

Ministry of Health of the Republic of Bulgaria

**Post Bremen – affordable ARV
initiative:
progress in Bulgaria**

10th Meeting of the “HIV/AIDS Think Tank”

9 - 10 April 2008 Brussels, Centre Albert Borchette

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control of AIDS, TB and STIs”**

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Bulgaria – Political Commitment to international initiatives

June 2001 – UNGASS Declaration of Commitment on HIV/AIDS

2003 – Report “Millennium Development Goals – Bulgaria 2003”, setting country targets to 2015

2004 – Dublin declaration on HIV/AIDS

Jan-Feb 2006 – national consultation on Universal Access to HIV Prevention, Treatment, Care and Support for all who need to 2010

March 2007 – Bremen Declaration on HIV/AIDS



EU-Presidency Conference in Bremen

Partnership and Responsibility - Together Against HIV/AIDS

- **II. We commit.....**
.....to co-operate to ensure access to affordable medication

- **IV. We invite**
.....the pharmaceutical industry,
 - to facilitate access to affordable treatment
 - to enter into partnerships with the public and the private sector
 - to support R&D and technology transfer,
 - and to co-operate in securing distribution channels for drugs against HIV/AIDS in cooperation with governmental institutions and NGOs.

Format of the initiative

- The German Government is committed to this project and will remain so beyond the time of the presidency
- The idea is to bring together the relevant actors:
 - representatives from the national governments
 - pharmaceutical companies
 - representatives of civil society
 - the European Commission and UNAIDS
 - the German government as a broker in order to facilitate

FIRST STEPS

12-13 March 2007 – Bremen, Ministerial Conference
"Responsibility and Partnership – Together against
HIV/AIDS"
– Statement of the German Federal Ministry of Health and the
research-based pharmaceutical industry

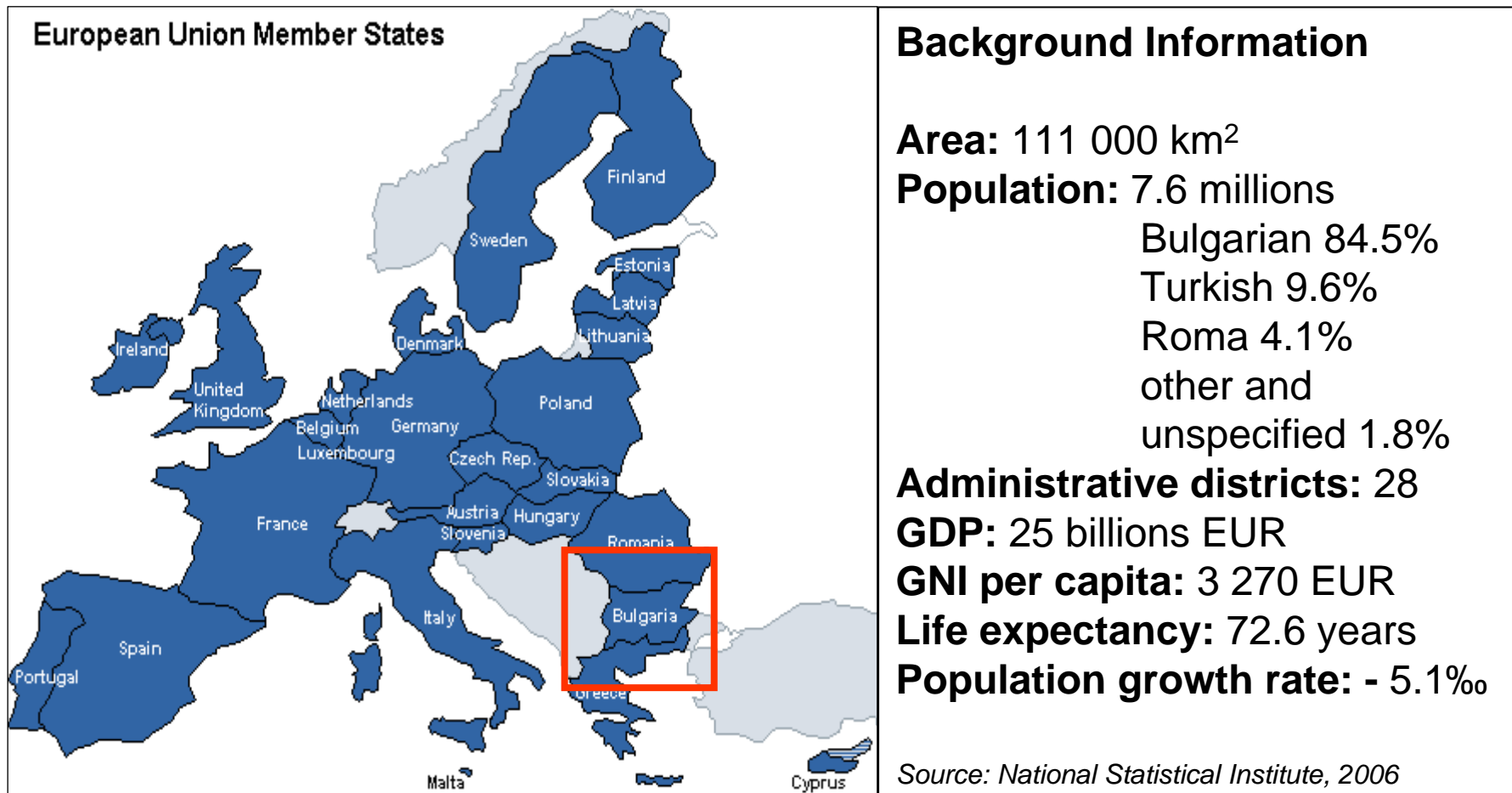
19-20 April 2007 – Aachen, Informal Meeting of Health
Ministers of the EU

15 May 2007 - Invitation letter for Bulgaria to join the
initiative, sent by Michael Schönstein, M.A. (Hons.), Federal Ministry
of Health, General European Health Policy Planning, EU Presidency
Task Force

31 May 2007 – Brussels, EPSCO meeting, announcement of
the initiative by the German Federal Minister of Health - Mrs. Ulla
Schmidt. Bulgarian Minister of Health – Prof. Radoslav Gaydarski,
states the readiness and commitment to take part in the initiative
through a country specific approach

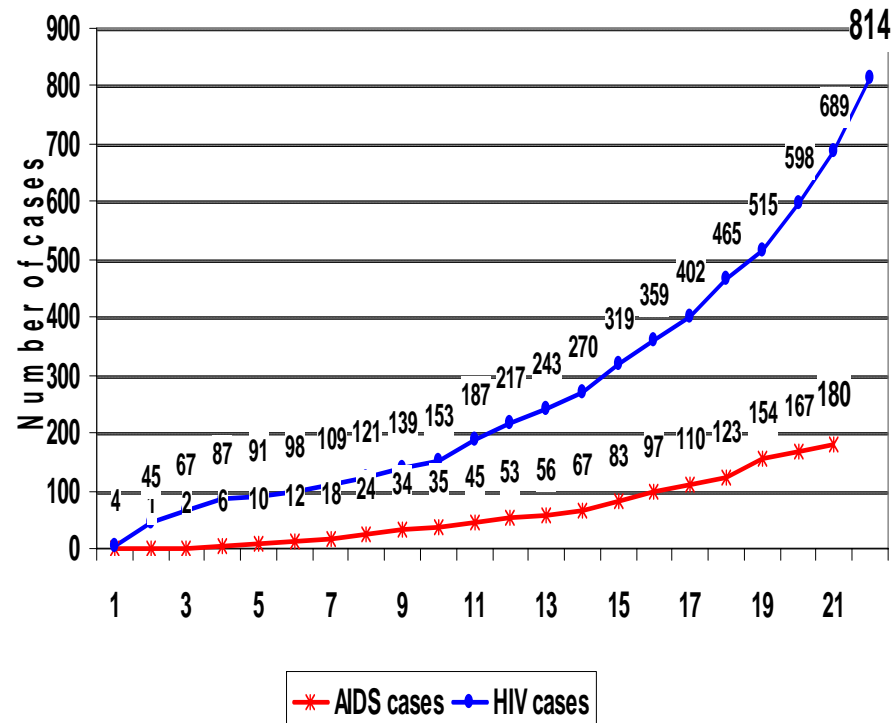
**Rationales for Bulgaria to join the German EU-
Presidency initiative to ensure access to
affordable ARV medication**

