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Impact Assessment

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Combating HIV/AIDS in the European Union and neighbouring countries, 2009 -2013

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Impact Assessment

This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission

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ABBREVIATIONS / ACRONYMS

AIDS	acquired immunodeficiency syndrome
ART	antiretroviral therapy/treatment
ARV	antiretroviral medicines
ECDC	European Centre for Disease Prevention and Control
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EFPIA	European Federation of Pharmaceutical Industries
ENP	European neighbourhood policy
EU	European Union
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria (the Global Fund)
Gilead	Gilead Sciences, Pharmaceutical company
HAART	highly active antiretroviral therapy
HIV	human immunodeficiency virus
IASG	Impact Assessment Steering Group
IDU	injecting drug user
IOM	International Organisation for Migration
MDG	Millennium Development Goals
MS	Member State of the EU
MSM	men who have sex with men
MTCT	mother-to-child transmission (of HIV)
PLWHA	people living with HIV-AIDS
QALY	Quality Adjusted Life Years
TESSy	The European Surveillance System
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNICEF	United Nations Children's Fund
UNGASS	United Nations General Assembly Special Session
UNODC	United Nations Office on Drugs and Crime
VCT	Voluntary Counselling and Testing for HIV
WHO	World Health Organization

GLOSSARY

AIDS - stands for 'acquired immunodeficiency syndrome' and is a surveillance definition based on signs, symptoms, infections, and cancers associated with the deficiency of the immune system that stems from infection with HIV.

Antiretroviral - an agent that is active against a retrovirus; in the context of the HIV/AIDS , any medication that is designed to inhibit the process by which HIV replicates.

ART – stands for an antiretroviral therapy that in a standard coverage consists of the use of at least three antiretroviral (ARV) drugs to maximally suppress the HIV virus and stop the progression of HIV disease. Given huge reductions have been seen in rates of death and suffering when use is made of a potent ARV regiment, ART is now considered an integral part of the comprehensive response to HIV prevention, care and support.

ARV – stands for antiretroviral drugs that are medications for the treatment of infection by retroviruses, primarily HIV.

Capacity building - an approach to working with the community that aims not only to involve the community in dealing with the problem at hand but also to increase the community's capacity to deal with any future problems that arise. In the context of HIV/AIDS, such an approach is used to establish community norms and standards that support health-enhancing behaviours.

Central Europe (Centre) – 25 countries: Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Czech Republic, Hungary, Former Yugoslav Republic of Macedonia, Montenegro, Poland, Romania, Serbia, Slovakia, Slovenia, Turkey

Clinical research - health research relating to individual patients and the development and evaluation of treatments for diseases.

Clinical trial - a research activity designed to test a drug or treatment in humans and so establish its efficacy and safety and to identify groups of patients who can be expected to benefit from such a drug or treatment.

Co-infection - in the context of HIV/AIDS, the term used to describe the circumstance in which a person is concurrently infected with HIV and another infectious agents such as tuberculosis or hepatitis.

Communicable disease - an illness caused by a specific infectious agent or its toxic products that arises through transmission of that agent or its product from an infected person, animal or other reservoir to a susceptible host.

Eastern Europe (East) – constitute 15 countries of the former Soviet Union, such as: Armenia, Azerbaijan, Belarus, Estonia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Lithuania, Republic of Republic of Moldova, Russian Federation, Tajikistan, Ukraine, Uzbekistan.

ENP - the European Neighbourhood Policy applies to the EU's immediate neighbours by land or sea – Morocco, Algeria, Tunisia, Egypt, Jordan, Lebanon, Syria, Israel, Occupied Palestinian Territories, Ukraine, Republic of Moldova, Armenia, Georgia, Azerbaijan, as well as Belarus and Libya..

Epidemiology - a study of the distribution and determinants of health-related states or events (such as likely routes of transmission of disease and trends in epidemics) in specified populations and the application of knowledge to deal with health problems.

HAART - is defined as treatment with at least three active anti-retroviral medications (ARV's) and is often called the drug "cocktail" or triple-therapy. HAART affords us a potent way of suppressing viral replication in the blood while attempting to prevent the virus from rapidly developing resistance to the individual ARV's. Suppressing viral replication with HAART allows the body time to rebuild its immune system and replenish the destroyed CD4 or T cells. HAART has been clearly shown to delay progression to AIDS and prolong life.

Harm reduction interventions/strategies - interventions designed to reduce the impacts of drug related harm on individuals and communities. Governments do not condone illegal risk behaviours such as injecting drug use, but they acknowledge that these behaviours occur and that they have a

responsibility to develop and implement population health measures designed to reduce the harm that such behaviours can cause.

HIV – stands for human immunodeficiency virus that is a lentivirus (a member of the retrovirus family) that causes *acquired immunodeficiency syndrome* (AIDS), a condition in humans in which the immune system begins to fail, leading to life-threatening opportunistic infections. Infection with HIV occurs by the transfer of blood, semen, vaginal fluid, pre-ejaculate, or breast milk. Within these bodily fluids, HIV is present as both free virus particles and virus within infected immune cells. The four major routes of transmission are unsafe sex, contaminated needles, breast milk, and transmission from an infected mother to her baby at birth (vertical transmission).

HIV prevalence - is a total number of PLWHA in the population at a given time, or the total number of PLWHA cases in the population, divided by the number of individuals in the population.

HIV prevalence rate – is given as a percentage of the population, meaning the total number of all individuals who have an attribute or disease (PLWHA) at a particular time or period divided by the populations at risk of having the attribute or disease at that time or midway through the period. In most cases, HIV prevalence cannot be accurately determined from reported cases because many infections are undiagnosed or unreported. The best estimates are mainly based on the results of surveys of large groups of people. In case of generalized epidemic the estimate of HIV prevalence is based on surveys of pregnant women attending antenatal clinics, and in case of low-level or concentrated epidemic HIV prevalence is based on data collected from population most at risk.

HIV incidence - is the number of new HIV infections in the population during a certain time period. People who were infected before that time period are not included in the total, even if they are still alive.

Human capital approach - measures the value of a person's life by his or her potential labour productivity. Because of the way this method assigns value, it may not place as much value on the lost productivity of persons who are elderly, unemployed, or children. No explicit value is placed on intangible costs, such as pain and suffering associated with illness or deterioration of quality of life.

Prevalence - a measurement of all individuals affected by the disease within a particular period of time, whereas **incidence** is a measurement of the number of new individuals who contract a disease during a particular period of time.

Non-communicable disease (NCD) - a disease which is not infectious. Such diseases may result from genetic or lifestyle factors. A non-communicable disease is an illness that is caused by something other than a pathogen.

People living with HIV (PLWHIV) - the 'number of people living with HIV' represents all people living with HIV infection, whether or not they have developed symptoms of AIDS, who are alive at the time given. Estimates of the number of people living with HIV are usually based on the estimated HIV prevalence and total population size, but minimum estimates may be derived from case reports. UNAIDS and WHO favour a terminology move away from PLWHA (people living with HIV/AIDS) to PLWHIV (people living with HIV) as a consequence of a HIV disease change from a series of inevitable stages to a spectrum.

Prevention – it encompasses different methods and dimensions: personal information and counselling, targeted information for vulnerable groups, the availability of testing facilities, and structural prevention which addresses the social and political environment of vulnerable people such as poverty and discrimination but also factors influencing behaviours e.g. availability of information, condoms and sterile syringes.

Western Europe (West) – 23 countries: Andorra, Austria, Belgium, Denmark, Finland, Germany, Greece, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Monaco, Netherlands, Norway, Portugal, San Marino, Spain, Sweden, Switzerland, United Kingdom

Willingness to pay (WTP) method – also called the contingent valuation method, places a value on life according to how much an individual is willing to pay to reduce the probability of illness or death. This approach measures the value that patients place on improving their health or preventing further deterioration of their health. The WTP method allows a consumer to evaluate treatment benefits from an individual perspective.

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EXECUTIVE SUMMARY

This impact assessment considers policy options for a possible EU initiative on HIV/AIDS as a follow up to a first Action Plan 2006-2009. The Commission announced such initiative in the 2009 work programme.

This assessment provides information on the previous EU action plan and its key deliverables and completed actions and what lessons can be drawn for the design of a successor plan, in particular for spending priorities and priority setting. It describes the current trends in infections and HIV prevalence rates for both EU and its neighbouring countries, in particular focused on Eastern Europe. Considering that HIV/AIDS as disease is more than a "medical problem", when compared to other chronic diseases, it implies significant social and economic burdens. This report explains the change of the disease from a deadly to a chronic condition and its implications for health services provision. It outlines a rationale for future EU action and proposes a number of options and related policy actions which are then appraised. Option 1 consists of a prolongation of the current Action Plan allowing for its comprehensive evaluation, option 2 assumes that EU activities would be ceased and option 3 introduces a new EU Action Plan for 2009-2013, setting also new objectives and priorities. The report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

Principle responsibility for action to address HIV/AIDS remains within a control of Member States, but EU policies have also a role through funding under the umbrella of the Health programmes, the Research Framework programmes and, EU-wide harmonised data gathering and surveillance as well as exchange of best practice and benchmarking. Thus, EU action appraised here explores options to support and complement the efforts of Member States and stakeholders and to mobilise EU policies towards HIV/AIDS prevention, treatment and care as well as research and medicines, with regard to the cross-border cooperation, in full respect of subsidiarity.

The possibility of EU action is to be also considered in the context of the economic crisis the EU and its MSs are currently facing. Given the rising strains between resources and needs, it is particularly important to re-iterate the long-term benefits of preventive health action for a communicable disease with high care costs.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Organisation and Timing

DG Health and Consumers (SANCO), as the service in lead of the HIV/AIDS policy for the EU and neighbouring countries, invited Commission services to contribute to an IASG, and received input from: ADMIN, AIDCO, DEV, EAC, ECHO, EMPL, ELARG, ENV, INFSO, SG, RELEX, RTD and TRADE.

The first roadmap for this project was established in June 2007. The impact assessment process was launched on 19 January 2009, and three meetings of the impact assessment steering group, composed of representatives of the above mentioned DGs, were held, on 22 January, 3 March and 6 May 2009. Written versions of the draft IA were circulated between meetings for comments. The final version of the IA report was agreed in a written procedure by the DGs on 26 May 2009, and then was sent to the IAB on 4 June 2009.

The IAB considered the document at its meeting of 24 June and provided its initial opinion on 29 June 2009. The IAB issued a second opinion on the revised draft IA report on 25 September 2009. This version of the document incorporates the following main changes in response to the comments and observations of the IAB.

(1) The section on the previous action plan has been expanded, in particular with regard to an assessment of the achievements and lessons to be drawn for future EU actions for policy and funding priorities. It has been better explained, in Option 1, why and which actions and political commitments within the current action plan have not been implemented yet.

(2) Options have been clarified and reorganised, in order to take into consideration the suggestion of the IAB to develop a new policy option – that is the continuation of the current action plan followed by its evaluation. Option 3 now provides for a comparison of priorities and objectives between Action Plan 2006-2009 and a new strategy (Option 3).

(3) Operational objectives in terms of specific deliverables, targets and deadlines have not been included in the report since they will be agreed along the broad lines defined in cooperation with relevant stakeholders (e.g. civil society forum, Think Tank, international organisations)playing a significant role in implementing the action plan. This will be developed further along with a new Communication and Action Plan.

(4) Finally, the assessment section has been divided, as suggested, into 2 parts analysing separately economic and social impacts.

1.2. Consultation and Expertise

SANCO has several permanent advisory groups in place, some with a special expertise on HIV/AIDS such as the HIV/AIDS Think Tank[1] (the Think Tank), the Civil Society Forum[2] (CSF) and the EU Health Policy Forum[3] (EUHPF). The Think Tank, the CSF and the EUHPF were consulted[4] in a targeted way with an opportunity for written comments on the project. The commentaries, received from civil society organisations (CSF, Aids Action Europe, European AIDS Treatment Group), economic operators and federations (Gilead, EFPIA), Member States (SL, PT, DE, ES) and international organisations (UNAIDS, IOM) concerned mainly the need for continuity of European initiatives and undertaking actions on targeted prevention, priority regions and most at risk populations. The responses were considered while drafting this IA as they fed into the development of potential objectives set out in section 5 and influenced the organisation of the actions under the three options, the appraisal process and the final decision on the best option.

RELEX carried out a general consultation with delegations in all neighbourhood countries to collect first hand information on the contribution, involvement, and usefulness of a Commission policy for the delegations' HIV/AIDS related activities in the partner countries. A number of delegations responded and delivered primary information, which is attached in Annex 1. The broad lines were included in the reasoning on an EU added value.

In terms of the broader policy contexts, general consultations organised prior to the adoption of the Renewed Social Agenda (2008)[5] and the EU Health Strategy (2007)[6] also touched upon communicable diseases, including HIV/AIDS.

2. BACKGROUND

2.1. HIV/AIDS - characteristics of the disease and epidemiology

The WHO and ECDC jointly report on epidemiological surveillance on HIV/AIDS in Europe. For the purposes of analysis and reflecting patterns of the epidemic, the surveillance is done in relation to western, central and eastern parts of the WHO European Region. The presentation of the following data is done within this framework and has no political signification.

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1 The HIV/AIDS Think Tank, established by a High Committee on Health in 2004, is a forum to exchange information between the Commission, the Member States, Candidate and EEA countries (Lichtenstein, Iceland and Norway)

2 The HIV/AIDS Civil Society Forum (CSF) is an informal advisory body established in 2005 by the European Commission to facilitate the participation of NGOs and networks.

3 The EU Health Forum, established in 2001 is an informal communication and consultation forum, which brings together umbrella organisations representing stakeholders in the health sector to ensure that the EU's health strategy is open, transparent and responds to the public concerns.

4 Date of consultations: The Think Tank and the CFP on 7/11/2008 and 24-25/03/2009; the EUHOF on 10/12/2008.

5 Consultation ended in February 2008, Social Agenda Forum took place on 5-6 May 2008.

6 Public consultation ended in early 2007.

2.1.1. *A chronic disease without a cure*

The human immunodeficiency virus (HIV) was discovered in 1983 and, according to WHO/UNAIDS statistics, there have been 33M people worldwide in 2007 living with the virus.

