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**Promotion et protection de tous les droits de l'homme, civils, politiques, économiques, sociaux et culturels, y compris le droit au développement**

### **Rapport du Rapporteur spécial sur le droit qu'a toute personne de jouir du meilleur état de santé physique et mentale possible, Anand Grover**

#### Additif

#### **Mission au Viet Nam \* , \*\***

##### *Résumé*

Le Rapporteur spécial sur le droit qu'a toute personne de jouir du meilleur état de santé physique et mentale possible, Anand Grover, s'est rendu au Viet Nam du 24 novembre au 5 décembre 2011. Il note que le Viet Nam se heurte à plusieurs obstacles qui l'empêchent de réaliser pleinement le droit à la santé. S'il est louable que le Gouvernement vietnamien se soit engagé à améliorer l'accès de la population à la santé, le Rapporteur spécial relève que les systèmes de santé et leur financement, l'accès aux médicaments ainsi que des questions liées au VIH/sida, notamment en ce qui concerne les centres de réadaptation, suscitent de profondes préoccupations.

Dans le présent rapport, le Rapporteur spécial examine les systèmes de santé et leur financement et note que la privatisation accrue du secteur de la santé et la décentralisation de la gestion de la santé posent de graves difficultés liées à l'accès à la santé et à l'augmentation des frais à la charge des patients. Le système national de sécurité sociale, notamment la couverture offerte et la qualité des services dispensés, suscite également des préoccupations. Le présent rapport traite aussi de l'accès aux médicaments au Viet Nam. Les mécanismes en vigueur de fourniture de médicaments et de réglementation des prix n'ont pas permis de réduire le prix élevé des médicaments dans le pays, qui est un obstacle majeur à l'accès à ces produits, en particulier pour les pauvres et les personnes proches du seuil de pauvreté. L'incidence potentielle de l'Accord de partenariat transpacifique sur l'accès aux médicaments est également préoccupante. Le Rapporteur spécial examine aussi des questions relatives à la prévention du VIH/sida au Viet Nam et à la lutte contre cette maladie, en mettant l'accent sur des domaines de préoccupation tels que la surveillance épidémiologique et la collecte de données, la stigmatisation et la discrimination des groupes vulnérables; et la réduction de l'aide fournie par la communauté internationale des donateurs. Il estime que la détention et le traitement obligatoire, dans des centres de réadaptation, des personnes qui consomment des drogues et des travailleuses du sexe sont particulièrement préoccupants. Il conclut son rapport par des recommandations à l'adresse du Gouvernement vietnamien.

### Annexe

[English only]

### **Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health on his mission to Viet Nam (24 November to 5 December 2011)**

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## I. Introduction

In the present report, the Special Rapporteur reports on his visit to Viet Nam, conducted at the invitation of the Government from 24 November to 5 December 2011. The purpose of the mission was to ascertain, in a spirit of dialogue and cooperation, how the country has endeavoured to implement the right to health, as well as the measures taken for successful realization of the right to health, and the obstacles encountered both at the national and international levels.

During the mission, the Special Rapporteur focused on the health system and health financing in Viet Nam; he also addressed the following issues: the international and domestic legal framework of Viet Nam; access to medicines, primarily related to drug procurement and the Trans-Pacific Partnership Agreement (TPPA); and prevention and control of HIV/AIDS, including rehabilitation centres. The Special Rapporteur visited Hanoi, Hai Phong and Ho Chi Minh City, as well as sites in Dong Nai, Ha Tay and Thai Nguyen.

The Special Rapporteur held meetings with senior Government officials from the Ministry of Foreign Affairs, the Ministry of Health, the Ministry of Labour, Invalids and Social Affairs, the Ministry of Finance, the Ministry of Natural Resources and Environment and the Ministry of Planning and Investment, as well as from the Office of the National Assembly. During the mission, the Special Rapporteur also held meetings with the representatives of civil society organizations, development partners, academics, legal experts and health professionals. The Special Rapporteur is grateful to the Government of Viet Nam for its invitation and its full cooperation during his visit. He also would like to thank all those who met with him, gave their time and extended cooperation to him during the mission.

## II. Viet Nam and the right to health

### A. Background

Over the three decades following its nearly 30 years of continual military conflict, Viet Nam has emerged as one of the world's fastest growing economies. This rapid economic growth has resulted in a nearly 75 per cent reduction of poverty in the country and a general increase in standards of living. In moving from near isolation to almost full integration into the global economy, Viet Nam has introduced fundamental structural changes to its economy, which have had significant impacts on aspects of the right to health and health systems. These structural changes, which first began in 1986 with a series of liberalizing economic reforms known as *doi moi* (renewal), are part of an overall process of restructuring the Vietnamese economy into a "socialist-oriented market economy". Additional changes to the Vietnamese economy, in particular the introduction of a new intellectual property law, have come about due to the country's accession to the World Trade Organization as of 2006.

During this period of economic transformation, Viet Nam has seen marked improvements in the well-being of its people. The country has made significant progress towards attaining the Millennium Development Goals, in particular with regard to reducing poverty and achieving universal access to primary education and gender equality. Moreover, the economic benefits of the country's growth have been distributed equitably among its people, permitting household incomes to grow along with increased household consumption and savings. Improvements to the health system in Viet Nam have to some degree corresponded with the country's economic rise, demonstrating a strong commitment to ensure access to health care for all. A functioning health system is the basis for the exercise of the right to health, and data indicates that admirable advances have been made in many key health areas, including child and maternal health. The Special Rapporteur commends Viet Nam on these significant advances.