BULGARIA – country profile

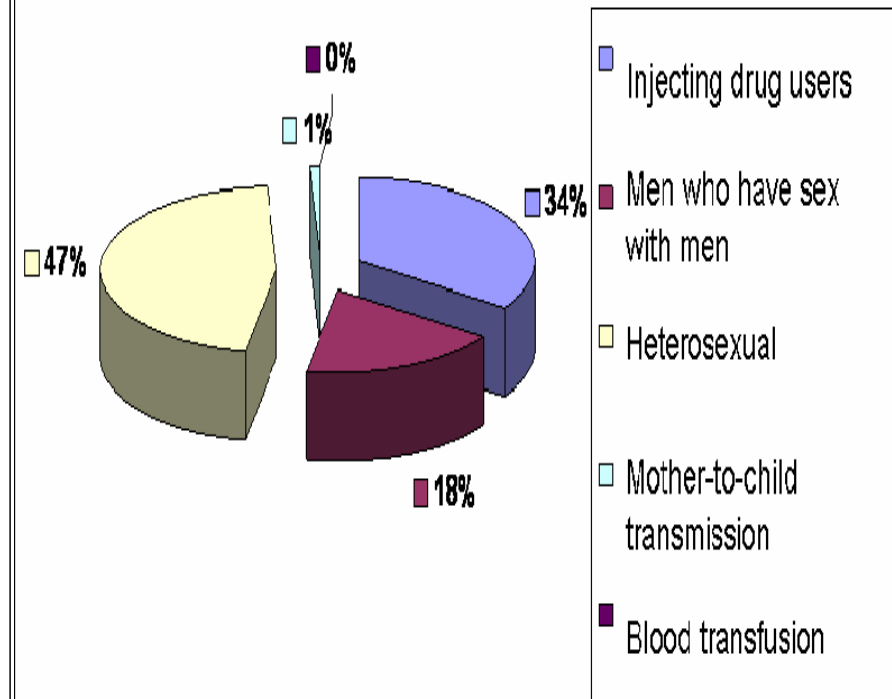


HIV epidemic in Bulgaria

Cumulative number of registered HIV and AIDS cases by year, Bulgaria, 1986 -2007

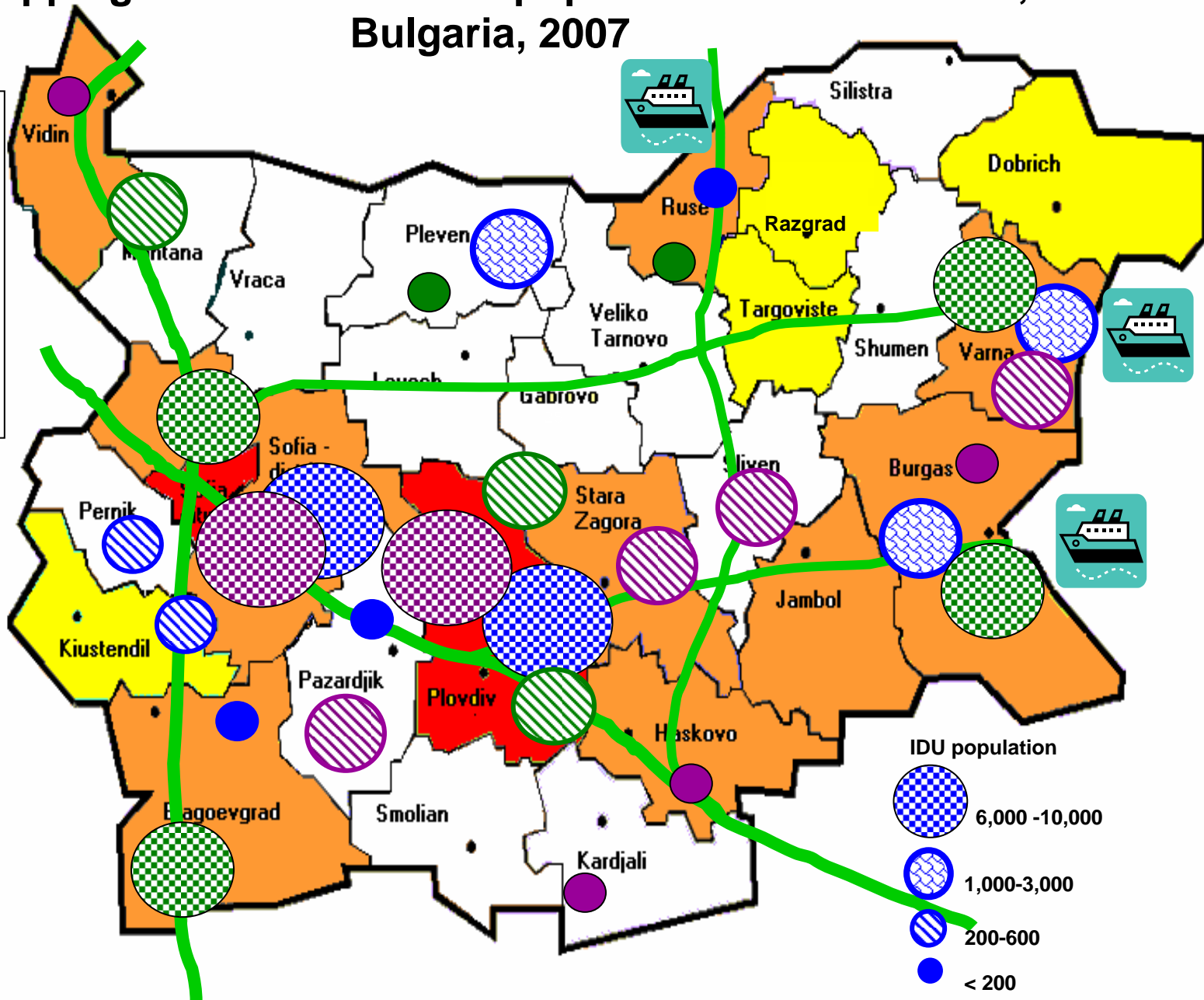
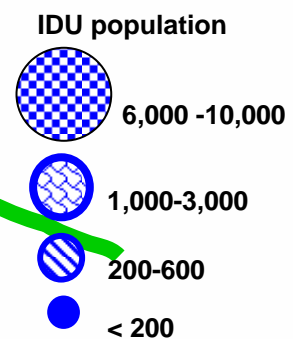
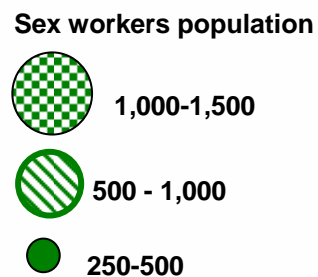
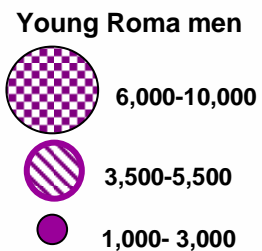
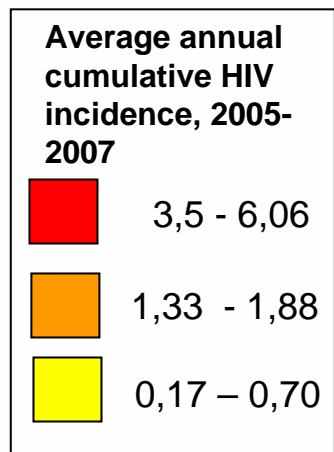