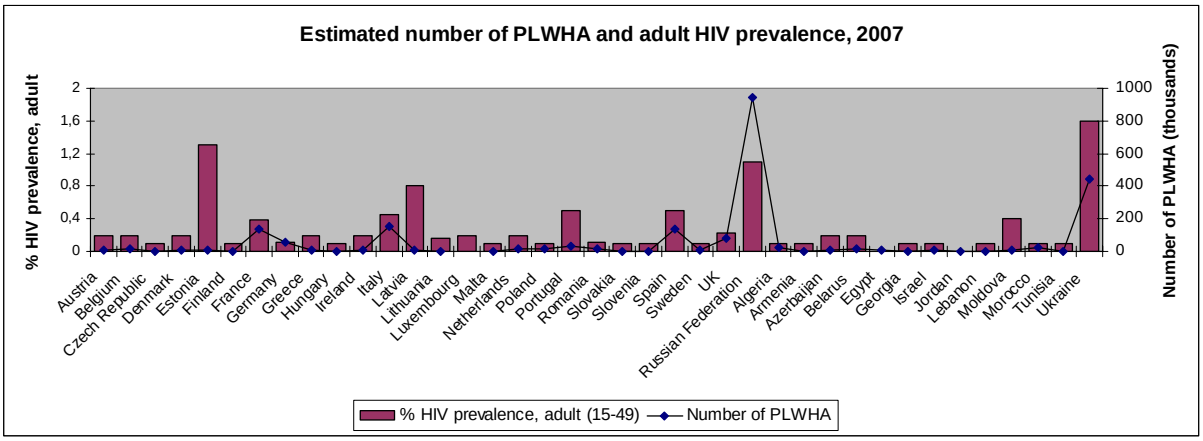
HIV/AIDS is a serious health problem since there is no cure or preventive vaccine for HIV infections available. While effective antiretroviral therapy (ART) has dramatically reduced the risk of illness and death for people living with HIV/AIDS (PLWHA) they still have an elevated mortality rate relative to the general population. HIV-infected people under effective treatment live longer[7] and are therefore at increased risk of progressive conditions such as a cardiovascular or liver disease, or non-AIDS-defining cancers, and may experience acute or long term side effects of the medication.

2.1.2. *Trends and epidemiology*

Effective combination of therapies, introduced in the mid-1990s and widely used in industrialised countries, have had a profound effect on the course of HIV infection, improving the quality of life and delaying the onset of AIDS and death of HIV-infected individuals. However, there is still a danger that this progress has contributed to complacency. Even though the number of people living with HIV/AIDS (PLWHA) in the EU is relatively small when compared with figures in Sub-Saharan Africa or Asia, HIV/AIDS is still perceived as a major public health issue[8].

In the EU and its neighbourhood[9] according to UNAIDS[10], the number of people living with HIV/AIDS increased in the years 2001 -2007 from around 1.5 million to 2.2 million, approximately 730.000 of which live in the EU. In 2007, as Figure 1 shows, among the EU members, the highest number of PLWHA were reported in FR, IT and ES, accounting for nearly 60% of the total EU. However, Russia and Ukraine have the highest number of PLWHA in Europe, accounting for nearly 90% of the region's total infections.

Figure 1: People living with HIV/AIDS (PLWHA) and adult HIV prevalence[11], 2007



Source: UNAIDS, WHO

7 The Lancet, 2008, 372, p.266

8 WHO, ECDC; www.euro.who.int, www.ecdc.europa.eu.

9 In this document, 'neighbourhood' or 'neighbouring countries' refer to the ENP members and the Russian Federation. Such a coverage of the neighbourhood corresponds to the definition of 'neighbourhood' addressed in COM(2005) 654 and the Action Plan 2006-2009.

10 http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp

11 HIV prevalence represents a relative number of PLWHIV, expressed as a percentage of a population of adult people (aged 15-49)

Figure 1 and Figure 2 show there are huge disparities of HIV prevalence rates among EU MSs and their neighbouring countries. Estimated HIV prevalence varies from below 0.1% in parts of Central Europe to above 1% in parts of Eastern Europe, with the highest rates in EE – 1.3%, Russia – 1.1% and Ukraine – 1.6%. Among other EU MSs, significantly high prevalence rates are observed in LV, IT, PT, ES and FR. In contrast, in SK, SI, MT and LT HIV prevalence remains at a relatively low level.

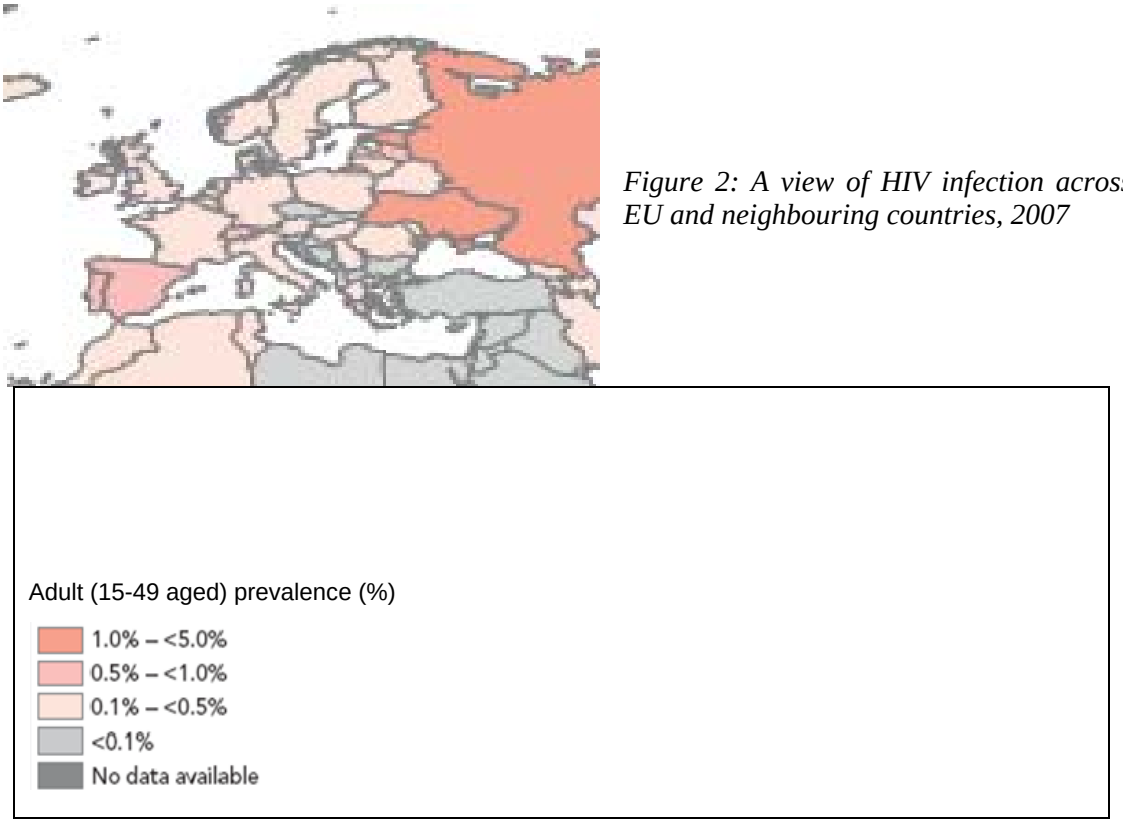
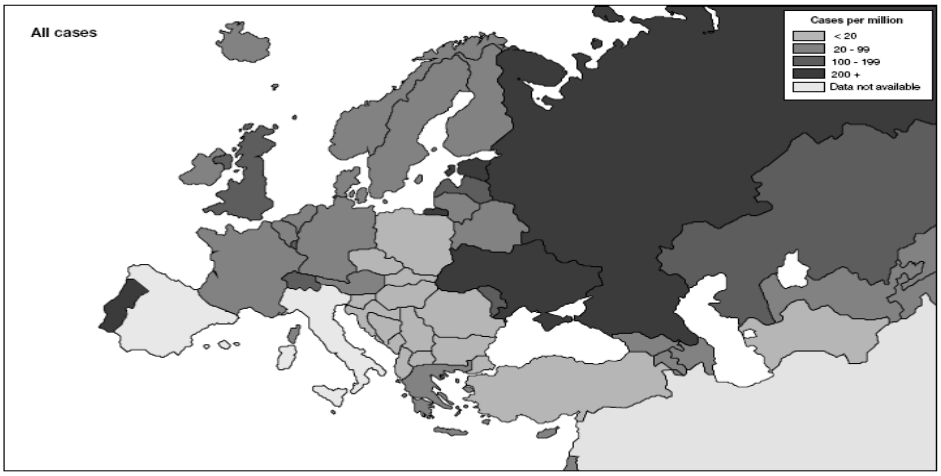


Figure 2: A view of HIV infection across the EU and neighbouring countries, 2007

Source: UNAIDS

A total of approximately 90.000 new HIV infections were diagnosed in 2007 in the European Union, Russia and Ukraine. Less than 27 000 of these diagnoses were, according to the ECDC, reported in the EU. The number of newly diagnosed infections in Russia and the Ukraine reached approximately 55.000 in 2007, according to UNAIDS.

Figure 3: Rates of newly diagnosed cases of HIV per million inhabitants, 2006



Source: Eurohiv

These trends and statistics indicate that **Eastern Europe** is highly affected and today this region reports the fastest spread of HIV epidemic in the world, often coming along with a high degree of co-infections such as (multi-drug resistant) tuberculosis or hepatitis B and C (ECDC[12]). Ukraine is suffering a steady increase in new infections comparable to high epidemic regions. The number of PLWHA in Ukraine doubled from 210.000 in 2001 to 440.000 in the year 2007[13]. The HIV epidemic in the Russian Federation continues to grow, although apparently at a slower pace than in Ukraine. The annual number of newly reported HIV diagnoses is also rising in the Republic of Moldova.

Regarding **Mediterranean partners of the EU** under the umbrella of the ENP, according to UNAIDS and WHO statistics, the threat of an expansion of the HIV epidemic from these countries to Europe is much lower. The HIV prevalence of adults in all these countries, where data are available, is below 0.2 % in 2007. The number of PLWHA in Algeria, Egypt, Israel, Jordan, Lebanon, Morocco and Tunisia estimates to 64.000 people that accounts for one sixth of PLWHA reported in Ukraine and only one fifteenth of PLWHA diagnosed in Russia.

Thus, the HIV epidemic and HIV/AIDS developments coming from Eastern Europe are much higher than those reported in the Mediterranean non-EU countries. Therefore, this IA concerns mostly the Eastern neighbours that HIV/AIDS developments, if not tackled, threaten to lead a generalised epidemic along the EU's borders.

The HIV epidemic in candidate and potential candidate countries to the EU remains at low and stable levels, although there is evidence of increasing sexual transmission in many countries.[14]

2.1.3. *Mode of transmission*

HIV can be transmitted in three main routes: (1) sexual transmission, (2) transmission through blood and (3) mother-to-child transmission. Wherever there is HIV, these three modes of transmission take place; however the predominant transmission group varies significantly by country and geographical area.

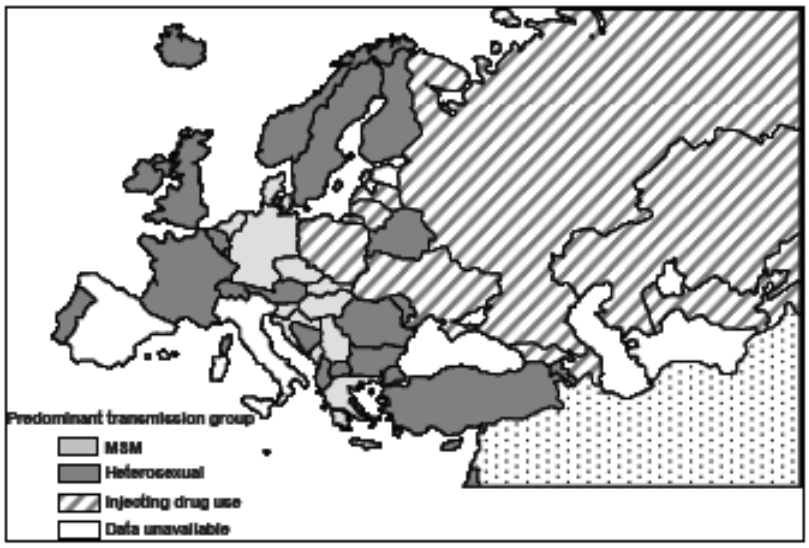
In EU/EFTA countries the highest proportion of new HIV cases was reported among MSM (39%). predominating in UK, DE, FR, NL, ES PT and BE. **IDUs** (injecting drug users) constitute the largest proportion in the Eastern part of Europe (57%), with Ukraine, Belarus and Republic of Moldova at the top, followed by the Baltic states - LV and EE. Among the EU MSs, the highest number of IDUs cases is reported in PT, UK, FR, DE and PL. There is a risk that the large number of

12 Tuberculosis facts sheet, http://ecdc.europa.eu/en/Health_topics/Tuberculosis/facts.aspx
13 UNAIDS global AIDS epidemiology report 2008, Annex
14 For more comprehensive data see HIV/AIDS Surveillance in Europe, ECDC/WHO, 2007.

young people in Eastern Europe who get infected through injecting drug use spread the infections to their partners and hence to the general population , especially women and children.

With 256 cases reported in 2007 for the EU, **MTCT** (mother-to-child transmission) accounts for just over 1% of all new HIV diagnoses[15], but most of these cases could still be avoided and need to be prevented to spare children from an unnecessary life long disease.

Figure 4: Rates of newly diagnosed cases of HIV per million inhabitants, 2006, with a distribution of transmission modes



Source: Eurohiv

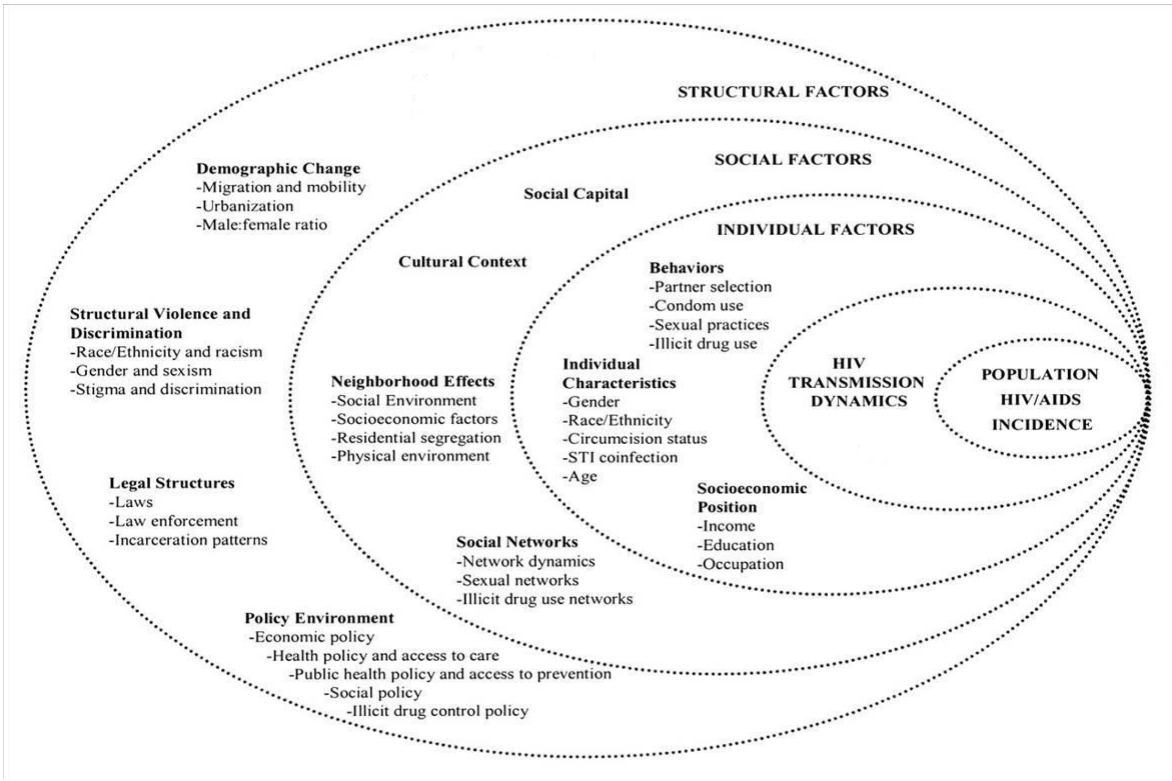
2.1.4. *Root causes driving the epidemic*

To date, there have been a number of studies on the causes and determinants of the infectious disease transmission and progression. Although, the root causes of a steady high number of new HIV infections are heterogeneous and can also differ across geographical location, according to Poundstone approach[16], factors of importance to HIV epidemiology may be conceptualised at three levels: individual, social, and structural (Figure 5).

