



HAI EUROPE RESPONSE

Amsterdam, 1 December 2009

Health Action International (Europe) response to the Global Health consultation

This response has been developed with contributions from HAI Europe members and southern partners including Health Action International (Asia-Pacific).

Response Summary

HAI Europe welcomes the Global Health Consultation and a communication that “will identify guiding principles, priority areas of action and coordinating mechanisms for an enhanced cross-sectoral and collective-EU *vision, voice and action.*”

An issues paper that attempts to address all the problems concerning health and development is ambitious but laudable; and the overview of issues in the paper is, indeed, comprehensive. However, in some cases problems are being identified and described with only a superficial and inadequate analysis, which results in an incomplete or inappropriate list of solutions. A more systematic analysis of the problems is necessary to provide more accurate indications of causality.

This is most obvious in cases where trade or (global) economic policy plays a role. Insufficient discussion of the problem results in inadequate solutions, which are most notable in the sections concerning access to medicines and health care.

This communication should aim to present a clear and undistorted view of global health, from a firm health and development perspective. Whereas communications from other DGs with a more market or trade oriented perspective will be written with another rationale, this communication should focus on the health rationale, with reference to other pertinent dynamics.

Countering growing health inequities will require coordinated and value-based action, where ample attention is given to the social determinants of health. Another prerequisite for a significant vision and strategy is to embrace the search for new models of innovation and knowledge management. The current models are exclusive and contribute to the existing health inequities within and between societies.

HAI’s expertise lies in medicines’ policy and so our response is focused largely in this field. In this response we intend to provide additional input to the current issues paper, to enable a stronger, more detailed and more coherent communication.

QUESTION 1: In your opinion, does the proposed concept ‘global health’ cover the most relevant dimensions? If not, which other essential factors would you suggest?

The issues paper does not present a proposed concept for global health but the roadmap – Annex 3- does contain the following definitions:

“Global health is the goal of improving health for all people in all nations by promoting wellness and eliminating avoidable disease, disabilities and deaths” (IOM definition), as well as the recent notion that includes the “objective of health equity among nations and for all people, through prevention and care in an inter-disciplinary way and includes attention at relevant trans-boundary issues through global cooperation.”ⁱ

The Scene-Setting paragraph contains a less controversial version of these definitions, which is less meaningful and, in fact, inaccurate. For it is not global health itself that is an ‘extensive multi-sectoral domain’ that links the many policy areas but rather, it is the instruments needed to achieve Global health that require a multi-sectoral or interdisciplinary effort. In other words, Global health does not include trade policy, but in order to achieve global health one must take health aspects into account when shaping trade policy. Hence, we recommend a combination of earlier definitions, such as:

“Global health is the goal of improving health for all people in all nations by promoting wellness and eliminating avoidable disease, disabilities and deaths. This goal includes the objective of health equity among nations and for all people, through prevention and care in an inter-disciplinary way and includes attention at relevant trans-boundary issues through global cooperation. Achieving global health requires linked efforts in the main policy areas of development, humanitarian aid, research and health, but also trade and foreign policy.”

Comments from HAI’s Southern Partners:

The first sentence should include another important policy area of development that links to health, namely human rights. In our opinion, we should approach global health from a human rights dimension as well. Linking human rights and other policy issues listed brings out a contradiction. There is a threat to human rights from the WTO Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS), which follows quite a different and incompatible logic from human rights. This surfaced with the Doha Declaration and the debate continues. This document almost completely ignores the human rights approach to global health. This has to be included.

QUESTION 2: Are the effects of globalisation on health, on the spread of diseases (whether communicable or life-style non-communicable) and on equitable access to health care sufficiently described?

The effects of globalisation on equitable access to health care are not sufficiently described. Globalisation is defined as “an ongoing process in which economies, societies and cultures are becoming increasingly integrated in a globe-spanning network or exchanges’. (Issues paper)

It would be important to separate the implications of globalisation that are due to political choices, such as trade and economic policies, from those more related to results of technological change or a global environmental change. The word globalisation is also commonly used, in a doctrinal sense, to describe the neoliberal form of economic globalisation. This refers to the impact of trade and global financial architecture as promoted by international institutions such as the World Bank and the IMF. The resulting social inequalities from this form of globalisation contribute to huge health inequalities.ⁱⁱ Within this globalisation paradigm, the focus is on growth, with the belief that growth will eventually lift the population out of poverty. Yet, evidence that trade liberalisation leads to growth is weak and growth is actually an increasingly ineffective means of poverty reduction because the benefits of growth rarely reach the world's poorest people.ⁱⁱⁱ

Furthermore, the policies and practices of the Bretton Woods institutions have consistently placed pressure on national administrations to limit expenditures in the social sector, especially limiting commitments that would lead to high recurrent costs such as salaries and consumables. These pressures have consistently led to medium term expenditure frameworks with extremely limited space for social expenditures including in the health sector and still do.^{iv}

Indeed, the globalisation of enforced 'fiscal restraint' has led to reduced expenditure for health in developing countries though it now seems that these institutions might be going for a different approach. However, partner country health authorities continue to state that social sector expenditure ceilings remain a real problem. The policies being forced onto states in particular by the IMF following the financial crisis continue to place constraints on health budgets. The EU, not least for policy coherence, should act within the governing bodies of the Bretton Woods institutions to ensure fiscal space is granted to the social sectors in general and the health sector, in particular.

Comments from HAI's Southern Partners:

The effects of globalisation on health and equitable access to health are not described sufficiently. The definition ignores the existing disparities in access to healthcare and technology between developing and the developed countries. We not only need equitable access to the advances in knowledge and tools but also existing knowledge and tools.

