DECLARATION ON ACCESS TO MEDICINES

An undeniable right slipping away: recommendations to avert a public health disaster

While great sacrifices are demanded from many citizens of the European Union (EU) solidarity and social justice, essential pillars of the Union, should be better protected by its policy makers. Under the banner of austerity, we have been seeing a curtailing of healthcare coverage for certain groups on the basis of their residence or insurance status that run against both human rights and sanitary principles. The proclamation "they save the banks, but not the people" is starting to ring uncomfortably true. **The EU cannot continue to ask for the sacrifices of deep budget cuts in basic services like health care without also taking clear measures to prevent significant and at times dire consequences on the lives of millions of people living across the EU.**

The enduring economic crisis is affecting the ability of many EU Member States to adequately provide many of the necessary medicines to the people living in their country as they are forced to take measures to scale down public pharmaceutical spending. Meanwhile, pharmaceutical companies continue to market their new medicines at increasingly high prices, for instance in the field of cancer[1], biological medicines and hepatitis C. In addition, opportunities to introduce policies aimed at a more rational use of medicines are being foregone. WHO estimates that half of all patients fail to adhere to prescribed treatment or fail take their medicines correctly[2]**. Not only is irrational use of medicines and non adherence expensive per se but also its side effects is a financial burden to already strained health systems. The crisis presented an opportunity to make the economic argument to reduce waste and**

[1] Kantarjian H. The Price of Drugs for Chronic Myeloid Leukemia; a Reflection of the Unstainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts (2013). *Blood* Magazine. accessed on May 2nd 2013

[2] The Pursuit of Responsible Use of Medicines: Sharing and Learning from Country Experience. World Health Organisation 2012

optimise treatment outcomes shift the response from rationing to rationalization: this opportunity is not being seized. In order to continue benefit from medicines use and accessibility basic principles of appropriate use, taking into account benefit-risk aspects and cost effectiveness issues have to be respected.

A number of public health crises caused by acute and chronic medicine supply shortages as a result of manufacturing/GMP compliance problems has been registered by medicine regulators[3]. First hand reports from health care professionals, for example pharmacists[4], and patients indicate that problem of medicine shortages in the EU is on the rise.

We are deeply concerned about the impact of certain measures taken to reduce public deficits on access to medicines in Europe, in particular, in the EU regions hardest hit by the crisis and with regards to vulnerable groups such as migrants, minority populations, the undocumented, uninsured, dependent persons and the elderly. This situation is at odds with the EU's own commitments to integrate health into all its policies and to achieve health equity across the EU, as reiterated in the Council Conclusions (Council Conclusions on Equity and Health in all Policies, 8 June 2010). Given the increasing role of EU institutions in shaping health system reforms, as evidenced by the loan conditions on Memorandum of Understanding (MoU) in programme countries, we call upon the European Union leaders to take the following concrete policy initiatives:

I. Evaluate the impact of fiscal consolidation measures on health and access to medicines, prevention and diagnostics

Today, the European Commission does not perform any research to assess the immediate effects of the fiscal consolidation measures on health. The European Commission has up until now only advised on budget cuts for health, without assessing the health impact of economic measures – in particular the measures responding to the crisis during negotiations with the Troika[5].

[3] Patient Health Protection – Reflection paper on medicinal product supply shortages caused by manufacturing /Good Manufacturing Practice Compliance problems, EMA/590745/2012 - November 2012

[4] Medicine Shortages in European Community Pharmacies, PGEU - Pharmaceutical Group of the European Union, May 2013 Ref 12.08.28E 003

[5] This is the European Commission, International Monetary Fund and European Central Bank, forming a group of international lenders provide bailouts to European Countries accompanied by measures to reduce public spending.

Therefore we:

- Call upon the European Commission to **carry out a health impact assessment of fiscal consolidation measures taken over the last two years** in EU Member States on national health systems to assess in particular their repercussions on the accessibility and the affordability of health services and medicines in the EU.

- Call upon the Commission to c**arry out an independent health impact evaluation** before any new fiscal consolidation measures are requested from Member States by the Troika and within Country Specific Recommendations in the European Semester with clear compensatory measures proposed with regards to access to medicines, with priority to life-saving treatment.

- Ask the Commission to **take immediate and effective measures to assure the protection of the right to health care and access to medicines of vulnerable groups within EU Member States**, such as migrants, the unemployed, the uninsured, the elderly, minority populations, prisoners, patients with disabilities and children. This should include taking measures that promote affordable and equitable medicines prices.

- Call upon the Commission to **recognise the urgency and patient safety impacts of worsening medicines supply chain shortages, their pan-European nature, and their connection in many cases to austerity measures being taken by national countries.** Further to this, the Commission should take a lead in evaluating the nature of the supply chain problems and the role of relevant European DGs and Agencies in improving the situation, including the development of more sustainable systems of medicines pricing and reimbursement in Europe that works for system payers, the supply chain, and most importantly, secures long term patient access to medicines.

II. Transparency

Publicly accessible prices of medicines do not always reflect the real transaction price. This is due to a number of strategies including rebates, discounts and pay-back mechanisms. Barriers to transparency also include secrecy around prices that health authorities and insurers pay for medicines, and a price determination process which limits opportunities for price comparison.

Informed price negotiation can be an effective way to control medicines expenditure without constraining health services in face of shrinking public health budgets. In addition, transparency of reimbursement decision making and clinical trials data is a must as it can enhance rational decision making.

