justice and Intellectual Property* (2008), p. 2.

⁵² Hawkins, "Competition Policy" (see Note 30 above) p. 41.

⁵³ *Ibid.*, p. 14.

context of ARV medicines, from 2000 to 2011, market competition induced by a significant number of generic companies in the market substantially reduced the prices of those medicines.⁵⁴ With respect to improving affordability of essential medicines, competitive public procurement⁵⁵ and generic substitution⁵⁶ has also proved successful. The Special Rapporteur encourages States to enact competition laws and formulate policies for their effective enforcement in order to ensure affordable prices for essential medicines.

C. Medicines lists

40. In order to ensure availability of essential medicines, States should first identify medicines required to address priority health needs of the population under a national essential medicines list (NEML). This is consistent with States' core obligation to provide essential medicines listed in the WHO Essential Medicines List (EML).⁵⁷ These include painkillers, anti-infectives, anti-bacterials, anti-tuberculosis, anti-retrovirals, blood products, cardiovascular medicines, vaccines and vitamins.⁵⁸

41. The NEMLs are based on the rationale that a limited range of priority medicines contributes to better health care and optimizes the use of financial resources in resource-limited settings.⁵⁹ The NEML also serves as a guide for public procurement of medicines and provides guidance for local production of medicines.⁶⁰ Notably, in both developed and developing countries NEMLs are used to guide cost-containment measures for pharmaceutical expenditures.⁶¹

42. Under the right-to-health framework, the process of selection of essential medicines should be evidence-based, transparent and participatory. It should also be a part of the national plan of action on medicines, aimed at ensuring availability and affordability of medicines. The WHO EML is revised every two years by the Expert Committee on the Selection and Use of Essential Medicines (the Expert Committee). Revisions should be based on documentary evidence and include the participation of various groups, such as pharmaceutical companies and patients' groups, through a transparent application process. In contrast, responses to the questionnaire received from States revealed that civil society and community representatives were often excluded in the process of selecting essential medicines for NEMLs. Participation by civil society and communities can also contribute towards providing some evidence of health issues faced by the population.

43. Inclusion in the WHO EML implies that States should make medicines affordable for those who need it, including patented medicines. The Special Rapporteur is, however, aware of concerns about selective practices in including patented medicines in the WHO EML. In more recent versions of the WHO EML, some expensive patented ARVs, anti-malarial and anti-tuberculosis medicines have been included, while such key ARVs as

⁵⁴ Médecins Sans Frontières (MSF), *Untangling the Web of Antiretroviral Price Reductions*, MSF Campaign for Access to Essential Medicines, 14th Edition (2011).

⁵⁵ Hawkins, "Competition Policy" (see Note 30 above) pp. 5-6.

⁵⁶ WHO, "Public-Private Roles in the Pharmaceutical Sector: Implications for Equitable Access and Rational Drug Use" (see note 39 above), pp. 62-63.

⁵⁷ E/C.12/2000/4, para. 43 (d).

⁵⁸ See current list at: <http://www.who.int/medicines/publications/essentialmedicines/en/>

⁵⁹ Jonathan D Quick, "Essential medicines twenty-five years on: closing the access gap", *Health Policy and Planning*, vol. 18, No. 1 (2003), pp. 1-3, p. 1.

⁶⁰ Medicines: essential medicines, WHO Fact Sheet No. 325, June 2010. <http://www.who.int/mediacentre/factsheets/fs325/en/index.html>

⁶¹ Hans V. Hogerzeil, "The concept of essential medicines: lessons for rich countries", *British Medical Journal*, vol. 329 (2004), pp. 1169-1172, p. 1169.

Raltegravir, Darunavir and Etravirine have not. It is important therefore to ensure that the revisions to the WHO EML are conducted in an inclusive and transparent manner that addresses concerns of all groups. The Special Rapporteur also notes that in some States, patented medicines are included on the NEMs to bring them within the purview of cost-control mechanisms that ensure their affordability. It has come to his attention however that some countries exclude patented medicines from the NEM, and thereby from cost-control measures to which they would otherwise be subject, which can detrimentally impact on the affordability to patients. Essential medicines, be they patented or off-patent, should be included in both the WHO EML and NEMs in a timely manner where indicated by evidence of the burden of disease.