Distribution of newly diagnosed HIV cases by transmission group, Bulgaria, 01.01-31.12.2007

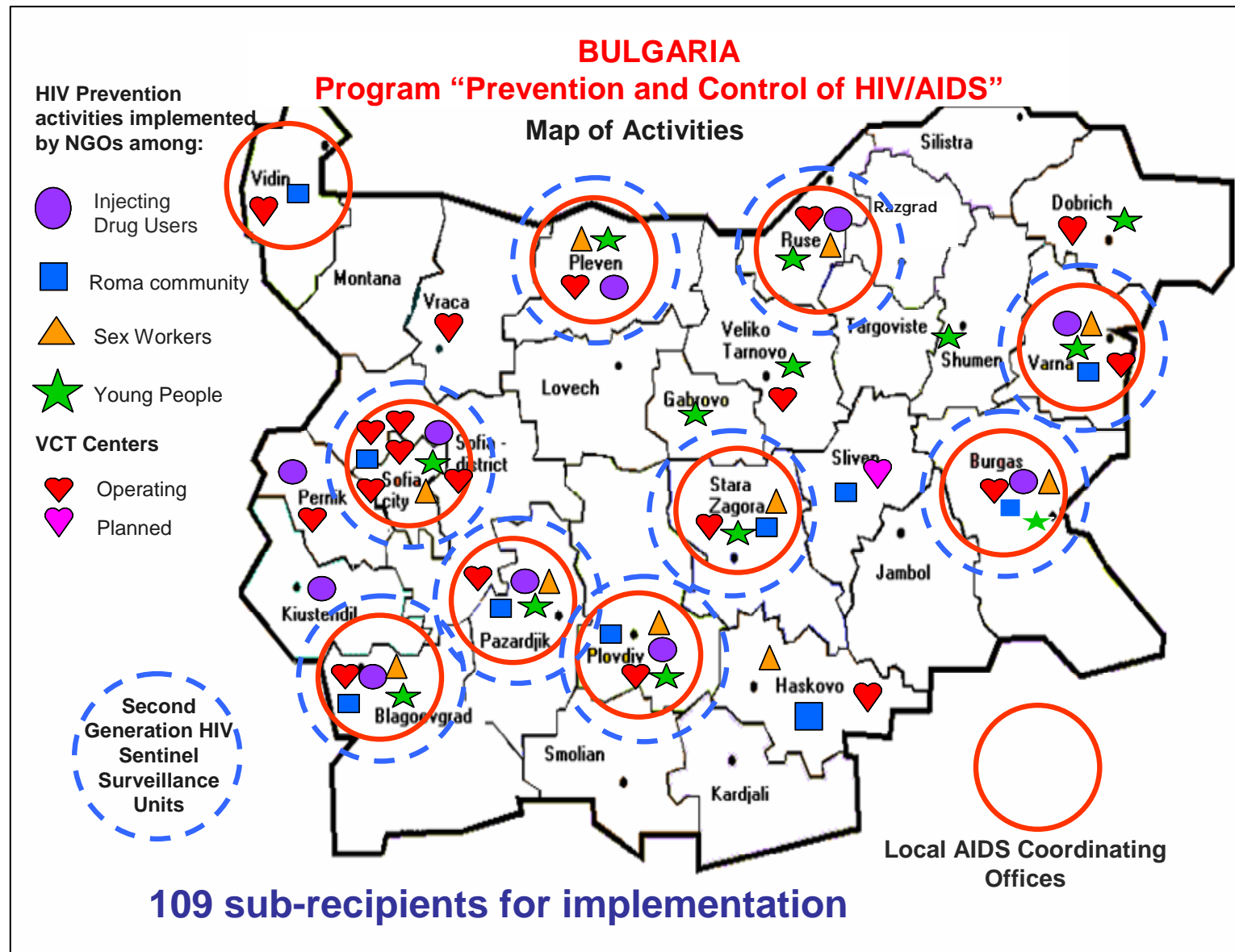


Source: Ministry of Health, Department for Prevention and Control of AIDS, TB and STIs, 2008