The positive and negative points of globalisation need to be explained from a neutral point of view and taking into account the existing disparities of the world. Globalisation cannot realise its potential unless rich and poor countries alike take action to make it work for the poor. That means re-distributing opportunities through new rules and new forms of international cooperation at a global level, and through more effective anti-poverty strategies.

Reference must be made to the social determinants of health

The philosophy underlying the global financial architecture, that of free markets and the Washington consensus with its three pillars of privatisation, liberalisation and fiscal restraint still guides many European policymakers and EU trade policy. Within the European Union, this policy has only been partially successful as it has clashed with European values and traditions of solidarity, equity and universality. Yet the EU is still exporting this doctrine through bilateral trade agreements where the EU policy intentions are to obtain further access to markets and guarantee privileged access for their companies.

Trade liberalisation in conjunction with the liberalisation of capital and financial markets, has brought unprecedented instability, also in countries with otherwise sound economic policies. Moreover, trade liberalisation has deprived developing countries, which are heavily dependent on tariffs, of needed revenues. When, as in the majority of case, no alternative sources of public financing are found, this is a prescription for decreases in health status.^v

Access to government procurement and health care services can be quite profitable for European-based companies. Yet the growing liberalisation of international trade in services has shown to have a negative effect on access to health care and medicines, as health care systems contribute most to improving health en equity when organised around the principle of universal coverage.^{vi} Bringing health care into the domain of the market tends to undermine this principle.

'Trade negotiations now impinge on areas traditionally within the domain of domestic regulation, including environmental protection and public health.'^{vii} Liberalising healthcare and water 'services', which are, in reality, public goods, has not shown to increase access to these same services. The EU should refrain from attempting to push for privatisation and liberalisation of basic services. It has become clear that that the social economic consequences of more market driven models are often negative for poor populations in developing counties, even when it is considered a successful business model for companies.

The globalisation of neo-liberal economic policy has led to reduced levels of social protection and has also had negative impacts on workers' protection. The globalisation of the idea of the need for a flexible workforce to increase competitiveness has a negative impact on health and health equity. This is illustrated by data that indicate mortality is significantly higher among temporary workers compared to permanent workers.^{viii}

Regional and bilateral trade agreements are an increasingly important component of trade and health governance. From 1990 to 2007, agreements multiplied from 20 to 159. At present, over 250 regional and bilateral trade agreements govern more than 30% of world trade.^{ix}

Access to Essential Medicines

What is also being globalised in this way is the 'western' IP system, first through TRIPS, and now through bilateral trade agreements. Trade agreements often include provisions that go beyond the WTO's provisions. The urgency of securing market access for exports can lead countries with limited bargaining power to accept provisions on intellectual property rights that undermine equitable access to essential medicines. In many cases, these stricter rules have little flexibility to protect public health.

The patent system, globalised under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS),^x is the dominant incentive framework for the development of new medicines, particularly where there is a profitable market. However this framework does not provide for innovation that meets health needs and added therapeutic value for use in countries where profitable markets do not exist.^{xi}

The EU is pushing a range of IP measures that would support the commercial interests of the pharmaceutical industry, while damaging the opportunities for innovation and access to medicines in developing countries. These measures include:

1. Introducing TRIPS-plus rules (IP rules that exceed obligations under WTO rules) through agreements, especially free trade agreements (FTAs) with developing countries.
2. Exerting bilateral pressure upon developing countries to prevent the use of TRIPS public health safeguards to reduce medicines prices.
3. Leading on a new global framework to enforce IP rules, within which elements of European legislation are resulting in the seizure of generic medicines in transit intended for developing countries.

EU demands exceed those pursued by the previous United States government, whose IP policies were criticised for their negative effects on health in developing countries for many years by developing country trade negotiators and Ministers of Health,^{xii} civil society groups^{xiii} and inter-governmental organizations.^{xiv} Strict levels of IP protection imposed through EU trade policies will result in a vast increase of expenditures for medicines purchased by donors, developing countries and households. India, which exports two thirds of the affordable medicines its generic companies produce to developing countries, including over 80 percent of the world's generic anti-retroviral medicines, could face severe restrictions that would deny affordable medicines to millions of people in India and jeopardise exports of its generic medicines to the world's poorest countries.^{xv}

QUESTION 3: Do you consider the health-related MDGs a sufficient framework for a global health approach? If not, what else should also be considered?

Comments from HAI's Southern partners:

HAIAP: MDGs ignore aspects of health system strengthening and the need for improving comprehensive health care. The focus on vertical programs by donors is encouraged through MDGs. This draws us further away from focusing on social determinants of health, which require more resources and commitment.

The health related MDGs are quite specific and do not sufficiently address (universal) access to basic healthcare and essential medicines. They also do not fully recognise the problem of non-communicable diseases. Although reducing child and maternal mortality are among the most basic health needs, this does not represent a comprehensive approach. Moreover, the single focus on malaria, HIV/AIDS and tuberculosis is not adequate. This strategy can stimulate donors and governments to take a fragmented (and uncontroversial) approach. Yet, as mentioned in the issues paper, progress towards the MDGs has stalled to a large extent due to 'weak health care services and insufficient access to health care.' That is the core of the problem and tackling it requires a structural, integrated and coherent approach.

The 2002 EU *Communication on health and poverty reduction in developing countries* shared this perspective. Since then, the EU's policy in health and development as noted in the issues paper has focused on helping developing countries to strengthen their health care systems and provide specific support for action on the main public health challenges in developing countries. But as the issues paper notes 'there is not yet a comprehensive EU strategy aiming at strengthening the overall capacity of health systems in developing countries to deliver

accessible health care.’ In the specific sphere of medicines, a framework based in global health policies should use essential medicines and rational use of medicines policy as a starting point.