44. Non-communicable diseases (NCD) also disproportionately impact developing countries, which face 80 per cent of the global NCD burden.⁶² However, only 22 per cent of the 359 essential medicines on the 2003 WHO EML relate to NCDs.⁶³ Several applications for the treatment of mental health, cancers and cardiovascular diseases are pending review by the WHO Expert Committee. Underrepresentation of medicines for NCDs in the WHO EML also limits guidance for States in the development of their NEMs.

45. During the consultations, concerns were raised about the lack of uptake by States of certain essential medicines listed on the WHO EML due to political, cultural and legal considerations, especially of medicines for mental health, palliative care, drug dependence and sexual and reproductive health. For example, access to medical abortion pills such as mifepristone with misoprostol, though included on the WHO EDL, are culturally and legally restricted in many States, limiting women's accessibility to sexual and reproductive health.⁶⁴ Criminalization of the activities of drug users in many States also restricts the availability of opioid substitutes, buprenorphine and methadone, proven to be effective in treating drug dependence, despite the fact that they are listed on the WHO EML.⁶⁵ The Special Rapporteur recalls that access to essential medicines for vulnerable and marginalized groups should not be impeded by political, legal and cultural considerations. States should take steps to ensure that these medicines are included in their NEMs and are made available and accessible to such groups.

46. States have devised ingenious ways in resource-limited settings to ensure access to the most essential medicines, as was highlighted during the Special Rapporteur's consultations. For example, in one country essential medicines are classified into different segments as per product: vital medicines (e.g. emergency medicines), essential medicines (e.g. to treat fever, headaches) and necessary medicines (e.g. multivitamins). According to the procurement rules in that country, health facilities should procure the required quantity of vital medicines first, then essential, and finally necessary medicines. This helps minimize stock-outs affecting the most vital health concerns while more sustainable solutions are devised to meet the needs for other medicine. The Special Rapporteur encourages such innovative approaches, which are tailored to local conditions and are consistent with the core right to health obligation of ensuring the availability and accessibility of essential medicines.

⁶² Global status report on noncommunicable diseases, WHO (2011), p. 9.

⁶³ T. K. Mackey and B A Liang, "Patent and Exclusivity Status of Essential Medicines for Non-Communicable Disease", *PLOS ONE*, vol. 7, No. 11 (2012).

⁶⁴ A/66/254, paras. 21 and 26. See also, Jane Cottingham and Marge Berer, "Access to essential medicines for sexual and reproductive healthcare: the role of pharmaceutical industry and international regulation", *Reproductive Health Matters* (2011), vol. 19, No. 38, pp. 69-84, p. 73.

⁶⁵ See *The War on Drugs and HIV/AIDS*, "How the Criminalization of Drug Use Fuels the Global Pandemic", Report of the Global Commission on Drug Policy (2012).

D. Procurement

47. Efficient and transparent procurement of medicines is central to ensuring the availability of medicines in sufficient quantities in all public health facilities. Procurement of medicines occurs at the international, national, regional and local levels. Inefficiencies of procurement at each level can cause unreliable medicine supplies and higher costs. An efficient procurement system is one that relies on transparent management, a limited drug selection that is based on a restricted list (for example, NEML), accurate and scientific forecasting of need, competitive tendering, bulk purchasing, pre-qualification of proposed suppliers and close monitoring of selected suppliers, and reliable financing.⁶⁶ The Special Rapporteur is pleased to note that most States that responded to his questionnaire have formulated national medicine procurement policies.

48. With respect to quantification of medicines needs, one developing country experience indicates reliance on historical data gathered from hospitals all over the country and the epidemiological pattern of disease, which are reviewed every six months. A 20 per cent buffer to account for shortages or seasonal increases in disease is then added. Stock shortages are nevertheless commonly reported in this State. Fewer than half of the respondent States had a policy in place to address medicines shortages. States attributed stock shortages to insufficient funding for procurement, inaccurate forecasting of needs, inadequate buffer stock of essential medicines, and inefficient distribution and record-keeping systems. Stock shortages can force patients to resort to more expensive private health centres, inappropriate medicines or even forego treatment altogether. Over-quantification of demand, on the other hand, is equally harmful, as it can lead to the wastage of scarce resources and the expiry of medicines, for which safe disposal systems are lacking in many States.⁶⁷ States are therefore encouraged to develop more scientific, reliable and evidence-based methods for forecasting and quantification such as the use of computerized methods for quantification and reliance on data about actual consumption where there are reliable records available.⁶⁸ Participation of civil society and the affected communities must be encouraged as it helps create information networks to monitor and inform competent health authorities on medicine stocks.