Figure 5: Poundstone's 3-level determinants of HIV model

[15] *Ibidem*

[16] Poundstone, K. E. et al. The Social Epidemiology of Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, Vol. 26, 2004



Source: Poundstone, K. E.: The Social Epidemiology of HIV/AIDS. This model has been adapted for the purpose of this impact assessment.

Individual factors include biologic, demographic, and behavioural risk factors that may influence the risk of HIV acquisition and disease progression.

Social-level factors include four categories: social capital, cultural context, neighbourhood effects and social networks. These social-level factors are critical pathways by which community and network structures link persons to society and constitute central structures to understanding the diffusion and differential distribution of HIV/AIDS in population groups and subgroups. All categories may affect the health outcome in the direct and indirect way.

Social networks generating the quality, density and structure of relationships between persons as well as communities may, among others, influence the health outcome through prevalence of infectious disease and network member mixing, access to medications and information or social support and influence. In contrast, *social capital* may impact health through the presence of health-promoting behaviours, access to services and infrastructure and greater political participation. *Neighbourhood-level factors* shaping population HIV/AIDS patterns include mechanisms that increase either the probability of a person to get in touch with a HIV-positive or the population vulnerability to HIV/AIDS (high unemployment, exposure to poor socioeconomic conditions). *Cultural context* can be defined as a complex aggregation of knowledge, beliefs, art, law, morals, customs and other capabilities and habits that people acquire within society.

Structural-level factors include four categories relevant to HIV/AIDS epidemiology: structural violence and discrimination, legal structures, demographic change, the policy environment. These factors affect HIV transmission dynamics and the differential distribution of HIV/AIDS.

Structural violence is reflected in discrimination based on race and ethnicity/gender, sexual orientation and HIV status. The effects of *stigma, discrimination and collective denial* include individual reluctance to seek HIV testing and a lack of empowerment to enact HIV prevention. Given that stigma and discrimination play a crucial role in shaping responses to HIV/AIDS epidemics, relevant interventions to overcome these problems shall result from the diffusion theory of actions focused on social networks, opinion leaders and disease virus change. *Legal structures* concerning laws, institutions and practices may affect health in a direct way (i.e. legal restrictions on access to sterile injection) or in an indirect way (i.e. the effect of tax laws on income inequality). Law implications

highlight several major social determinants of HIV/AIDS such as poverty, racism, income inequality. *Demographic change* may impact HIV/AIDS through population mobility and migration, urbanisation and the age and gender of subpopulations that may be perceived as modifying interactions between susceptible and infected persons in populations. Structural-level *policies*, including macroeconomic policy, health and social policy as well as illicit drug control policy, play a crucial role in governing prevention, treatment and care, having impact on trends in the HIV/AIDS epidemics. Furthermore, policies that guide decisions about the allocation of resources in public and private sectors and the policy environment are essential in the emergence and control of HIV/AIDS epidemic.

This implies that a successful HIV/AIDS policy needs to be based on health-sector interventions for HIV/AIDS prevention, treatment and care including interventions based in individual and communities and health facilities, delivered through outreach to most at risk populations as well as EU wide measures for supporting service delivery.

All 27 EU Member States have already endorsed national HIV policies, strategies, laws or guidelines that focus on prevention, testing and treatment, some on laboratory and health systems, epidemiology, infrastructure or non-discrimination (see Annex 2). It is, however, important that action plans are fully comprehensive, adequately resourced and focused and are properly implemented, ensuring delivery of policy interventions that are physically accessible, publicly acceptable, affordable and of satisfactory quality. Therefore, the EU role, especially regarding the policies within structural determinants of the HIV/AIDS epidemiology is essential as a guiding and supporting institution, with a full respect of subsidiarity.

Box 1: ***Examples of HIV/AIDS interventions at national level***

Example from the EU: the German authorities, alarmed by increasing numbers of new infections since 2000/2001 concluded that new prevention campaigns are essential, as well as more support to civil society to reinforce targeted prevention among groups most at risk and young people. It is not yet determined whether reinforced prevention is the reason for the current halt in increase of new infection in Germany, but the trend has stabilised since 2008.

Example from a third country: Cambodia launched a 100% condom use programme in 1998, leading to a 96% rate of condom use among brothel-based sex-workers in 2003, from 42% in 1997. The result was a corresponding decline in HIV prevalence in sex workers from 42,6% in 1998 to 28,8% in 2002[17].

2.2. Social and economic burden of HIV/AIDS

While many people living with HIV/AIDS can now take up work and live more normal lives, the psycho-social burden of HIV infection remains significant and is further compounded by the potential social stigmatisation and discrimination which can affect many areas of life – family, work, education, travel, housing, insurance, finances, etc. PLWHA and immigrants being over proportionally affected by HIV/AIDS are often hardly accepted in a society, facing a problem of social exclusion.. HIV/AIDS as disease is more than a "medical problem", when compared to other chronic diseases. The HIV/AIDS-infected individuals are also faced with the social burden that derives from the change in dependency caused by death or illness of working-age persons. Consequently, loss of economically productive individual or a breadwinner due to the HIV/AIDS infection reduces the stock of skills and experience of the labour force. In other words significant losses in human capital constitute economic burden in terms of productivity loss and social exclusion.

[17] WHO – Towards universal access by 2010: how WHO is working with countries to scale up prevention treatment, care and support. 2006

Thus, social limitations are strongly interrelated and complementary to the economic burden of HIV/AIDS especially when formulating evidence-based policy and for decision-making. Examining economic burden of HIV/AIDS helps quantify the effect of the epidemic on populations and support policy-makers in allocating public and private health resources. The economic costs attributable to HIV/AIDS can be measured through direct and indirect costs of illness[18].

Direct costs represent the value of resources used for treatment and care of PLWHA, of which majority is spent on ART and also recently HAART[19] (a combination of antiretroviral drugs). Treatment based on provision of ART and HAART has proved to delay progression of the disease, increase the length and quality of life of HIV-infected patients, making HIV a chronic disease and not a death sentence, as well as to reduce the onward transmission of the virus and affect the epidemic's development. However, HIV/AIDS medication costs remain an important barrier to treatment. As it places a severe strain on health care budgets across Europe, levels of availability of treatment and care differs significantly by country and the geographical area (review sentence: strange causal link). **Estimated ARV costs in the EU are on average between 4.000 to 15.000 euro per year per patient** and ART represents a life-long regime[20]. EE, the country with the highest number of new infections per million inhabitants in Europe (two times higher ratio than Russia or Ukraine) spent ten times more (about 6M euro) for treatment in 2008 than in 2005 (0,64M euro), whereas the absolute number of new infections stabilised around 600 per year since 2005[21] which shows the delayed cost implications of prevention. Prospective budget planning is therefore important, but it has to include sufficient funding for prevention measures of new HIV infections. Yet ARV costs amount only to a fraction of total treatment and follow-up costs for care of people with progressing diseases.

Indirect costs, that can be significant in terms of e.g. reduced economic growth, loss of income, reduced incentives to invest or slower growing markets, represent productivity losses, measured with a use of two commonly known methods: human capital (basal health and stock of education and skills) and willingness to pay (WTP). The human capital method determines the production losses attributable to premature mortality and, because of limitations to estimate economic value of the future earnings produced for each of the potential years of life lost, is rather considered a lower bound to a person's willingness to pay for a decreased risk of death[22]. WTP approach, based on the welfarist economics, reflects the value of life and health at the individual level.

According to a 2006 study by the Kiel Institute for the World Economy, the aggregate individual welfare losses from HIV/AIDS would have a total welfare loss of around 16 % of the annual GDP in a region of 25 Eastern European countries over the seven years, between 1995 and 2001, hence an average of 2.2 % of GDP per year in that region of 25 countries[23]. However, the most affected by HIV/AIDS problematic countries (EE followed by LV and LT) would suffer the highest per capita welfare loss in that region. In terms of social welfare costs, given the diversity of the prevalence and incidence rates among countries, the highest losses would amount to more than 150% of GDP in EE, app. 100% of GDP in Russia, 43% of GDP in LV and 18% of GDP in Ukraine, Russia and Republic of Moldova). In contrast, in remaining EU member states under the study (BU, CZ, HU, PL, SK, SI, RO) **social welfare costs** would range between 0.1% and 2.6 % of GDP in SK and CZ respectively. The study shows that countries experiencing already quite a high degree of HIV/AIDS infection are particularly threatened by the further epidemics expansion and hence the greater size of the welfare losses.

The actual economic impact is also a matter of the respective economic strength, resources, health care and social budgets, level of industrial development, and measures in place to integrate PLWHA as

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[18] Terry A., Gregory W. (1998): The economic burden of HIV/AIDS in Canada. CPRN Study No H[2], Ottawa
[19] HAART stands for Highly Active Antiretroviral Therapy.
[20] PT for example spends half of its budget for medications for HIV and cancer regimes.
[21] ECDC epidemiology report 2007.
[22] Terry A., Gregory W. (1998): The economic burden of HIV/AIDS in Canada. CPRN Study No H[2], Ottawa
[23] Fimpel, J., Stolpe, M. (2006). The Welfare Costs of HIV/AIDS in Eastern Europe: An Empirical Assessment Using the Economic Value-of-Life;
http://siteresources.worldbank.org/INTUKRAINE/Resources/328335-1147812406770/ukr_aids_eng.pdf

much as possible into social and labour processes. Especially in the wake of the financial crisis when most economies in Europe are contracted facing with severe budget constraints, more attention shall be given to prevention and treatment however in view of a process of reprioritisation of HIV/AIDS programmes and reallocation of funding. Such balanced approach focused on HIV/AIDS program efficiency and effectiveness shall contribute to maintaining the economic growth in the long term and help reverse the size of welfare losses from HIV/AIDS epidemic that many of the European countries are expected to incur.

2.3. The first EU action plan 2006-2009

The EU launched a first European HIV/AIDS action plan in December 2005, which has been implemented from 2006 onwards and comes to an end in 2009.

The action plan served as the guiding document for funding through the Health Programmes and the Research Framework programmes (6^{th} and 7^{th}) and proposed about 50 different actions in the main three strands, sub-grouped in 7 chapters as follows:

(A) POLITICS, AWARNESS, CIVIL SOCIETY
(i) Leadership and advocacy
(ii) Involvement of civil society (iii) Neighbourhood countries

(B) SURVEILLANCE, RESEARCH and MEDICINE
(iv) Surveillance
(v) Treatment care and support
(vi) Research

(C) PREVENTION
(vii) Prevention of new infections

Key developments and achievements of the Action Plan have been realised in terms of **EU policies and actions, Health Programme and 7th Framework Research Programme as well as actions at MS level and by stakeholders, ensuring coordination** among major stakeholders over the last years. Commission services have regularly monitored progress in implementation and have reviewed actions taken under the Action Plan in collaboration with Member States, international organisations and stakeholders.

EU Member States authorities and ministries, in particular EU Presidencies, the European Centre for Disease Control and Prevention (ECDC) and the Executive Agency for Health and Consumers (EAHC, the Agency), European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), multiple NGOs and networks, academic organisations, international organisations like WHO Europe or UNAIDS and business operators contributed to the realisation of activities set out in the first Action Plan. Funding priorities for HIV/AIDS defined in the annual work programmes of the Public Health Programme followed Action Plan priorities. The Commission, in the framework of the European Heath programme (2003-2008) and second Health Programme (2008-2013) co-funded numerous projects, amounted to over 30M Euros. A detailed description of projects and the EC co-funding for HIV/AIDS is attached to this impact assessment (Annex 3).

The first Action Plan was successful in increasing the political commitment of European leaders to keep HIV/AIDS on their agenda and empowering civil society in the European Union

Reaching a high level of **political leadership and involvement of civil society** may be perceived the most prominent achievement because without the political will to address HIV/AIDS neither prevention nor treatment is accessible in a specific country. While the impact of activities focusing on surveillance, research and medicine can be measured, since specific results are obtained that correspond to the expectations or not, the influence of political leadership is more difficult to describe, but it may be concluded that raising awareness and keeping a particular item high on the political agenda has a political impact. This may be reflected in identifying HIV/AIDS as a priority and addressing the problematic by several EU presidencies (Germany, Portugal, France), the emergence of new national HIV/AIDS policies and strategies, or in taking up HIV/AIDS issues in the bilateral

agreement on health with the Russian Federation. Therefore, political support for future investments and efforts (surveillance, prevention, services) should be continued in particular to reach the main drivers of epidemics.

The **empowerment of Civil Society** through partnership and operational grants allowed to improve both fields in which gaps have been identified, namely the advocacy for human rights and the training of the rather weak NGOs in the Eastern European neighbouring countries for example through twinning projects.

Certain progress has been made in improving **surveillance** due to relatively effective coordination role of the ECDC, which continues to realize remaining projects set in the Action Plan through its work programme, particularly with a focus on developing behavioural data collection, setting up sentinel surveillance and improving country data reporting.

In the Action Plan, the Commission has institutionalised a fully operational **surveillance system** for HIV/AIDS, and expanded the knowledge base on important HIV issues through programmes realised by ECDC. In order to enable the ECDC to deliver more comprehensive data all MSs are to be fully involved in reporting data to the ECDC surveillance system.

Within **the treatment, care and support** block, planned actions have been only partially implemented. Feasible outcomes are observed in improving access to treatment and care services through realizing projects focused on the capacity building, trainings of health professionals or promotion campaigns, and availability of ARV (successful price reduction in Bulgaria). However, comprehensive addressing all needs for treatment and care was limited partly due to Member States responsibility for treatment and the curricula of universities and training obligations.

Research priorities have been realised in terms of the establishment of networks for treatment, prevention and vaccine and microbicides research, however tangible outcomes outcomes with a public health relevance especially in the field of the development of new vaccines and microbicides have not been achieved. Nevertheless, in the framework of research investments on HIV/AIDS, an RTD conference on poverty-related diseases in November 2008 was organized that enabled to identify major research needs necessary for the future (i.e. discovery and development of new affordable medicines for HIV/AIDS, malaria and TB and effective measures to control these diseases).