Comments from HAI’s Southern Partners:

If the commitments and promises made by Heads of State at the UN Summits like the social summit, and summits on food, environment, education and the historic 1978 Alma Ata Declaration on Health for all by the year 2000, had been delivered there would have been no need for MDGs. All these failed because the finances promised by developed countries were not met. There is a need to look for alternate funds. We recommend that the EU revisit the Tobin Tax. Professor Tobin’s had two objectives: namely reining in market volatility through a penalty on short term speculation in currencies, and raising revenue for international aid. The idea has been largely ignored by politicians since it was first proposed in the 1970s because of pressure from the banking sector, who would incur a small cost of about 10-15 cents for every USD 100. But the potential benefits are huge considering the fact that approximately USD 1.8 trillions of currency are traded daily. Tobin originally proposed one percent tax. Now it has been lowered to 0.1 to 0.25. The potential benefits are huge, estimated at 100- 300 USD every year to spend on global priorities. This enormous amount will be more than adequate to eradicate poverty, provide health care, education and control climate change and make earth a more sustainable planet.

The UK financial services authority chairman, Lord Turner is now supporting renewed calls to establish a currency transaction levy (CTL); a Tobin Tax by another name. Civil society campaigners developed the idea prior to the G20 meeting in London earlier this year and Turner’s support for it has caused outrage in the banking sector. Philippe Douste-Blazy, the former French foreign minister and now the UN Secretary General’s special advisor on innovative financing for development has also lent his support to the idea. If, as is becoming increasingly likely, investment from western countries decreases and aid commitments fail to reach countries in need, Douste – Blazgy’s blunt assertion is undeniable; “We cannot continue like this. We have to redefine the system”. Much more money is needed since the MDGs.

Furthermore, in our view MDGs are minimalistic because the targets of Goal 1:

- Halve between 1990 and 2015 the proportion of people whose income is less than USD 1 a day
- Halve between 1990 and 2015 the proportion of people who suffer from hunger

The MDGs expect halve the proportion of people living in poverty and suffering from hunger to continue to live in poverty and suffer from hunger. This way of approaching the problem is not adequate.

QUESTION 4: In your opinion, which are the main strengths and weaknesses of the current EU policy on health and development cooperation, and which dimensions should be given greater attention in order to face the challenges ahead?

The current strength of the EU policy and development cooperation lies in EU expertise in supporting health systems and health systems research, as well as its capacity to mediate initiatives across different countries and distinct development policies.

As noted in the issues paper, the main weakness of the EU policy on health and development cooperation is that 'there is not yet a comprehensive EU strategy aiming at strengthening the overall capacity of health systems in developing countries to deliver accessible health care – covering the priorities in mother and child care and communicable and non-communicable diseases – to wide strata of the population and at sharing other responsibilities inherent in being part of the global health systems.' After the publication of the WHO Commission report on Social Determinants of Health, which calls for reducing health inequities, global actors have to take responsibility. The report states that taking action is 'an ethical imperative as social injustice is killing people on a grand scale'. Hence, the EU also has to take this responsibility and its role seriously. Coherent attention to global health equity means the promotion of social spending and redistribution policies, to ensure basic health services and basic conditions of healthy living for all. In this regard the EU has not recognised the problems associated with dependence on funding from foundations such as the Bill and Melinda Gates Foundation – there is no public role in the setting up of their priorities and these foundations are only answerable to their boards.

It is imperative to foster a stream of EU-based independent thinking, based on the experiences and values of European health systems. Such an EU focus would need to be distanced from the more disease-driven North American based approach to Global health, which follows a line of specific campaign issues and the MDGs, rather than a health-systems based focus.

A main weakness of the EU policy on development cooperation is the policy incoherence between this policy and other EU policies such as Trade. Currently, the European Commission takes with one hand what it gives with the other and that is regrettable. This is particularly damaging to development as it is considered as a low priority policy within the Commission. DG Development is then curtailed from influencing ongoing DG Trade's policies or shaping future ones, while at the same time it does not hold sufficient policy space to develop a policy of its own.

QUESTION 5: Could you identify health problems that have been neglected by the EU and international health research agenda and propose the best means to support innovation to address them, especially in low- and middle-income countries?

Most neglected diseases have not been a focus of the EU as opposed to other conditions with higher visibility, e.g. TB, HIV/AIDS, malaria.

The fact that global IP protection does not deliver innovation that addresses the needs of developing countries has become undeniable. The WHO Commission on Intellectual Property, Innovation and Public Health, in a landmark report, asserted that 'for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to the market.'^{xvi} Increasing levels of IP protection, it continued, will not reverse the neglect of R&D, noting that 'there is no evidence that the implementation of the TRIPS Agreement in developing countries will significantly boost R&D in pharmaceuticals on Type II, and particularly Type III diseases.'^{xvii} Insufficient market incentives are the decisive factor.'^{xviii} IP rules can, in fact, inhibit innovation as excessive patenting of both compounds and research tools hinders follow-on public and private research.

Medicines for neglected diseases account for only 1 per cent of new chemical entities reaching the market.^{xix} Although the WHO declared Tuberculosis (TB) a 'global emergency' in 1993, therapies to treat the disease have advanced little in over nearly two decades.^{xx} Similarly, the dearth of new antibiotics should be viewed against the backdrop of an alarming rise in resistant infections worldwide that threaten global public health. In general, levels of innovation by the pharmaceutical industry have been disappointing.^{xxi}

The most important 'reason for all this is economics: companies direct their research where the money is, regardless of the value to society.'^{xxii}

WHO Member States, including EU Member States, agreed to a comprehensive 'Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' at the WHA in May 2008.^{xxiii} The strategy promotes measures to increase access to medicines, while exploring new approaches to innovation, including some that are outside the IP-based system. Ensuing promising developments and initiatives entail the establishment of an Expert Working Group on Alternative financing and potential setting up of an *Essential health and Biomedical R&D treaty*. The commitment to such an R&D treaty would enable global norm setting on many crucial issues. As part of this commitment it is essential to retain the WHO as a stakeholder in the exploration and development of such a treaty.