Mapping HIV incidence and population size estimates, Bulgaria, 2007

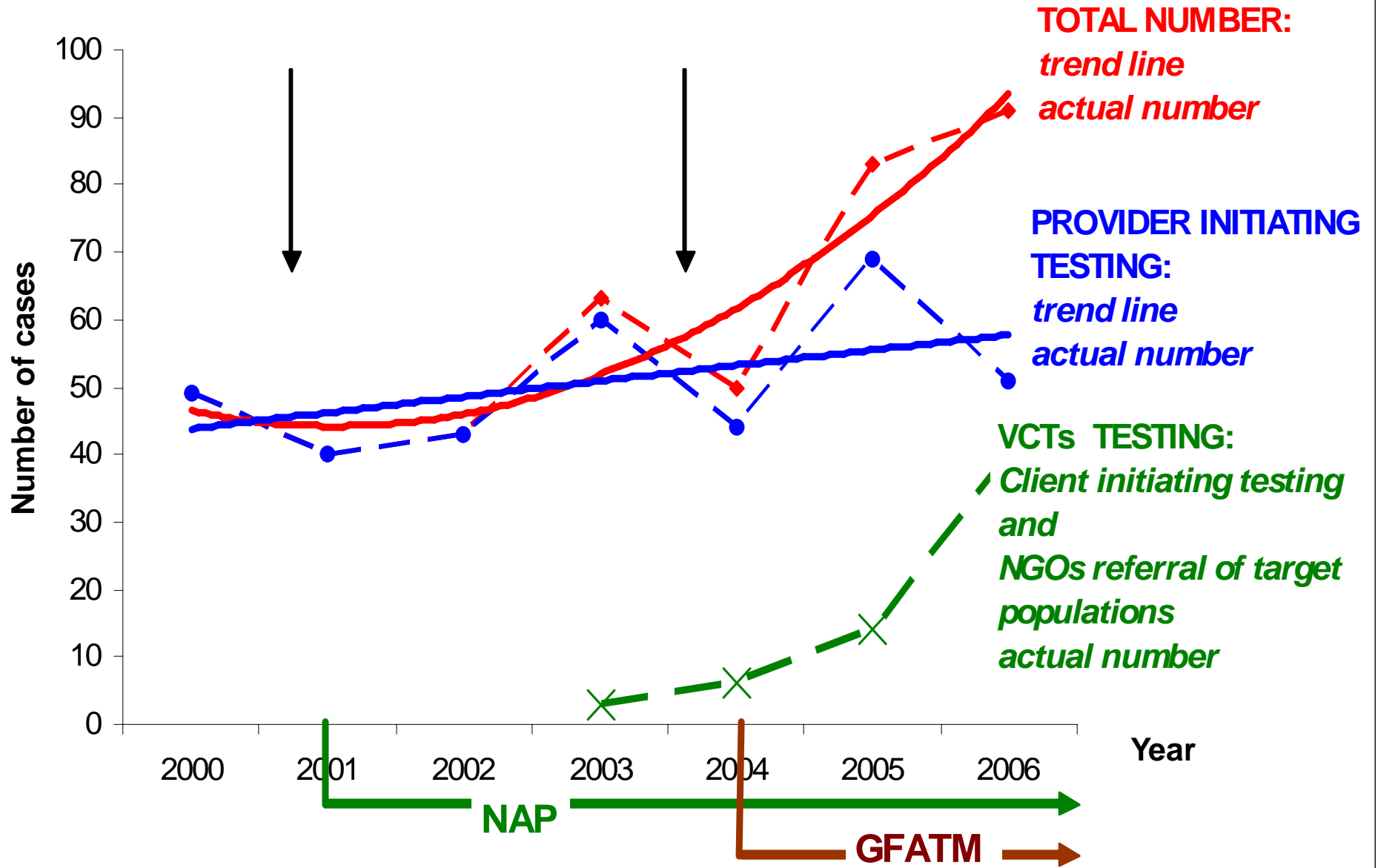


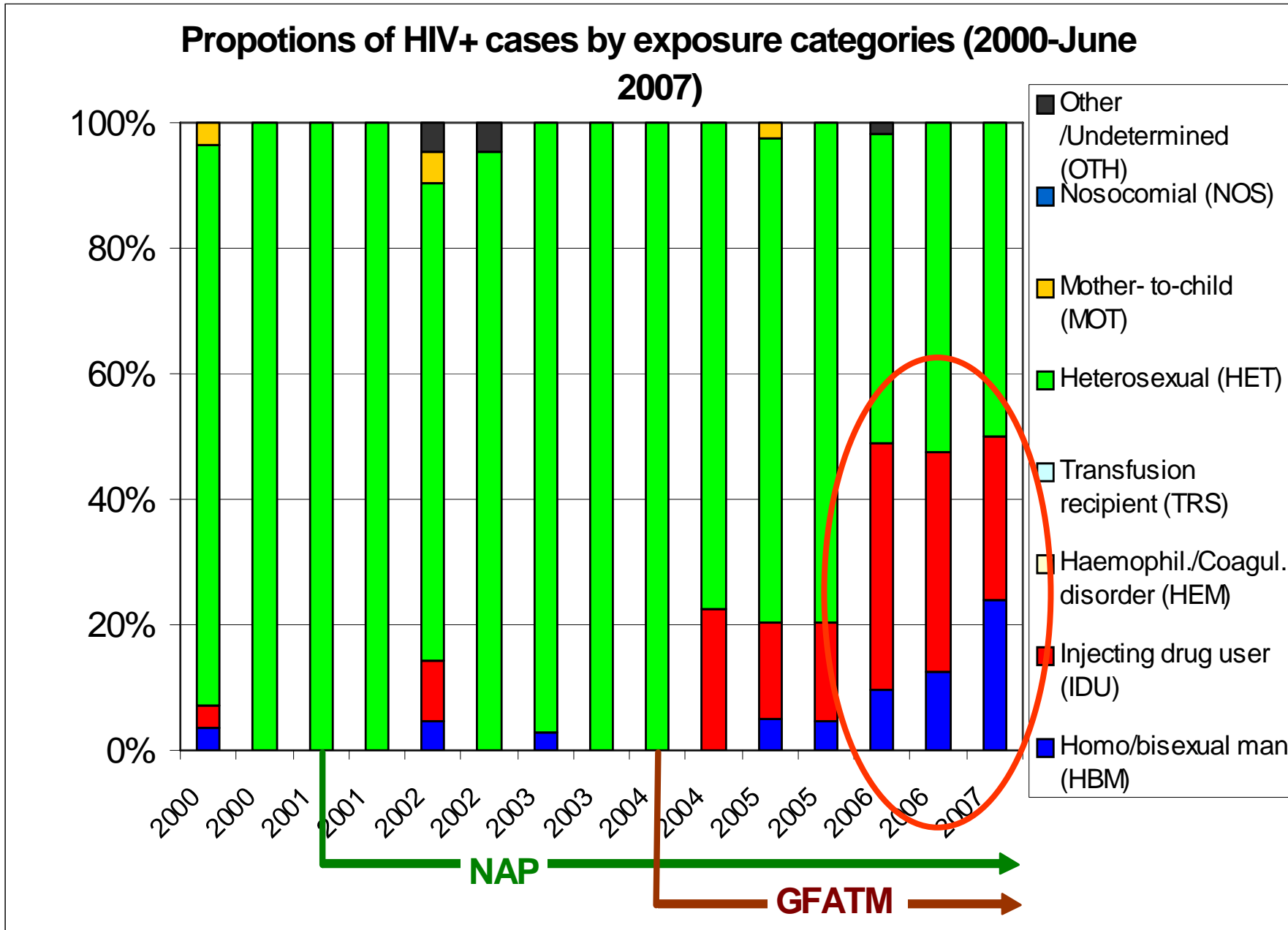
Prevention activities among vulnerable groups



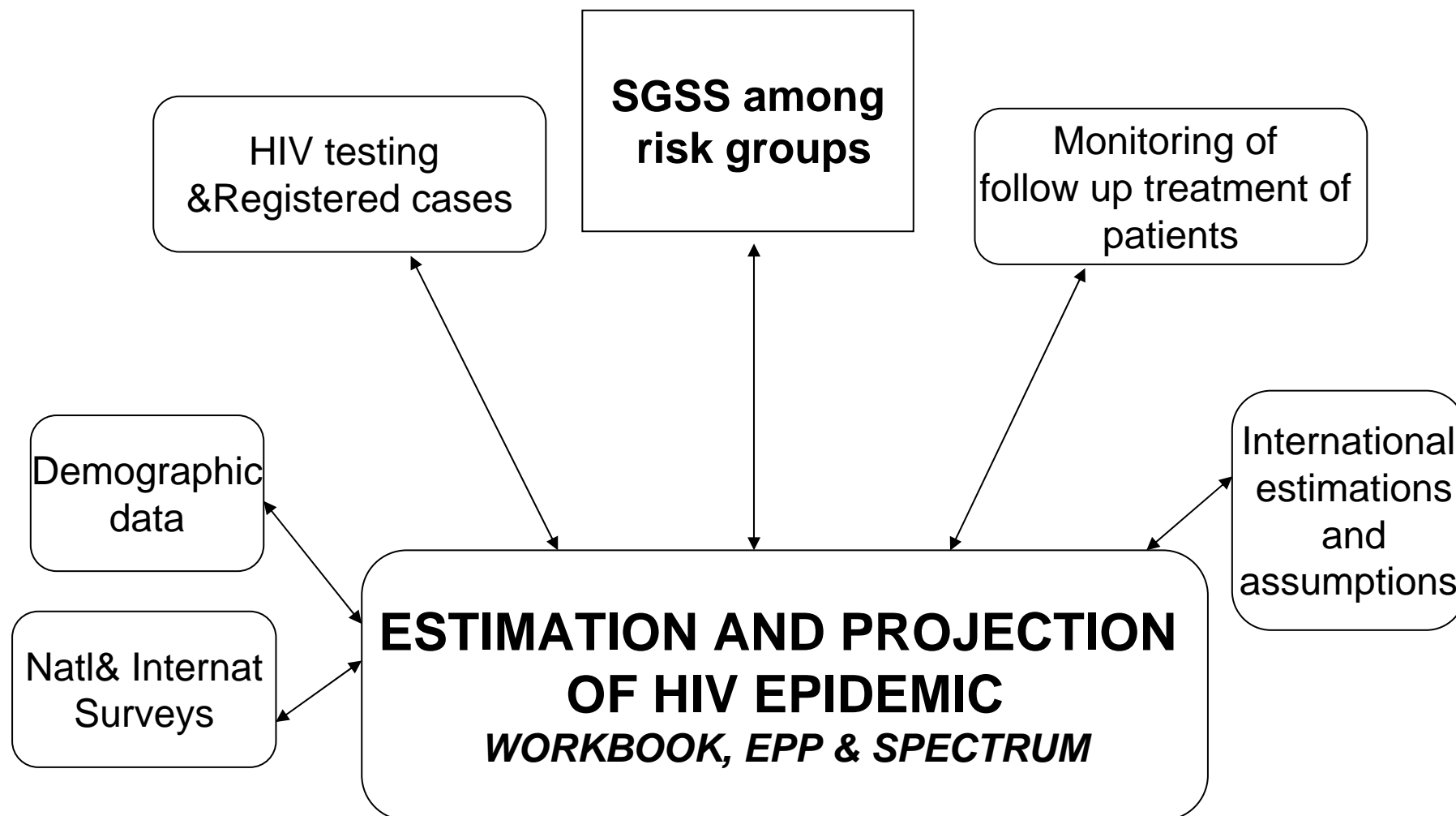
The Program is implemented in 19 priority districts (out of 28)