49. International shortage of medicines, especially cancer medicines, was also raised as an issue by civil society participants to the survey. Such shortages in medicines are attributed to a limited number of manufacturers, shortages of raw materials, production problems and stockpiling.⁶⁹ They negatively impact States' ability to procure medicines for public health facilities and seriously affect their availability to patients. States should therefore identify particular medicines markets that face such shortages and promote the development of local production of these medicines to ensure supply sustainability in the long term.

50. The Special Rapporteur satisfactorily notes that a majority of States surveyed by the Special Rapporteur reported the use of competitive bidding for public procurement of medicines. A transparent competitive bidding process, both at the national and international

⁶⁶ Essential Drugs and Medicines Policy Interagency Pharmaceutical Group, WHO Operational principles for good pharmaceutical procurement (Geneva, 1999).

⁶⁷ Roger Bate et al, Antimalarial medicine diversion: stock-outs and other public health problems, *Research and Reports in Tropical Medicine*, vol. 1 (2010), pp. 19-24, pp. 22-23.

⁶⁸ Chap. 18, "Managing Procurement", in *Management Sciences for Health* (2011), pp. 18.9-18.10, and p. 18.4.

⁶⁹ Monika L. Metzger et al, "The Impact of Drug Shortages on Children with Cancer - The Example of Mechlorethamine", *New England Journal of Medicine*, vol. 367 (2012), pp. 2461- 2463.

level, can bring down prices and save substantial medicine-related expenditure by States.⁷⁰ The success of competitive bidding largely depends on transparent management, which provides clear and sufficient tender information to all government agencies involved.⁷¹ Efficient and transparent management can also protect against bid-rigging practices in public procurement systems.⁷²

51. In decentralized systems, however, poor financial and procurement capacities combined with weak governance present challenges which has even led to different prices in different regions of the same country. Decentralized systems also pose challenges for bulk procurement, which is routinely used in public procurement systems around the world.⁷³ While decentralized procurement has the advantage of increasing local level accountability, it is susceptible to fragmentation, which causes duplication of procurement and negatively impacts coordinated negotiations, resulting in less favourable contract terms for governments.⁷⁴ To maintain purchase volumes, some States have adopted systems to centrally negotiate prices while requiring lower levels of government to order their requirements through the successful bidder at the price negotiated at the central level.⁷⁵ The Special Rapporteur recommends streamlining guidelines at the national level to ensure better coordination and efficient decentralized procurement.

52. Good procurement practice requires that suppliers be certified for Good Manufacturing Practices (GMP) to ensure quality assurance. A robust, multi-level tender process would exclude suppliers that do not meet GMP standards. Suppliers' licensing agreements must also be strictly monitored throughout the supply chain until the time of delivery. States should publish the names of manufacturers who do not meet GMP standards and disqualify them from future bidding.

53. Accountability mechanisms are essential for addressing corrupt practices, especially in the selection, procurement and registration of medicines. The States, civil society and pharmaceutical companies that participated in the Special Rapporteur's questionnaire raised concerns about corruption within the public procurement system. To prevent corruption in government procurement, different procurement functions of selection, quantification, pre-selection (eligibility) of suppliers and adjudication of tenders should be independently managed by different offices and trained individuals. Such separation of functions will allow for transparency and avoid potential conflict of interest.⁷⁶

⁷⁰ Ezekiel Emanuel et al, A Systemic Approach to Containing Health Care Spending, *New England Journal of Medicine*, No. 367 (2012), pp. 949-954 at p. 950.

⁷¹ OECD, "Guidelines for fighting bid rigging in public procurement: Helping governments to obtain best value for money". Available at <http://www.oecd.org/competition/cartelsandanti-competitiveagreements/42851044.pdf>

⁷² Ibid.