Despite these improvements, many critical health areas still need to be addressed. Changes in the economic system of Viet Nam have brought about additional concerns, such as increasing inequality. Moreover, the country's transition to a middle-income economy will also mean that it will be the beneficiary of less overseas development assistance, which comprises the majority of funding in some critical health areas, such as HIV/AIDS prevention and treatment. Many important donors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Department for International Development of the United Kingdom of Great Britain and Northern Ireland, have already indicated that they would scale back their in-country programming and support. At the same time, the Vietnamese economy has felt the reverberations of the global economic crisis, which has resulted in, among other things, the reduction of central Government spending on health.

### B. International and domestic legal framework

Viet Nam is a party to a number of international treaties that recognize the right to health, including the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination against Women, and the Convention on the Rights of the Child, including its two Optional Protocols. Viet Nam has signed but not ratified the Convention on the Rights of Persons with Disabilities. In the national legal order, international treaties must be given effect through domestic law.

At its universal periodic review in May 2009, the Government of Viet Nam supported the review's conclusions and recommendations, which called, *inter alia*, for the country's accession to or ratification of further principal human rights instruments, namely the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment; the International Convention on the Protection of the Rights of all Migrant Workers and Members of Their Families; the Convention on the Rights of Persons with Disabilities; the International Convention for the Protection of All Persons from Enforced Disappearance; as well as the Optional Protocols to the International Covenant on Civil and Political Rights, the International Covenant on Economic, Social and Cultural Rights and the Convention on the Elimination of All Forms of Discrimination against Women (A/HRC/12/11, para. 99). In that context, the Special Rapporteur urges the Government to take concrete measures with a view to achieving that commendable objective in a timely manner.

The 1992 Constitution of Viet Nam (revised in 2001) contains a number of provisions relating to the right to health. Article 50 refers to the State's obligation to respect and provide for "human rights in all respects", including economic, cultural and social rights. It is specifically stated that "citizens are entitled to health care" (art. 61), and that citizens have a right to have their health protected by law (art. 71). The Constitution also provides that the State has a duty to "develop ... health care" (art. 112). The State's role in the financing, developing and administration of health protection, disease prevention, dispensing of medication, health-care insurance and health care generally is described in article 39. This provision specifies "mountain inhabitants" and ethnic minorities as vulnerable groups to whom preferential treatment should be directed.

### **III. Health systems and financing**

The Vietnamese health system, until the early stages of *doi moi*, was funded and administered entirely by the State and was available to Vietnamese free of charge. In 1989, however, Viet Nam instituted partial user fees as a method of financing public health-care goods and services. In 1993, the Regulation on Health Insurance issued under Decree No. 299 provided for the first time an insurance-based system in the country. Since the introduction of the national health insurance programme, Viet Nam has moved towards a more mixed public/private system of health-care financing and provision.

During the mission, the Special Rapporteur learned that the Government's current strategy towards ensuring the economic sustainability of the health system consists primarily of issuing government bonds and encouraging greater foreign and domestic private investment, including through public-private partnerships. This strategy is part of a more systemic shift toward the socialization policy aimed at expanding non-State payments for social services and promoting the role of non-State actors in delivering health, education and other services. The socialization policy has resulted in a greater involvement of the private sector in the provision of health goods and services on a for-profit basis and increased reliance on individual households to cover health-care costs. The Special Rapporteur notes with appreciation that Viet Nam is still laudably committed to providing health care for all. This is demonstrated by National Assembly resolution 18, which commits the Government to ensure the growth rate of spending on health consistently exceeds the growth rate of overall government spending, and the fact that Government spending on health has risen from 4.8 per cent to 10.2 per cent between 2002 and 2008.

Privatization, however, poses numerous challenges to ensuring full realization of the right to health, particularly for the poor and near poor. Privatization of health care often results in a number of troubling outcomes, including increased inequity in the accessibility of health care and greater out-of-pocket expenditures. For example, since the introduction of health insurance in Viet Nam, household health expenditure has grown to approximately 60 per cent of all total health expenditure. These outcomes result from a reliance on profit-generation to ensure the continued existence of the health system, in contrast to a public system funded largely or entirely by the State. While in many cases the substitution of State-delivered services with private services may be acceptable or even an improvement, it is unlikely that the private sector will fill all the gaps left by the effective withdrawal of the State from the health sector. Studies have demonstrated that privatization of health care in Viet Nam has already led to a growth in inequity and has reduced access for some populations, as hospitals increasingly tailor the quality of health services according to patients' ability to pay.

One of the primary responsibilities of the State under the right to health, however, is to ensure that all persons have access to affordable health care. The Special Rapporteur commends Viet Nam for its commitment to ensuring health care for all, as discussed below, but notes that the Government should remain vigilant in order to prevent privatization from negatively impacting the realization of the right to health.

In addition to privatization, a hallmark of the country's reforms since *doi moi* is the process of fiscal decentralization, which ranged from the increased proportion of taxes assigned to local governments, since 1996, to the growing decentralization of the budgetary process to provinces, following the adoption of the State Budget Law in 2002. Provinces can borrow in domestic markets to finance capital expenditures and infrastructure investment approved by the People's Council. Viet Nam has also decentralized its health system and health financing mechanisms, partially in response to decreased funding from the central Government. As a result, provincial-, district- and commune-level health facilities have been granted greater management autonomy from the central Government. While this may provide local authorities with flexibility to better address their local situations, it also shifts the financial burden of health care from the central Government to local authorities and institutions.

Experience from other countries shows that decentralization may generate and exacerbate inequities in the health system by restricting the availability and accessibility of health goods and services. Decentralization creates strong incentives for local health authorities and

institutions to generate revenue by increasing the costs of goods and services. Increased costs may further limit access for the poor and near poor, particularly given the high rates of inflation in Viet Nam. Moreover, decentralization has already resulted in the increased provision of new and high-tech medical services in hospitals. While this is a necessary improvement to the health system, the Government must ensure this does not come at the expense of a limited availability of less profitable preventative services.