Trends in the number of new registered cases 2000-2006





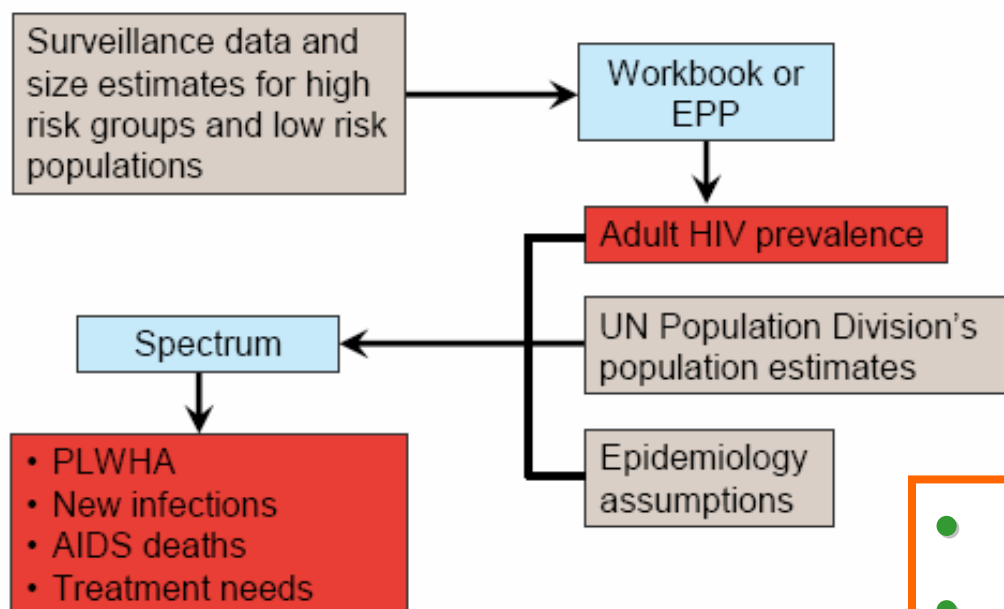
HIV surveillance system in Bulgaria



Algorithm for estimation and projection of HIV epidemic in Bulgaria, 2008-2015



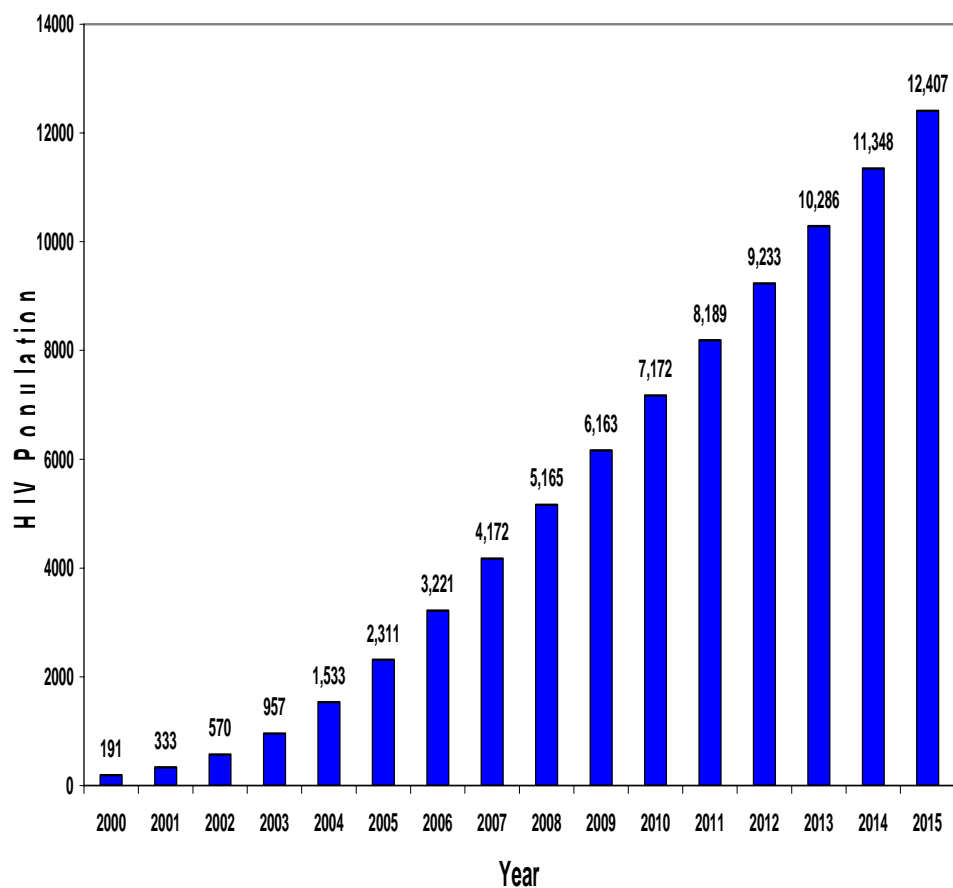
Overview for low-level/concentrated epidemics



