



EUROPEAN COMMISSION

HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate C - Public Health and Risk Assessment

C5 - Health strategy

IMPROVING ACCESS TO AFFORDABLE

ANTI-RETROVIRAL TREATMENT

Background note for the Think tank meeting on 20 Jan 2005

1. INTRODUCTION

This note provides background information on what actions the Commission has taken to review the situation in the Baltic States as regards the availability of ARV-drugs and to facilitate the process to improve the situation.

The issue of improving availability of affordable anti-retroviral (ARV) treatment has been identified as one of the key actions in the Commission working paper "*Coordinated and integrated approach to combat HIV/AIDS within the European Union and in its Neighbourhood*".

The Baltic States have signalled that based on the estimates of rapidly rising HIV/AIDS patient numbers, they are not able to provide sufficient treatment for all patients in need in the coming years. In addition, there is a wide difference in cost of treatment between the Baltic States [6392€ -10 000 €].

2. FACT FINDING

The Baltic States have provided information through the questionnaire and a summary of the key findings has been prepared. The pharmaceutical industry is in the process of preparing a report on the actions that the companies are taking in the Baltic States.

A roundtable meeting was convened on 30 November 2004 between the Baltic States, pharmaceutical industry, a patients' organization and the relevant Commission services to clarify what actions the governments and the pharmaceutical industry have taken to overcome any problems, and to identify pragmatic solutions.

3. PRACTICAL SOLUTIONS

Price negotiations

Price has been one of the main issues under discussions between the key stakeholders. Regarding the purchasing of medicines Estonia has funding from the Global Fund. In Lithuania the state patient fund under the Ministry of Health purchases ARV-medicines and in Latvia medicines are paid from the state budget.

The industry representatives have been very clear that as there are already on-going price negotiations between the individual governments of the Baltic States and the pharmaceutical industry, there is no need for further discussions on price. From the industry perspective there is a need to look at the HIV/AIDS treatment issue in more comprehensive way i.e. prevention, harm reduction, social care and treatment instead of focusing only to the pharmaceutical treatment.

Furthermore, the representatives of the pharmaceutical industry have expressed concerns if possible solutions on price reductions would cause unwanted effects such as leakage of drugs, parallel exports, impact on prices elsewhere.

Concerning the threat of leakage of medicines the risk is small because the treatment is organised centrally in all the Baltic States and the distribution channels can be controlled and monitored.

Public procurement

Centralised purchasing is already done by the Baltic States with regard to provision of vaccines and similar approach has been suggested as applicable to ARV-medicines. According the Community law national authorities of different states can act together for public procurement. However, national law may have rules about who can act for whom (e.g. budgetary authority to make commitment from public funds).

Local manufacturing

Latvia has one pharmaceutical company which could have a capacity to manufacture ARV-medicines. Regarding the patented products there are two possible ways to manufacture; to agree voluntary licence with right holder or order grant of compulsory licence for manufacture.

Generics

Currently only Latvia uses generics from Cipla (India) and HEXAL. Estonia and Lithuania do not use generics on ARV-drugs.

EU financial support mechanisms

Currently the Structural Funds are being used (2000-2006) to finance mainly health infrastructure but also some health innovation and cross border co-operation projects. As from 2007, the scope of financing will be extended to include issues like modernization of health infrastructure, technical assistance, productive investment including medical equipment, medical devices, laboratories, introduction of IT systems in medical services. However, medicines can not be financed.

The financial instruments (loans) of the European Investment Bank are complementary to other financial mechanisms and therefore could be taken into consideration already when planning a large scale health project.

4. CONCLUSIONS

(1) The Roundtable meeting held on 30 Nov agreed on the importance of developing an effective action to tackle HIV/AIDS in the Baltic States and that ensuring full access to ARV-drugs is a key part of that.

(2) The representatives of the Baltic States, pharmaceutical industry and patients' organisation agreed on the desirability of continuing dialogue on this topic with a wide range of stakeholders such as WHO, UNAIDS, patient representatives, and relevant NGOs.

(3) The Think Tank is now invited to consider the following;

- Do other EU Member States face problems in ensuring full access to affordable ARV-treatment?
- Is there a need to establish a working group or a platform to continue discussion on this topic and to develop an action plan on how to take work forward in practical terms?