Privatization and decentralization in Viet Nam could thus undermine the availability, accessibility and affordability of health care for all, particularly for the poor, near poor and ethnic minorities. Privatization shifts costs to the consumer and often makes health care more expensive. Decentralization, as currently structured, creates incentives for lower level government authorities to approach health care as a for-profit system in order to generate needed revenue, rather than as a public good. The combined effect of privatization and decentralization is greater autonomy for subnational-level health authorities to seek private investment in public health entities in order to generate revenue, in part to account for decreased central Government funding. The likely result is greater inequity in the health-care system, expressed through higher costs for goods and services, increased out-of-pocket expenditures, reduced rural access, and reduced availability of services that generate lower profit margins, such as primary care.

Privatization and decentralization have resulted in partial private ownership of public hospitals. In some instances, this has led to an increase in the abuse of services, including unnecessary testing and the use of high-tech services, over-prescription of medicines and patient overload. These results are exacerbated by the predominant use of the fee-for-service payment mechanism in Viet Nam. The Ministry of Health has recommended that Viet Nam continue to “assess and implement joint ventures, business partnerships and participation of private investors in investments in curative care facilities”. The Special Rapporteur encourages the Government to take a cautious approach, in line with its previous decision to temporarily halt the sale of shares in public hospitals due to concerns relating to equality and efficiency. All further decisions to “equitize” (part-privatize) public health entities must be critically assessed in the light of deleterious impacts on the right to health, and the impact on accessibility for vulnerable groups in particular.

In order to ensure adequate public funding for health services at the provincial, district and local levels, the Special Rapporteur encourages the Government to consider alternative revenue-generating mechanisms, such as progressive taxation, instead of relying solely on privatization. During the mission, it was indicated that the Government is considering an excise tax on tobacco products and a step increase in the social insurance tax from 4.5 to 6 per cent to generate funds to be directed toward public health expenditures. Such measures would be welcome developments. Furthermore, in order to reduce costs and facilitate efficient public spending on health care, the Government must take additional steps. For instance, it must consider reforming the fee-for-service payment system to one that better controls costs, such as capitation or bundled payments. This would protect the user from abuse of services and lead to lower costs for the health system as a whole.

As part of the shift from a fully public health-care system to a mixed one, the Government has developed a national social health insurance programme (SHI) and instituted user fees. Commendably, the Government has also attempted to address some of the concerns arising from this restructuring by introducing programmes specifically targeting the poor and the near poor, such as the Health Care Funds for the Poor policy, which has now been incorporated into the SHI as health insurance for the poor (HIP). As currently implemented, the SHI comprises two types of insurance: compulsory health insurance and voluntary health insurance. Compulsory health insurance, created in 1992, was initially limited to formal sector employees, retirees, war veterans, the disabled and select other groups. However, it has since expanded to include the poor, near poor, ethnic minorities, and persons from communes in difficult socio-economic circumstances, through Health Care Funds for the Poor, and children under 6, through a pre-existing policy providing free health-care for this group. Formal sector employees are compulsorily enrolled and a premium is drawn from their salary accounts, while those covered under HIP receive 100 per cent support for their premium from the State and children under 6 do not pay any premium at all. Voluntary health insurance currently covers all persons ineligible for compulsory health insurance, including students and farm workers.

The Special Rapporteur commends the Government for its commitment to expanding the scope of SHI coverage, as demonstrated by the fact that SHI expenditure as a proportion of total public health spending rose from 7.9 per cent to 17.6 per cent between 2005 and 2008. The SHI, however, in its current form still does not adequately ensure universal access to health care. Health insurance coverage is still relatively low, standing at 60 per cent. Moreover, although HIP has allowed many vulnerable groups to gain access to care, the scheme requires refinement in order to ensure physical and economic accessibility for the poor, near poor and ethnic minorities. For example, there are significant problems with respect to the portability of benefits. All insured persons are registered at the nearest local health facility once they enrol in SHI. While enrollees can obtain a letter of referral from their designated facility in order to change their designation, it is difficult to do so and therefore referrals are infrequently obtained. Moreover, many communal health centres are incapable of referring patients to higher levels because they have not yet been incorporated into the institutional system. Even when referrals are made, district and provincial health-care facilities are often hesitant to accept such patients—though they are required by law to do so—due to the lengthy and complicated processing procedures necessary to obtain reimbursement. This is particularly problematic for HIP enrollees, most of whom are registered at the commune level, where services are limited and the quality of services is perceived to be poorer as compared to the district and provincial level.

There is also a concern that not all populations in need benefit from subsidized coverage under SHI. Under the compulsory health insurance programme, only the individual worker is covered and not his or her dependents. In 1991, the Government introduced a programme that provides free health insurance for all children under 6. However, the implementation of this programme has been limited and, according to some reports, there are still approximately 1 million children under 6 who are not yet enrolled in the scheme. Moreover, according to the Government, nearly 1 million children under 6—12 per cent of all children under 6—have not yet received their insurance cards. In the interim, however, the Government notes that children may use their birth certificate instead of an insurance card to receive health insurance benefits. Considering the serious problems in Viet Nam relating to the malnourishment of children under 5, it is essential that the Government make all efforts to ensure that all children under 6 are enrolled in the SHI and have uninterrupted access to health insurance benefits under the programme.

