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De Economische Partnerschapsakkoorden (EPA) en de gevolgen voor de volksgezondheid

VERSLAG

NAMENS DE COMMISSIE VOOR DE BUITENLANDSE BETREKKINGEN EN VOOR DE LANDSVERDEDIGING UITGEBRACHT DOOR

MEVROUW **TEMMERMAN**

De commissie voor de Buitenlandse Betrekkingen en voor de Landsverdediging heeft op 27 april 2010 een conferentie georganiseerd over de Economische Partnerschapsakkoorden (EPA) en de gevolgen voor de volksgezondheid.

Volgende sprekers kwamen aan bod :

— Professor Ronald Labonté, *Faculty of Medicine, Institute of Population Health, University of Ottawa*, Canada;

— de heer Juan Garay, *Health team coordinator, DG Development, European Commission*;

SÉNAT DE BELGIQUE

SESSION DE 2009-2010

27 AVRIL 2010

Les accords de partenariat économique (APE) et les répercussions sur la santé publique

RAPPORT

FAIT AU NOM DE LA COMMISSION DES RELATIONS EXTÉRIEURES ET DE LA DÉFENSE

PAR

MME **TEMMERMAN**

La commission des Relations extérieures et de la Défense a organisé en date du 27 avril 2010, une conférence sur les accords de partenariat économique (APE) et les répercussions sur la santé publique.

La commission a entendu les orateurs suivants :

— Professeur Ronald Labonté, *Faculty of Medicine, Institute of Population Health, University of Ottawa*, Canada;

— M. Juan Garay, coordinateur de l'équipe santé, DG Développement, Commission européenne;

— Dr. Valbona Muzaka, *lecturer in Global Politics, School of Social Science/Politics, University of Southampton*;

— de heer Rangarirai Machemedze, *Health and Trade specialist*, Seatini/Equinet, Zimbabwe.

Inleiding door mevrouw Temmerman, voorzitter van de commissie voor de Buitenlandse Betrekkingen en de Landsverdediging

2010 wordt een belangrijk jaar, zowel op Belgisch als op Europees en internationaal niveau.

Op Belgisch vlak staan we aan de vooravond van het Europese voorzitterschap. Dat betekent dat België in de tweede helft van het jaar de kans krijgt om nog meer zijn stempel te drukken op het Europese beleid. We moeten van deze gelegenheid dan ook gretig gebruik maken om enkele fundamentele punten onder de aandacht te brengen op het Europese niveau.

Dit jaar zal het Economisch Partnerschapsakkoord (EPA) tussen de Europese Unie en de Cariforumlanden aan de nationale parlementen ter ratificatie worden voorgelegd. De Cariforum-EPA zal als precedent gelden voor alle volgende EPA's en vormt dus een belangrijke stap naar het toekomstige handelsbeleid van de EU.

Daarnaast zal op internationaal niveau in september van dit jaar te New York een herziening van de Millenniumdoelstellingen plaatshebben. Het is nu al volop duidelijk dat vele van die doelstellingen, vooral de gezondheidgerelateerde doelstellingen, niet zullen worden gehaald. Een extra inspanning en een meer gefocuste aanpak zullen noodzakelijk zijn.

Gelet op al deze belangrijke momenten leek het ons dan ook opportuun om net dit jaar wat dieper in te gaan op de link tussen de Europese vrijhandelsakkoorden met ontwikkelingslanden en de gevolgen ervan voor de gezondheidszorg.

Gezondheid is een mensenrecht. Dat recht omvat niet enkel gezondheidszorg, maar ook indirecte vormen van gezondheid, zoals de toegang tot zuiver water en sanitaire voorzieningen, degelijke huisvesting, voeding enzovoorts. Staten hebben de plicht erop toe te zien dat elke burger van dat recht kan genieten. Dat brengt met zich mee dat staten een handelsbeleid moeten voeren dat consistent is met hun wettelijke verplichtingen op het vlak van gezondheid.

We zien op verschillende vlakken een duidelijke impact van de vrijhandelsakkoorden op de volksgezondheid.

