Antiretroviral Medication Policy for Refugees

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## The UN Refugee Agencies' Antiretroviral Medication Policy for Refugees

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### **A) Introduction**

The introduction of effective antiretroviral therapy (ART) in the 1990s dramatically changed the prognosis of people suffering from HIV and AIDS and provided hope for millions of people around the globe. Of the 39 million people currently living with HIV in low and middle income countries, 6.5 million of them are in need of ART; however, by the end of 2005, just over 1.3 million people were receiving the treatment.<sup>1</sup> Although ART is not a cure and there are many side-effects and concerns about resistance, ART greatly improves the quality of life by reducing morbidity and mortality among people living with HIV. ART has revitalised whole communities. Not all persons who are HIV positive need ART. Rather, only those with reduced immunity, shown by clinical symptoms and signs or a specific blood test, require treatment.

In recent years, the international community has made a strong commitment to increase the availability and accessibility of antiretroviral medications (ARVs) in an equitable manner. Numerous initiatives by Governments, international organisations, and multilateral and bilateral donors have been undertaken to address this critical issue, including the development of the World Bank's Multi-Country AIDS Programme for Africa, the creation of the Global Fund to Fight AIDS, Tuberculosis and Malaria, the United States' President's Emergency Plan for AIDS Relief, and the introduction of the World Health Organization (WHO)-led '3x5' Initiative which has subsequently become the Universal Access Initiative.<sup>1</sup>These initiatives have been accompanied by a significant reduction in prices of ARVs as well as improvements in technology and production of guidelines that have allowed ARVs and ART to be provided in a clearer and more simplified manner.

### B) Objective of the policy and scope of its application

The United Nations High Commissioner for Refugees' (UNHCR) ARV policy for refugees is designed to offer guidance to UNHCR and its implementing and operational partners as well as to host Governments on the provision of the different forms of available ARVs, namely short-term preventive ARVs to avoid mother-to-child transmission (PMTCT) and post-exposure prophylaxis (PEP) to reduce the likelihood of HIV transmission in certain situations as well as long term ART. This document sets the objectives as to the availability of ARVs and ART for refugees and outlines the scope of engagement and the responsibilities of UNHCR offices in working towards the achievement of these objectives. The document complements earlier UNHCR policy papers and guidelines related to HIV/AIDS<sup>2-5</sup> and is consistent with international recommendations relating to ART.<sup>1,68</sup> As with all HIV and AIDS policies and programmes, ARV interventions must be linked to prevention, care and support programmes. ARVs should not be implemented as a parallel intervention but rather as part of an integrated HIV/AIDS programme which is in itself linked to other existing services (e.g. reproductive health, protection, nutrition, education and social services).

While this ARV policy focuses on refugees, most of the principles stated in this document also apply to other persons of concern to UNHCR, including internally displaced persons (IDPs) though the range of activities and the level of UNHCR's involvement will depend on UNHCR's mandate, specific responsibilities and the levels of engagement of the organisation with respect to such persons.

With regard to asylum-seekers, a distinction must be made between the provision of ARVs for the purposes of prevention (i.e. PMTCT and PEP) and ART which requires long term provision. The policy governing the provision of ARVs for the purposes of prevention applies equally to asylum seekers as it does to refugees. Numerous factors need to be considered with regard to the provision of long term ART to asylum seekers. This includes the prospective for sustained longer term treatment, which again may depend on the anticipation of the likelihood of the person remaining in the country due to being granted refugee status or benefiting from complementary forms of protection or on the possibility to continue treatment of rejected asylum-seekers following their return to the country of origin.