Additionally, access to insurance benefits for all SHI enrollees is further constrained because local public health facilities are allowed to establish private wards for fee-paying patients. These patients may thus gain access to better quality care than insured patients,

including on-demand services such as choice of doctor, choice of room and choice of scanning technology. As a result, critical modalities of treatment and necessary space are allotted to fee-paying patients, while insured patients may be forced to seek treatment elsewhere.

The Special Rapporteur notes with satisfaction the Government's commitment to the poor under HIP, however, there are a number of concerns regarding both the scope and coverage of the programme. While HIP provides full health insurance coverage for the poor and 50 per cent coverage for the near poor, it appears to have reduced out-of-pocket expenditures only by 13 per cent. This reduction is not sufficient to ensure financially accessible health care required under the right to health, because out-of-pocket expenditures account for nearly 50 per cent of all household health expenditures in Viet Nam.

Moreover, catastrophic health costs in Viet Nam have steadily remained at approximately 12 per cent. While under HIP the poor should not have to make co-payments for covered services, in reality they are often required to make such payments. Additionally, studies suggest that while those who are enrolled in HIP are entitled to the same benefits as those enrolled in other forms of the SHI, in fact, they often receive fewer benefits. This is especially true for people under the direct reimbursement model, in part because providers must often wait long periods of time for government reimbursement.

The poor and near poor, especially those in rural and mountainous areas predominantly populated by ethnic minorities, are often burdened by additional expenditures on food, travel and accommodation in order to access basic health services. In many instances, these expenditures amount to more than the cost of the health services sought. The Special Rapporteur was informed by the Government of its decision to increase the level of reimbursement for basic health services for the near poor from 50 per cent to 70 per cent since 2012, along with subsidies for travel and food expenses for the poor. The Special Rapporteur commends this development, but cautions that there is a need for more robust support for the poor and near poor in order to fully realize their right to health. Moreover, even these subsidies will be undermined if informal payments to health providers, or "envelope" payments, are not addressed. Envelope payments increase out-of-pocket expenditures for all users in the health system and impede access to health-care goods and services for the poor and the near poor.

The Government recognizes that there are concerns about the general quality of health care, both public and private. During the mission, Government officials further acknowledged that particular populations have voiced complaints regarding the quality of health-care services, especially in rural areas. The rural-urban disparity in health-care quality is of significant concern to the Special Rapporteur. The disparity is more apparent at the communal level and for persons enrolled under HIP than at higher service levels or for those with other versions of the SHI. The right to health requires the Government to ensure that good quality health goods and services are available and physically and economically accessible without discrimination for all segments of the population, regardless of geographic location.

Rural-urban disparity is not unique to Viet Nam. In most countries, the quality of health care in rural areas is inferior to that available in urban areas, and is often at an unacceptably low level. In Viet Nam, the issue is exacerbated by the fact that ethnic minorities live predominantly in rural areas, and are thus especially vulnerable. The Government has a special obligation to ensure that vulnerable groups, including ethnic minorities, have access to good quality health goods and services. Ethnic minorities in Viet Nam also face widening disparities in the provision of social services, including education, and access to water and sanitation. The right to health requires States to ensure access for all to the underlying determinants of health, including safe and potable water, adequate sanitation, housing, food and health-related education.

## **IV. Access to medicines**

### **A. Drug procurement: international reference pricing and decentralization**

As the Committee on Economic, Social and Cultural Rights underlines in its general comment No. 14 (2000) on the right to the highest attainable standard of health, State parties have an obligation to provide access to safe, efficacious and affordable medicines, and to ensure access for vulnerable populations, such as ethnic minorities, the rural poor and people living with HIV. The obligation to fulfil the right to health requires States to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards achieving full realization of the right to health. In the case of access to medicines, this means adopting policies that ensure safe, efficacious and affordable medicines are available.

Prices for some medicines in Viet Nam are substantially higher than in other countries that are similarly economically situated, and in many instances even higher than similar medicines in high-income countries. Although Viet Nam has reduced poverty levels considerably, per capita gross domestic product (GDP) remains relatively low and a sizeable portion of the population is still impoverished. The country's per capita GDP is currently about US\$ 1,300 per year, placing it in the world's bottom third. As previously indicated, the majority of health-care expenditures are out-of-pocket expenditures, and medicine purchases constitute the bulk of those expenditures. Rising medicines costs will thus result in an even greater portion of household income devoted to health expenditures. Therefore even small increases in medicines prices will result in reduced accessibility of drugs for much of the country's population, especially vulnerable populations, including the poor and near poor. The State's responsibility under the right to health therefore includes a strong imperative to ensure low medicine prices.

In 1989, Viet Nam began to liberalize the pharmaceutical sector through measures such as the reduction of restraints on the production and sale of pharmaceuticals. Soon after, medicines prices increased many times their international reference prices and became increasingly unaffordable for most people, according to some reports. In 2003, the Government acknowledged the problem and issued Circular 08, which provided guidelines for price management for essential medicines. Unfortunately, the Circular was unsuccessful in reducing medicine prices. In 2004, the Government issued Decree 120, which was the first legal instrument specifically designed to control medicine prices. Joint Circular No. 11/2007/TTLT-BYT-BTC-BCT was later implemented to control wholesale mark-ups of medicines in the supply chain through the declaration of a reasonable wholesale price to the Ministry of Health. Through a series of other decrees and circulars, the Government of Viet Nam has attempted to establish a system of

international reference pricing to control the price of medicines. The Special Rapporteur commends the Government for recognizing the gravity of the matter and seeking to address it. He cautions that the measures currently in place to control drug prices are both inadequate and unenforced, and calls on the Government to critically assess its current price referencing system.