Regarding **prevention activities**, a number of training projects have been implemented especially focused on HIV transmission prevention, receiving the biggest part of financial funding of HIV/AIDS projects from the Health Programme. However, prevention strategies in terms of public awareness and education have not been extensively tackled, as anticipated in the Action Plan. Given that new generation are growing and new challenges have to be addressed, prevention has to be an essential activity and the priority with targeted needs for future promotion.

Less direct success is observed in the fields of actions on **neighbourhood policies**, majority of which have only started. As the epidemic is regionally expressed at different levels, present and future efforts on a European level have to concentrate on particular regions of the EU - mostly affected by HIV/AIDS, i.e. those in Eastern Europe, including the cross-border cooperation with the eastern partners that have proved to threaten the serious spread of the HIV/AIDS infections in the EU MSs Regions where HIV/AIDS is still progressing shall be given greater attention, support and cooperation in order to enable them to implement effective measures towards containing the epidemics.

More detailed evaluation of the Action Plan, including a state of implementation of the specific actions, main achievements and lessons learned is presented in Annex 4, attached to this report.

2.4. Funding resources

2.4.1. *Health Programmes*

The Commission has been running programmes to address HIV/AIDS and communicable diseases since the 1990s and provides budgetary support through its Health Programmes (HP) to support projects to combat HIV/AIDS in Europe. The Health Programme (HP) provided the means to realise projects touching on commitments specified in the current action plan and from 2003 to 2008 funded

28 projects focusing on prevention of new HIV infections with 15,4 million euro. A more extensive description of achievements through HP funded projects, prepared by the Executive Agency for Health and Consumers, is attached to this report as Annex 2.

2.4.2. *Research Framework Programmes*

The Commission's Research Framework Programmes also provide support for projects in the field of HIV/AIDS research.

Research on HIV/AIDS was a top priority under the 5th, 6th EU Research Framework Programme (FP) and is continued under the 7th Research Framework Programme (2007-2013). This priority is closely related to the priority for external and development policies.

During the 6th FP the Commission has re-structured the European HIV/AIDS research field with a multifaceted approach, supporting basic as well as translational research for a broad range of vaccine and drug candidates. In addition, it has been financing research on microbicides, continuing the support of cohort studies which provide follow-up and guidelines for treatment to European patients (including MTCT and children), and creating two big Networks of Excellence (NoE) on prevention and on treatment involving most of the main European research centres in the field. The budget allocated to HIV/AIDS research in the 6th FP was about 126 million euro (of which 50% on prevention and 50% on treatment).

In the 7th FP the Commission is pursuing the research priorities started earlier aiming at improving research concerning the prevention of future infections and the treatment of people currently living with HIV/AIDS. Until now around 75 mln euro has been invested in research projects that will address the development of new HIV vaccines, microbicides, drugs and therapeutic options, as well as HIV/AIDS drug resistance.

A call for a Network of Excellence (NoE) on cohort studies (seroconversion, MTCT, infected children and adults) has been launched in 2009. The grouping of all main European cohorts under a single NoE will allow construction of larger multi-cohort collaborations offering more robust prevention and treatment guidelines and a better public health impact.

Furthermore, in order to promote coordination of European national research programmes on preclinical and translational research against HIV/AIDS a call on HIV ERA-NET was launched in 2008 involving funding institutions from Member States.

2.5. Fundamental Rights and equal treatment in employment and occupation

Taking action at EU level in the areas covered by the Communication would have a favourable impact on a number of rights recognised in the European Convention on Human Rights, the UN Convention on the Rights of the Child and the EU Charter of Fundamental Rights, in particular the right to health care (Article 35 of the Charter), rights of the child (Article 24), the right not to be discriminated against (Article 21), the right to respect for private and family life (Article 7) and the right to the protection of personal data (Article 8).

In 2000 the European Union adopted Directive 2000/78/EC establishing a general framework for equal treatment in employment and occupation. This Directive aims at prohibiting discrimination on the grounds of religion or belief, disability, age or sexual orientation as regards employment and occupation. It is based on Article 13 of the EC Treaty, which grants the European Union powers to take appropriate action to combat discrimination based on those four grounds, as well as on sex and racial or ethnic origin.

In the case Chacón Navas[24], the European Court of Justice (ECJ) held that "sickness cannot as such be regarded as a ground in addition to those in relation to which Directive 2000/78 prohibits discrimination."

24 C 13/05 Chacón Navas v. Eurest Colectividades - (Directive 2000/87/EC Equal treatment in employment and occupation)

This Directive does not provide for a definition of disability. The ECJ held that as regards employment and occupation, the concept of 'disability' mentioned in the Directive must be understood as referring to "a limitation which results in particular from physical, mental or psychological impairments and which hinders the participation of the person concerned in professional life". In conclusion, HIV infected people are protected by Directive 2000/78/EC insomuch as they have a disability.

2.6. External policy dimension

At the international level, the Commission works with Member States in the framework of "***A European Programme for Action to confront HIV/AIDS, Malaria and Tuberculosis through External Action (2007-2011)***" and the United Nations Convention on the Rights of the Child and HIV/AIDS with its commitments to the right to life, survival and development and the right to non – discrimination. The Programme for Action covers external action related to developing and middle-income countries and hence is a complementary document to the *"Communication on Combating HIV/AIDS in Europe and the Neighbouring Countries 2006 - 2009*". The programme Action is focused on global action in areas where the EU can add value such as research on new tools and technologies, access to safe and affordable medicines and human resources for health.

In the framework of ***the Programme for Action***, the Commission finances HIV/AIDS responses in developing countries through an annual contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFTAM, the Global Fund) that in 2008 amounted to 137 mln US$. The EU and Members States collective contributions (half from the budget and half from the EDF) to the Global Fund have almost quadrupled, from a total of US$ 403 million in 2003 to US$ 1.546 million in 2008, representing around 55% of total contributions in the years 2004-2008.

In the period 2007-2011, the Commission's support, covered by the Programme for Action, to strengthen health systems and confront communicable diseases, including HIV/AIDS, also in the context of MDGs, has been realized due to a financial instrument ***Official development Assistance (ODA)*** that financing earmarked for health estimated to total 3.043 euro. This financing includes support for research and technological development, where more than 200 million euro has already been allocated in the *7th Research Framework Programme (2007-2013)* specifically for research on the three diseases.

Under the umbrella of the ***European Neighbourhood Policy (ENP)*** the Commission seeks to address HIV/AIDS as public health concern in agreements with third countries[25] where the HIV/AIDS problematic is severe (e.g. Ukraine, Republic of Moldova). Health dialogue with partners has been stepped up over the past years on the basis of the bilateral agreements with partner countries and ENP Action Plans, covering a host of subjects such as health policy and communicable diseases including HIV/AIDS and tuberculosis. HIV/AIDS related actions are realised within the *Communication on Combating HIV/AIDS in Europe and the Neighbouring Countries 2006 – 2009*.

In the framework of development of new tools and interventions for the three diseases the Commission has created ***the European and Developing Countries Clinical Trials Partnership (EDCTP)*** and ***the Alliance of ESTHER*** - 'Network for Therapeutic Solidarity in Hospitals against AIDS' that represent innovative approaches seeking to involve a large number of research and health institutions and civil society organisations in Member States and partner countries in capacity building through twinning programmes and networking.

The EDCTP was established in June 2003 to tackle the challenge of an increased prevalence of HIV and other poverty-related diseases infections resulting from the lack of adequate preventive and therapeutic tool. The strategic objectives of the EU intervention were to (1) develop new interventions and products against poverty-related diseases; (2) build sustainable public health and research capacity in Africa; (3) coordinate European Member States' research policies. Since its inception, the EDCTP Programme has financed around 145 projects for over 100 mln euro, including 42 clinical trials. This

[25] The ENP applies to the EU's immediate neighbours by land or sea – Morocco, Algeria, Tunisia, Egypt, Jordan, Lebanon, Syria, Israel, Occupied Palestinian Territories, Ukraine, Republic of Moldova, Armenia, Georgia, Azerbaijan, as well as Belarus and Libya.

network, although its prime focus is sub-Saharan Africa, has major implications on European HIV/AIDS research.

The Alliance of ESTHER's objective is to implement capacity building activities developing twinnings between hospitals and health structures in the developing countries, in order to provide comprehensive and quality treatment (assurance of ART) and care for people living with HIV/AIDS. In years 2002-2008, more than 120 hospital twinnings have been launched from in about 40 developing countries allowing the implementation of a wide range of activities (i.e. prevention of MTCT, paediatric care, equipment, psychosocial activities, operational research, monitoring and evaluation, technical assistance at country level, strong involvement in University diplomas, networking with civil society, PPPs).

Regarding ***the Central Asian countries*** that experience high levels of economic migration, with attendant vulnerability to HIV transmission and are in the early stages of drug injection-associated epidemics of HIV infection, set against a background of high rates of sexually transmitted diseases and poor access to ARV treatment, the Commission provides financial support for different projects implemented by NGOs in the fight against HIV/AIDS in Central Asia countries, as well as a specific programme – Central Asia Drug Action Programme (CADAP) to prevent drugs consumption and enhance treatment of addicted people. CADAP is financed by the EU and implemented by UNDP.

Considering HIV/AIDS a cross cutting priority, the EU tries to reflect the HIV/AIDS related problems in all areas of development cooperation, in collaboration with, among others, WHO, UNAIDS, UNICEF, UN or G8.

3. PROBLEM DEFINITION

Against the background of the epidemiological trends of both HIV prevalence and new infections (as shown above), the identification of the root causes and determinants of the HIV/AIDS epidemic, the preliminary assessment of the Commission Action Plan 2006-2009, as well as the outcome of the stakeholders consultations, the following issues can be identified:

3.1. Political commitments have not been achieved

While many political commitments agreed by Member States and the Commission were expressed in the Dublin[26], Vilnius[27] (2004) and Bremen[28] ministerial declarations (2007), or the Health Council conclusions of May 2007, not all of them are yet fully realised, and the international community, including the EU is still behind agreed targets and realisable goals, such as universal access to prevention, treatment, care and support, or the involvement of civil society in policy development, implementation and monitoring. The EU declarations translate internationally agreed commitments and principles expressed in UNGASS HIV/AIDS declaration of 2001[29] as well as the UNAIDS 'Three Ones' key principles[30]., endorsed in 2004, for coordination of national responses to HIV/AIDS All declarations stress the need for collective action to tackle HIV/AIDS through a deepening of coordination, cooperation and partnership within and between countries, which are "encouraged (…) to strengthen the capacity of the European Union to fight effectively against the spread of HIV/AIDS". These declarations promote the **active involvement of the institutions** of the European Union to **fund**, improve, and harmonise **surveillance systems**.

[26] http://www.sante.gouv.fr/htm/actu/europe_sante/sida/declaration_dublin.pdf
[27] http://ec.europa.eu/health/ph_threats/com/aids/docs/ev_20040916_rd03_en.pdf
[28] http://www.eu2007.de/en/News/download_docs/Maerz/0312-BSGV/070Bremen.pdf
[29] http://data.unaids.org/publications/irc-pub03/aidsdeclaration_en.pdf
[30] These are guiding principles, agreed on 25 April 2004, for national authorities and their partners, endorsed to achieve the most effective and efficient use of resources, and to ensure rapid action and results-based 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.

Box 2: **Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia**

Date of signature: 24 February 2004

Signatories: 53 Members of the WHO European Region plus invited observers, including the European Commission

It sets out **33 actions for governments** to undertake as related to ***leadership***, ***prevention***, ***living with HIV*** (including treatment and care) and ***partnership*** in the 53 countries of the WHO European Region, among those several commit to meeting specific targets:

Action 8: ***by 2005 at least 90% of young men and women aged 15-24*** have access to the information, education and services necessary to develop the life skills required to reduce their vulnerability to HIV infection.

Action 9: ***by 2010 80% of the persons*** at the highest risk of and most vulnerable to HIV/AIDS are covered by a wide range of prevention programmes, including intensified cross-border collaboration, sharing best practices.

Action 12: ***by 2010 less than 2% of all new infections*** are required ***by an infant from its infected mother*** in Europe and central Asia.

Action 14: ***by 2005 national and regional strategies and programmes*** targeted to ***women and adolescent girls*** are developed.

Action 21: ***by 2005 universal access*** to effective, affordable and equitable prevention, treatment and care is provided, including ART.

The **outcome of the 'Progress report...'** implies several **present and future imperatives for HIV efforts** in the European region, such as:

• a need for ***greater accountability***;
• ***amending legal and regulatory frameworks*** as to better address ***HIV-related stigma, exclusion and discrimination***;
• ***strengthening*** national and regional ***HIV and STI surveillance***;
• ***improving*** and ***harmonizing monitoring and evaluation efforts***, including greater disaggregation of data for key indicators;
• ***intensifying, scaling up and improving the targeting of HIV efforts*** to reduce inequities;
• a need for greater ***harmonization of prevention and treatment*** programmes and policies;
• ***increasing civil society and private sector involvement***

Box 3: **Vilnius Declaration on Measures to Strengthen Responses to HIV/AIDS in the European Union and in Neighbouring Countries**

Date of signature: 17 September 2004

Signatories: Health ministers from the EU and neighbouring countries and international partners plus a Member of the European Commission

The declaration endorsed a roadmap for tackling HIV epidemic in the EU and its neighbourhood, stating involvement of national governments, civil society and NGO-s, as well international partners in activities fighting against the HIV/AIDS epidemic, in line with the actions set out in the Dublin declaration.

Commission commitments:

- more ***research and development activities***, including raising funding, investing in new preventive technologies, promoting the participation of new MSs and neighbouring countries;
- better ***surveillance systems***, in view of behavioural and social data access;
- facilitating cooperation and networking on HIV/AIDS;
- supporting the ***development of health care infrastructures for HIV/AID***S related purposes;
- establishing ***fora and mechanisms***, including the involvement of civil society and PLWHA for assessment of progress.

EU MSs commitments:

- promoting the fight against the epidemic recognizing the fundamental factors of equality;

- addressing ***the vulnerability of particular groups of people*** as well as ***the specific needs of immigrants***;
- working progressively on ***the behavioural and epidemiological data collection*** in line with adequate and comprehensive national surveillance, monitoring and evaluation systems;
- providing ***universal, affordable, non-judgmental and non-discriminating access to prevention, care and treatment*** (i.e. voluntary and confidential counselling and testing, ART and harm reduction measures);
- developing new preventive technologies and reinforcing targeted education efforts;
- developing and implementing ***relevant regulatory frameworks*** with regard to non-discrimination, social inclusion, protection of human rights.