⁷³ East African Community, A Situational Analysis and Feasibility Study on Regional Pooled Bulk Procurement of Essential Medicines and Other Health Supplies in the East Africa Community Partner States, Final Report (2007). Available at <http://apps.who.int/medicinedocs/documents/s18414en/s18414en.pdf>

⁷⁴ See Prabal Vikram Singh et al, "Replicating Tamil Nadu's Drug Procurement Model", *Economic and Political Weekly* (2012), vol. XLVII, No. 39.

⁷⁵ Ibid.

⁷⁶ Australian Government/AusAID and WHO, "Measuring Transparency in Medicines Registration, Selection and Procurement: Four Country Assessment Studies" (2006), p. 19.

E. Distribution

54. The right to health obliges States to ensure that distribution systems function in a manner that secures physical accessibility to quality essential medicines at all points of distribution. The distribution chain places various responsibilities on different entities, and may include private actors, who also have a responsibility to ensure that their actions do not adversely impact on the right to health. Most States consulted by the Special Rapporteur have national regulations in place for distribution of essential medicines in the public and private sector. These regulations cover storage, transport and handling of medicines and temperature sensitive products.

55. To control the quality of medicines through the distribution chain, medicines must be maintained at the required temperature and according to labelling requirements, and stored in clean, dry and well-sanitized areas.⁷⁷ States reported several challenges in meeting these requirements. Poor warehouses and cold storage facilities were cited as the major obstacles to maintaining the quality of essential medicines in developing countries, especially in rural areas. In some countries temporary storage was resorted to which lacked temperature or quality control standards. Such practices can be detrimental to the quality of medicines and this calls for urgent investment to develop adequate distribution infrastructure for public health facilities. Alternatively, States may consider including in the procurement contract a condition requiring medicines to be delivered directly to district level stores or health facilities.

56. The involvement of numerous agencies throughout the distribution process would necessitate continuous monitoring of timely distribution and medicine quality. Diversions of donated low-priced medicines from public health facilities into the private sector were observed in some countries.⁷⁸ This can be addressed through effective monitoring of the distribution chain. States surveyed by the Special Rapporteur, however, reported weak data collection and monitoring systems, partly due to lack of skilled personnel to manage these systems. There is therefore an urgent need to build government capacity for identification of weaknesses in distribution systems and to devise cost-effective methods to monitor the performance and suitability of distributors. To address this situation, States may consider adopting certification programmes for distributors, a successful practice in some developing countries.⁷⁹ Additionally, States could invest in cost-effective Internet- and mobile phone-based technologies linked to centralized computer data systems, relaying real-time data to monitor the movement of medicines from procurement through distribution and transportation and finally to delivery at health centres. Participation of communities and civil society is vital for making such measures effective.

F. Rational and appropriate use

57. The State obligation of ensuring access to acceptable medicines under the right to health relates to how medicines are prescribed, dispensed, sold and used. Errors in choosing or writing prescriptions, dispensation errors by pharmacists and incorrect consumption of medicines by patients can cause adverse health events and drug reactions.⁸⁰ States'

⁷⁷ WHO good distribution practices for pharmaceutical products, Annex 5, WHO Technical Report Series, No. 957 (2010).

⁷⁸ Roger Bate et al (see Note 71 above), p. 23.

⁷⁹ Center for Global Development, "Drug Resistance: Improving Standards in the Medicine Distribution Chain". Available at http://www.cgdev.org/doc/DWRG/distribution_chain.pdf

⁸⁰ J.K. Anderson, "Medication errors: what they are, how they happen, and how to avoid them", *Quarterly Journal of Medicine*, vol. 102 (2009), pp. 513–521, p. 514.

obligation to protect health also extends to safeguarding the public against the proliferation of irrational use of medicines, which results in wastage of scarce supplies and widespread health hazards.

58. Standard Treatment Guidelines (STGs) are invaluable for rational prescription of medicines, as they provide guidance on the most appropriate treatment options with respect to the local burden of disease. Unfamiliarity with STGs has been demonstrated in the instances of inappropriate use of antimicrobials for non-bacterial infections, over-use of injections where oral formulations are indicated and irrational combinations for fixed dose medications.⁸¹ Incorrect choice of medicines by physicians has been linked to higher levels of resistance, increased costs, morbidity and mortality in patients.⁸² As a good practice, prescribers and health-care workers should be regularly trained in STGs to promote rational prescribing to patients. Regularly updating, monitoring and evaluating the effectiveness of STGs promote adequate access to appropriate medicines. However, this has not been done in many countries, which is a challenge that States ought to overcome.