### C) The scope of the challenge

The number of individuals of concern to the UNHCR, which include refugees, IDPs, returnees (refugees and IDPs who have returned to their countries/places of origin), asylum-seekers and stateless people, rose 6 percent in 2005 to 20.8 million, with refugees constituting 40% of the total.<sup>9</sup> Many countries, already overburdened by the impact of HIV/AIDS, are often unable or unwilling to provide these populations with the HIV-related services they require. This failure to provide HIV prevention and care to refugees and displaced people not only undermines effective HIV prevention and care for host country populations. By the end of 2003, refugee populations remained on average in their host country for 17 years,<sup>10</sup> the implications for them as well as host countries are profound.<sup>2</sup>

At the United Nations (UN) General Assembly Special Session on HIV/AIDS in 2001,<sup>11</sup> Governments recognised that "populations destabilised by armed conflict, humanitarian emergencies and natural disasters including refugees, internally displaced persons, and in particular women and children, are at increased risk of exposure to HIV infection; and where appropriate, factor HIV/AIDS components into international assistance programmes;" The session called upon "all United Nations agencies, regional and international organisations, as well as non-governmental organisations (NGOs) involved with the provision and delivery of international assistance to countries and regions affected by conflicts...to incorporate as a matter of emergency HIV/AIDS prevention, care and awareness elements into their plans and programmes".<sup>11</sup> Thus, in this forum and in many others, it has been acknowledged that HIV is a critical factor to be considered in the context of forced displacement.<sup>12</sup>

Providing HIV-related services to displaced populations is a difficult yet critical undertaking,<sup>13</sup> which is firmly rooted in international human rights law and which requires that any activity undertaken by States and UNHCR must be consistent with international refugee and human rights law. The 1951 Convention relating to the Status of Refugees stipulates in its article 23 that "Contracting States shall accord to refugees lawfully staying in their territory the same treatment with respect to public relief and assistance as is accorded to their nationals" and this provision would encompass "public relief and assistance" related to health needs and services." Protection offered under international human rights law and in particular, article 12 of the International Covenant on Economic, Social and Cultural Rights reaches further as it encompasses "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"." The scope of human rights obligations, which relate to everyone on the territory or under the jurisdiction of a State party to relevant treaties and include the principle of non-discrimination require countries of asylum to ensure equal and non-discriminatory access to existing health services for refugees on the same basis as nationals. Unfortunately, however, the HIV-related needs of refugees, as well as other persons of concern to UNHCR such as IDPs,<sup>14</sup> are often not included in National Strategic Plans of Governments and/or in national HIV/AIDS proposals submitted to major donors.<sup>15</sup> This is detrimental to the HIV prevention, care and treatment needs of both the affected populations and host surrounding populations.<sup>2</sup>

## D) Human Rights considerations governing UNHCR's ARV policy

- Refugees (as do asylum-seekers, IDPs and other persons of concern to UNHCR) may benefit as any other individual, from the *"right of everyone to the enjoyment of the highest attainable standard of physical and mental health"* as explicitly codified in the International Covenant on Economic, Social and Cultural Rights (ICESCR)<sup>iv</sup>, irrespective of their nationality or residence status.<sup>v</sup>
- 2. This right requires State parties to this instrument to take steps which are necessary for "the creation of conditions which would assure to all medical service and medical attention in the event of sickness" (Article 12(2)(d) ICESCR).<sup>V</sup>
- 3. ARVs have been included on the WHO's model list of Essential Medicines indicating that its medically indicated use reflects the highest attainable standard of physical and mental health.
- 4. The respect for protection and fulfillment of human rights is primarily the obligations of states and extends to all persons within a state's territory or subject to its jurisdiction.
- 5. The concept of "progressive realization" does not relieve states from the obligation to urgently, promptly and effectively addressing acute health crises and needs. As the Committee on Economic, social and Cultural Rights explained in its General Comment, No 14 on the Right to highest attainable standard of health (art 12), para. 31: "The progressive realization of the right to health over a period of time should not be interpreted as depriving States parties' obligations of all meaningful content. Rather, progressive realization means that States parties have a specific

and continuing obligation to move as expeditiously and effectively as possible towards the full realization of article 12."