It is important to develop and establish innovative models for R&D and financing for diseases that disproportionately affect people in developing countries and for which there is not a profitable market. Models that delink the costs of developing medicines from the prices of medicines would be especially promising. At present, the costs of R&D provide the rationale for maintaining high medicines prices. These costs are the reason for granting patents (and therefore a monopoly), which provides the primary incentive for innovation. Delinking the costs of R&D and the prices of medicines and finding alternative incentives to stimulate medical innovations therefore would seem to be a promising exercise.

Examples of such initiatives would be:

- *Patent Pools* - Through a collective management structure for medicines patents, known as a patent pool, UNITAID seeks to improve access to patents and foster the development and production of life-saving and affordable, medicines. To an extent the patent pool can be seen as an alternative to compulsory licensing (and voluntary licensing) as it also intends to reduce medicines prices through generic competition.
- *Prize funds for innovation* - Inducement prizes can be used to address a wide range of policy issues. In the area of medicines, they can be used as an alternative to monopolies to reward successful innovation.
- *Advanced Market Commitment models*, when appropriately applied.
- *US FDA priority review voucher* - This is an implemented initiative which stimulated interest from pharmaceutical companies in developing medicines for neglected diseases.

It is also vital to support the exploration and development of an *Essential Health and Biomedical R&D treaty*, which is currently under discussion at the WHO. While the WHO frequently considers the importance of global cooperation and coordination in various areas of biomedical R&D, there has not been an extended discussion of the purposes and objectives of a possible biomedical R&D treaty by Member States.

A variety of proposals for global R&D agreements have emerged, also among submissions to the WHO Commission on Intellectual Property Innovation and Public Health and the WHO Intergovernmental Working group negotiations on Public Health Innovation and IP.2

These proposals are diverse in objectives and scope:

- Some focus on specialised areas of research (such as R&D for specific diseases or categories of diseases) while others are more general.
- Some proposals focus on global sharing of the costs of financing clinical trials,
- Others address topics such as medical ethics, transparency, priority setting, open medicine projects, technology transfer.
- Some proposals link innovation and access in the same agreement, while others focus only on research or product development.

While not all major stakeholder groups have agreed on proposals for global R&D initiatives, nearly all have acknowledged the need for initiatives requiring international cooperation and norm setting. The challenge currently facing the EWG and WHO Member States lies in identifying areas where global cooperation and global norm setting are both useful and feasible. It is of extreme importance that the EU plays a constructive role in this process and allows it to be taken forward in a meaningful way under the auspices of the WHO.

A biomedical R&D treaty should also be anchored in, consistent with, and designed to advance the objectives contained in resolution WHA 61.21, the most recent, comprehensive and relevant WHO statement on these issues. Retaining the WHO as a stakeholder is essential to the success and legitimacy of the process of developing an effective and robust mechanism, in the form of a global R&D treaty that is of major value for the promotion of public health.

Over the last decade, some avenues to improve R&D for poor people have emerged, including Product Development Partnerships (PDPs), which are funded by a mix of public and private resources; clinical trial and manufacturing facilities in developing countries; and basic academic and laboratory research.

In gross terms in 2007, according to a recent report released by the George Institute, the EU spent approximately \$121 million on R&D while both the Commission and EU Member States collectively invested nearly \$385 million.^{xxiv} While this is seemingly a considerable sum of money, it is still insufficient, especially when compared with annual financial contributions by the US and even the Gates Foundation.^{xxv} Although recent studies have demonstrated that the EU is more productive than the US in terms of overall R&D for medicines, funding for neglected diseases still lags far behind. Insufficient funding has immediate implications for global health. Recent figures from the Treatment Action Group indicate a global funding shortfall of nearly \$800 million per year for TB R&D.^{xxvi} Under-funding of PDPs may mean that, 'the eight or nine drugs that PDPs might be expected to bring to market in the next five years will stay where they are – in the pipeline.'^{xxvii}

QUESTION 7: How do you think fragmentation of aid for health could be reduced, with a view to increasing aid effectiveness and preventing detrimental health spending?

This could be achieved by reducing the focus on vertical programs by donors and more focus on the social determinants of health. This allows for more attention for aspects of health system strengthening. Fragmentation could be reduced through stronger engagement of legitimate intergovernmental agencies and governments in public health as well as improved coordination of global initiatives and networks. In terms of nongovernmental initiatives, stronger requirements should be made with respect to transparency of financing sources as well as their longer term presence and focus.

One idea is the creation of a formalised framework to coordinate donor funding initiatives. Working within such a framework donors could examine the synergistic effects of different incentive mechanisms and at the same time help to ensure that money is allocated proportionately amongst the different competing priorities. A single agency could also keep records about which chemical compounds have already been rejected during screening, so that other researchers would not needlessly duplicate efforts. Finally, a formalised framework would provide an avenue for recipient countries to participate and provide input about actual funding needs, priorities, and approaches that are appropriate in their countries. This idea is also being proposed by Oxfam.

QUESTION 8: In the context of aid effectiveness and alignment of financing to national priorities, what can be done to make sure that adequate attention is paid to health priorities and to strengthening health systems?