59. In many developing countries, pharmacies are the first point of contact for patients with the health-care system. Despite regulations restricting the sale of prescription medicines over-the-counter (OTC), in many developing countries this practice is rampant. In the case of antibiotics, unrestricted sale combined with irrational prescription have led to the public health threat of increased resistance to antibiotics.⁸³ Countries with more restrictive antibiotic prescription have recorded relatively lower rates of resistance.⁸⁴ Rational use of appropriate medicines requires strong enforcement of regulations by States. It also requires pharmacies and health centres to restrict OTC sale of medicines in accordance with law.

60. Numerous stakeholders perceive unethical commercial marketing and promotion of medicines by pharmaceutical companies as a serious concern. Billions of dollars are spent by the pharmaceutical industry on marketing through sales representatives, samples and advertising.⁸⁵ Doctors are offered gifts under the pretext of continued medical education.⁸⁶ Multinational pharmaceutical companies have been fined for promoting unapproved medicines,⁸⁷ with little impact on their practices. Unethical promotion negatively affects the prescribing patterns of doctors, who would then tend to prescribe less rationally and to quickly adopt new medicines.⁸⁸ Prescribers consequently obtain information on medicines from pharmaceutical companies,⁸⁹ rather than consulting STGs. During the consultations, some States pointed to the existence of voluntary national industry codes to address

⁸¹ Promoting rational use of medicines: core components, WHO Policy Perspectives on Medicines, WHO (2002), p. 1.

⁸² David H. Howard et al, The Global Impact of Drug Resistance, *Clinical Infectious Diseases* (2003), vol. 36, No. 1, pp. s4-10, p. s7.

⁸³ WHO, The evolving threat of antimicrobial resistance: Options for action (2012), pp. 38-39.

⁸⁴ H Goossens et al, Outpatient antibiotic use in Europe and association with resistance: a cross-national database study, ESAC Project Group, *The Lancet* (2005), vol. 365, pp. 579-587.

⁸⁵ WHO/HAI, Pauline Norris et al, Drug Promotion: what we know, what we have yet to learn: Review of materials in the WHO/HAI database on drug promotion (2005), p. 1.

⁸⁶ G Harris, Medical Marketing - Treatment by Incentive; As Doctor Writes Prescription, Drug Company Writes a Check, *New York Times*, 27 June 2004.

⁸⁷ Drug giant Glaxo pleads guilty, fined \$3B for drug marketing, *USA Today*, 2 July 2012.

⁸⁸ Norris et al, Drug Promotion: what we know, what we have yet to learn: Review of materials in the WHO/HAI database on drug promotion (see Note 89 above), p. 38.

⁸⁹ Serhat Vancelik et al, "Impact of pharmaceutical promotion on prescribing decisions of general practitioners in Eastern Turkey", *BioMed Central Public Health*, vol. 7, No. 122 (2007).

pharmaceutical promotion. However, these have been criticized as ineffective.⁹⁰ The Special Rapporteur recommends formulating strong enforceable regulatory systems, with accountability measures, to discourage unethical marketing and promotion of medicines by pharmaceutical companies.

G. Quality

61. According to the right-to-health framework, States are required to protect the population from unsafe and poor-quality medicines. Quality assurance for medicines includes such aspects as registration and marketing of good quality, safe and efficacious products under ethically and medically validated clinical trials, continuous regulation of the quality of production of medicines and prevention of sub-standard and spurious medicines from being sold on the market after registration.

62. Poor quality medicines are genuine products that do not meet quality specifications due to poor manufacturing practices. They can cause drug resistance, adverse effects and even death.⁹¹ Contrary to popular belief, recent studies indicate that there may be fewer poor quality medicines on the market than previously estimated.⁹² A potential explanation for this could be the tendency to conflate poor-quality with counterfeit medicines.