Box 4: **Bremen Declaration on Responsibility and Partnership – Together Against HIV/AIDS**

Under **German Presidency**

Date of signature: 13 March 2007

Signatories: Health Ministers and representatives of Governments from the EU and neighbouring countries and international partners in the field of HIV/AIDS and the European Commission

Commission commitments:

- implementing the action plan, highlighting HIV/AIDS prevention, treatment , care and support
- ensuring the FP7 provides sufficient funding for HIV/AIDS projects and programmes
- promoting exchange of best prevention practices by ***setting up a clearing house for models of good practice***;
- involving ***civil society in twinning projects***
- initiating ***the extension of the Council regulation 953/2003 to countries in need of price reduced drugs for PLWHA***

EU MSs commitments:

- fully implementing the UNGASS Declaration of Commitment on HIV/AIDS 'Global crisis – global action' (2001) and 'Political Declaration on HIV/AIDS (2006);
- involvement in facilitating inclusive country-driven processes of scaling up HIV prevention, treatment, care and support (in line with UNGAR, 2005);
- providing the political leadership at all levels to fight against the epidemic and exchange of best practices on the prevention of HIV/AIDS and STIs;
- respecting human rights, especially addressing stigma and discrimination;
- promoting ***universal access to evidence-based prevention***;
- reducing MTCT of HIV and promoting comprehensive sexuality education, counselling and services on/for HIV/AIDS;
- involving civil society and other international and national partners;
- increasing research and development activities for new preventive technologies
- cooperating with regard to affordable medication access

Most MSs fulfil the declarations commitments when implementing the relevant strategies, framework legislation or policies regarding HIV/AIDS related issues; however a degree and extent of compliance differ from country to country.

While there are many commitments solemnly adopted by Member States, there has not always been adequate monitoring of their implementation. The report on "Progress on implementing the Dublin Declaration on Partnership to Fight HIV/AIDS in Europe and Central Asia[31]", published in 2008 by UNAIDS and WHO/Europe has provided a descriptive view of the implementation of the Dublin Declaration. However, no comprehensive monitoring framework based on indicators against which the implementation of Dublin commitments as the most comprehensive document could be monitored, has yet been developed.

Box 5: **Example of Action Plan 2006-2009's unachieved action**

[31] http://europeandcis.undp.org/hivaids/show/799D79A1-F203-1EE9-B241692C98378A9F

Analysing Action 21 (universal access to effective, affordable and equitable prevention, treatment and care, including ARV) it has to be admitted that not everybody has access to effective prevention even in the EU where social systems are strong and well developed. Many people - present late for testing and hence receive treatment only late.. One measure to improve the access to prevention, testing, treatment, care and support would be to improve that the information is available for everybody including immigrants.

3.2. Data gaps in the centralised EU monitoring and reporting system

Much progress has been made since the ECDC started its surveillance work on HIV/AIDS, which became fully operational only in 2008 though. However, still not all MSs (missing: IT[32], ES) and Eastern countries (Russia, Ukraine) have consistently reported data to EuroHIV/ now ECDC and will until remedied undermine, EU level surveillance. Given the differences in national surveillance and reporting systems, the quality and coverage of 'data source' are not always consistent, and therefore interpretation and cross-country comparisons still have to be made with caution as the amount of under-diagnosis and under-reporting differs across countries. Thus, in order to obtain a complete picture of HIV/AIDS epidemic in Europe, the HIV/AIDS surveillance in the European region, particularly in EU/EFTA, needs to be strengthened with respect to completeness, comparability and compatibility, and quality of data. The ECDC also experiences problems with data availability on the nature of the epidemic, migration in terms of access to testing, treatment and care, or infection and resistance patterns (and genotypes) across Europe.

A future focus for EU level surveillance could be the cross-border dimension of HIV infections on which currently only piecemeal data is available, but which is expected to raise in importance along with increased mobility of people. Overcoming these data gaps would enable policy-makers to develop a comprehensive understanding of the drivers of the epidemic and therefore to develop and implement fully adequate policy responses.

3.3. Imperfect prevention and treatment activities and potentially diminishing health budgets

A large number of PLWHA have not been diagnosed yet in Europe. It is estimated that between 15% in Sweden to 32% in the UK and 60% in Poland of people, infected with HIV, have not yet been diagnosed and hence are not aware of their status. There is therefore a need to improve the effectiveness of **prevention** strategies[33]. The provision of **counselling and voluntary testing** is, more specifically, an important instrument of HIV prevention as it is beneficial, both for the person concerned, and for society. Recent literature concluded that "new sexual HIV transmission could be reduced by 30% if all persons already infected learn about their HIV status …" and "estimated transmission is 3,5 times higher among persons who are unaware of their infection than among persons who are aware of their infection"[34]. But it requires functional infrastructures and access to counselling and testing, implemented according to internationally agreed principles, which is not yet the case in all settings across Europe.

In addition to this, HIV/AIDS is a disease, which mostly affects **specific groups** of the populations, e.g. injecting drug users, MSM, and immigrants, in particular those from high prevalence regions. In order to effectively reach these populations most at risk, HIV/AIDS policies have to be targeted towards these specific groups and adapted to the specific problems they are confronted with (e.g. discrimination and stigmatisation, the social situation).

32 Since 2009 the notification of new cases of HIV infections has been compulsory in Italy, thus their national data are expected to be included in the next year's data collection.

33 Prevention encompasses different methods and dimensions: personal information and counselling, targeted information for vulnerable groups, the availability of testing facilities, and structural prevention which addresses the social and political environment of vulnerable people such as poverty and discrimination but also factors influencing behaviours e.g. availability of information, condoms and sterile syringes.

34 Marks et al., AIDS, 2006.

Between the year 2000 and 2006 the number of new HIV infections among **MSM** nearly doubled based on an analysis of figures from 23 countries in Europe[35]. For instance, in the UK, cases increased by 91%, and the number of annual diagnoses more than doubled in several countries, including Finland, Germany and Norway.

IDUs represent the most serious risk population for HIV/AIDS in Eastern Europe with the highest rate of new HIV cases. In countries like EE, LV or Ukraine, the group of IDU has a HIV prevalence of 60% or more, that significantly increases the risk of infecting their sexual partners.

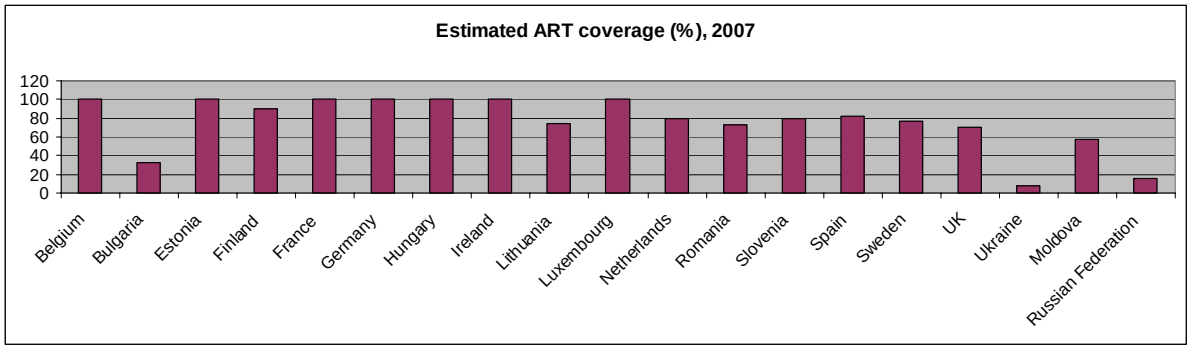
Immigrants, both documented and undocumented, also represent an increasingly important share of people potentially infected by heterosexual transmission, which often occurred already in their country of origin. Often faced with severe economic, social and cultural problems and difficulties to access health services, they hardly reach prevention and treatment and at the same time are particularly vulnerable to HIV/AIDS.

NGOs can be helpful in bringing them closer to medical services but in certain MSs, the involvement of civil society in the design and implementation of HIV/AIDS policies has not always been secured due to low political support for NGOs.

According to UNAIDS[36], many countries in Europe have already adopted different policies or strategies to promote **HIV prevention**. However, translating these strategies into a prioritised set of interventions based on evidence of impact has proved difficult and certain difficulties have been encountered to bring to scale prevention services for populations at higher risk of HIV exposure.

Commitments have been undertaken towards universal access to testing and treatment coverage across Europe and the neighbourhood, initially targeted for 2010 (MDG 6, UNGASS 2001, Dublin 2004 commitments). However, **access to treatment**, in particular antiretroviral treatment still varies across Europe[37]. As shown, among reporting selected MSs[38] in 2007 from 8% to 100% people with HIV infections received ARV treatment, with an exception of BU where the percentage of ART coverage accounted for 33%[39]. The lowest coverage of ARV treatment, however, is observed in the neighbouring countries, with Ukraine accounting only for 8%.

Figure 6: Estimated coverage of antiretroviral treatment in selected MSs and neighbouring countries.



Source: UNAIDS

Note: Data not available for: AT, CY, CZ, DK, EL, It, LV, MT, PL, PT
EE - the costs cover those receiving therapy; FI – number shown relates to coverage for adults and children, as for pregnant women it is 95%; RO – according to UNGASS estimation coverage accounts for 100%.

35 Likatavicius G et al. An increase in newly diagnosed HIV cases reported among men who have sex with men in Europe, 2000–6: implications for a European public health strategy. Sexually Transmitted Infections 84: 499-505, 2008.
36 UNGASS Country Progress Reports, 2008
37 Costs for antiretroviral HIV treatment and treatment of AIDS related symptoms can be significant, knowing that ARV costs only amount to a fraction of total treatment and follow-up costs for care of people with progressing disease.
38 BE, BU, EE, FI, FR, DE, HU, IE, LT, LU, NL, RO, SI, ES, SE, UK
39 Source: UNAIDS,

The changing character of the disease from a deadly threat to a chronic condition implies a need to review policies and strategies. As HIV/AIDS places a severe strain on health care budgets across Europe, it will be indispensable for MSs to reflect on how to ensure the sustainability of healthcare budgets as stated in the Lisbon reform agenda. The challenge is even bigger in the wake of the current financial and economic crisis that has hit public finances of most EU MSs, with a budget deficit set to more than double in 2009[40]. In response to the fiscal and budget threats, governments are more inclined to compress public resources, especially through cuts within health care allocations[41], risking an insufficient delivery of critical health services, including HIV/AIDS related treatment and care and programmes. This is also worrying concerning prevention programmes, which are particularly exposed to cuts in the health budget. Thus, a role of the EU would be to make national governments aware of the importance of communicable diseases actions, and encourage them for prioritisation of the public health spending with a special focus on the vulnerable groups and preventive health services.

3.4. Persisting knowledge gaps

As explained above, many research activities have already been carried out, at both national and EU level, in a wide range of fields. However, these research activities have so far not closed the knowledge gaps in certain fields, such as:

(i) Social science with particular regard to the behavioural aspects of the transmission of HIV. Research in this field appears necessary to better map and to understand the drivers of the epidemics, and the ways to address these drivers in a targeted manner. This research would also feed into ECDC activities.

(ii) Socio-economic analysis, to improve understanding of the cost effectiveness of prevention and the economic and social implications of the new trends,

(iii) The development and implementation of novel prevention technologies,

(iv) The cross-border dimension of the disease in EU and neighbouring countries (infections of non-residents, immigrants from third countries etc.)

(v) More intensified biomedical research on the HIV virus remains necessary to develop biomedical solutions, as until now it has developed neither a cure nor a vaccine. . Despite relevant investments into the research of vaccines and microbicides, continued cost intensive efforts are required to develop safe and efficient preventive vaccines and microbicides.

3.5. Worrying trends in several Eastern European countries

As already shown, the situation in several Eastern neighbouring countries is particularly worrying. Today, Eastern Europe (Baltic Member States, Ukraine, Republic of Moldova, Belarus, the Russian Federation) is one of the regions in the world with the fastest spread of HIV that calls for a prompt action in order to avoid a more generalised epidemic along the EU's borders. Cross-border movements are to a certain extent relevant to the spread of HIV (e.g. including[42], labour movement, sex tourism). Also, in this region, HIV often comes along with a high degree of co-infections such as (multi-drug resistant) tuberculosis or hepatitis B and C, diseases which are communicable.

Box 6: **Example of HIV/AIDS problematic in one of the Eastern neighbouring countries - Ukraine**

[40] 10133/1/09

41 According to OECD report 'Health and the economic crisis' (July 2009), the greater proportion of public expenditure goes to health services, public health allocations are more likely to decrease. This is the case for majority of MSs that government health expenditure as a %of total public spending accounts to between 10% and 23%, and as a percent to GDP to between 21% and 57%.

[42] Paraskevis, D. et al. Tracing the HIV-1 subtype B mobility in Europe: a phylogeographic approach. Retrovirology, 2009.

Ukraine is suffering a steady increase in new infections, in particular among IDU. With a total population of 46 million, about 0,44 (0,34-0,54) mln people already live with HIV/AIDS. More than 13000 people become infected every year, and the antiretroviral treatment coverage reaches only about 8 (7-11) % of people in need.

Despite a new governmental AIDS Concept and Programme for the period 2009-2013, based on the results and recommendations of the external evaluation of the recent National AIDS Programme, which was conducted in 2007, UNAIDS still sees large challenges in the response to HIV/AIDS in Ukraine, that are, among others:

- a scale-up substitution maintenance therapy for IDU to prevent the transmission of HIV and to promote compliance with antiretroviral therapy among opiod addicted patients with advanced HIV infection.
- a lack of adequate funding to scale-up and sustain HIV/AIDS programmes and activities. While there has been
- a significant increase in funding for HIV/AIDS in recent years, the overall needs to scale-up prevention, treatment, care and support programmes still exceeds available resources.

In 2007, of about 5200 pregnant women living with HIV, only an estimated 58% received antiretroviral treatment to prevent mother to child transmission (UNAIDS).

At the Think Tank meeting in March 2009, UNICEF strongly expressed its concerns about a large number of street kids in Ukraine, many of whom use drugs and risk HIV infections, or are already infected.

First actions have been undertaken as foreseen in the action plan from 2006-2009. As the main course of infection in the ENP is drug injection HIV /AIDS affects people who are not a priority group for the government. Some Member States, UNAIDS, WHO and the GFATM have worked since the beginning of the epidemics to convince the governments of the need to tackle the disease. However, this requires a change of attitudes which is a long term process. It is not facilitated by the present crisis. Health systems are not well equipped, the government changed frequently, prevention through information is a completely new concept as compared to the prevailing repressive epidemic control approach and NGOs did not have a voice neither in the development of policy nor in the implementation. The latter has changed especially through the GFATM, that entrusted the distribution of ARV to NGOs after the government had failed to deliver.

In this situation the few projects funded by the EU were a beginning. The inclusion of government representatives in the Think Tank and of civil society organisation into the civil society forum was an important step. These are fora where open discussions take place and prevailing perceptions can be challenged. While the Ukrainian NGOs took part in both Think Tank and civil society meetings the Ukrainian government that was invited to present did not attend the meeting. Integrating NGOs and the governments of the ENP into EU's mechanisms to exchange good practices is paramount to support the design and implementation of national HIV/AIDS policies.

It would furthermore be important to involve this region more in the surveillance work carried out by ECDC, and to harmonise systems of monitoring and reporting.

In summary, many reports from various organisations on countries in the East underline that political will has improved over the years, but much needs to be done. And therefore, cooperation at European level, using all existing approaches, including external relations instruments, is needed to contribute to an improvement of the situation.