Viet Nam seeks to control medicines prices through international reference pricing. International or external reference pricing is “the practice of using the price(s) of a pharmaceutical product in one or several countries in order to derive a benchmark or reference price for the purposes of setting or negotiating the price of the product in a given country”. Reference pricing is only effective at securing the lowest-priced drugs when the level of economic development in the countries selected as reference points is similar to that of the purchasing country. However, according to some reports, while a tentative list of reference countries has been suggested, including Cambodia, Indonesia, Malaysia, Thailand and the Philippines, no reference country basket has yet been adopted. In addition to the selection of a basket of reference countries, international reference pricing must specify both the type of price for comparison and the standard of pricing. The type of price refers to the point on the supply chain at which the price is assessed. Because prices differ at each level of the supply chain (for example, the wholesale price will be different from the price at point of purchase), specification of the appropriate type of price is essential to setting an effective benchmark with which prices in Viet Nam are to be compared. The type of price to be used in the comparison, however, has not been specified by the decrees.

Further, the pricing standard used in Decrees 120 and 79 is the highest price standard compared to medicines in the same category. This standard allows for the reference price to be “no higher than” the highest price found in the reference countries for the same category of medicine. The problems stemming from this price standard were sought to be corrected by Joint Circular No. 11/2007/TTLT-BYT-BTC-BCT, which uses an average price standard, meaning that medicines must be no higher than the average price for the same medicine found in reference countries. However, even if an average price standard is used and if the reference basket includes some countries that have very high drug prices, then the average price will be artificially buoyed.

Even if the flaws in the current system are addressed, however, studies indicate that international reference pricing is open to manipulation by pharmaceutical companies. International reference pricing, if used at all, should be utilized in conjunction with other price control mechanisms. Moreover, the Special Rapporteur encourages the Government to explore alternative mechanisms to ensure that medicines are procured at the lowest prices possible, thereby maximizing access to medicines as required by the right to health.

The decentralization process has exacerbated problems relating to access to medicines in Viet Nam. The Government has shifted some drug procurement responsibilities to the provincial and district level authorities along with other health-care management responsibilities. In doing so, it has unnecessarily forfeited its bargaining power as a bulk purchaser. This will likely lead to higher medicine prices and greatly varied costs of medicines throughout the country. Additionally, the purchase of medicines by sub-national institutions is made through a tendering process, as compared to direct purchasing. While two circulars have granted the Ministry of Health the authority to set maximum tender prices, the Ministry has not yet determined the way forward, and therefore no maximum tender price list exists. Lack of maximum tender prices and the reduced bargaining power of sub-national buyers have worked together to apply further upward pressure on medicines prices, thus negatively impacting realization of the right to health.

## **B. Trans-Pacific Partnership Agreement**

The Special Rapporteur is concerned about the country’s negotiations towards the adoption of the Trans-Pacific Partnership Agreement (TPPA) with a view to increasing exports for the country. The TPPA is a multilateral free trade agreement among Brunei, Chile, New Zealand and Singapore that first entered into force in 2006. Six additional countries are now in negotiations to join the agreement: Australia, Japan, Malaysia, Peru, the United States of America and Viet Nam. The TPPA is meant to further liberalize the economies of the Asia-Pacific region and increase trade among members of the agreement. In negotiating free trade agreements, States bear responsibility for ensuring compliance with pre-existing legal obligations, including commitments under international human rights treaties. Under article 12 of the International Covenant on Economic, Social and Cultural Rights, Viet Nam is obliged to respect, protect and fulfil the right to health. The obligation to respect requires that States do not interfere with the right to health. Thus Viet Nam must ensure that any agreement it enters into does not interfere with the availability and accessibility of safe, efficacious and affordable medicines, as required under the right to health.

Of the countries currently involved in the negotiation of the TPPA, Viet Nam is by far the least economically developed. As previously stated, most recent estimates place the per capita GDP of Viet Nam at approximately US\$ 1,300. Peru, which is most closely situated to Viet Nam among the negotiating parties, has a per capita GDP of over US\$ 5,500; the remaining parties, including the United States and Australia, have substantially higher per capita GDP figures. Less developed economies rely heavily upon the availability of generic medicines in order to make medicines affordable for the majority of their populations. As stated in earlier reports of the Special Rapporteur, intellectual property protections increase drug prices by restricting or preventing generic pharmaceutical competition from entering the market (see, for example, A/HRC/11/12). If recent draft versions are any indication, the final version of the TPPA is likely to contain provisions that significantly alter the scope of Vietnamese intellectual property law, as the agreement would be primarily oriented towards benefiting more economically developed countries. Most of the other negotiating countries currently employ greater intellectual property protections and will seek to maintain at least their current levels of protection in the agreement. If Viet Nam adopts recent drafts of the TPPA, it will delay or prohibit low-cost generic drugs from entering the market, further restricting access to medicines.

During the mission, Government officials informed the Special Rapporteur that the Government of Viet Nam is interested in promoting the growth of its domestic generic pharmaceutical industry in order to ensure the availability of low-cost medicines and to promote development. While this is welcome, the Special Rapporteur urges the Government to realistically assess the numerous and complex challenges involved in developing such local industries. Large-scale generic medicine production would serve to reduce medicine prices and further the economic development of Viet Nam. Intellectual property provisions in recent drafts of the TPPA, however, would make it very difficult, if not impossible, for generic drug manufacturers to enter and remain viable in the market.

The negotiating power of Viet Nam is weaker than that of the more developed countries in the TPPA negotiations, due to the country's greater need for increased access to developed country markets. In addition, Viet Nam is more likely to have fewer resources devoted to the negotiations and less technical capacity to interpret the intellectual property provisions of the agreement in order to determine their impact on the right to health.