63. Accessibility of information with respect to the quality, safety and efficacy of medicines is necessary for the enjoyment of the right to health. Before acquiring marketing approval, pharmaceutical companies are legally required in most countries to provide data demonstrating the safety, quality and efficacy of new medicines, generated from medically and ethically valid clinical trials. However, during the Special Rapporteur's consultations, diverse stakeholders noted non-transparency of clinical trial data as a concern. Trial data is not made public by pharmaceutical companies and regulators on the ground of protecting commercial information.⁹³ Moreover, data relied upon for registration of medicines is often subject to publication bias (only positive results are published or are overrated), which is misleading and potentially harmful for patients.⁹⁴ The Special Rapporteur notes with satisfaction that national and regional regulatory bodies are taking steps to make this data available through clinical trial registries. However, critics still point to content and functionality shortcomings in these registries.⁹⁵ The Special Rapporteur encourages States to take regulatory measures to ensure that information on the safety, quality and efficacy of medicines, even if negative, is made publicly available in functional trial registries.

64. Poor-quality medicines are not related solely to imported medicines, as it is popularly perceived. Therefore quality inspections cannot be limited to border controls and inspections. It is important to have standard regulatory requirements for both domestically produced and imported medicines, along with regular inspections of production facilities and distribution chains for which persistent shortages have been reported.

⁹⁰ Joel Lexchin, Voluntary Self-regulatory Codes: What Should We Expect? *The American Journal of Bioethics*, vol. 3, No. 3 (2003), pp. 49-50.

⁹¹ P. N. Newton et al, "Impact of poor-quality medicines in the 'developing' world", *Trends in Pharmacological Sciences*, vol. 31, No. 3 (2010) pp. 99-101.

⁹² WHO, Survey of the quality of selected antimalarial medicines circulating in six countries of sub-Saharan Africa (2011), pp. 65-66.

⁹³ Ben Goldacre, *Bad Pharma: How drug companies mislead doctors and harm patients*, HarperCollins (2012).

⁹⁴ *Ibid.*

⁹⁵ *Ibid.*

65. Regulators in some of the developing countries surveyed by the Special Rapporteur reported the use of outdated methods and processes for enforcement, largely due to the lack of technical capacity, financial and human resources. For example, one such State regretted having sufficient inspectors to guard only 3 out of 41 ports of entry. Inspection of foreign production sites is an even greater challenge for resource-constrained importing countries. Regulatory bodies in many countries are generally funded by user fees, collected through licensing fees and inspection activities.⁹⁶ However, these funds are insufficient to sustain effective regulation, given the scale and volume of production and import in most countries. States should therefore substantially increase budgetary support for their regulatory authorities to sustain the quality control activities and increase recruitment and training of staff. Regulatory bodies of importing developing countries could cooperate with their counterparts in the exporting countries to build regulatory capacities, share local inspection information of companies under their jurisdiction, and conduct joint inspections through cost-effective use of resources.

66. The Special Rapporteur also notes the ongoing global debate to deal with the growing challenge of counterfeit medicines. He points out that since the term “spurious/sub-standard/falsely-labelled/falsified and counterfeit” (SSFFC) medicines was coined, it has regrettably been used as a catch-all phrase to represent anything from poor-quality to “counterfeit” medicines, which is specific to the domain of trademark violations.⁹⁷ Such a linkage is counterproductive to access to medicines. This type of conflation was demonstrated by incidents in which unilateral action was taken by some countries against legitimate generic medicines as being counterfeit and even under the national laws in some countries which included generic medicines under the definition of counterfeit medicines, thereby threatening their import into that country. The Special Rapporteur expresses concern that an international legal remedy focusing on enforcement of trademark rights to counter the problem of counterfeit medicines takes away from the public health focus of strengthening of regulatory capacities in developing countries to deal with poor quality medicines and instead diverts limited State policing machinery to enforce private rights.

IV. Recommendations

67. The Special Rapporteur calls upon the States to shift from the dominant market-oriented perspectives on access to medicines towards a right-to-health paradigm in promoting access to medicines. He emphasizes that access to affordable and quality medicines and medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central elements for the enjoyment of the right to health.

68. The Special Rapporteur urges States to adopt and implement a national plan of action on medicines and ensure that the right-to-health framework for access to medicines is fully integrated in the plan of action.