The situation in the Southern neighbouring countries is different. Here, human rights issues are more a matter of concern, and are therefore vigorously observed by the Think Tank and particularly by the Civil Society Forum. One organisation from Morocco is currently a member of this group and actively providing first hand information as the EC delegations in these countries do. It should be noted that Commission addresses its HIV/AIDS policy to all ENP countries but data suggest that a focus on Eastern countries is most needed in view of the development of the epidemic.

4. THE RATIONALE FOR EUROPEAN ACTION

Addressing the HIV/AIDS challenge at EU level would take place in the context of the overall health and social policy orientation. Embedded in the EU health strategy (2008), a second HIV/AIDS initiative would respond to political commitments taken by the European Union and its Member States

and specifically by the Commission, as e.g. expressed in the Dublin, Vilnius (2004) and Bremen ministerial declarations (2007). The Health Council conclusions of May 2007, and the European Parliament's reports on HIV/AIDS of April 2007 and of November 2008 underline the broad political support and commitment to EU action in this field. Tackling HIV/AIDS is fully in line with the renewed EU Sustainable Development Strategy[43]. The EU Health Programme[44] continues to provide financial support for EU action in Member States and additional eligible countries.

HIV/AIDS has changed its character from an immediate threat of death to a chronic disease. When diagnosed and treated early, PLWHA in Europe have a longer life expectancy and a higher quality of life compared to when treatment did not exist. While condoms remain the best way of preventing HIV, new modes of prevention are discussed and available. They raise new questions and require new answers. While there is on the one hand, a need for the continuity of promoting prevention there is a need on the other hand for new strategies on how to best approach PLWHA and people at risk with prevention messages and treatment options. Fears in society of working together and living together with PLWHA have to be addressed.

4.1. Subsidiarity

The EU Member States and the neighbouring countries have the prime responsibility for protecting and improving the health of their citizens. As part of that responsibility, it is for the countries to decide on the organisation and delivery of health services to patients, or on the delivery of prevention means to protect their citizens from avoidable health challenges.

However, Article 152 of the Treaty explicitly acknowledges that the EU has a role in addressing health issues in support of Member States: "Community action, which shall complement national policies, shall be directed towards preventing human illness and diseases, and obviating sources of danger to human health". This is in particular relevant for communicable diseases, which do not halt at national borders. Article 152 EC also calls for ensuring a high level of human protection in the definition and implementation of all Community policy and activities. In this respect, Community activities in other fields like research, education and youth, external relations, social and labour policy, migration of third country nationals are relevant to HIV/AIDS related aspects and actions.

4.2. Necessity Test

HIV/AIDS is a communicable disease and can only be addressed when national governments coordinate their efforts. This is obvious when considering population flows. Free movement of persons is one of the key political pillars of the European Union. People cross borders for various reasons such as work, travels, etc. There is also a constant flow of people to and from third countries. Cross-border movements are to a certain extent relevant for the spread of HIV (e.g. including sex tourism of sex workers and their clients[45]). We do not yet have a total overview of the cross-border dimension of HIV/AIDS for all EU MSs, but can refer to various studies. The 2006 study of the Kiel Institute for the World Economy indicated cross border infections at least for a few countries and found out that e.g. in Cyprus most HIV infections occurred in non-permanent residents and that in Croatia 90% of men were infected outside the country.

An estimated total of 64 million migrants from third countries currently live in the EU. Although there is an enormous diversity in the proportion of migrants with HIV infection in the different countries, immigrants in the EU have a relevant share (up to 50%) of new heterosexually transmitted HIV infections. As this group is also at risk of social exclusion, they often experience difficulties in accessing diagnosis, prevention, treatment and care.

The European Union needs a harmonised surveillance system in order to follow the infection trends and assist Member States in taking adequate public health measures, arising e.g. from mobility and

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[43] 10917/06

[44] According to the EU Health Strategy (COM(2007)630), the general objective stipulated in article 152 of the EC treaty was extended, including problems and solutions across borders, through the coordinated approach to combat HIV/AIDS in the EU and neighbourhood countries.

45 Sex work, HIV/AIDS and human rights in Central and Eastern Europe and central Asia, CEEHRN, 2005.

migration. Given the frequent cross-border movements within the EU, it is necessary that all MSs contribute to the reporting of HIV infections, should the surveillance system be reliable.

The EU needs to continue to pursue a common research agenda and to exploit economies of scale from joint efforts at EU level and between public and private research. As has already been demonstrated, the latter is today already centralised by a few private players at EU level and has thus long transcended national boundaries.

It is finally in the interest of the European Union to include the neighbouring countries in the response to HIV because there are frequent movements of persons across the borders. An effective response to HIV/AIDS cannot be limited to the national territory as the virus spreads from one country to the other in an area of open borders, mobility of workers and a great deal of tourism including sex tourism[46] as a recent study on the phylogeny of different HIV subtypes suggests. Cooperation at European level could contribute to supplement multilateral and bilateral cooperation, which could suffer from the current economic crisis and potential reduction of the resources available to address HIV/AIDS.

The promotion of effective prevention policies can have an important positive impact on the incidence rate in the EU and the neighbourhood. A common understanding and an exchange of approaches to tackle HIV/AIDS across borders is of particular importance for more effective cooperation and measures between EU MSs and neighbouring countries.

4.3. Added-Value Test

As highlighted in contributions from Member States and the Civil Society during the consultation, there is a clear expectation that the Commission should continue to play an important role in facilitating and coordinating efforts across Europe on multiple levels, public health, research, external and development policies. The political support delivered so far has been widely recognised. This is especially relevant for those regions where the HIV/AIDS burden is highest. HIV infections are preventable. Consequently, the need to share experiences and best practices becomes obvious as a cost-effective undertaking. The Commission provides a firm data base, a forum for discussion and targeted exchange of practices between Member States to promote the transfer of ideas and approaches. Single Member States can hardly maintain this kind of cross-border cooperation.

The EU could mainstream HIV as public health challenge across relevant EU policies, in particular in those related to the free movement of people, the protection of human rights, research and discrimination and gender equality. Countries may benefit if they adopt elements of their own policies on the basis of better knowledge of European good practice.

With regard to HIV, there is a strong difference in experience between old and new Member States and neighbouring countries. HIV has been a relatively new phenomenon in the new States and has hit some of them like Estonia quite strongly. An exchange of best practice can accelerate effective measures in response to the epidemic.

In the past, work under the current action plan has led to a better cooperation among civil society organisation, between authorities and civil society, and international organisations such as UNAIDS or WHO. As a practical example, Commission services have supported the ARV pricing initiative of the German - Portugal - Slovenia Trio Presidency, which resulted in reduced prices for ARVs in Bulgaria in the range of about 30%, as compared to the level before price negotiations.

Moreover, among business operators, HIV medication remains an economically and socially challenging business despite the strong position of generic drug producers. A recent merger of the HIV/AIDS businesses of two important pharmaceutical companies shows this. It also underlines the need of EU level involvement and cooperation of research activities to avoid redundancy and to spend funding in the right direction.

46 Paraskevis, D. et al. Tracing the HIV-1 subtype B mobility in Europe: a phylogeographic approach. Retrovirology, 2009.

The EU can finally also complement action at the global level, with the WHO developing technical standards and clinical guidance and the EU focussing more on political advocacy and areas with clear EU added-value (such as research and pricing issues).

A major benefit resulting from the current action plan was that all stakeholders, including WHO, UNAIDS, ILO, IOM, other international organisations, or civil society organisations, engaged in fighting HIV/AIDS, had been assigned to tasks and deliverables. In this particular field of public health, the EC is in the unique position to be able to define an action plan based on a policy framework for such a large range of stakeholders. This results in a strong commitment to address relevant aspects in combating HIV/AIDS as defined in a European consensus. Consequently, a translation of appropriate actions into trans-national, national or regional settings helps to lower the impact of HIV/AIDS in a particular setting.

Through bringing together Member States and neighbouring states, with different knowledge of all factors necessary for the fight against HIV e.g. in the Think Tank or in high level conferences, the Commission can raise awareness and underline important aspects such as the human rights of vulnerable groups and PLWHA.

The EU advocates its common principles such as non-discrimination in global policy to the Member States. This policy is not forced upon Member States or neighbouring countries, they remain actors on their own in most fields of public health, including measures against HIV/AIDS. The exchange of practices and making declarations at European level will, however, facilitate the possibility of taking action for vulnerable groups. Concrete polices and related health measures remain a matter of national competence.

5. POLICY OBJECTIVES

5.1. General objective

The general objective is to contribute to the prevention and reduction of human illness and diseases stemming from HIV infections, to obviate sources of danger to human health, as laid down in Article 152 of the Treaty as well as to improve the quality of life of PLWH and most at risk of infection. As mentioned above, this general objective was stipulated already in the EU Health Strategy as well as in the EU Sustainable Development Strategy (SDS).

5.2. Specific objectives

(a) To maintain political leadership and all stakeholders' commitment and involvement and ensure regular monitoring of implementation of targets on HIV/AIDS, as agreed on the political and stakeholders' agenda and stipulated in international agreements

(b) To complete HIV/AIDS epidemiological data including monitoring, primary and secondary surveillance and reporting in order to improve the basis for HIV/AIDS policy development and implementation.

(c) To encourage and support EU Member States and neighbourhood countries, also in the framework of cross-border cooperation, in designing and implementing effective public health interventions aiming to:

- reinforce a focus of national HIV/AIDS strategies and activities on populations most at risk (i.e. MSM, IDU, immigrants), with focus on prevention and testing
- improve the quality of life and living conditions of the vulnerable people, at high risk of HIV infection and ensure universal access to high-quality care and treatment services

– adapt national HIV/AIDS strategies and activities to non-resolved and/or newly emerging challenges (under-diagnosis, new prevention methods, new treatment options, economic and social burden, etc)

– with regard to the current economic crisis, ensure that sufficient public and private funding is allocated to HIV/AIDS actions,

(d) To address research and knowledge gaps in treatment development, vaccine and microbicide research and development, public health research, behavioural science, socio-economic analysis.

6. POLICY OPTIONS

In order to realise the objectives proposed in the previous section, three different options have been envisaged. Option 1 calls for a continuation of implementation of the current action plan, thus maintaining 'status quo' policy. It is considered to be the baseline option in order to facilitate a comparison between option 2 – discontinuing existing EU policy - and option 3 – enhancing and setting another focus on activities to be implemented along agreed actions, in response to current and future challenges. Thus, effects and impacts of options 2 and 3 can be assessed against the level of remaining actions of option 1 and identified in a more discernible and comprehensive way.

6.1. Option 1: baseline – further implementation of current action plan, and evaluation

The initial "baseline option" would consist of extending the lifespan of the current action plan and continuing the implementation of open actions. An extension of the current strategy would still provide a political chapeau and demonstrate that HIV/AIDS remains in political agendas at an European level, along the lines already defined in the current action plan[47]. This option would allow the Commission and stakeholders to continue the implemention of those activities which have not been completed yet as well as to continue activities which have proven to be successful.

While this option would consist in rolling over the current action plan, as it currently is, one new element would be to include a set of indicators, in order to more concisely monitor its implementation and the resulting effects of progress. This would allow for a more comprehensive evaluation of the current action plan.

Actions around surveillance and research would be continuously implemented, based on the existing set of priorities.

Box 7: **Action Plan 2006-2009 – areas with open actions**

Prevention: Actions in the area of education and information campaigns have not been implemented everywhere in Europe. The process of exchange of experience started but it needs time to generate first of all confidence among partners and secondly concrete results.

Actions concerning laboratory networking and university and medical education (e.g. integration of HIV

[47] The current Communication covering 2006-2009 states the following: "The Commission (will) focus on prevention, which remains the cornerstone for all other activities within the comprehensive approach to tackle HIV/AIDS. The other areas of action which need strengthening are human rights issues, surveillance, and actions targeted at specific vulnerable groups. Providing political leadership and advocacy is the main value added of the EU activities on HIV/AIDS. The Commission will continue to keep HIV/AIDS and related issues on the wide political agenda and provide leadership to combat stigma and discrimination, and promote the provision of universal access to prevention services, ARV treatment and harm reduction services for injecting drug users. Coordination, facilitating the development of a common knowledge base, provision of common tools for decision-making and additional funds to support national activities and research and development programmes in this field are other areas where joint action at EU/European level can add value to the work done elsewhere."

prevention into the curricula) could still be wider addressed. But this needs an active role of competent entities, e.g. international organisations, medical associations and MS authorities responsible for university and education curricula.

Health infrastructure is a MS jurisdiction with very different financing systems - therefore difficult to reach equal levels of implementation. The same applies to sex education, access to treatment and treatment preparedness. Here, the Commission remains in a coordinative role.

More progress has to be made in access to affordable of ARV drugs, even in the European Union, but particularly in neighbouring countries.

The promotion and development of training modules for of medical staff, in particular regarding diagnoses, awareness, co-infections, sexually transmitted infection etc. should become one focus in the future action plan. Due to the many actions suggested SANCO had to choose priorities that could be achieved at European level

The cooperation with media could be strengthened in a new strategy as actions in this area could not yet be realised, probably due to conceptual and financial shortcomings. .

Surveillance at European level has improved but still ECDC does not receive data from all MS yet.

No activities have been carried out with regard to data protection

The report on Mother to Child transmission (MTCT) has not yet been commissioned, but ECDC issues every year numbers on the level of MTCT across Europe.

6.2. Option 2: no EU policy and action plan addressing HIV/AIDS as a single topic

The Commission will not opt for a new HIV/AIDS-specific policy initiative (action plan plus communication).

This option would not exclude a further cooperation and intervention of the EU in the field through financial and technical support. The Commission would focus on existing funding activities/programmes, such as the Research Framework Programme, the Public Health Programme, European Social Fund, European Neighbourhood Policy Instruments (ENPI), external HIV policies, and would also continue to provide technical support through specialised agencies such as ECDC, or EMCDDA.

However, without an updated EU guidance document for activities on HIV/AIDS, HIV-related spending could be re-attributed to other policy areas. Indeed, in the case of the Health Programme 2008-2013, priorities are defined on an annual basis and the budget is allocated on a competitive basis (i.e. no budget has been earmarked for HIV/AIDS specifically). Similarly, spending within the framework of the 7th Research programme would continue as currently planned, but research priorities defined in annual work programmes would risk to be assigned to other research activities.

Surveillance by ECDC would continue independently, without taking into account the new policy needs though. Any improvement of the surveillance would stem from ECDC, without the guidance of an action plan on specific data needs.

6.3. Option 3: Current plus – a new Commission policy and action plan on combating HIV/AIDS in Europe

The Commission would provide a political chapeau to ensure that HIV/AIDS remains a priority in political agendas and would depict the main priorities for policies in the fight against HIV/AIDS in the form of a second action plan covering the years 2009-2013.