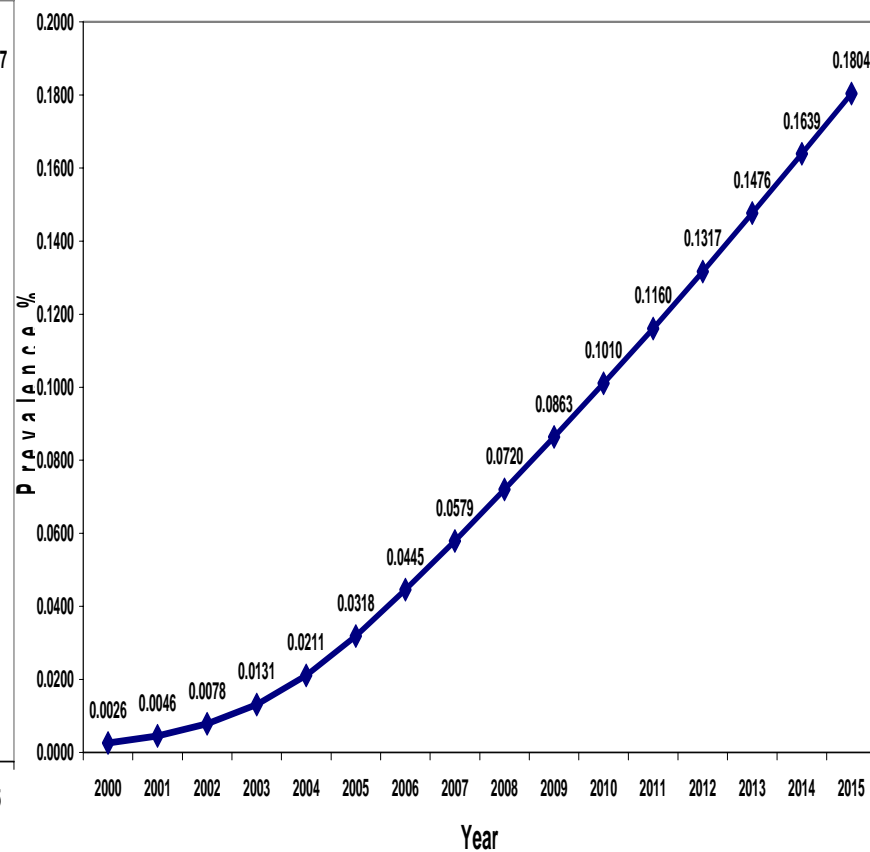
- Workbook
- Spectrum
- Resource Needs Model

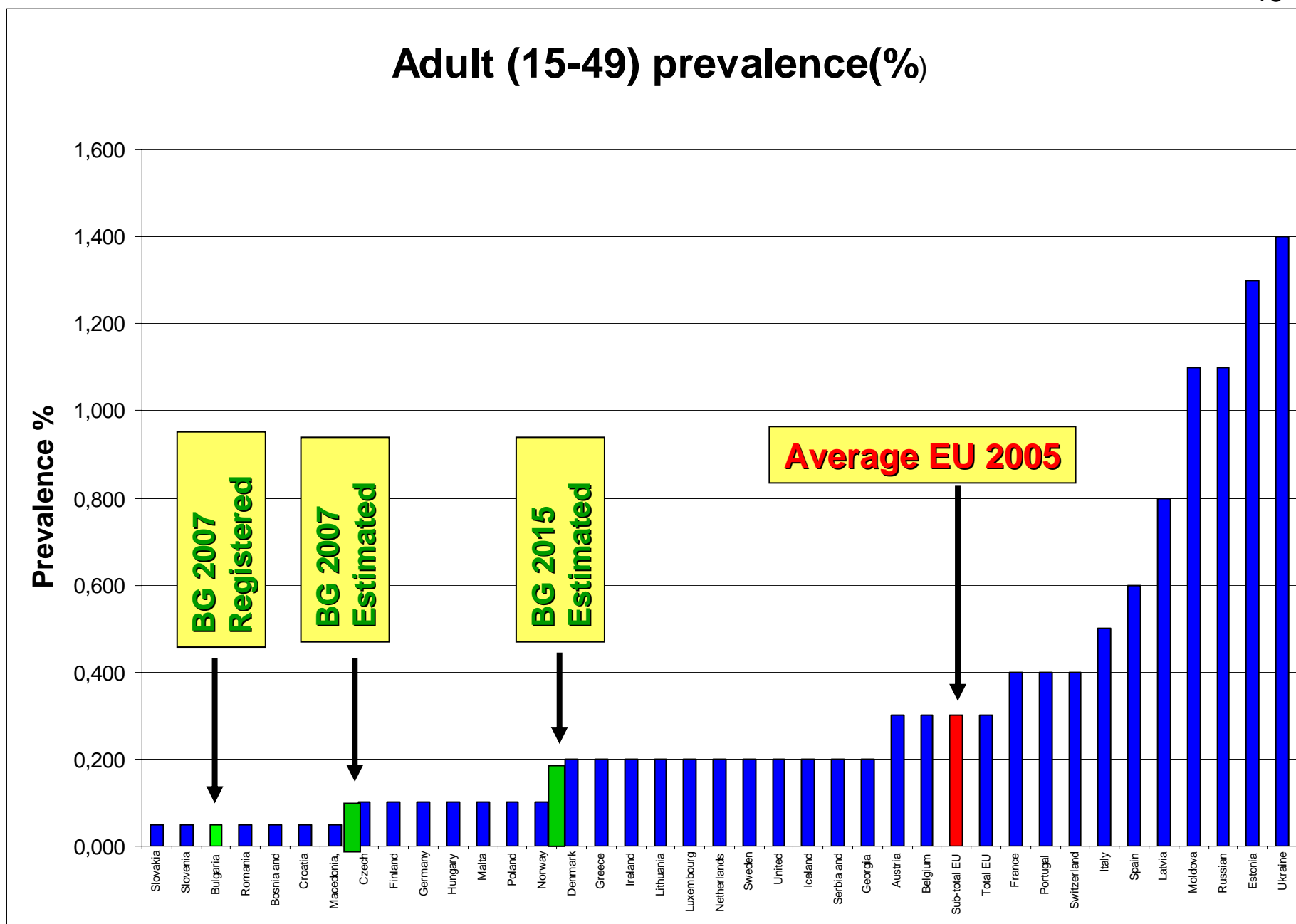
HIV prevalence estimates

Estimation and projection of the number of people living with HIV,
15+ years, 2000-2015, Bulgaria



Estimation and projection of adult HIV prevalence, 15+ years,
2000-2015, Bulgaria





Source: data from ECDC annual report 2007 – modified with estimations for Bulgaria for 2007 and 2015

Voluntary counseling and testing network

– since 2003

Goal – Increase from 33% in 2007 to at least 85% in 2015 the coverage of voluntary counseling and testing services provided to the most-at-risk groups in order to increase the proportion of HIV-infected people who know their status

Goal – By 2015 increase at least to 85% through both Provider-Initiated Testing and Counseling and VCT the proportion of HIV infected people who know their status

Challenges:

- Confidentiality
- Quality counseling,
- Partner notification
- Etc.