69. The Special Rapporteur encourages States to ensure that central principles of non-discrimination, transparency, accountability, and multi-stakeholder participation, particularly of affected communities and vulnerable groups, are

⁹⁶ A. Breckenridge and K. Woods, Medicines regulation and the pharmaceutical industry, *British Medical Journal*, vol. 331 (2005), pp. 834-836.

⁹⁷ Gaurvika M. L. Nayyar et al, Poor-quality antimalarial drugs in southeast Asia and sub-Saharan Africa, *Lancet Infectious Diseases*, vol. 12 (2012), pp. 488-496, p. 488.

adequately reflected in the policies and activities under the national plan of action on medicines.

70. With regard to long-term security and affordability of medicines, the Special Rapporteur recommends that States:

- (a) Develop a policy framework on local production of medicines to ensure long-term accessibility and affordability of medicines;
- (b) Strengthen the regulatory framework to increase the competitiveness of the local industry and provide administrative and financial support, subsidies and guaranteed purchases;
- (c) Use flexibilities under the TRIPS Agreement to promote regional collaboration to pool resources and facilitate competitiveness of local production.

71. With regard to ensuring affordability of medicines, the Special Rapporteur recommends that States:

- (a) Adopt price control measures in pricing and reimbursement policies with a view to ensuring access of the population, and vulnerable groups particularly, to affordable medicines;
- (b) Select countries with a similar level of economic development to that of the State concerned as reference countries in order to secure the lowest price medicines through external reference pricing;
- (c) Monitor and regulate, if necessary, manufacturers' selling prices as well as distribution mark-ups in the supply chain, while ensuring incentives for wholesalers and retailers for sustainable distribution;
- (d) Resist trade policies that undermine the ability of States to reimburse the price of essential medicines to local pharmaceutical companies;
- (e) Eliminate import tariffs on medicines, except when considered to be strategic to the promotion of local production of essential medicines;
- (f) Remove taxes on all medicines, especially essential medicines, and consider other revenue options for health, such as excise taxes on socially harmful goods such as tobacco, alcohol and junk foods;
- (g) Adopt competition laws and policies to prevent pharmaceutical companies from indulging in anti-competitive practices and promote competitive pricing of medicines together with strong enforcement.

72. Promote competitive policies across therapeutic markets to secure reductions in prices of medicines over tiered pricing to secure a greater government role in decision-making related to prices of medicines.

73. With regard to ensuring availability of essential medicines, the Special Rapporteur recommends that States:

- (a) Adopt a national essential medicines list and regularly update it by selecting essential medicines that are evidence-based and adequately reflect the national burden of disease, irrespective of cost or patent status, including through a transparent and participatory determination process;
- (b) Ensure that access to essential medicines for treating mental health, drug dependence, sexual and reproductive health and palliative care is based purely on health needs and evidence and not restricted on account of extraneous non-health considerations;

(c) Ensure that the list of National Essential Medicine is arrived at with participation of all stakeholders, including the affected communities, particularly the vulnerable groups.

74. With respect to efficient and transparent procurement and distribution systems, the Special Rapporteur recommends that States:

(a) Adopt scientific and evidence-based quantification of essential medicines, ensure competitive bidding, require stringent prequalification for suppliers, monitor delivery of medicines and formulate effective policies to address stock-outs;

(b) Increase financial, technical and logistical support to strengthen distribution networks, maintain the quality of medicines in transport and storage and adopt distributor certification programmes.

75. With regard to rational and appropriate use of medicines and their quality, safety and efficacy, the Special Rapporteur recommends that States:

(a) Develop and regularly update Standard Treatment Guidelines and ensure adequate training of prescribers as a part of continuing medical education policies;

(b) Regulate pharmacies, including online pharmacies, and retailers to ensure appropriate dispensation of medicines;

(c) Prohibit unethical commercial marketing and promotion of medicines by pharmaceutical companies through legal accountability measures based on strict penalties and cancellation of manufacturing licences;

(d) Ensure transparency of data related to quality, safety and efficacy of medicines, including the mandatory publication of adverse data;

(e) Increase budgetary support for national regulators and increase recruitment of inspectors at competitive salaries;

(f) Improve South-South cooperation to conduct joint inspections of manufacturing facilities and share information and good practices;

(g) Avoid conflation of poor-quality medicines, a quality control issue, with counterfeit medicines, a trade issue.