Er is de sociale impact van de liberalisering van de handel. Voor de plaatselijke bevolking heeft die liberalisering immers vaak een negatieve impact op

— Dr. Valbona Muzaka, *lecturer in Global Politics, School of Social Science/Politics, University of Southampton*;

— M. Rangarirai Machemedze, *Health and Trade specialist*, Seatini/Equinet, Zimbabwe.

Introduction par Mme Temmerman, présidente de la commission des Relations extérieures et de la Défense

2010 est une année importante, tant sur le plan belge que sur le plan européen et international.

La Belgique est à la veille de la présidence européenne. Cela signifie qu'au cours du second semestre de l'année, elle pourra davantage marquer la politique européenne de son empreinte. Nous devrons dès lors profiter de cette occasion pour attirer l'attention des autorités européennes sur quelques points fondamentaux.

Cette année, l'accord de partenariat économique (APE) entre l'Union européenne et les pays du Cariforum sera soumis aux parlements nationaux pour ratification. L'APE Cariforum servira de précédent pour tous les APE suivants et constitue dès lors une étape importante vers la future politique commerciale de l'Union européenne.

En outre, une révision des objectifs du Millénaire aura lieu à New York, en septembre prochain, au niveau international. Il est dès à présent tout à fait clair que bon nombre de ces objectifs, essentiellement liés à la santé, ne seront pas atteints. Un effort supplémentaire et une approche plus ciblée seront nécessaires.

Compte tenu de ces moments importants, il nous semblait opportun, cette année, d'examiner plus en profondeur le lien entre les accords européens de libre-échange avec les pays en développement et leurs conséquences en matière de soins de santé.

La santé est un droit humain. Ce droit n'englobe pas seulement les soins de santé mais également les formes indirectes de santé, telles que l'accès à l'eau et aux équipements sanitaires, à un logement décent, à la nourriture, etc. Les États ont le devoir de veiller à ce que chaque citoyen puisse jouir de ce droit. Cela implique que les États doivent mener une politique commerciale cohérente par rapport à leurs obligations légales en matière de santé.

Nous constatons sur différents plans un impact clair des accords de libre-échange en matière de santé.

Il y a l'impact social de la libéralisation du commerce. Pour la population locale, cette libéralisation a en effet souvent un impact négatif en matière de

tewerkstelling, voedselzekerheid, inkomen en ongelijkheid.

Ook de inkomsten van de overheid dalen aangezien ontwikkelingslanden een groot deel van hun inkomsten uit douanetarieven halen. Dat heeft tot gevolg dat de overheden uit het Zuiden ook minder kunnen investeren in bijvoorbeeld gezondheidszorg, onderwijs en tewerkstelling.

De te beperkte investeringen van ontwikkelingslanden in lonen van gezondheidspersoneel, in zorginfrastructuur en in werkingsmiddelen lokken het weinige hoogopgeleide personeel naar het buitenland en duwt de gezondheidszorg in de ontwikkelingslanden steeds meer in handen van de privé-markt.

Wanneer privé-maatschappijen de gezondheidszorg in handen krijgen, bestaat de kans dat vooral rijke burgers ervan kunnen genieten en dat de lagere sociale klassen, die de diensten vaak het meest nodig hebben, in de kou blijven staan.

Voorts zijn er de geneesmiddelen. Volgens de wereldgezondheidsorganisatie gaat 25 tot 66 % van de uitgaven voor gezondheidszorg naar geneesmiddelen. Het beperken van de kosten voor geneesmiddelen is dus een essentieel punt in het opkrikken van het niveau van de gezondheidszorg. Toch blijkt Europa met zijn handelsakkoorden ook hier stokken in de wielen te steken. Zo was er recent in het nieuws nog de oproep van Artsen Zonder Grenzen om in de onderhandelingen van de nieuwe handelsovereenkomst tussen de EU en India de bepaling van « exlusiviteit van gegevens » te schrappen. Zo wordt vermeden dat producenten van generische geneesmiddelen geconfronteerd worden met financiële barrières.