The decision-making process followed by Viet Nam during the TPPA negotiations has lacked transparency and has not involved the participation of civil society and affected communities. This is despite concerns raised by civil society organizations about potential adverse impact on the right to health in Viet Nam in the event of the adoption of the TPPA. The participation of the population in all health-related decision-making at the community, national and international levels is an important aspect of the right to health. Allowing input from civil society and affected communities groups during the TPPA negotiations is therefore essential. Additionally, input from these stakeholders will strengthen the Government's capacity to critically assess the draft agreement in order to, among other things, ensure access to affordable medicines in Viet Nam.

If adopted on the basis of recent drafts, the TPPA may limit the use of Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities and introduce TRIPS-plus provisions. For example, the TPPA would eliminate pre-grant oppositions to patents in Viet Nam. Pre-grant oppositions allow third parties to challenge the legitimacy of a patent application prior to completion of the review process by the patent authority. Pre-grant opposition is critical in countries with reduced technical capacity to review patents because it allows interested third parties with additional capacity to supplement the review process. Moreover, the elimination of pre-grant oppositions may delay the entrance of generic drugs into the market because generic producers must wait to challenge patents in separate proceedings following review by the patent authority. Such limitations will further increase medicine prices, as evidenced by the experience of other countries. Numerous recent studies have demonstrated the pricing impact of free trade agreements that introduce TRIPS-plus provisions, such as expanded data exclusivity protections, or that restrict the use of TRIPS flexibilities.

Increased medicine prices not only affect the individual but also have serious implications for the sustainability of the entire health system. Expenditures on medicines account for the majority of health-care costs in Viet Nam, amounting to approximately 60 per cent of all health expenditures. Prices for medicines have increased substantially in recent years, and this trend appears likely to continue. Unless the Government of Viet Nam intervenes by improving its drug procurement and pricing regulations and ensures that access to medicines is not restricted by the TPPA, the overall health system may become crippled by excessive medicine prices. With a view to ensuring the accessibility of medicines in Viet Nam, the Special Rapporteur calls on the Government to ensure that, if Viet Nam accedes to the TPPA, it retains the ability to use all TRIPS flexibilities and that it does not accept TRIPS-plus measures and/or expand intellectual property protections beyond that which currently exist under Vietnamese law.

## **V.Prevention and control of HIV/AIDS**

The number of people living with HIV in Viet Nam remains high, despite an apparent stabilization in the rate of seroconversion. While HIV prevalence according to official statistics is among the lowest in the region, at 0.47 per cent for people aged 15 to 49, due to the country's large population the absolute number of affected individuals is significant. The official reported number of people living with HIV in Viet Nam is 244,656, but other sources estimate that the number is higher. Lack of accurate official data, in part a product of underreporting, is a systemic concern. The role of epidemiological surveillance and data collection in realizing the right to health, in particular with respect to the prevention, treatment and control of diseases, is paramount. Accurate data is essential in order to identify disease trends, design effective interventions, and monitor and evaluate these interventions. Deficiencies in HIV/AIDS data and statistics represent a barrier to addressing the epidemic in Viet Nam.

Problems of data collection and intervention design are exacerbated by the stigmatization of vulnerable groups. The Commission on AIDS in Asia confirmed that the HIV epidemic in Asia is largely driven by vulnerable groups, including female sex workers (FSWs), injecting drug users (IDUs) and men who have sex with men (MSM). Stigmatization and discrimination of IDUs, FSWs and MSM often arises from, and is perpetuated by, criminalization (or de facto criminalization) of the activities of these groups. Stigma contributes to the spread of the epidemic by deterring affected individuals from accessing such health services as HIV testing and treatment for fear of criminal sanctions, violence and discrimination. Furthermore, stigmatization and discrimination present barriers to the development and implementation of preventative measures tailored to the needs of these vulnerable groups.

International donors provide about 70 per cent of all HIV/AIDS funding in Viet Nam. As Viet Nam has grown into a lower middle-income country, however, international donors have already begun to reduce funding. The reduction in funding has affected HIV/AIDS prevention, treatment and care programmes and the effect will worsen as donors continue to reduce their support. The Government of Viet Nam should take measures to ensure that adequate resources are channelled into HIV/AIDS programmes as international funding decreases. The measures should aim not only to maintain current levels of prevention, treatment and care for people living with HIV, but also to expand these programmes in future, as it is likely that even less international support will be available then.

### **A.Detention and de facto criminalization**

The Special Rapporteur has commented extensively, in previous reports, on the negative impacts of criminalization and stigmatization on the right to health of sex workers and people who use drugs (PWUD) (see, for example, A/HRC/14/20 and A/65/255). The HIV/AIDS epidemic in Viet Nam is aggravated by the de facto criminalization of drug use and sex work. In Viet Nam, sex work and drug use are classified as social evils and are amenable to administrative penalties. PWUD and FSWs can be referred to "rehabilitation centres" and detained in order to receive compulsory treatment for 3 to 18 months, in the case of FSWs, and 1 to 4 years, in the case of PWUD. The law also applies to minors aged 12 to 18 years. Deprivations of liberty resulting from administrative sanction in Viet Nam are indistinguishable from criminal detention, and thus generate and perpetuate the stigmatization of PWUD and FSWs. With regard to minors, article 37 (b) of the Convention on the Rights of the Child explicitly provides that the arrest, detention

or imprisonment of a child “shall be used only as a measure of last resort and for the shortest appropriate period of time”.

The Department of Social Evils Prevention in the Ministry of Labour, Invalids and Social Affairs is in charge of the overall management of rehabilitation centres, including the provision of health services. While the Ministry of Health is responsible for the governance and guidance of health, health care and the health industry of Viet Nam, it is not directly involved with health services delivery in the centres.