- 6. As with other social rights, the right to the *"highest attainable standard of physical and mental health"* requires States party to the ICESCR *"to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures". <sup>viii</sup> The explicit reference to international assistance and co-operation clarifies that co-operation with and assistance offered through or with support by UNHCR is one means for States to fulfill their human rights obligations under the ICESCR including in relation to refugees.*
- 7. UNHCR has a mandate to provide international protection to refugees pursuing the objective to *"assure refugees the widest possible exercise of [their] fundamental rights and freedoms"*, which, taking into account the dynamic development of international human rights law, entails the right to the highest attainable standard of physical and mental health.
- 8. While this mandate is primarily exercised by promoting policies and practices and assisting States (e.g. through capacity building measures, including advice and technical assistance) to fulfill their protection obligations vis-à-vis persons of concern to UNHCR, substitutional measures and the provision of direct assistance, including medical assistance, is one well established means of exercising UNHCR's international protection mandate, in particular where States are unable or unwilling to fully fulfill their human rights obligations vis-à-vis refugees and other persons of concern to UNHCR.
- 9. This does not give the individual refugee a subjective right vis-à-vis UNHCR on a specific form of assistance, such as ARVs. However, if UNHCR engages in the direct provision of medical assistance, such must be oriented at the highest attainable standard of physical and mental health and must be offered without discrimination. Although the principle of non-discrimination would not prohibit a differentiation in the policy, such as preferential treatment for women and children in certain circumstances, any such differentiation would have to be based on the most updated medical knowledge, with a full appreciation of the situation of the principle of proportionality.
- 10. The following more detailed *sections* on key considerations and principles governing the use of ARVs in UNHCR's operations" (see E and F) serve to translate the above human rights-based considerations into operational practice while ensuring necessary consent and confidentiality.

# E) Key considerations governing the provision and use of ARVs in UNHCR operations

- 1. Refugees often live for years in **relatively stable settings** in their host country. By the end of 2003, refugee populations remained in their host country for an average of 17 years.<sup>10</sup>
- 2. A minority of refugees in numerous countries are already finding their own **innovative ways** to begin ARVs.
- 3. The increase of ARV **resistance** by stopping and then re-starting the therapy in a controlled fashion is not considered to be more of a risk for populations that have been displaced by conflict than other populations. The largest threat to developing ARV resistance remains persons taking ARVs in an incorrect manner; this threat is no larger for forcibly displaced populations than other populations.<sup>6</sup>

# F) Key principles governing the provision and use of ARVs in UNHCR's operations

- 1. Facilities and services providing HIV testing and the possibility of the provision of ARVs where medically indicated<sup>6</sup> should be planned for and included in the **earliest possible stages of an emergency response** to forced displacement.<sup>16</sup>
- 2. **Continuity of ART** is a priority in order to ensure treatment effectiveness and avoid the possibility of developing resistance. UNHCR and its partners should attempt to ensure as a priority that ART continues to be provided to persons who were previously taking ART before conflict and/or displacement.
- 3. As with all public health interventions, refugees should receive **equivalent services** as those available to surrounding host communities while ensuring that minimum essential services are provided,<sup>3,17</sup> this refers to all types of settings (e.g. camps and outside of camps).
- 4. Interventions are to be initiated only where and once the minimum criteria to implement such activities (relating for example to the availability of resources, sufficiently trained persons, protocols, confidentiality, supervision)<sup>3</sup> as established in internationally agreed upon guidelines are met.
- 5. **Diagnostic and treatment protocols should follow those of the host community** unless they are ineffective, non-evidenced based or do not respect consent and confidentiality (e.g. chloroquine treatment for malaria in chloroquine resistant areas).<sup>3</sup>
- 6. **Sustainability** of ART is a key challenge to be addressed. In principle treatment should be life long. However, this may not always be possible to guarantee in developing and underdeveloped countries regardless of whether they are affected by conflict or displacement. Many

large HIV donors provide funds for 2 to 4 years with the possibility, but not a guarantee, of future funding; this is distinct from humanitarian donors who often provide funding for one year.<sup>2</sup> UNHCR recommends having a minimum of 1 year funding secured before the implementation of therapeutic (long term) ART programmes is started. The goal is to have renewed funding so that ART can be continuous for those persons that need it.