19 stand-alone VCT centres

12 Mobile medical units



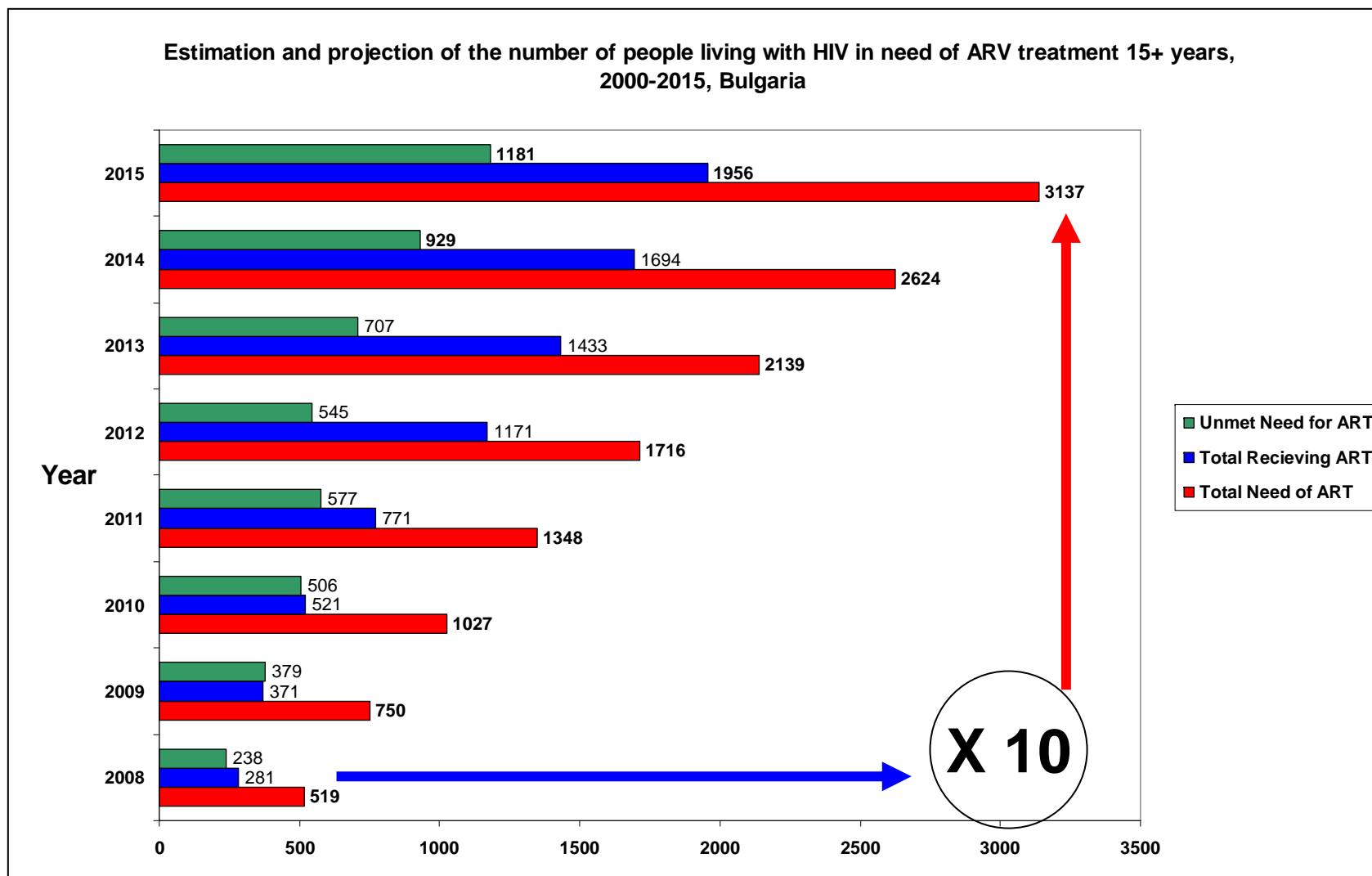
8 Health centers in Roma communities



5 Drop-in Centers for IDUs



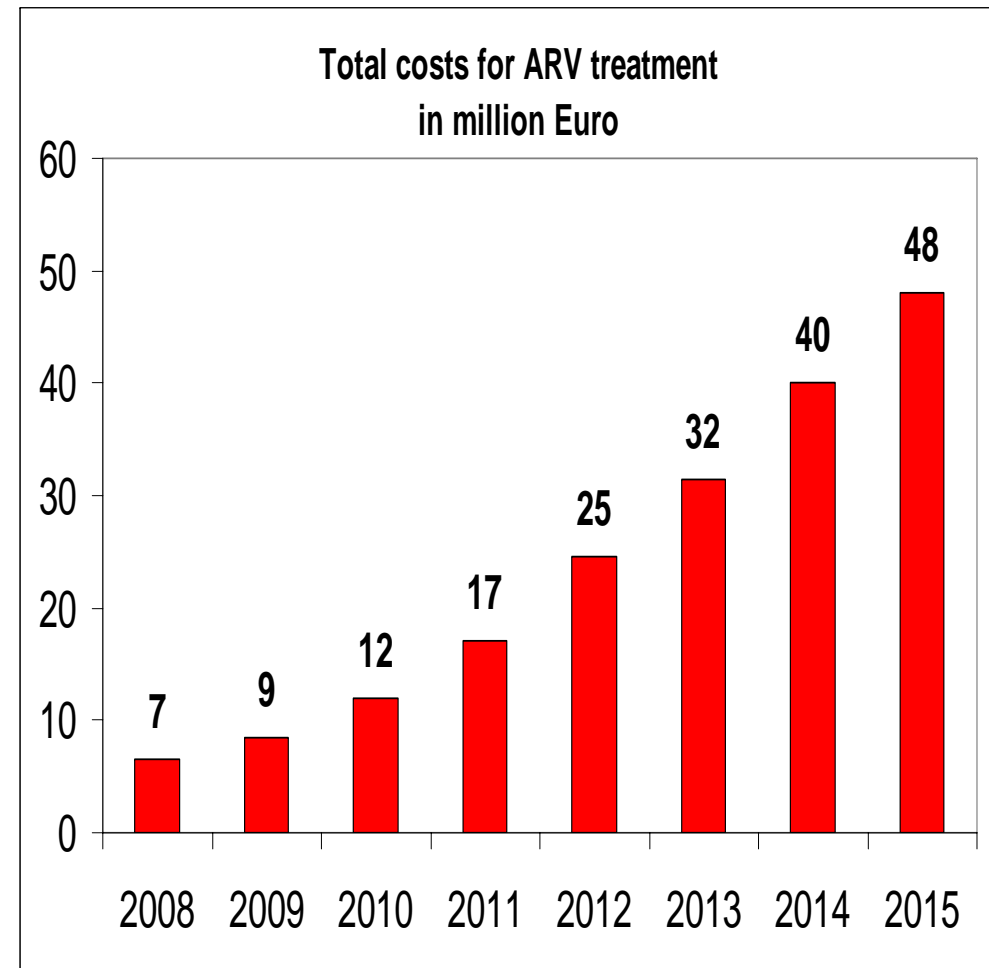
Estimated number of people needing ARV treatment