There are two categories of rehabilitation centres: “05 centres” for FSWs and “06 centres” for PWUD. During meetings with representatives of the Ministry of Labour, Invalids and Social Affairs, the Special Rapporteur learned that there are 183 rehabilitation centres with 46,000 detainees (also called “learners”). Between 2000 and 2010, approximately 309,000 people, including minors, had been detained. The stated purpose of these centres is to “improve [the] health, living and occupational skills” of detainees and to “construct their awareness about the value of the labour, and their responsibilities toward themselves and their communities”. In order to accomplish these goals, the centres employ variety of approaches: labour therapy, moral education and vocational training. As a part of labour therapy, detainees are forced to perform labour for little to no remuneration. While some treatment for communicable diseases, including HIV/AIDS and tuberculosis, is available in some of the centres, many centres do not possess adequate HIV/AIDS and tuberculosis prevention, treatment and care services.

During the mission, the Special Rapporteur was informed that rehabilitation centres have been ineffective in dissuading drug use and sex work, which is their stated objective. The Special Rapporteur was also informed by a number of PWUD who had been detained in rehabilitation centres that they returned to using drugs upon their release. Furthermore, the majority of detainees currently in the centres have been detained at least once before.

Compulsory detention in the centres raises serious concerns about the due process rights of detainees, because they have no right to formally challenge their determination as PWUD or FSWs prior to detention and after determination; in practice, it is effectively impossible to do so. Treatment in the centres is mandatory in the majority of cases. Thus detainees are denied the right to be free from non-consensual treatment and the right to informed consent, which are core components of the right to health. In its general comment No. 14, the Committee on Economic, Social and Cultural Rights holds that: “The right to health contains both freedoms and entitlements. The freedoms include the right to control one’s health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation” (para. 8). According to the United Nations Office on Drugs and Crime, “only in exceptional crisis situations of high risk to self or others can compulsory treatment be mandated for specific conditions and for short periods that are no longer than strictly clinically necessary”.

The right to health requires the availability of good quality, evidence-based treatment. Treatment provided for PWUD and FSWs in rehabilitation centres is not evidence based. It is also ineffective, as demonstrated by high rates of relapse to drug use and the absence of evidence globally supporting the effectiveness of detention in preventing women from returning to sex work after release. The right to health further requires medical practitioners and other health professionals to meet adequate standards of education and skill. In 2008, the Ministry of Labour, Invalids and Social Affairs reported that 49 per cent of the staff at centres had only primary level education, 15 per cent had received training in health care, and most had only a basic knowledge of HIV or overdose prevention.

Rehabilitation centres are also counterproductive to the Government’s HIV/AIDS efforts. Persons detained in most centres do not receive adequate HIV/AIDS and tuberculosis prevention, treatment and care services. Although HIV prevalence is approximately 50 per cent in the centres, most lack even basic HIV services and there are currently only 14 centres that provide antiretroviral therapy for people living with HIV.

Furthermore, the threat of detention discourages at-risk and affected populations from seeking out HIV/AIDS prevention, treatment and care services. From discussions with health professionals, it became evident that many people living with HIV do not access health-care services until their health deteriorates to a terminal state. As a result, they die unacceptably premature deaths. In one regional hospital, visited by the Special Rapporteur, there were about five AIDS-related deaths per month. This provides strong evidence that the country’s response to HIV among PWUD is not working. It is unlikely that this number of AIDS-related deaths would occur in an environment free of stigmatization, including the threat of detention and non-consensual treatment.

## **B. Access to treatment and therapy**

The Special Rapporteur is concerned that the law in Viet Nam does not effectively distinguish between drug use and drug dependence. Drug dependence is a chronic, relapsing disorder that involves psychosocial and biological factors, including altered brain function. By contrast, drug use is not a medical condition. Importantly, there is strong evidence supporting medical treatment for drug dependence, specifically opioid replacement therapy (ORT) for opioid dependence, while medical treatment is not indicated for drug use alone. Indeed, most PWUD do not develop a dependence disorder and therefore do not require medical treatment.

The Special Rapporteur notes with satisfaction that the Government of Viet Nam has implemented a number of pilot methadone maintenance therapy programmes. Following the visit, the Special Rapporteur learned that the Government has authorized the HIV/AIDS Prevention and Control Department of the Ministry of Health to approve a plan to scale up ORT programmes in the country. The Government also informed the Special Rapporteur after the visit that it was considering the issuance of a decree on ORT with a view to providing a legal framework for the introduction of ORT nationwide. The Special Rapporteur welcomes both developments.

ORT programmes are cost-effective and have been demonstrated globally to be more effective in reducing drug use and facilitating the reintegration of people who are dependent on opioids back into the community (A/65/255, paras. 50-55). ORT also allows people to receive treatment while continuing their lives within the community, which has the additional benefit of de-stigmatizing people who are drug dependent. Moreover, given the existing evidence base confirming the safety and efficacy of ORT and the global acceptance and adoption of such therapy as an effective medical treatment for drug dependence, clinical testing of ORT in Viet



Nam is unnecessary. In its current guidelines on the subject, WHO acknowledges the strength of the evidence in favour of ORT in reducing drug use, criminal activity, HIV risk behaviours and transmission, as well as overall mortality. The Guidelines recommend that the following procedures, among others, be adopted in all settings as minimal requirements for treatment of opioid dependence: widely accessible pharmacological treatment, to be administered by trained health care professionals; mandatory informed consent for all treatment; and psychosocial support for all opioid dependent patients.

In the light of all of the above, it is the Special Rapporteur's view that the existence and continuation of rehabilitation centres violate the right to health.