We kunnen ons dus vele vragen stellen bij deze handelsakkoorden en hopelijk biedt de conferentie vandaag ook enkele antwoorden.

Uiteenzetting door professor Ronald Labonté, *Faculty of medicine, Institute of Population Health, University of Ottawa*, Canada

Wat zijn de verbanden tussen vrijhandel en volksgezondheid ?

travail, de sécurité alimentaire, de revenus et d'inégalité.

Les revenus des autorités diminuent également étant donné que les pays en développement tirent une grande partie de ceux-ci des tarifs douaniers. Cela a pour conséquence que les autorités du Sud peuvent investir moins, par exemple en matière de soins de santé, d'enseignement et d'emploi.

Comme les pays en voie de développement n'investissent pas assez en salaires pour le personnel, en infrastructure médicale et en moyens de fonctionnement, les rares cadres hautement qualifiés tendent à émigrer et les soins de santé dans les pays en voie de développement sont de plus en plus souvent aux mains du secteur privé.

Lorsque des sociétés privées sont responsables des soins de santé, le risque existe que ce soient surtout les riches qui y aient accès tandis que les couches sociales modestes, qui ont le plus besoin de ces services, restent sur le carreau.

Il y a aussi les médicaments. Selon l'Organisation mondiale de la santé, de 25 à 66 % des dépenses de santé sont consacrées aux médicaments. Limiter le coût de ceux-ci est donc un élément essentiel dans l'amélioration des soins de santé. Il apparaît cependant que l'Europe, par ses accords commerciaux, met aussi des bâtons dans les roues. Par exemple, récemment, Médecins sans Frontières a appelé à supprimer la clause d'« exclusivité des données » lors des négociations en vue d'un nouvel accord commercial entre l'UE et l'Inde. On évite ainsi que les producteurs de médicaments génériques soient confrontés à des barrières financières.

On peut donc se poser pas mal de questions sur ces accords commerciaux; espérons que notre conférence d'aujourd'hui répondra à certaines de os interrogations.

Exposé du professor Ronald Labonté, *Faculty of Medicine, Institute of Population Health, University of Ottawa*, Canada

Quels sont les rapports entre le libre-échange et la santé publique ?

As an introduction, I would like to emphasize that the critique that I might make about trade liberalization is not a critique about trade itself as it is a very long standing part of human societies. But when trade moves beyond the village level of barter, we very much begin to see power and elite interests and we have seen historically the forced openings around trade with Britain and China with the USA and Japan, and more recently the more economically coerced openings in Latin America and Africa through structural adjustment.

So this leads to the two questions I have been asked to address. I will not speak a lot about the American trade agreements per se, but I will speak about how trade improves economic development and health. The Chair has already mentioned some of the ways

that this can be accomplished but I do wish to give a broader perspective and focus on the different pathways by which trade can improve or indeed even undermine development and health, with reference to the economic partnership agreements.

The first thing which is important to understand in terms of the arguments around trade, is that since the rise of capitalism, the support for trade has been largely based on a country's net welfare gains that arise from efficiencies in doing increased competition and has led each country trade by its comparative advantage. This is still being used in defence of trade liberalization polices today. But we do have to question how relevant this eighteenth and early nineteenth century theory is today. Given some of the extreme differences that we now experience, that finished goods no longer trade across borders but that we have global production chains where most of the international trade is within different branches of the same multinational company. Capital used to be immobile and now it is hyper-mobile. The difference in wealth and power between country quintiles has grown enormously and unlike the previous dislocations of industrial capitalism, where the surplus or displaced agricultural workers could migrate to a new world, we have an overpopulated world with actually no place to move effective workers. The one comparative advantage claimed about trade liberalization for developing countries in terms of lower wage costs has really been eliminated now by the entrance of a billion low wage workers in India and China.