As for the current action plan, the new action plan would denominate the lead parties for implementation. A new Commission policy could provide the broad action lines and the Commission services and their principal stakeholders, assembled in the Think Tank and in the Civil Society Forum, will decide on a specific action plan. In addition to lead parties, this plan would identify particular indicators to measure and describe the degree and the quality of realisation. These indicators would

ideally be selected among the set of 33 indicators or currently applied by the ECDC in the framework of the monitoring of the Dublin declaration implementation[48]. If this set of indicators would not be specific enough, new indicators would be established, in order to monitor the implementation of the new action plan and the resulting progress. This would allow for a more comprehensive evaluation of the new action plan.

More importantly, items of the new action plan will correspond to the upcoming priorities for the next years, including for research and EU Health Programme spending. This option would take into consideration the new trends and challenges deriving from HIV/AIDS at EU and neighbouring countries level, already identified in the problem definition.

As presented in the illustration below, any future EU action should draw lessons from the experience of the first EU action plan 2006-2009 and shift the attributed weights towards more action under pillars: prevention, treatment and care as well as research, with slightly reduced action under awareness/stakeholders and maintained efforts for monitoring. Research could become a separate strand. More specifically, actions under these pillars should focus on the topical priorities: prevention, Eastern Europe and most at risk populations. A new action will therefore be more focused, outcome oriented and less generic than the first action plan. A stronger focus will help to achieve greater effects along the above mentioned lines.

[48] ECDC project 2009/2010: monitoring of the Dublin declaration on partnership to fight HIV/AIDS in Europe and Central Asia.

Table 1: Comparison of priorities and objectives between Action Plan 2006-2009 and a new Action Plan (Option 3)

Action Plan 2006-2009		**A new EU policy and action plan (Option 3)**		
(A) ***Politics/Awareness /Civil Society***	⇒	**(A)** ***Politics/Awareness /Civil Society***	↑ Cross-border cooperation (Western-Eastern Europe) ↓ Political leadership and stakeholders involvement ↓ Overall budget reduction	**More focus on:** - EU – Eastern Europe cooperation and partnership projects -address stigma and discrimination more as principal barriers to effective prevention - mainstreaming of HIV in EU policies and bi-/ multi-lateral agreements
(B) ***Surveillance, research and medicine***		**(B)** ***Surveillance***	↑ Data collection and reporting ↑Cross-border cooperation → Overall budget kept on same level as in previous action plan	More focus on: - close outstanding data gaps in the EU and in cross-border dimension - behavioural surveillance - timely translation of data into effective policy responses
(C) ***Prevention***		**(C)** ***Prevention, treatment, care and support***	↑ New preventive methods ↑ Prevention, treatment and care targeted at most at risk groups ↑Promotion of VCT in vulnerable groups ↑ Overall increased action and budget	strengthen the focus on: - reiterated comprehensive prevention as the approach towards controlling the spread of HIV - improving quality of life of all people affected by HIV/AIDS and in particular vulnerable groups - UNIVERSAL access to prevention, treatment, care and support - refocus of activities to reach priority groups including undiagnosed (MSM, IDU, immigrants from high prevalence countries) as well as priority regions
		(D) ***Research and medicine (to become a separate strand in any future EU action)***	↑ Funding for research and knowledge ↑Overall budget increase	More focus on: - more investments and strength to overcome research and knowledge gaps (behavioural science, new prevention methods, drug resistance, co-infections)

		- more Public-Private Partnerships for innovations on medicines and vaccines development

Weight given as compared to the previous action plan (↑ more; ↓ less; → same)

Box 8: **Possible actions under Option 3**

Possible actions under such an option could include:

(A) **Political leadership/ stakeholders** (including neighbouring countries cooperation)

- Establish political agreements between the EU and neighbouring countries addressing i.a. HIV/AIDS.

- Cooperation with private sector (business, media, public personalities etc.), e.g.on social marketing of condoms

- do more to achieve an efficient exchange of information and good practices to strengthen effective multilateral/ cross-border cooperation, in particular regarding promotion of human rights of vulnerable people and evidence based prevention and treatment.

(B) **EU surveillance**

- Encourage all Member States and neighbouring countries to consistently report to ECDC their relevant data at national level (as opposed to regional level) and on certain crucial issues where data gaps remain at European level (e.g. drug users or other vulnerable groups).

- Assess the implications of cross-border movements and migration

(C) **Prevention, treatment, care and support** - Encourage and support training of medical staff (diagnosis, testing, treatment) and social workers

- Encourage ENP countries and other decision-makers to improve infrastructures to provide state-of-the-art HIV services and the social and legal environment to encourage populations at risk to present for testing, treatment and care through exchange of experience and exploring the potential of existing EU funding. HP, ENP budget

- Encourage and empower civil society in Eastern Europe and promote effective peer education and exchange

(D) **Research and medicine**

- Encourage public-private partnerships against HIV/AIDS, and in particular in cost-intensive research fields such as vaccines and microbicides development

- intensify social science research, in particular on behavioural aspects

6.4. Option 4: discarded options

Legislation: HIV/AIDS is a health and often a social problem with a considerable political dimension, but the Treaty does not give room for a legislative intervention in form of a HIV-specific directive or a regulation. Member States and neighbouring countries design their national plans and programmes, but comprehensive national approaches benefit greatly by access and exchange of good practices, experiences and evidence based solutions.

Campaign: A European campaign on HIV could not be targeted enough to respond to all particular situations and cultural sensitivities in different regions of Europe. It would not be possible to reach in an effective, targeted way all populations at risk, and would hence neither be cost-effective nor leading to the desired results.

7. ANALYSIS OF IMPACT

Considering that the EU only comes as one of many actors in HIV/AIDS policy interventions (e.g. WHO, UNAIDS, MSs, NGOs, private sectors, etc.) and given that EU level spending represents just part of the overall public and private spending to combat HIV/AIDS in Europe, it is difficult to

quantify the potential social and economic impacts of the options outlined above. Their non-binding nature hinders even more the ability to put a figure on these impacts. However, a generic assessment describing qualitative impacts has been performed. Whenever possible, estimates are provided, notably regarding the economic and social burden of HIV/AIDS, partial costs of action plans and research funding devoted to HIV/AIDS, present and future HIV/AIDS trends and finally anecdotal evidence from policy interventions at national level. All budgetary costs are estimates based on the expenditures under the action plan 2006-2009.

This IA assumes that any reprioritisation of actions will have an impact, to a larger or lesser extent, on financial resources re-allocation. At the EU level, the Health Programme, for example, is implemented by means of annual work plans which set out priority areas and the funding criteria, taking into account existing multi-annual framework policy documents (e.g. action plan). Projects are then selected on a competitive basis[49]. HIV/AIDS-related actions can be funded under the following three objectives: to improve citizens' health security; to promote health, including the reduction of health inequalities; to generate and disseminate health information and knowledge. However, no specific budget is automatically earmarked for HIV/AIDS in the Health Programme. This annual system also applies to FP7.

Environmental impact is negligible and will not be considered further.

7.1. Option 1: Baseline option – further implementation of the current action plan

Economic impact

In this option, the different tasks to implement the action plan would continue to be distributed among all stakeholders involved in its realisation. Already, the first action plan was mainly implemented through financial means of the Health Programme, research framework programme, other EU funding instruments, through national co-financing or complete financing of national authorities or of NGOs and the commitment of industry.

The **direct costs for the EU**, although this all depends on the annual priorities set out in these programmes, and on the quality of proposals received, would most probably amount for similar levels of spending as over the previous period (2006-2009) which is, as far as the Health Programme is concerned, in the range of about 5 million euro per year of spending, and on average 25 million euro per year allocated through the Research Framework Programme. Through the **evaluation** of the activities implementing the action plan, this option would be instrumental in assessing how far EU and national investments, both financial and political, have had an impact on the epidemic.

This option, by maintaining the emphasis on HIV/AIDS as a priority at the EU level, would send a message of continuity and would constitute an incentive to maintain high level of investment for **multiple stakeholders** engaged in research, service provision, training and support activities, public health aspects and more.

Under this option, it is expected that **spending for activities financed through national budgets** would remain stable, as compared to 2006-2009 period. None of the activities in the action plan would present an obligation for any involved party. This action plan offers an array of reasonable and useful measures to be considered in order to improve national or regional policies and measures to respond to HIV/AIDS in a particular setting. It fosters cooperation and efficiency. Many examples demonstrate that, investments in effective measures against HIV/AIDS and for the benefit of people affected by the disease and its associated problems pay back in the future - ethically, socially and financially.

[49] All projects must cover one or more of the specific objectives set out in the annual work plan. They will be assessed on the basis of: policy and contextual relevance – projects should provide added value at European level and support developments at European level in the field of health; technical quality – projects should be innovative, with a clear evaluation and dissemination strategy, and management quality and budget.

Germany, e.g., estimates that its **prevention** means and campaigns (average investments at federal level between 11 and 13 million euro in the last years) resulted in annual savings of 450 million euro for therapy costs through 30.000 avoided HIV infections. Costs may increase for national health systems in the short term when more people are tested and given access to treatment and prevention. But it results in cost reduction on multiple medical and social levels in the long term, since prevention, earlier diagnosis and treatment prevent or respectively delay the progression of the disease, and keep infected people in the labour market. This example underlines the win-win situation that effective prevention and treatment reduces human suffering in the short, medium and long term as well as the costs for national health systems in the long-term.

Treatment costs rise massively through an accumulation of more patients over time even if the number of new infections decreases or stagnates over the same period (as the case of Estonia, explained above, illustrates). Increasing the access to ART would have an economic impact on national health-care systems and budgets. Prospective budget planning is therefore important. An agreed action plan backed up by a strong political commitment, an effective exchange of good practices, and a solid data base, reduces inefficiencies and duplication of efforts for the development and implementation of policies and could support appropriate planning on national levels.

However, in time of **economic downturn**, as demonstrated in OECD report[50], health national spending is expected to be increasingly affected by budget cuts or budgetary measures, especially in the short and medium term. There is a risk that HIV/AIDS-related expenditures could follow this trend.

No additional costs on MSs for **reporting and surveillance** are to be expected. The ECDC surveillance work is financed through EU budget and would remain unchanged – the ECDC has a total annual budget of about 50 million euro, of which 1.1 million euro are earmarked for HIV/AIDS, Hepatitis and Sexually transmitted diseases.

Social impact

This option would not result in specific changes but will maintain the political focus, for the continuation of projects, in areas such as efforts to improve the access to prevention, treatment and care, or modified and improved general policies on national or regional level, as well as projects focusing on training programmes for NGOs, education or other issues of the current action plan not yet fully implemented.

This option is expected to improve access to prevention, treatment and care and in turn, bear positive social impacts. Indeed, effective prevention programmes contribute to a **reduction of further transmission of HIV**. Prevention, earlier diagnosis and treatment prevent or respectively **delay the progression of the disease**, **keep infected people in the labour market**, which eventually positively influence the **quality of life of PLWHA**.

However, if **international and EU political commitments** would be maintained and could continue to be supported by the existence of an EU action plan (e.g. The WHO 'Three Ones' requirement, focused on actions, coordination and monitoring, as a key in the response to HIV/AIDS would be to a certain degree satisfied), without the development of a specific monitoring framework of these political agreements, progress could be hindered towards the achievements of these targets.

ECDC surveillance would not take into consideration new challenges and related data needs. The existing data gaps (nature of the epidemic, migration in terms of access to testing, treatment and care, or infection and resistance patterns (and genotypes) across Europe, cross –border dimension of HIV infections) would not be bridged. Therefore, policy-makers would encounter difficulties in developing a comprehensive understanding of the drivers of the epidemic and, in turn, proposing and implementing fully adequate policy responses.

[50] OECD: Health and the economic crisis. DELSA/HEA (2009)1, June 2009.

7.2. Option 2: no EU policy and action plan on HIV/AIDS as a single topic

Economic impact

The **direct costs for the EU** – mostly through the Health Programme and the Research Framework Programme – would probably decrease as compared to the current situation, however not to a large extent. Indeed, the effectiveness of the political and financial support might be diminished, due to a lack of political guidance in setting priorities. Furthermore, the lack in political motivation for EU cooperation in the field of HIV/AIDS could impact the choice of these programmes' annual priorities, and given the competitive basis for projects' selection, favour other non-HIV/AIDS priorities, supported by an EU policy. Any attempt to receive funding for HIV/AIDS activities at EU level could be counteracted by the reference to the discontinuation of the strategy. This may in the medium-term have an impact on EU research funding and action on HIV/AIDS. In the face of 2.7 million new infections annually worldwide and the need for a vaccination or a definitive cure for HIV/AIDS, this appears difficult to justify.

A discontinuation or putting less emphasis on HIV/AIDS as priority would also have serious repercussions on **multiple stakeholders** engaged in research, service provision, training and support activities, public health aspects and more. This could e.g. lead the **pharmaceutical sector** to decrease research in AIDS vaccines research. As any potential vaccine will have to be paid for by international donors, the pharmaceutical sector will carefully take decisions of a donor like the Commission into account when planning its research agenda. In addition, in time of the economic crisis and potential reduction of the resources available for addressing HIV/AIDS, the lack of political commitment at EU level would **not** necessarily be **compensated** by bilateral or multilateral cooperation without EU funding.

The key drawback of such an option is the political message that this would send to EU MSs and neighbouring countries. Governments within the EU, and particularly in the neighbouring countries, could follow the EU example of complacency and **reduce national spending** (varies considerably across Europe, depending on number of patients, investments in prevention, testing, treatment, care, depending on social systems). As previously mentioned, this risk exists all the more so in time of the **economic crisis**. According to a recent UNAIDS/WB report on "The Global Economic Crisis and HIV Prevention and Treatment Programmes: Vulnerabilities and Impacts"[51], the negative implications of the economic crisis (e.g. exchange rate devaluation, budget cuts) are expected to have an adverse impact on **ART**, in the medium and long term, through either increasing the cost of ARV drugs or decreasing the sufficient public ART cost coverage. In addition, HIV/AIDS **prevention** programmes are particularly vulnerable to the effects of potential health budgets cuts. Given that prevention has an influence on transmission rates of infectious diseases, **public health costs** could be higher through the increased number of infections and higher treatment costs as well as social, economic and labour market effects in the medium and long term.

No additional costs on MSs for **reporting and surveillance** are to be expected. The ECDC surveillance work is financed through EU budget and would remain unchanged – the ECDC has a total annual budget of about 50 million euro, of which 1.1 million euro are earmarked for HIV/AIDS, Hepatitis and Sexually transmitted diseases.

Social impact

This option could result in changes in areas such as efforts to improve the access to prevention, treatment and care, or modified and improved general policies on national or regional level. However, this option bears the risk that without a strong political support from the Commission, HIV/AIDS might disappear from the radar screens of certain funding mechanisms.

Without an EU political guidance, it is difficult to anticipate which specific actions will be undertaken and implemented by MSs and stakeholders. However, it may be assumed that **internationally agreed targets** in the fight against HIV/AIDS, such as universal access to prevention, treatment and care,

[51] http://data.unaids.org/pub/Report/2009/jc1734_econ_crisis_hiv_response_en.pdf

would not be reached in all European countries (e.g. the WHO 'Three Ones' requirement, focused on actions, coordination and monitoring, as a key in the response to HIV/AIDS would only be satisfied in countries more pro-active in combating HIV/AIDS), solely through multinational not funded cooperation on a technical and operational level. That, in turn, could lead, in the medium and long term, to adverse social impacts, reflected in an increase of HIV/AIDS incidence, influencing negatively the **quality of life of PLWHA**.