The Special Rapporteur, however, notes with satisfaction that the draft administrative reform law pending at the National Assembly would expand key due process protections for PWUD and discontinue detention of FSWs in rehabilitation centres. These changes are welcome and would have significant positive health impacts, especially with respect to HIV/AIDS. The Special Rapporteur was also pleased to learn that the Government was planning to review and reorganize the system of rehabilitation centres towards investing in small and medium-sized voluntary drug treatment centres at the community level. There is also a perspective within the Government and the National Assembly that favours the closure of centres. The Special Rapporteur wholeheartedly supports the closure of the rehabilitation centres and recommends the implementation of alternative treatments for PWUD, including methadone treatment and community-based vocational training.

### **C.Participation in decision-making**

The participation of affected populations in health decision-making is an essential component of the right to health. Community participation is vital for effective health governance at every level, including the collection of accurate data, the formulation of effective interventions, the successful implementation of those interventions, and the ongoing monitoring of their impact. In the *Joint Annual Health Review 2010* it was acknowledged that community and civil society participation in health-related decision-making is limited. It is crucial that the Government encourage and incorporate inputs from affected populations in the provision of health-care services in order to effectively address the HIV epidemic in Viet Nam and improve the health system at large.

Participation in health-related decision-making is also critical to empowering vulnerable groups. Empowerment of affected populations, particularly IDUs, FSWs and MSM, will encourage community-guided and community-led initiatives towards raising awareness of the issues faced by these groups. Such initiatives will also help combat the stigmatization and discrimination in the society. This will assist with the rehabilitation of IDUs and their reintegration into the wider community, ultimately improving the health outcomes of these populations. Moreover, other experiences show that community-led initiatives are more sustainable in the long run. For these reasons, the Special Rapporteur encourages the Government to facilitate the participation of vulnerable populations, including IDUs, FSWs and MSM, in the formulation and implementation of all decisions affecting their health. The Special Rapporteur also encourages community-based peer groups of current and former PWUD and FSWs, such as those currently operating in Hanoi, Hai Phong and Ho Chi Minh City, which offer support to PWUD and FSWs through group meetings, small loans, overdose prevention and connections to health and harm-reduction services.

## **VI.Conclusion and recommendations**

**The Special Rapporteur notes with appreciation the advances made in the overall health system of Viet Nam, including the Government's efforts to improve child and maternal health and its stated commitment to ensuring access to health goods and services for the poor and near poor.**

**The Special Rapporteur urges the Government of Viet Nam to consider the following recommendations pertaining to its health system and health financing:**

- (a) Complete an official assessment of the effects of privatization on the health system, including its impact on the right to health and the accessibility of health goods and services for the poor, near poor and ethnic minorities;**
- (b) Consider alternative revenue-generating mechanisms for provincial-, district- and commune-level health-service providers, such as progressive taxation;**
- (c) Expand the scope of health insurance coverage for the poor to fully subsidize the near poor;**
- (d) Subsidize fully travel, food and accommodation for the poor and near poor who must travel in order to receive health services;**
- (e) Reduce the complexity of referral procedures in order to ensure maximum insurance portability, especially from the commune level to district and provincial levels;**
- (f) Ensure that all children under 6 receive free health care in accordance with the existing Government policy.**

**The Special Rapporteur urges the Government to consider the following recommendations in the area of access to medicines:**

- (a) Develop policies to foster the use of generic drugs;**
- (b) Apply international and domestic drug reference pricing methods, which adequately ensure the economic accessibility of medicines;**
- (c) Monitor and make transparent the retail and purchase prices of drugs;**

(d) Ensure that a reference pricing basket is established for use in drug procurement, which would accurately reflect the level of economic development of Viet Nam;

(e) Consider implementing alternative mechanisms to ensure that medicines are procured at the lowest prices possible, in order to maximize access to medicines;

(f) Increase transparency and ensure the participation of civil society and affected communities in the Trans-Pacific Partnership Agreement (TPPA) negotiation process in order to promote the full realization of the right to health and to strengthen the Government's technical capacity in the area of access to medicines;

(g) Ensure that, if Viet Nam accedes to the TPPA, it retains the ability to use TRIPS flexibilities and does not accept TRIPS-plus measures, and that intellectual property protections in the agreement do not expand protections beyond that which currently exist under Vietnamese law;

(h) Explore carefully the possible development impacts of the TPPA, and in particular, its effect on the development of local generic pharmaceutical production in Viet Nam.

The Special Rapporteur urges the Government to consider the following recommendations in the area of HIV/AIDS:

(a) Ensure accurate and complete epidemiological surveillance and data collection regarding HIV/AIDS;

(b) Eliminate stigmatization and create an enabling environment, in which at-risk populations, including injecting drug users, female sex workers and men who have sex with men, are able to effectively access health care, by de-penalizing drug use and sex work;

(c) Develop a strategy to account for reductions in international assistance in order to ensure that access to HIV/AIDS prevention, treatment and care is maintained and expanded;

The Special Rapporteur urges the Government to consider the following recommendations with respect to people who use drugs and rehabilitation centres:

(a) Close all "05" and "06" rehabilitation centres, with a view to replacing the current practice of compulsory detention and non-consensual treatment with alternative forms of treatment, care and support in compliance with international human rights standards;

(b) Distinguish, in all Government policies, between drug dependence as a medical disorder, for which medical treatment may be indicated, and drug use;

(c) Employ only evidence-based therapies in the treatment of drug dependence;

(d) Scale-up available opioid replacement therapies, including community-based methadone maintenance pilot programmes;

(e) Support and encourage community-based peer groups of current and former people who use drugs and female sex workers that offer support through group meetings, small loans, overdose prevention and connections to health and harm-reduction services.