There is a need to ensure that equitable financing of health systems remains on the agenda. The EU should use its scope and influence in the World Bank and the IMF, and the ways in which fiscal sustainability is considered in their lending programmes so as to secure sufficient levels of public financing for health systems.

Priority setting will need to involve health care workers on the ground in developing countries and the people who will be the direct recipients of any new research initiatives. At a minimum, this will require building up research capacity in the developing world and creating career structures for clinicians and scientists so that they are able to fully participate at the global level.

QUESTION 13: What should be the role of civil society in the health sector, at national and local levels?

QUESTION 26: What is the role of civil society in global and national health governance and how can potential conflicts of interest between advocacy and service provision be avoided?

Civil Society – common understanding is that civil society embraces the general public at large, representing the social domain that is not part of the state or the market. Lacking the coercive

power of the state and the economic power of market actors, civil society provides the social power of its networks of people. Its ideas, information, services and expertise are used to advance the interests of people by seeking to influence the state and the market. It is a sphere where people join together for the collective interest to engage in activities with public consequences. Civil society organisations make an essential contribution to policy on health by providing technical and practical assistance to low-income and middle income countries, and by mobilising public opinion to regulate the behaviour of powerful states and corporate interests.^{xxviii}

Civil society should be informed and consulted on a regular basis by governments and international institutions. Civil society organisations should be allowed a seat at the table in important policy debates on health.

Within the health sector, civil society is usually active in two distinct but complementary fields of activity: advocacy and service provision.

Civil society in national contexts should first and foremost help to institutionalise communication channels with relevant government departments, whilst fostering inter-sectoral cooperation for collaborative action towards improved health outcomes. In this sense, civil society has a great role to play not only by supporting a participatory health sector dialogue, but also by bringing other players to the table. The inclusion of the government's trade and finance ministries or departments from the very early stages of this participatory inter-sectoral dialogue is crucial to the development and formulation of any comprehensive strategy on access to health.

Advocating with a strong evidence-base is important so that policy makers and government officials can take civil society voices seriously. Civil society can contribute to the soundness of research evidence by either collecting data itself or partnering with independent research and academic institutions to conduct research and publish its findings for policy reform.

An important area of monitoring that can be done by civil society concerns budget analysis, i.e. tracking budget expenditure on healthcare to promote governmental transparency and accountability, and suggesting improved spending mechanisms. This has been done, for example, in Kyrgyzstan, where civil society, with the support of Health Action International Global, has analysed the functioning of different health insurance schemes and found inefficiencies or inconsistency in their use by healthcare professionals. In collaboration with such professionals and the Mandatory Health Insurance Fund, civil society organisations have formulated their own recommendations for an improved mechanism of such budgetary schemes, to ensure follow-up of their research findings.

Civil society organisations with a mandate of service delivery must ensure greater coordination of externally funded programmes according to national targets and priorities. Thus, there is a need for increased coordination and harmonisation of domestic and international health financing, health action strategies and division of labour. National health strategies must be evidence-based and the result of a consultative process amongst all stakeholders directly and indirectly concerned, and should be founded upon the principle of equitable access to basic health services. Civil society must strengthen the accessibility and affordability of healthcare by supporting patients in accessing drugs and services and by empowering them to participate in health care decision making, health promotion and education.

QUESTION 16: What are the keys to ensuring equitable access to medicine and how could the EU help to do more on this, including by supporting innovation and management of intellectual property rights?

Comments from HAI's Southern partners:

In the issues paper it is stated: *“During the decade now drawing to an end, TRIPS Agreement (on trade related aspects of intellectual property rights) has provided an appropriate framework, in particular due to the flexibility it offers, to allow access to medicine for developing countries.”*

This statement is factually incorrect. The TRIPS Agreement has damaged the (affordable) generic drug industry in India, which is in a position to provide quality generic equivalents to many developing countries. Retail prices have increased in all developing countries.

An emerging consensus requires governments to promote and protect the right to health, including the provision of essential medicines. This responsibility should be confirmed and supported through global policy on health. Essential medicines should be provided by the state or at least through a health care system with universal coverage. This responsibility cannot be traded away to accommodate the commercial interests of multinational pharmaceutical companies.

Competition, and therefore generic market access, is key to ensuring affordable prices for medicines. Policy space for developing countries is necessary here so that they can act on public health needs. For example, allowing the freedom for countries to determine their own patentability criteria and the use of other TRIPS flexibilities is imperative.

To this end it should be ensured that aid and trade policies promoted by the European Commission are coherent and complementary, and not only benefit EU citizens, but also meet the needs of people in developing countries.

Since TRIPS, the rationale for the IP policies promoted by the pharmaceutical industry has lost credibility. Instead, there is a growing consensus amongst developing countries, civil society groups, and inter-governmental organisations that IP rules should be sufficiently flexible that they might meet public health needs,^{xxix} and that alternatives to a patent-based system are needed to stimulate therapeutically valuable innovation.^{xxx}

The prices of old and new anti-retroviral medicines indicate the need for a different model:

Successes and challenges with HIV and AIDS treatment
Prices of anti-retroviral (ARV) medicines have fallen dramatically due to generic competition, which has reduced prices for 'first-line' ARV medicines from \$10,000 per patient per year to less than \$80 for the lowest-price combination. ^{xxxi} But new ARVs, protected by patents and other forms of IP, cost between five and ten times as much as first-line medicines. ^{xxxii} In the absence of price competition they are likely to remain unaffordable. UNITAID, the global purchasing facility, has identified the high price of new anti-retroviral medicines and the lack of innovation for new formulations and combinations, as two key barriers to scaling up HIV and AIDS treatment across the developing world. ^{xxxiii} UNITAID is working to create a market for these products so that prices decrease while availability improves.