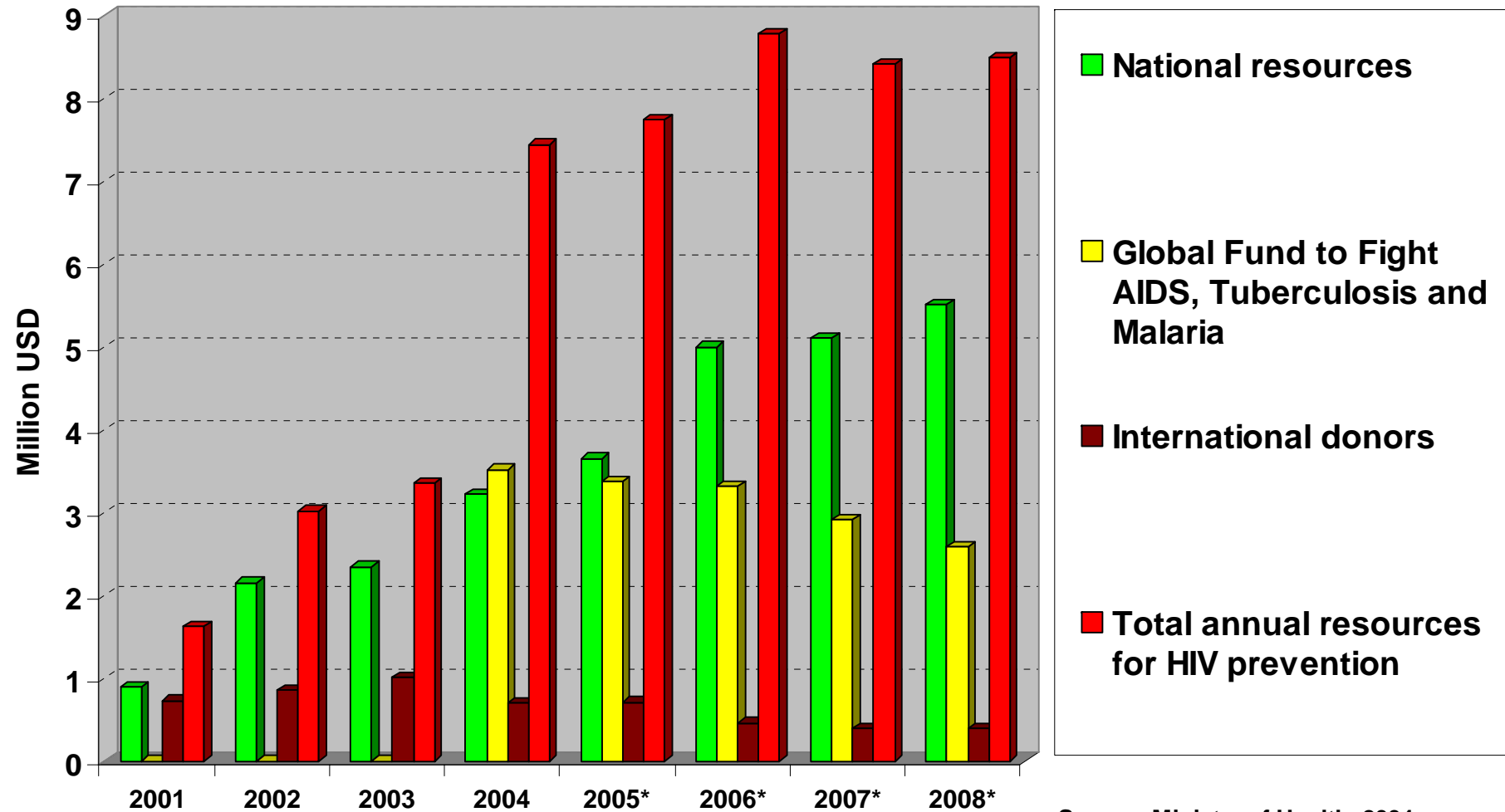
Strategy: To ensure universal access to treatment, care and support for all PLHIV

Goal – By 2015 ensure that **ALL diagnosed HIV infected people** have access to treatment.

Goal – By 2015 ensure that at least **85% of diagnosed HIV infected people** have access to care and support.



Financial Resources for HIV/AIDS Prevention and Control, Bulgaria, 2001-2008



Source: Ministry of Health, 2004

* Data for 2005-2008 is based on budget forecasts

ARV-TREATMENT COST PER PATIENT IS HIGH

	Bulgaria	Germany
Budget ARV	1.663.686 €	
Patients treated	205	
ARV cost / patient	8.116 €	14.000 €
GDP / capita	2.502 €	25.658 €
GDP corrected ARV cost / patient*	83.232 €	14.000 €
%	595%	100%

Compared to GDP/capita
Bulgaria pays relatively 6 x more
for ARV treatment than Germany**

** Other parameters c/should be considered, disease burden, purchasing power, ...

- **Post Bremen –affordable ARV initiative:
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ARV initiative at country level (1)

19 June 2007 – Bulgarian Ministry of Health, preliminary working meeting between representatives of the Ministry of Health of Bulgaria and representatives of the Federal Ministry of Health of Germany

25 June 2007 – Brussels, confirmation of ministerial commitment of Bulgaria, Estonia and Romania at an official meeting of the EU trio presidency, together with European Commissioner for Health, Markos Kyprianou, and Director General of DG Enterprise and Industry, Mr. Heinz Zourek,

10 July 2007 – Order of the Bulgarian Minister of Health was issued to establish a Working group responsible for the coordination and implementation of processes in Bulgaria related to the country participation in the initiative

- **Members of the Working group (12 people) include key representatives of:**
 - **Ministry of Health**
 - **Bulgarian Drug Agency**
 - **Representative of People living with HIV/AIDS**
 - **UNAIDS**

ARV initiative at country level (2)

11 July 2007 – Bulgarian Ministry of Health, preliminary meeting with representatives the pharmaceutical companies in Bulgaria

13 July 2007 - Sofia: political meeting between representatives of Minister of Health of Bulgaria, Federal Ministry of Health of Germany, and European Commission representatives

ARV initiative at country level (3)

21 September 2007 – Brussels, meeting with the participation of the Bulgarian MoH, German Federal MoH, representatives of European Commission (DG SANCO and DG Enterprise and Industry) and European pharmaceutical industry

November 2007 – Sofia, individual meetings with the participation of representatives of the Bulgarian MoH and pharmaceutical industry in Bulgaria

ARV initiative at country level (4)

December 2007 – Sofia, pharmaceutical companies with market authorization for ARV on the territory of Bulgaria officially state to MoH their readiness to actively participate in country-level processes and propose mechanisms for future cooperation

5-7 February 2008 – Sofia, expert meeting with participation of representatives of Program “Prevention and Control of HIV/AIDS”, National Centre of Infectious and Parasitic Diseases, ARV treatment departments for patients living with HIV, UNAIDS and US headquarters of Merck Sharp and Dohme (MSD), discussion of mechanisms to join the initiative

28 March 2008 – Sofia, Bulgarian Country Coordinating Mechanism to Fight AIDS and Tuberculosis takes decision to invite representatives of the pharmaceutical industry to become a member

ARV initiative at country level (5)

31 March–1 April 2008 – Sofia, meeting of delegation of the German Federal MoH, headed by Minister Ulla Schmidt, and representatives of Bulgarian MoH, headed by Minister Prof. Radoslav Gaydarski, participation of a representative of DG Enterprise and Industry, representatives of pharmaceutical companies in EU and Bulgaria

Next steps

January-March 2008 – Sofia, preliminary estimations and projections on the number of people in need of ARV treatment to 2015 and financial forecasts on resources needed for ARV medication

April 2008 – finalize of draft National Strategy and costed Action Plan for prevention and control of HIV/AIDS/STIs for the period 2008-2015

May-June 2008 – present draft National HIV/AIDS/STIs Strategy and costed Action Plan to pharmaceutical companies; and conduct negotiations on the concrete steps to ensure accessible and affordable ARV treatment and financial commitments from pharmaceutical companies to the implementation of the National Strategy and Action Plan

Bulgaria – accessible ARV treatment

Summary

- Ministerial political commitment
- Pharmaceutical industry commitment
- Participation of people living with HIV
- Existing prerequisites for successful implementation
 - National ARV treatment guidelines based on **EACS** guidelines
 - Since 1998 access to ARV treatment for all in need.
 - National Regulations and System for centralized ARV drugs procurement and distribution.
 - National Electronic Information System for HIV patients and ARV drugs monitoring
 - ARV drugs reserve for uninterrupted supply

Thank you for your attention

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