Therefore we:

- Call upon the European Commission to facilitate negotiations between the European Parliament and Council **to revise the Transparency Directive[6] to make sure it mandates the creation of an online database with comparable information on prices across Member States (procurement prices, reimbursement prices, patient prices,** etc. This tool should be publicly accessible and updated annually by the Commission based on information collected from EU Member States.

- Call upon the European Parliament, European Commission and the European Council to **take legislative steps to assure the transparency and public accessibility of all clinical trial results** with the objective of permitting public health authorities, health professionals and patients to choose the best possible treatment based on efficacy, risk-benefit balance and effectiveness of medicines.

- Ask the Commission to take steps **to assure the transparency, data sharing and public accessibility of EU Member State medicine evaluation committees** with the highest degree of independent review and public participation.

- Call upon the European Parliament and the EU **to demand transparency**, and to pharmaceutical companies to be transparent on the cost structure of pharmaceutical R&D and the justification for market prices.

[6] The Directive 89/105/EEC of 21 December 1989 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion within the scope of national health insurance systems.

- Call upon the Commission **to take legislative measures and monitoring to assure a greater level of transparency and free public access to EU financed health-related data and clinical trial data** with the aim of greater efficiency, expert evaluation and public scrutiny.

- Call upon **European Medicine Agency to continue implementation of its transparency policies** and to go ahead with publication of Clinical Trial database.

- Call upon Commission to recognise that **therapeutic, safety and commodity advances should become part of the key criteria for the marketing authorisation** process.

III. Cooperation at EU level

EU Member States have different national GDPs, different levels prevalence of diseases, thus the financial burden of buying medicines varies from one country to another. Moreover, **many of those in need cannot afford and access truly innovative medicines** in a number of member states - *e.g* cancer, rare diseases, auto-immune diseases , viral hepatitis, tuberculosis and HIV. In 2010 already, Council Conclusions on Innovation and Solidarity in Pharmaceuticals called on member states and the Commission to "examine how to facilitate availability to innovative medicinal products throughout the EU.[6]

Despite the fact that more than half of patients do not take their medicines appropriately, **there is very little attention to research and policy on rational use of medicines and adherence.** Rationalising use of effective medicines that are currently on the market can bring about the same benefits in terms of patient and system outcomes as development of innovative treatments.

Therefore we:

- Call upon the European Commission **to consider coordination among EU Member States on joint procurement of medicine**s where such cooperation could be beneficial for all Member States to help assure affordability of these products in cases such as emergence of European wide health threats.

- Call upon Commission **to facilitate dialogue on cost-containment tools to ensure access to medicines**, including price reductions for innovative medicines and facilitate pilot projects on innovative approaches to ensuring affordability of medicines for chronic diseases. Amongst others tools, the Commission should help member states to revisit the Bremen

initiative on affordable ARVs[7] based on its lessons learned; investigate mechanisms of tiered price on expensive innovative medicines in the EU, by GDP and burden of disease, etc".

- Call upon Commission **to promote policies and best practices aiming to address rational use of medicines and adherence.**

- Call upon Member States **to ensure that clear strategies and policies supported by research are in place** and framed within the organisation of the healthcare system as a whole and vision which gives due consideration to the role and contribution of all involved in the rational use of medicines process.

IV. New innovation models

The current innovation model is failing to satisfy the unmet health needs such as TB, HIV/AIDS, antimicrobial resistance, etc and the equity of access to medicines across the EU. For publicly financed research to revert into the public good, a new legal framework is needed to ensure that research results fulfil broad social objectives.

Therefore we:

- Call upon the European Commission **to address the issue of access (affordability and availability) to medicines in upcoming proposals**, such as the action plan on chronic diseases, the action plan to combat HIV/AIDS, and action plan against cancer.

- Ask all EU institutions **to make full use of the opportunity Horizon 2020 provides to explore the "de-linkage" of research and development (R&D) costs from the final price of medicines to improve needs driven innovation and affordable medical products.** This could entail pilot programmes and econometric studies on new innovation models for biomedical research that include innovation inducement prizes, patent pools, open source research and public development partnerships.

- Ask the European Institutions **to ensure that EU´s research and innovation funding better reflects the opportunities presented by knowledge sharing and open innovation for medical innovation.** EU research funding, in particular Horizon 2020 should require OpenAccess to research publications and promote open access to research data.

[7] European Perspectives in Personalised Medicine. Project Group on facilitating supply in small market: Position Paper and Recommendations. European Commission .

- Ask the Commission **to explore the possibility of creating product development partnerships,** within the context of Horizon 2020, for the R&D of new pharmacological treatments of cancer, HIV-AIDS cardio-vascular diseases, diabetes and other serious chronic diseases with the aim of producing affordable and effective innovative medicines responding to key health needs. Ask the Commission to take measures to ensure the affordability and accessibility of medical products through licensing terms in EU investments and public risk taking in pharmaceutical research that is financed from tax payers' money.

➢ ***This declaration is signed by:***

- *Active Citizenship Network*
- *Collectif Interassociatif Sur la Santé (CISS)*
- *Doctors of the World*
- *European AIDS Treatment Group (EATG)*
- *The European Public Health Alliance (EPHA)*
- *Health Action International – Europe (HAI Europe)*
- *Salud por Derecho - Right to Health Foundation*
- *Trans Atlantic Consumer Dialogue (TACD)*