Nonetheless, let us unpack the dominant argument around trade liberalization and health. At the core of this is that trade liberalization leads to economic growth, through increased competition, foreign investment, technology diffusion and economies of scale. All of that in turn generates new wealth, lifting increasing numbers out of poverty, and health improves as this poverty declines. The increase in wealth can also be taxed for investments in human capital such as health and education and women's empowerment which can then create more productive and skilled workers. These up-skilled workers can in turn spur the economy to ever greater growth and eventual trickle down health, and so the circle closes virtuously upon itself. This is a very persistent argument that comes out of trade liberalization proponents and finance ministers around the world. It is compelling, but the problem with it is that there are empirical challenges to virtually every link in this chain.

If we consider the first one, we find that liberalization led to growth for some but not for others, and for those that did grow, which were mostly Asian countries, these remained much more closed economies. Those countries which either stalled or declined during the last three decades were either in Africa or Latin America. These stalled or declining countries were already more globally open economies and they traded globally as much — if not more — than the Asian growing group. So they stalled for reasons other than global market integration. Many argue that this was primarily due to their premature integration into the global economy as a result of the Developing World Debt Crisis and structural adjustment programmes.

Most economic studies find that trade liberalization on average is associated with better growth, but there is no consensus on the direction of that relationship. Is it that growth leads to liberalization, or does liberalization lead to growth ? In a review of these studies it concluded that any positive relationship that might exist is « neither automatically guaranteed nor universally observed ». It depends in part on the ongoing flexibilities that the developing countries have to manage their development and growth and it is those flexibilities that are now being challenged by trade treaties.

This applies to EPA negotiations as to any other set of trade negotiations. Despite starting out on the principle of improving development potential for the 74 affected African, Caribbean and Pacific Island partners, the EPA really transformed into the way of the European Union inserting several more trade related issues into the negotiations which it did not have to. It has long been cautioned that the EU and the USA are using bilateral agreements to ratchet up provisions on intellectual property rights, on services trade, on investment government procurement, that they are unable to negotiate multilaterally. The expectation is that these areas of economic interest in themselves will eventually be so widespread amongst developing countries that they will become

part of the multilateral WTO rules. This process was explicit in the EU's 2006 trade strategy, where the Commission said it would negotiate by lateral free trade agreements by tackling issues that are not ready for multilateral discussion.

The current EPA negotiations were required as a part of WTO rules. But the EU chose the path of reciprocal preferences whereby, all the ACP countries would have to commit to opening up their markets to all forms of trade within a period of time. But by extending unilateral preferences, which could have been a request for a longer waiting period for compliance and an extension of the general system of preference, plus to low income countries to be eligible for everything but arms preferences, this would have allowed for much more flexibility to developing countries in the « it depends case by case particulars » of the trade and growth relationship. Of course that is now water under the bridge.

But if we assume there is trade related growth, it does not inevitably trickle down to let people out of poverty. Most of the extreme poverty reduction that we witnessed in the last three decades occurred before 1987 and the rate of decline has since slowed by a full order of magnitude. This entire decline is accounted for by the growth in China, where half of its poverty reduction occurred before it embraced domestic or global market reforms. Poverty reduction during globalization's peak decades of liberalized trade, during which economic growth quadrupled, has been modest at best. That has led Martin Ravallion, the senior World Bank Economist, to conclude that it is hard to maintain the view that expanding trade is a powerful force for poverty reduction in developing countries.

Despite its equivocal effect on poverty reduction, there is some evidence that trade openness may be good for health, and the findings of a panel study at least challenge the notion that international trade is necessarily unhealthy. But interestingly, the authors conclude that the best explanation for their findings lies in the greater exchange of health technologies, public health knowledge and foreign aid between high and low income trading partners and that countries that are more open adopt domestic economic policies associated with better health outcomes. In other words, it has very little to do with how trade is supposed to increase growth and lead to that trickledown effect of poverty reduction. This finding also echoes other studies that found that most of the health gains to developing countries over the past half century have arisen not from economic growth itself, but from the free exchanges and support for health technologies and knowledge, and those exchanges are now compromised by the extension of intellectual property rights. We also see that developing countries, as a result of trade liberalization, are falling further behind.