Developing countries now face a growing burden from non-communicable diseases (NCDs) as well as infectious diseases. WHO estimates that over 80 per cent of all deaths from NCDs today occur in developing countries. It is clear that, in order to meet health needs in these countries, all disease groups need to be addressed.

The strategy paper ‘Global Europe’,^{xxxiv} aimed at maximising the competitiveness of European companies abroad, provides the framework within which the EU pursues its IP policy. To this end, the EU has focused on extending monopoly protection for patented medicines in developing countries, while limiting the ability of developing countries to use TRIPS safeguards to protect public health. Strategies used by the EU include: free trade agreements, bilateral pressure and enforcement rules.

In response to this criticism, the European Commission mentions its commitment to the Doha Declaration on TRIPS and Public Health, as well as a tiered pricing policy to improve access in developing countries.^{xxxv} Yet its reference to the Doha Declaration is often an empty gesture as it does not overcome the parallel efforts to impose stringent IP rules upon developing countries. These parallel efforts run directly counter to the spirit and intent of the Doha Declaration. Furthermore, tiered or differential pricing, while supported by Oxfam as one measure to improve access, has been barely used by pharmaceutical companies and there is no consensus on whether tiered pricing can ensure sustainable access, by itself, in the long term.^{xxxvi}

In order to improve innovation and access to medicines for developing countries, Health Action International (Europe) recommends the following:

1. The European Commission and EU Member States should honour commitments under the MDGs, the Doha Declaration on TRIPS and Public Health, and relevant World Health Assembly (WHA) resolutions on innovation and access to medicines, including full implementation of the WHO ‘Global Strategy and Plan of Action’.
2. The EU should ensure its trade policy is in line with its development objectives, including specifically enhancing access to health care and access to medicines, in line with its Treaty obligations. EU Member States must act to hold the EC accountable when the EC fails to uphold these principles.
3. With respect to IP:
 - The EU and Member States should not misuse FTAs to introduce TRIPS-plus IP rules in developing countries that extend monopoly protection and introduce new enforcement measures, which limit access to medicines.
 - The European Commission should stop exerting pressure on governments that attempt to introduce safeguards and flexibilities to protect and promote public health.
 - The European Commission should amend its customs regulation to ensure it does not have a detrimental impact on developing countries, by excluding border measures for violations of pharmaceutical patents, especially for medicines in-transit.
 - The EU should ensure that the Anti-Counterfeiting Trade Agreement (ACTA) does not set a new global standard for Intellectual Property Rules (IPR) that impedes access to medicines in developing countries. Therefore, the EU should ensure that patents are excluded from any agreed framework.
 - The European Commission and Member States should identify and support other measures to improve access to generic medicines in developing countries, including the UNITAID patent pool for HIV and AIDS medicines.

4. With respect to R&D:

- European donors, including the Commission, should scale up financial contribution to R&D to address diseases that disproportionately affect people living in developing countries, especially through alternative funding mechanisms that promote therapeutic innovation.
- The EU should also support Product Development Partnerships (PDPs) that are designed to deliver affordable and effective new products, and it should continue building R&D capacity in developing countries.
- The EU should support the implementation of the World Health Organization Global Strategy and Plan of Action (GSPA) on Public Health, Innovation and Intellectual Property and the Expert Working Group in its efforts to explore new models of innovation that increase both innovation and access.
- The EU should allow discussions on an Essential Health and Biomedical R&D Treaty to take place at the multilateral body of the WHO.
- The European Commission should take appropriate measures to ensure that specific initiatives such as the Innovative Medicines Initiative (IMI) meet real health needs and that both the IMI and the EUs regulation on children's medicines can also be to the benefit of developing countries.

For more detailed information, please read the Annex I: Trading Away Access to Medicines

QUESTION 21: Which do you think are the priority areas for coherence on global health policies, and how should they be addressed?

A coherent approach to health issues impacting people in developing countries is needed. There is a fragmentation of initiatives and no global strategy, nor leadership. WHO should be given the opportunity to take the lead, with the support and cooperation of the EU.

The European Union, under the present Treaty and under the Lisbon Treaty, commits itself to the principle of 'Health in all Policies',^{xxxvii} which guarantees that a "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities."^{xxxviii} The Treaty also stipulates that all the European Union's external policies should be coherent with the EU's development objectives. Yet the European Union, led by the European Commission, particularly the Directorate-General (DG) Trade, is acting in ways that will reverse progress made by many towards achieving better access to medical products in developing countries.

Priority areas:

Access to Essential Medicines

Instead of implementing coherent policies to improve public health, the EU has introduced policies and practices that undermine access to affordable medicines by strengthening IP protection in developing countries to advance the interests of multinational pharmaceutical companies.

EU trade policies therefore undermine obligations that EU Member States assumed under the Doha Declaration on TRIPS and Public Health, their commitments in numerous World Health Assembly (WHA) resolutions, and their responsibilities to reach the Millennium Development Goals (MDGs) by 2015. These commitments established a moral obligation amongst EU Member States to protect public health and promote development. Member States should ensure that this stance is reflected in trade policies implemented by the European Commission.

Financial architecture / Sustainable financing

European Union Member States and the European Commission (EC) have taken some steps to improve access to health services, including access to health technologies in developing countries. Yet, by promoting fiscal restraint and putting pressure on social spending they are directly affecting health budgets. This incoherence needs to be addressed systematically and comprehensively.

QUESTION 22: How could the legitimacy and efficiency of the present global health governance be improved and which role should the EU play in this?

The lack of coherence in global health governance is a major hindrance to effective policy. Increased support for the WHO is essential. In addition, it is important to ensure that financial support is directed to the core budget rather than to extra budgetary streams. Funding WHO through extra budgetary streams makes it much more difficult to set coordinated priorities.

