



Concept Paper

Ensuring access to essential medicines in Europe

The event will take place in the European Parliament on the 16th of May 2013 and will be hosted by Alejandro Cercas, MEP, (S & D Spain) who has been active in issues relating to access to medicines and fundamental rights. The event will be an activity of European Public Health Alliance with the collaboration of the Transatlantic Consumer Dialogue, Health Action International and the Pharmaceutical Group of the European Union. The project aims to focus attention on the state of access to medicines inside the EU, particularly in Southern and Eastern Europe- the countries the most hit by austerity measures and cuts to health budgets. Through a high-level conference we intend to influence and initiate major policy debates in the EU institutions and on national level on legal, financial and scientific measures that could be employed to secure the width and breadth of access to medicines that does not compromise equity. Besides being among the first of its kind, this event has the added value of bringing together groups of people whose expertise seldom gets gathered in one event.

What is EPHA doing?

EPHA has been dedicating an increasing amount of work to issues related to health in the economic governance processes at the EU level, namely health impact of the current financial crisis and subsequent austerity measures. The project addresses an essential issue within this area. It focuses attention on the current state of access to medicines inside the EU, particularly in Southern and Eastern Europe, the areas hardest hit by the crisis. Through a high-level conference we intend to initiate major policy debates in the EU institutions and on national level on legal, influence future processes that impact access to medicines and highlight financial and scientific measures that could be employed to safeguard an equitable access to medicines.

Co-Hosted by:

MEPs- To be identified from all major political groups and countries with medicine shortages.

- EPP MEP to be identified, preferable Peter Liese
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Organised by:

European Public Health Alliance

With the collaboration of Transatlantic Consumer Dialogue, Health Action International, and the Pharmaceutical Group of the European Union

Where and when:

European Parliament (Brussels)

Room: to be identified by MEPs

16th of May 2013 9.00-17.30.

Political and Policy Context:

The event will build on work done by the Cypriot Presidency when the Network Meeting of Competent Authorities on Pricing and Reimbursement (NM CAPR) discussed access to medicines in Europe that exchanged best practices and expertise in controlling pharmaceutical expenditure, in equal patient access to medicines and in rewarding innovation among Member States. The Meeting of the Heads of Medicines Agencies (HMA) on the 20-21/9/2012 and The European Medicines Agencies Cooperation on legal and legislative Issues meeting (EMACOLEX) received a presentation from, George Antoniou, Senior Pharmacist of

the Pharmaceutical Services has presented the problems faced by Cyprus concerning the access of medicines. In the Senior Level Working Party on Public Health there is a working group on cost-effective use of medicines that will draft a policy paper by the end of 2013.

The current financial crisis has had a profound impact on the ability of EU member states and public health systems to adequately provide many necessary medicinal products for people living in Europe. Through gathering experts in the field of pharmaceutical pricing, access to medicines, and health economics EPHA and partner organisations aim to develop recommendations to be presented to multilateral institutions, Ministries of finance, research and health.

This project aims at presenting information on the current situation of access to medicine in Europe and to consider possible responses to this problem. Issues to be dealt with would be the prices paid for the most important (essential) medicines in different member states, the degree of coverage for health expenditures or out of pocket payments of patients across Europe, the current biomedical innovation model and the effects of the sovereign debt crisis on access to medicines. Experts will present to policy-makers possible alternatives to the high price of medicines and will consider **new models of biomedical innovation that is inter-alia affordable and health needs-driven.**

Although the health impacts of the crisis and budget cuts to public health care are visible and felt by the public, quantifying and measuring the impacts i.e. on access to medicines remains difficult, due to a time lag in the availability of data. This poses a challenge to policy makers who today have to take decisions on where to make savings without reliable scientific evidence.

One of the overarching goals for EU policy making is to achieve financial sustainability, in the field of health, which entails modern and sustainable health systems. Subsequently the proposed event will be relevant politically for several reasons.

First countries receiving financial assistance from the International Monetary Fund, EU, and European Central Bank receive specific recommendations on making health systems financially stable, including public procurement, pharmaceutical pricing, and use of generics.

Secondly the issue should be high on the political agenda, as revised EU Legislation on serious cross-border threats to health would also allow member states to purchase vaccines jointly, thus enabling more equitable access to vaccines at a better price. This is an issue of growing public concern, which the project would reflect in an attempt to deliver tangible results for people living in Europe. In March 2011 the European Parliament adopted a resolution on reducing health inequalities in the EU. In the text MEPs “*Urge(s) the Commission, in the context of its collaboration with the competent authorities of the Member States, to promote best practices on pricing and reimbursement of the cost of medicines, including workable models for pharmaceutical price differentiation so as to optimise affordability and reduce inequalities in access to medicines;*” Therefore, the project would be an example of civil society collaborating with EU policy makers to improve health.

In addition the project will explore new models of biomedical innovation that would generate accessible and affordable medicines for people living in Europe. This will build on the Council Conclusions of 2010 that calls on the EU to explore models that dissociate the cost of Research and Development and the prices of medicines.

Steering Group for the event:

A steering group will be set up in order to deal with the organization of the event. It will be composed of Leonardo Palumbo, Matthias Schuppe and Joana Lima (EPHA). EPHA members will also participate. Javier Del Gado (EPHA) will join the Steering Group meetings where communication aspects are discussed. David Hammerstein from TACD, Tessel Mallema and Katrina Perekhodoff from HAI will also participate as will Giovanna Giacomuzzi from PGEU.

Draft Agenda- to be developed by EPHA with support from project partners

Speakers:

- Hosting MEPs
- Experts from academia
- Experts from WHO and OECD
- Activists from Civil Society
- Patients from affected countries
- Possible ECOFIN and IMF
- Representatives from MoHs

In addition the recommendations could feed into a number of political processes:

- The "European Innovation Partnership on Active and Healthy Ageing" is a pilot project under the Innovation Union flagship initiative. It aims at enhancing Europe's innovation potential for tackling the challenges of demographic change associated with ageing.
- Creation of a panel of independent experts to work on the improvement of health care systems;
- The revision of the Directive on Medicinal Products for Human Use: transparency of measures regulating the prices and their inclusion in the scope of public health insurance systems;
- The revision of the Clinical Trials Directive;
- The conclusions of the negotiations between the Parliament and the Council on Horizon 2020, the future research framework programme;
- The creation of a network of national authorities and bodies responsible for Health Technology Assessment (HTA) at EU level, (expected to be launched in late 2012, therefore work would begin in 2013).
- Revision EU's action plan on combating HIV/AIDS 2009-2013, (ends in 2013 one priority is to improve access to prevention, treatment, care and support)
- Revision Cancer Action Plan, (ends in 2013 one of the action areas to be access to medicines)
- Hearing of the EP working group on health. Wednesday, 18 September, 13.00-14:45 Effectiveness of medicines and therapies.

The expected outcomes are:

- to raise awareness of impacts of financial crisis and austerity measures on access to medicines:
- the development of policy recommendations in the area of biomedical innovation to ensure adequate and affordable access to medicines in Europe in the future,
- the identification of best practices in times of austerity for example socially responsible licensing and open source medical research,
- the creation of a network of experts in Europe on access to medicines in the EU;
- to link interested policy makers at EU and national level, (Ministries of health, MEPs, Commission Officials),
- to strengthen the network of civil society to be able to jointly promote access to medicines within the EU,
- to deepen the evidence base for financial decision making and its impacts on access to medicines,