A completed round of the Doha negotiations might add at best 0.25 % to Global Economic Product. That is a pretty insignificant gain for the price the developing countries would have to pay. Now the benefits, come from the World Bank's most realistic estimates of the completion of the Doha round and the costs in turn refer to tariff losses, non agricultural market access, under proposals which are fairly current in terms of what high income countries would like to see. These losses are not insignificant for developed nations, but very steep for developing countries. An earlier study of the economic gains and losses that used four different scenarios of the Doha round completion, estimated that the annual real income gains for developed countries would be between 6 and 8 billion dollars each for Japan, USA and the EU-15, but annual real income losses of almost 250 million dollars for sub-Saharan Africa. So what we see is the general notion that somehow trade will lead to growth, which will lead to poverty reduction and improved health. This really is more statement of ideology rather than a statement based upon existing evidence.

What can we say about the specific pathways by which trade liberalization affects health ? The first has already been referred to by the Chair, which is the loss of tariff revenues. A fundamental goal of all trade liberalization is the reduction of tariffs, which is at the core of the economic partnership agreements that have been negotiated, and a requirement for reciprocation. Despite years of such reductions in tariffs under structural adjustment or World Bank-International Monetary Fund advice, tariffs still

remain an important source of public revenues in many developing countries, but are almost insignificant in developed countries. In theory developing country governments should be able to shift their tax basis from tariffs to sales or income taxes, assuming that their economies grow. In reality most low income countries have not been able to do so and for a majority suffering from tariff losses there has been a net decline in overall public revenues, with implications for health spending, education or public regulations that can affect primary and secondary prevention of chronic or infectious disease. In fact this situation could get much worse. I have already mentioned estimated tariff losses through WTO negotiations, which are roughly twice as great for developing countries as for developed countries, and a similar asymmetry applies with the economic partnership agreements. The ACP countries over a period of time that range from immediately to up to fifteen years and in a few cases to twenty-five years, will have to reduce their tariffs on 80 % of European Union exports to their markets. This is a WTO Plus set of negotiations, requiring more of the developing countries than the WTO multilateral agreements require. Given the most favourite nation rule in EPA's and that is a provision not required to be WTO compliant, ACP countries will be unable to offer more preferential bilateral trade agreements with the emerging developing economies such as China, India and Brazil, which are of much greater interest now to ACP countries, without also offering it to the EU. In return for this market opening they will receive duty free and quota free access to the European market. Using 2006 data, researchers from the UK Overseas Development Institute estimated that the total ACP gains from completed economic partnership agreements will amount to roughly 12.7 million euros annually and maybe more once the sugar import barriers are removed. This quite small gain is due to the already duty free and quota free access for the least developed ACP countries under the « everything but arms » preference scheme.

While again, the loss of tariff revenue under conditions of weak institutional tax capacity is likely to be substantial, and although EU is pledging annual increases in trade related aid to these countries, these commitments are not presently written into the actual trade agreements and so will remain uncertain, and they are allocated to trade development and infrastructure and not to the replacement of lost tariff revenue. Besides locking in tariff reduction, the EPA's also forbid the use of export taxes, which is something again not required to be WTO compliant. Export taxes have been used by the developing countries on their raw commodity exports to help finance the development of value added industries, or to slow the exports of primary commodities by private producers that the country might need for food security or development purposes. The use of export taxes on food products is one example in terms of food security which is not allowed.

EPA's have also standstill clauses, again not required for WTO compliance, which means that it freezes current tariff levels even if they are not slated for reduction or opening for another ten to twenty years. This removes another tool of policy flexibility that ACP governments could use to help finance health, education, and other important social protection programmes. Even if the trade benefits to ACP'S exceed the 12.7 million euro annual estimate of gains in excess of the current « everything but arms » scheme, history basically tells us that whatever Europe will extend to ACP countries, they will likely extend to other countries. This means that the preferences that they get in terms of market access will quickly disappear.

The combined effect of trade and financial liberalization has also increased economic and employment insecurity. Both forms of insecurity are linked to poverty and stress related diseases. However, one of the benefits of trade liberalization may be women's social empowerment from increased employment opportunities in export oriented industries. But the potentially health enhancing economic gains for women arising from labour income and work related entitlements to benefits, may be undermined by the off-sighted characteristics of poor working conditions for women in export processing zones and other export industries.