7. **"Pilot" programmes** are possible to provide an important service to refugees and other persons of concern with the hope of stimulating a similar service for the local populations; they should be implemented in line with national policies to ensure harmonisation (e.g. the "Threeones"<sup>(h)</sup>)

## **G) Essential ARV and ART interventions**

Essential provision of ARV and ART interventions are listed below with a view to setting out what type of interventions should be made available to refugees under which circumstances. UNHCR offices will need to carefully assess the availability of these different types of ARVs and ART for all refugees and other persons of concern in the country of operation so as to identify possible gaps, and to assess the need for capacity building measures, promotional activities serving the inclusion of refugees into existing ARV and ART programmes or the establishment of UNHCR (co-)funded ARV and ART programmes.

#### 1. Post-Exposure Prophylaxis (PEP)

Twenty-eight (28) day course of ARVs that reduces the likelihood of HIV transmission after exposure to a possible HIV positive source:

- a. The provision of PEP is an essential response within the clinical management of rape and part of the sexual and gender based violence programmes for refugees, IDPs and other persons of concern to UNHCR.<sup>3,8,13</sup>
- b. Non-occupational (e.g. cases of rape) exposure to HIV, a person should receive PEP within 72 hours after exposure, following host country or UN guidelines.<sup>8</sup>
- c. All occupational (e.g. needle stick) exposure in line with the UN and NGO occupational guidelines for provision of PEP.

#### 2. Prevention of Mother-to-Child Transmission (PMTCT)

Provision of ARVs to an HIV positive pregnant woman and newborn to reduce the likelihood of HIV transmission from mother to child:

- a. PMTCT programmes should be implemented for refugees as soon as feasible.
- b. In cases of repatriation to sites with unknown or poor access to ARVs, similar to treatment for tuberculosis, the pregnant woman and her family should be advised to delay repatriation until after delivery in order to complete PMTCT.
- c. If PTMCT programmes exist in areas of return, cross-border programmes should be established to coordinate PTMCT follow-up and referrals for those pregnant

women who have been diagnosed early in pregnancy and who insist upon repatriation, in order to ensure they and their newborns receive appropriate care, treatment and follow-up.

- d. PMTCT programmes should be as comprehensive as possible and at a minimum include comprehensive maternal-child healthcare; counselling and testing services; counselling and support about safe infant feeding practices, optimal obstetrical care practices; short-course ARVs for HIV infected pregnant women and newborn; family planning counselling and services linked to voluntary counselling and testing. Such programmes must follow international standards and norms.<sup>7</sup>
- e. Other components of PMTCT, such as long term ART and care of the mother should be considered in all PMTCT programmes.

#### 3. Therapeutic (long term) provision of ART

This intervention refers to the provision of ART to HIV positive persons who fit the medical criteria for ART (which is lifelong) and requires a differentiated policy approach for different scenarios, with the view to secure the essential sustainability of treatment. The following scenarios must be distinguished:

- a. For refugees, who had been on ART in their country of origin prior to flight, every effort should be made to secure prompt continuation of treatment.
  - i. If ART is available in the area/district where the refugee stays, the refugee should be referred to the existing facilities without delay in order to continue ART.
  - ii. If ART is not available in the area/district, action should be taken without delay to either move the refugee and his/her family to a suitable location where treatment is possible or to bring services to the concerned area in a concerted effort involving UNHCR, the HIV UN Theme Group (of which UNHCR is a member), the host Government, and NGOs.
- b. For refugees, who did not receive ART prior to their flight, at a minimum, ART should be provided when such treatment is available to surrounding populations.
  - Every situation is different and depending upon the HIV prevalence of the various populations, availability of HIV earmarked funds, and other factors, deviations from this principle may occur during the scaling up period of ART.
- c. In situations where voluntary repatriation is considered imminent the following considerations should govern the decision to commence ART.
  - i. ART is a lifesaving treatment and should be considered for refugees regardless of whether repatriation is imminent.
  - ii. If ART is already available in the country of origin and accessible upon return, there is no reason to abstain from or delay the start of ART. However, measures to secure the continuity of treatment of returnees under ART must form an integral component of the planning of the repatriation operation.