The potential of **empowering NGOs** in the neighbouring countries – which are instrumental in advocating human rights for vulnerable group – through regular and funded participation in civil society meetings would risk being lost.

This option may not be effective enough to sustain and further develop a broad scale of cooperation across Europe and among interested stakeholders - specifically to steer actions towards the **new issues and challenges** identified earlier in this report. In particular, this option would probably not enhance efforts to address the **social issues** around HIV/AIDS, related to fear, stigma, discrimination, non respect of human rights, deprivation of harm reduction measures, tolerance towards effective, targeted evidence based prevention, the social situation of people living with or affected by HIV/AIDS, and more to the necessary extent.

As in the case of Option 1, **ECDC surveillance** would not take into consideration new challenges and related data needs. The existing data gaps (nature of the epidemic, migration in terms of access to testing, treatment and care, or infection and resistance patterns (and genotypes) across Europe, cross – border dimension of HIV infections) would not be bridged. Therefore, policy-makers would encounter difficulties in developing a comprehensive understanding of the drivers of the epidemic and, in turn, proposing and implementing fully adequate policy responses.

7.3. Option 3: Current plus – a new EU policy and action plan on combating HIV/AIDS in Europe

Economic impact

In this option, the different tasks to implement the new action plan would be distributed among all stakeholders involved in its realisation. Already, the first action plan was mainly implemented through financial means of the Health Programme, research framework programme, other EU funding instruments, through national co-financing or complete financing of national authorities or of NGOs and the commitment of industry.

The **direct costs for the EU**, although this all depends on the annual priorities set out in these programmes, and on the quality of proposals received, would most probably amount for similar levels of spending as over the previous period (2006-2009). It is expected that political support but also the increased focus on new challenges and trends – namely on actions targeted at most-at-risk groups and enhanced cooperation with eastern neighbouring countries – could increase the efficiency of implementation, trough resources' reallocation towards more efficient interventions. Through the **evaluation** of the activities implementing the new action plan, this option would be instrumental in assessing how far EU and national investments, both financial and political, have had an impact on the epidemic.

This option, by maintaining the emphasis on HIV/AIDS as a priority at the EU level, would send a message of continuity and would constitute an incentive to maintain high level of investment for **multiple stakeholders** engaged in research, service provision, training and support activities, public health aspects and more. In particular, a new emphasis would be given to research activities, with a stronger focus on overcoming research and knowledge gaps (behavioural science, new prevention methods drug resistance, co-infections), encouraging public-private partnerships to be more involved in research on medicines and vaccines. This could e.g. lead the **pharmaceutical sector** to increase research in AIDS vaccines research.

Under this option, it is expected that **spending for activities financed through national budgets** would remain stable, as compared to 2006-2009 period. None of the activities in the action plan would

present an obligation for any involved party. However, this is expected that emphasis put on new priorities could lead to **reallocation of national resources** towards, in particular, new preventive methods, prevention, treatment and care interventions more targeted at most-at-risk groups (MSM, IDUs, immigrants from high prevalence countries) and stronger eastern cross-border cooperation, resulting in more cost-effective interventions.

As previously mentioned, in time of the **economic downturn**, HIV/AIDS-related interventions could be adversely impacted on by the negative implications of the economic crisis (e.g. budget cuts or budgetary measures, exchange rate devaluation), having potentially negative repercussions on **ART**, in the medium and long term. In addition, **prevention** programmes could be threatened with potential health budgets cuts, and, according to a survey of UNAIDS, WHO, and WB staff in 71 countries carried out in March 2009 and whose results are presented in a recent report on "The Global Economic Crisis and HIV Prevention and Treatment Programmes: Vulnerabilities and Impacts"[52], this concern referred to vulnerable target groups (MSM, IDUs, immigrants) and was most pronounced in the Eastern European countries. In this highly uncertain context, this option would represent an incentive for EU MSs and neighbouring countries, to maintain a certain level of public spending into prevention programmes and services, in particular targeted at most-at-risk populations, while encouraging a reallocation of resources towards the most cost-effective health interventions.

Improved **reporting and surveillance** may impose additional costs on the very few countries, which do not report as complete data as required to ECDC. All other countries will not have any additional burden, and will benefit from a better planning based on better data – this is usually cost-effective. The ECDC surveillance work is financed through EU budget and would remain unchanged – the ECDC has a total annual budget of about 50 million euro, of which 1.1 million euro are earmarked for HIV/AIDS, Hepatitis and Sexually transmitted diseases.

Social impact

From a European perspective, a Commission communication would underline **continuity** and **political will** towards the realisation of existing **international commitments**, as defined in the diverse political UNGASS, Dublin, Vilnius declarations that could continue to be supported by the existence of an EU action plan (e.g. the WHO 'Three Ones' requirement, focused on actions, coordination and monitoring, as a key in the response to HIV/AIDS would be satisfied). This new action plan would lay down precise targets to be met through intensive cooperation among stakeholders and could result in **better and targeted resource allocation and more effective infrastructures** on a national level.

This option would have an important **positive impact especially on civil society** and their work, **people affected by HIV/AIDS** and **industry** contributing - through stronger political leadership and civil society involvement - to improving the living conditions for all people affected by the disease. The Commission's example could serve as a reason or justification for EU Member States or neighbouring countries, as well as international organisations and resources. The development of a specific **monitoring framework of these political agreements**, would lead to a better achievement of these targets.

Technically, it would provide a framework for action for the identification of **projects** to be funded by the Health Programme and Framework Research Programme. This option would maintain the political focus, for the continuation of projects, in areas such as efforts to improve the access to prevention, treatment and care, or modified and improved general policies on national or regional level, as well as projects focusing on training programmes for NGOs, education or other issues of the current action plan not yet fully implemented.

In addition, this option should be effective not only in sustaining but also in further developing a broad scale of cooperation across Europe and among interested stakeholders - specifically to steer actions towards the **new issues and challenges** identified earlier in this report. By shifting the focus on certain priorities, the efficiency of the interventions contributing to the implementation of the action plan is expected to increase. As explained above, this will be all the more important to target interventions as

[52] http://data.unaids.org/pub/Report/2009/jc1734_econ_crisis_hiv_response_en.pdf

the economic context could lead to budget constraints. This should particularly be the case regarding the new emphasis given to new preventive methods, prevention, treatment and care interventions more targeted at most-at-risk groups (MSM, IDU, immigrants from high prevalence countries) and stronger cooperation with Eastern European countries. More effective prevention, earlier diagnosis and treatment prevent or respectively **delay the progression of the disease**, **keep infected people in the labour market**, which eventually positively influence the **quality of life of PLWHA**.

In particular, through increased targeting of interventions towards more-at-risk groups, which are also often most-at-risk socially, this option would support efforts to address the **social issues** around HIV/AIDS, related to fear, stigma, discrimination, non respect of human rights, deprivation of harm reduction measures, tolerance towards effective, targeted evidence based prevention, the social situation of people living with or affected by HIV/AIDS, and more to the necessary extent. Specifically, NGOs in the European neighbourhood countries (and in particular in Eastern European countries) could be actively supported and thus the response in these countries would be strengthened. This option would lead to more influential civil society, which is indispensable for service provision, advocacy against discrimination and stigmatisation of marginalised groups, policy development as well as implementation and monitoring of policies.

This option would help to monitor the dimension of the HIV/AIDS epidemic and co-infections, such as tuberculosis, hepatitis and sexually transmitted infections, – at national and cross border level, in Europe, and help to map and disseminate best practices towards planning of efficient prevention, treatment, health and social care options. It would serve to bring together experts to draw up responses to future challenges. **Improved and complete surveillance and monitoring at European level,** mostly by **ECDC**, would be the basis of effective and sustainable public health measures in all affected countries

8. COMPARING THE OPTIONS

Table 2: Comparison of options

	OPTION 1	OPTION 2	OPTION 3
ADVANTAGES	- An action plan would offer a wide range of tools to strategically translate political Commission goals into action. - It provides guidance for EU level action (including research spending and HP activities) -It provides a political back-up for a partnership among all relevant stakeholders and facilitates the exchange of good practices -Transparency and specificity of the EU goals and targets leading to implementation of set actions for HIV/AIDS related problems. - The evaluation of the activities implementing the current action plan would allow for assessing how far EU and national investments, both financial and political, have had an impact on the epidemic. -EU surveillance and monitoring system would be enhanced and improved however to a limited extent. - Research and knowledge gaps could be partially overcome	- No additional continuous funding required - HP would continue to support measures to address HIV/AIDS, thus occasional funding would be possible. There may be a risk of money transfer to other health policies. -Research framework programme (FP7) would probably continue to support HIV/AIDS research. There may be a risk of money transfer to other research priorities. - No potential administrative costs caused in MSs. - A certain degree of continuity could be provided– but only at technical level.	- An action plan would offer a wide range of tools to strategically translate political Commission goals into action. - It provides guidance for EU level action (including research spending and HP activities) - The Commission could facilitate a focus on activities around the specific objectives identified above.-It provides a political back-up for a strong partnership among all relevant stakeholders and facilitates the exchange of good practices -Transparency and specificity of the EU goals and targets leading to implementation of set actions for HIV/AIDS related problems, including new trends and challenges. - The evaluation of the activities implementing the new action plan would allow for assessing how far EU and national investments, both financial and political, have had an impact on the epidemic. - EU surveillance and monitoring system would be enhanced and improved - Research and knowledge gaps would be overcome.
DISADVANTAGES	- No new incentive - Loss of political momentum to present a future-oriented action plan based on current evidence,	- The EU sends a negative political sign of complacency, lost political opportunity to recall importance of prevention policies for HIV in times	- Potential budgetary implications for MSs (e.g. increased access to ARV would increase costs for national health budgets)

	data and needs, lost political opportunity to recall importance of prevention policies for HIV in times of budgetary constraints. - Potential budgetary implications for MSs (e.g. increased access to ARV would increase costs for national health budgets) - EU surveillance and monitoring system would continue in its present shape, and would remain incomplete.	of budgetary constraints - Long term costs related to reduced push for prevention. Potential budgetary implications for MSs (e.g. increased access to ARV would increase costs for national health budgets) - No framework for action/guidance would be provided to correlate thematic priorities to available budget. - No guidance for EU level action (including research spending and HP activities) - Expectations as expressed by MSs or the civil society would not be met, commitments would not be realised. - The EU would no longer contribute to a political coordination of activities in the field of HIV/AIDS, and could not defend the rights of PLWHA in a particular manner. - Civil society would lose much support across Europe, in particular in countries where civil society is traditionally not very strong. - EU surveillance and monitoring system would continue in its present shape, and would remain incomplete.	- Potential additional reporting duties of MSs for surveillance and monitoring (e.g. cross-border movement and migration) resulting in additional administrative burden

The following table summarises the impact of the three options on the specific objectives as defined in section 5.2.

Table 3: Impacts summary

Contribution towards specific objectives	**Option 1**	**Option 2**	**Option 3**
Political leadership and guidance towards reaching agreed targets	+	-	++
Strengthened surveillance and epidemiology to support policy development and implementation and monitoring	+	+	++
Encourage MSs and neighbouring countries to reinforce the focus of their activities and policies on most at risk populations	+	-	++
Encourage MSs and neighbouring countries to improve the quality of life and living conditions of the vulnerable people, at high risk of HIV infection and ensure universal access to high-quality care and treatment services	+	-	++
Encourage MSs and neighbouring countries to adapt national HIV/AIDS strategies and activities to non-resolved and/or newly emerging challenges (under-diagnosis, new prevention methods, new treatment options, economic and social burden, etc.)	+	-	++
Encourage MSs and neighbouring countries to, with regard to the current economic crisis, ensure that sufficient public and private funding is allocated to HIV/AIDS actions,	+	-	++
Address research gaps by integration of resources and activities	+	+	++
Costs of achieving the specific objectives	***estimation***	***estimation***	***estimation***
Budgetary impacts for the EU: Health Programme	approx. 20M euros	approx. 20M euros or less, reallocation of HIV funding to other policies covered by the HP	approx. 20M euros reallocation to priorities defined in new action plan
Research Framework Programme	approx. 100M euros	approx. 100M euros or less reallocation of HIV funding to other policies covered by the HP	approx. 100M euros reallocation to priorities defined in new action plan
ECDC (surveillance and monitoring)	approx. 4.4M euros	approx. 4.4M euros	approx. 4.4M euros reallocation to priorities defined in new action plan
Budgetary impacts for MSs:			

Costs for health budgets (prevention, treatment…) and research	n/a stable	n/a risk of budget cuts, due to economic crisis	n/a stable reallocation to priorities defined in new action plan
Costs of reporting (surveillance)	no additional administrative burden for EU MSs	no additional administrative burden for EU MSs	administrative costs stemming from new data reporting requirements

9. MONITORING AND EVALUATION

This impact assessment has identified a number of open topics for future action to combat HIV/AIDS in Europe. The HIV/AIDS Think Tank and the Civil Society Forum are impartial and objective bodies, thus in a good position to monitor on a regular basis, in cooperation with ECDC, the progress made on specific objectives. Broader key elements could focus on an assessment of the impact on: national policy-making and spending, EU policy and policy outcomes.

All specific objectives addressed in the impact assessment would be translated into actions and linked to lead organisations, indicators and target deadlines (as presented above). Achievements will be traced regularly and a monitoring report, based on data compiled by ECDC, could be published by the Commission in 2012 and 2014, respectively.

A regular monitoring contributes to a timely dissemination of results and achievements among all stakeholders engaged in combating HIV/AIDS in Europe. Good practices, opportunities for coordination and cooperation would become more transparent and accessible to and among all major stakeholders.

More specific indicators for the monitoring could focus on:

- the progress made in most at risk populations in form of highly disaggregated data
- the progress made in particularly affected countries
- mid-term planning established on countries most affected
- the progress made on a political level, degree of the political influence on the implementation of measures against HIV/AIDS: indicators selected
- degree of involvement of civil society on a national and regional level
- the progress made towards a harmonised and meaningful epidemiology and surveillance, in support of policy and decision making.
- the progress made towards research in identified fields where knowledge gaps persist.
- national spending allocated to HIV/AIDS interventions (in particular with regard to the negative implications of the economic crisis).

Suitable indicators will be selected by the Think Tank with the technical support of ECDC and UNAIDS and could derive from the current work carried out in the frame of the regular monitoring of the implementation of the Dublin declaration.

LIST OF ANNEXES

1. Assessment of responses on RELEX questionnaire received from EU delegations in ENP countries.
2. Compilation of EU Member States that have a specific HIV/AIDS action plan and or national strategy in place or under preparation.
3. Report on contribution of projects funded by European Health Programme 2006 – 2008 to the implementation of the HIV/AIDS Action Plan 2006-2009.
4. Action Plan 2006-2009 – a preliminary internal European Commission evaluation.