Without sufficient core funding, a programme is vulnerable to donor preferences, which generally favour funding of infectious diseases over politically sensitive programmes or issues.

QUESTION 23: Do you think a definition of a universal minimum health service package would facilitate a rights approach and progress towards more equitable coverage of services? If so, how could such a universal minimum standard be defined?

Yes, and it would be in line with a rights-based approach. When one considers access to basic health care as a human right, one comes to the conclusion that a universal minimum health service package should be provided by governments.

The aim of the package would be to *Prevent, Treat & Control Disease by ensuring:*

- Access to Essential medicines*
- Access to primary care facilities*
- Perinatal care*
- Child and maternal healthcare*

Other aspects influencing health, which are also important, are access to clean water and sanitation, adequate nutrition.

QUESTION 24: What, in your opinion, should be the main principles guiding equitable social protection for health? See Question 28:

QUESTION 28: Do you think that an EU social model could inspire global health equity?

The EU social model could inspire global health equity and should be actively promoted. The EU social model, in which Member States ensure health care for all its citizens, is an attribute of the welfare state that should be cherished. To a certain extent, the value of solidarity underlies the European model, i.e. citizens are relatively comfortable with the notion that the healthy pay for the sick and that these roles are interchangeable.

The insurance model, whereby an individual insures itself and where there is in principle no relation to the rest of society is less frequent in Europe. This model can lead to an absolute denial of solidarity (as one can see currently in the US where sick people pay more or cannot insure themselves). This undermines the entire European notion of healthcare where healthy citizens help shouldering the burden of the ill.

Taking a rights-based approach, and considering health as a basic human right, it would seem that healthcare together with education and sanitation are the basic provisions and public goods a government should ensure its citizens. The national framework governing a healthcare system, either through general taxation (a public funded scheme) or with some mandatory universal insurance scheme is optional; provided that certain basic principles are adhered to: universal and equitable access to healthcare and solidarity in the sharing of costs.

Comments from HAI's Southern Partners:

In EU Member States, health is generally not market-governed, but sits in the social sector and is regulated. Health care is free at the point of delivery and is paid for by social security either funded by general taxation or by compulsory social health insurance. Out-of-pocket payments by consumers for healthcare are less than 20 percent of the total health expenses. On the other hand, in the majority of other countries, health is in the private market and consumers pay about 50-85 percent out of pocket of the total health expenses. The World Bank and the IMF have pressured developing countries' governments through poverty reduction strategy papers (formerly structured adjustment programmes) to reduce expenditure in the social sector – health and education and leave them to the market. As long as this system continues, healthcare for all cannot be realised. The EU policy document should clearly state these issues.

EU health ministers have agreed that health services must be underpinned by:

- **Universality** Access to healthcare must be open to everyone living in the EU
- **Access** to good quality care
- **Equity** Equal access to healthcare regardless of ethnicity, gender, age, social status and ability to pay
- **Solidarity** Linked to financial arrangements for funding health systems

What HAI wants is that universality, access, equity and solidarity should underpin the health services in developing countries.

ENDNOTES

ⁱ Lancet, 6 June 2009.

ⁱⁱ Commission on the Social Determinants of Health. Closing the gap in a generation: health equity through action on the social determinants of health, WHO 2008

ⁱⁱⁱ Woodward D, Simms A. Growth isn't working: the unbalanced distribution of benefits and costs from economic growth. London: New Economics Foundation, 2006.

http://www.neweconomics.org/NEF070625/NEF_Registration070625add.aspx?returnurl=/gen/uploads/hrfu5w555mzd3f55m2vqwty502022006112929.pdf

^{iv} Ted Schrecker, Ronald Labonté, Roberto De Vogli, Globalisation and health: the need for a global vision, *Lancet* 2008; 372: 1670–76

^v Joseph Stiglitz, Trade agreements and health in developing countries, *Lancet* Vol 373 January 31, 2009

^{vi} Commission on the Social Determinants of Health. Closing the gap in a generation: health equity through action on the social determinants of health, WHO, 2008, p 94-97

^{vii} Kelley Lee, Devi Sridhar, Mayur Patel, Bridging the divide: global governance of trade and health, *Lancet* 2009; 373: 416–22

^{viii} Commission on the Social Determinants of Health. Closing the gap in a generation: health equity through action on the social determinants of health, WHO, 2008 p5

^{ix} Kelley Lee, Devi Sridhar, Mayur Patel, Bridging the divide: global governance of trade and health, *Lancet* 2009; 373: 416–22

^x Agreement on Trade-Related Aspects of Intellectual Property Rights, Annexure 1C to the Marrakesh Agreement Establishing the World Trade Organisation, signed in Marrakesh, Morocco, on April 15, 1994, (TRIPS), Articles 28.1 a and b.

^{xi} P. Trouiller et al, "Drug Development for Neglected Diseases: A Deficient Market and a Public Health Policy Failure," *Lancet* 359 (2002), p. 2188

^{xii} See Declaration of Ministers of South America over Intellectual Property, Access to Medicines and Public Health, Geneva, 23 May 2006. The Ministers of Health were from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela at lists.essential.org/pipermail/ip-health/2006-May/009594.html. See also Gabarone Declaration, 2nd Ordinary Session of the Conference of African Ministers of Health, Gabarone, Botswana, 10-14 October 2005, CAMH/Decl.1(II), lists.essential.org/pipermail/ip-health/2005-October/008440.html.