- It must be agreed that in exercise of their freedom of movement, returnees should be allowed and assisted to return to areas where continuation of ART can be secured.
- UNHCR with UN HIV Theme Groups, NGOs and Governments must work to ensure that there is good communication and strong linkages with national programmes in both countries (or with other organisations if Governments are not providing ART to these populations). These interventions should preferably be an integral part of the health systems and not be parallel programmes.
- Issues such as ART protocols, adherence and other key factors need to be considered beforehand, hence the need for regional/subregional initiatives that can harmonise drug and treatment protocols.
- iii. If ART is not and cannot promptly be made available within the country of origin upon return, the refugee should be informed about this fact and receive comprehensive counselling on the medical situation and on the options available for him or her, including on the possibilities to (temporarily) remain in the country of asylum, thereby allowing him or her to make an informed decision.
  - If a refugee does not wish to repatriate because lifesaving medicine is not available upon return, UNHCR, respecting the voluntary nature of repatriation, cannot actively be engaged in returning the individual and must take the utmost efforts to advocate for this person to be permitted to stay in the country of asylum on humanitarian grounds until sufficient medical services will be established in the country of origin.
  - During that time, UNHCR, UN HIV Theme Group and other organisations should advocate for and aid in the coordination of ART to be available in the country of origin and in particular in areas to where the repatriates return. This may include innovative solutions such as:

Cross-border ART provision.

Working with NGOs to establish ART programmes in specific areas while Government prepares to do so in the longer term.

Support person to stay in part of country of origin where ART is available until treatment becomes available in area of origin.

- d. Voluntary repatriation for those who are already on ART.
  - Refer to G)3.c.ii-iii, while noting in particular that where a refugee is already on ART and insists on voluntary repatriation, although ART is not and cannot promptly be made available upon return within the country of origin, proper counselling must ensure that the refugee fully understands the medical consequences of discontinuing the treatment. This counselling and the informed decision of the refugee must be properly documented.
- e. Different ART protocols between host country to county of origin
  - National ART protocols should be followed except under certain circumstances (see F.5)
  - Advice may be needed when changing from one protocol to another.

## H) How should provision of essential ARV and ART intervention for refugees be secured?

Funding ARV and ART interventions is not limited solely to the cost of the medications. Numerous other associated costs with the provision of treatment need to be considered, including but not limited to transport, lab tests, and treatment of side effects. Depending on the size and profile of the refugee population, there are a variety of practical options available for the provision of ARVs and ART. Options include but are not limited to the following: utilising existing Government services; integration of ARVs and ART provision into existing partners' programmes that are already providing medical services; a specific implementing or operational partner focussing on such provision; a partner medical practitioner or refund scheme allowing a refugee to receive the necessary treatment from the private sector with reimbursement to the provider.

#### 1. **Post-Exposure Prophylaxis**

a. PEP is an essential intervention with a limited course of 28 days (see G.1).<sup>8,13</sup> It is apart of WHO's Essential Medication list. UNHCR must ensure that PEP is available in all of its programmes during all phases. If Governments, other UN agencies or NGOs are not providing PEP, UNHCR should arrange for such treatment through its own programmes and financial resources.

#### 2. **Prevention of Mother-to-Child Transmission**

- a. PMTCT is an essential intervention with a limited timeframe (i.e. provided to woman during her pregnancy and labour (depending upon protocol) as well as to the newborn; therapeutic ART intervention for the women is discussed below –see G.2).
- b. When appropriate and feasible, PMTCT should be provided in refugee situations. If Governments, other UN agencies or NGOs are not providing PMTCT, UNHCR should arrange for such treatment through its own programmes and financial resources.

