





Initiative on sustainable access to ARV drugs

Presentation for the 09th Meeting of the HIV/AIDS Think Tank

Ortwin Schulte
Fed. Min of Health Germany







Bremen Conference March 2007

"Responsibility and Partnership – Together Against HIV/AIDS"

Main results

- Bremen Declaration on prevention, strategy and role of civil society
- → Debate on HIV/AIDS on heads of state level
- → Common statement of Presidency and eight ARV producing pharmaceutical companies







Common Statement

Commitments of pharmaceutical industry

- holistic and joint effort with all stakeholders
- adressing barriers to access ("complex puzzle involving (..) cost for treatment")
- ensure affordability and accessibility







Implementation process (overview)

steps already taken

- nomination of pilot countries within EC
- coordination with European Commission
- → Deputy Ministers meeting with pilot countries
- Coordination meeting with ARV-producers
- in-depth discussion with pilot country and selected ARV producers







first participating countries

first participating countries

- → Bulgaria
- → Romania
- → Estonia

participating institutions

- → European Commission (SANCO, ENTR)
- → Trio presidency (DE, PT, SLO)







coordination with European Commission

involved GDs

- → SANCO (health policy, HIV/AIDS strategy)
- → ENTR (pharmaceutical industry)
- → COMP (antitrust law, competition law)
- → MARKT (reimports within EC)
- → TRADE (external trade, distribution line)







Deputy Ministers meeting with pilot countries

Main topics

- → analysis of current HIV/AIDS situation
- perspective on need for ARV treatment
- → health budget available for ARVs
- current prices paid for ARVs
- price negotiation techniques







Coordination with ARV-producers

Chair

Germany together with DG SANCO and ENTR

Main topics

- reminder for commitment of industry
- need for individualised solutions company by company (no coordinated offers)
- presentation of progress reached so far







in-depth discussion with pilot countries and ARV producers

purpose of the meeting

- discussion of holistic approach with COM, concerned state and key players of industry
- presentation of prevention policies and HIV/AIDS strategy, but no negotiations on policy contents with ARV producers
- general debate on possible price differentiation techniques







Cross-cutting issues (1)

AIDS policy

- → ARV prices can not be isolated from political decisions on HIV AIDS prevention, strategy and treatment.
- → Political decision have to be taken by member states. Industry can comment on decisions but not be included as a contracting partner.







Cross-cutting issues (2)

Negotiation process on ARV prices

- different techniques and different results among member states of EU
- no common basis for entering into negotiations with industry at EU level
- country by country approach







Cross-cutting issues (3)

Price situation on ARVs inside EU

- Current situation does not reflect differing levels of GDP in member states
- → Intransparency of prices very complex process of comparison.
- Price reductions for new member states are urgently needed.
- → Prices for ARVs needed in small quantities are often far too high.







Cross-cutting issues (4)

Negotiation position of ARV producers

- → Industry is generally trying to play for time, although at least some companies understood the message.
- → Nearly no willingness of companies to talk about prices, but about overall cost for treatment (natural rebates) and response to HIV (cofinancement of prevention projects)







Cross-cutting issues (5)

New pricing techniques

- current situation call for tenders; price negotiations; reference pricing; special prices for health insurances
- new instruments budgets for treatment instead of prices per unit; advance agreement on price degression for increase in ARV treatment







Global issues

Influences from outside EU

- negotiations on compulsory licensing for ARV products in some non-EU countries
- entitlement through Art. 31 TRIPS agreement
- additional import waiver for states without own pharmaceutical industry







Consequences for EU-debates

- → starting point: inapplicability of TRIPSprovisions inside EU
- no provisions about compulsory licensing in European patent law
- justification of national measures of compulsory licensing under EU law needs clarification
- common interest on sustainable solutions under the ARV initiative

This paper was produced for a meeting organized by Health & Consumer Protection DG and represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.