^{xiii} See also 'Access to Medicines at Risk across the globe', Briefing Note, MSF Campaign for Access to Essential Medicines, May 2004, www.accessmed-msf.org/documents/ftabriefingenglish.pdf

^{xiv} See WHA 56.27, May 2003, www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf and also see 'Public Health, Innovation and Intellectual Property Rights', World Health Organisation, April 2006 – for example, see recommendation 4.21 at www.who.int/intellectualproperty/report/en

^{xv} Ellen t' Hoen, The Global Politics of Pharmaceutical Monopoly Power, AMB, 2009, p XVII

^{xvi} WHO, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Right, Innovation, and Public Health (Geneva WHO, 2006).

^{xvii} **Type I diseases** are incident in both rich and poor countries, with large numbers vulnerable population in each. Examples of communicable diseases include measles, hepatitis B, and Haemophilus influenzae type b (Hib), and examples of non-communicable diseases about (e.g. diabetes, cardiovascular diseases, and tobacco-related illnesses). Many vaccines for Type 1 diseases have been developed in the past 20 years but have not been widely introduced into the poor countries because of cost.

Type II diseases are incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries., HIV/AIDS and tuberculosis are examples: both diseases are present in both rich and poor countries, but more than 90 percent of cases are in the poor countries..

Type III diseases are those that are overwhelmingly or exclusively incident in the developing countries, such as African sleeping sickness (trypanosomiasis) and African river blindness (onchocerciasis). Such diseases receive extremely little R&D, and essentially no commercially based R&D in the rich countries. When new technologies are developed, they are usually serendipitous, as when a veterinary medicine developed by Merck (ivermectin) proved to be effective in control of onchocerciasis in humans..

Type II diseases are often termed *neglected diseases* and **Type III** diseases *very neglected diseases*. WHO, Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property

Right, Innovation, and Public Health (Geneva WHO, 2006), p13

^{xviii} Ibid

^{xix} Neglected diseases are defined by WHO as those that 'affect almost exclusively poor and powerless people living in rural parts of low-income countries'. They include leishmaniasis, onchocerciasis, Chagas disease, leprosy, TB, schistosomiasis, lymphatic filariasis, sleeping sickness, and dengue fever. P. Hunt (2007) 'Neglected Diseases: A human rights analysis,' World Health Organization. Available at: www.who.int/tdr/publications/publications/pdf/seb_topic6.pdf (last accessed October 2007).

^{xx} Preventing and managing M/XDR – TB: a global health imperative, 1 April 2009 at http://www.who.int/dg/speeches/2009/mxdr_tb_prevention_20090401/en/index.html

^{xxi} In France a survey published in April 2005 concluded that 68 percent of the 3,096 new products approved in the country between 1981 and 2004 brought 'nothing new' over previously available preparations. Similar data in Canada and in the United States indicate declines in innovation. Prescrire, 2005

^{xxii} Joseph Stiglitz, Trade agreements and health in developing countries, *Lancet* Vol 373 January 31, 2009

^{xxiii} United Nations World Health Assembly, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, WHA 61.21 (May 24, 2008),

^{xxiv} G-Finder Report, Neglected Diseases Research and Development: How much are we really spending?, The George Institute For International Health, 2008,

^{xxv} Ibid.

^{xxvi} Treatment Action Group, Tuberculosis Research and Development: A Critical Analysis of Funding Trends 2005-2007: An Update, at

http://www.treatmentactiongroup.org/uploadedFiles/About/Publications/TAG_Publications/2009/2009%20TB%20web%20new.pdf. See also "Cough Up for TB: The Underfunding of Research for Tuberculosis and other Neglected Diseases by the European Commission", *Medecins Sans Frontieres* (2008).

^{xxvii} Mary Moran, "A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs we Need", *Plos Med*: 2(9) at <http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.0020302>.

^{xxviii} Kelley Lee, Devi Sridhar, Mayur Patel, Bridging the divide: global governance of trade and health, *Lancet* 2009; 373: 416–22

^{xxix} Ibid, p40-45

^{xxx} WHO Expert Working Group on Research and Development, http://www.who.int/phi/R_Dfinancing/en/index.html

^{xxxi} "AIDS, drug prices and generic drugs", at <http://www.avert.org/generic.htm>.

^{xxxii} All-Party Parliamentary Group on AIDS, The Treatment Time Bomb: Report of the Enquiry of the All Party Parliamentary Group on AIDS into long term access to HIV medicines in the developing world, July 2009.

^{xxxiii} See: <http://www.unitaid.eu/en/The-Medicines-Patent-Pool-Initiative.html>

^{xxxiv} See: http://ec.europa.eu/trade/issues/sectoral/competitiveness/global_europe_en.htm.

^{xxxv} Council Regulation (EC) 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines: "The purpose of this Regulation is to achieve the objectives of the " Programme for Action: Accelerated action on HIV/AIDS, malaria and TB in the context of poverty reduction" by setting up a system enabling pharmaceutical producers to sell developing countries essential medicines at reduced prices while ensuring that these products do not find their way back to the EU. The ultimate goal is to give the developing countries greater access to the essential medicines they need to fight the major communicable diseases" http://europa.eu/legislation_summaries/development/sectoral_development_policies/l21166_en.htm

^{xxxvi} Oxfam response to EC working document on Tiered Pricing, 2003 <http://www.oxfam.org.uk/resources/policy/health/downloads/tiered.pdf>

^{xxxvii} Ministry of Social Affairs and Health (Finland) and European Observatory on Health Systems and Practice, "Health in all policies: Prospects and Potential" at http://ec.europa.eu/health/ph_information/documents/health_in_all_policies.pdf accessed on 8 October 2009.

^{xxxviii} Public Health is currently dealt with in Article 152 of the EC Treaty and will be dealt with in Article 168 of the Lisbon Treaty. <http://www.eph.org/a/336>