#### 3. Therapeutic (long term) provision of ART

- a. Therapeutic ART is an essential intervention that requires long-term and sustained treatment. It is apart of WHO's Essential Medication list.
- b. Whenever possible, the host Government should pay the cost of ART for refugees by including them in their national programmes and funding proposals. Since many low income countries host refugees, most if not all of these funds will come from donors. There are numerous reasons why host Governments should cover the cost of ART for refugees:
  - Human rights considerations (see D).
  - Substantial international donor funding from multilateral and bilateral sources is available to support host Governments to extend ART to refugee populations; this funding is primarily provided to Governments and not to UN agencies. Hence, Governments can include populations of humanitarian

concern, including refugees and other persons of concern to UNHCR, in their HIV fund raising activities and proposals to donors. This mechanism will not reduce the amount of funds provided to their citizens and will be more cost-effective than creating parallel systems.

- The number of refugees needing ART is very small compared with the approximately 6.5 million persons worldwide who are estimated to need ART at present; of the 8.9 million refugees of concern to UNHCR<sup>\*</sup> approximately 25,000-35,000 would currently need ART. Therefore, it would be much more efficient for host countries to provide ART to refugees through national health facilities, in conjunction with those organisations already working with refugees, than for another entity to do so on its own.
- On a case by case basis, UNHCR or NGOs who have earmarked funds of at least 1 year may decide to pay for long term ART while continuing to advocate for the inclusion of refugees in the host country's ART programme.

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## J) Endnotes

- <sup>i</sup> The '3x5' Initiative set out to provide 3 million persons in developed countries ART by 2005; at the recent G-8 summit in Glen Eagles (2005) there was a call to go beyond this initiative to have universal access for all by 2010.
- ii Moreover, article 24 of the 1951 Convention foresees equal treatment with respect to "social security", subject only to narrowly confined limitations.
- iii Similarly in art 24 of the Convention on the Rights of the Child "State parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health", and the provision further specifies related appropriate measures to be taken by a State Party.
- iv Art 12, para 1 ICESCR reads: "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health".
- As all ICESCR rights, the right to the highest attainable standard of physical and mental health has to be respected, protected and fulfilled without discrimination as codified in Art 2 para 2 CESCR according to which "The States Parties to the present Covenant undertake to guarantee that the rights enunciated in the present Covenant will be exercised without discrimination of any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status." In view of the close linkages between the right to the highest attainable standard of physical and mental health with the right to life as explicitly protected by art 6 of the ICCPR reference may also be made to the General Comment 31 (CCPR/C/21/Rev.1/Add.13) of the Human Rights Committee on The Nature of the General Legal Obligation Imposed on States Parties to the Covenant, (para 10), in which the Committee expresses that "States Parties are required by article 2, paragraph 1, to respect and to ensure the Covenant rights to all persons subject to their jurisdiction. This means that a State party must respect and ensure the rights laid down in the Covenant to anyone within the power or effective control of that State Party, even if not situated within the territory of the State Party... the enjoyment of Covenant rights is not limited to citizens of States Parties but must also be available to all individuals, regardless of nationality or statelessness, such as asylum seekers, refugees, migrant workers and other persons, who may find themselves in the territory or subject to the jurisdiction of the State Party."
- vi Art. 12, para 2 ICESCR: "The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness."
- vii Art 2 para 1 ICESCR: "Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures."
- viii Preamble to the 1951 Convention relating to the Status of Refugees.
- <sup>ix</sup> UNAIDS' "Three Ones" principles, to achieve the most effective and efficient use of resources, and to ensure rapid action and resultsbased management: One agreed HIV/AIDS Action Framework that provides the basis for coordinating the work of all partners. One National AIDS Coordinating Authority, with a broad-based multisectoral mandate. One agreed country-level Monitoring and Evaluation System.
- <sup>X</sup> This excludes those Palestinian refugees that are covered by another UN entity, UNWRA.