Finally, while evidence suggests that some of the impacts of trade related, economic and employment insecurity can be offset through enhanced social protection and

employment programmes, and especially in enhanced programmes to help women who are simultaneously responsible for family or child caring duties, often in export processing zones, they find that actually they have no benefits and no ability to even care for sick children. If those were offset by greater investments in economic and employment programmes, the estimated cost of doing so, in terms of employment adjustment and skills enhancement of completed economic partnership agreements in all the ACP countries, has been estimated at 3.6 billion euros. Where will the ACP's get this money and at what cost to other aspects of the countries' health and development security ?

Another pathway by which trade can affect health is through trade and health damaging goods. As the liberalization of trade in tobacco goods increases, so does the consumption and health related diseases. The Framework Convention on tobacco control, the world's first big global health treaty does require signatory countries, ratifying governments, to enact tobacco advertising bans, implement warning labels and consider raising tobacco taxes or even suing tobacco companies. Notably, although it acknowledges the link between trade and tobacco, this convention contains no provisions to address or to restrict it. Furthermore, it is also unclear how domestic tobacco control measures will be protected from future trade disputes. There is now a challenge that Philip Morris has made to a Uruguay policy to have 80 % of cigarettes packages covered by health warnings, and the tobacco company claims that this violates its trademark and intellectual property rights, and discriminates against some of its brands. It is not filing this challenge to the WTO, which has greater latitude of political oversight in disputes to the appellate body, but through a Swiss Uruguay bilateral investment treaty, which allows corporations to directly sue foreign governments and whose settlement processes are slightly slanted towards commercial law rather than any public interest.

Health concerns also exist about liberalized trade in alcohol and that is an item included within the EPA tariff reductions and many of the policies than can help reduce alcohol related harm such as tariffs, taxes, licensing, or labelling, are considered as potential barriers to trade. There is a case that involves the EU and Chile on how the taxation limits on the basis of alcohol content gave more beneficial tax treatment to the local product called Pisco that had lower alcohol content, in comparison to imported alcohol products. The European Union won that case. It has now a similar challenge before the WTO concerning differential taxes charged on imported alcohol by the Philippines, with the Philippines arguing that it is doing so to give preferential treatment to poor indigenous groups who are trading locally in traditional alcohol beverages, using coconut and sugar cane. There are also health concerns over potential trade challenges concerning alcohol advertising, restrictions on which have been part of public health harm reduction strategies in many countries. In both the EU and USA in its current GATT negotiations are aggressively pursuing unlimited liberalization commitments in advertising. The World Spirits Alliance has described the Doha Round as offering « excellent opportunity for the international distilled spirits industry to create new opportunities to expand its exports to world markets ». More trade in alcohol, more consumption in alcohol, and therefore more alcohol related diseases.

The growth in global food trade in turn is also associated with negative health effects, primarily in nutrition transition in many low and middle income countries that is creating obesogenic food environments and increasing the prevalence of chronic disease. As liberalization opens up channels for foreign direct investment in food, fast food chains increase with direct and statistically significant correlation between increases in the number of fast food outlets and obesity.

Poor direct investments in food production, advertising and retailing is also shifting demand from home produced food or food produced in traditional markets to an increased dependence on « Starbuck » foods and especially processed foods that are high in health damaging content and low in nutritional content. This also raises the issue of food security. Decades of advice to grow through export agriculture has transformed many developing countries with high levels of population growth into net food importers, and it is especially the case with land locked least developed countries

in Africa and also small island Caribbean and Pacific nations. Any value of primary food that they might export is likely to be eclipsed by the value added processed low in nutrition food products they have to import.

Food security enters particularly around the economic partnership agreements as to whether such trade increases or decreases the availability and affordability of healthy foods, and whether rich country farmer subsidies undermines world food prices, and whether openness to these imports destroys smaller scale producers tied to local markets. There is quite a lot of evidence on this last point, although trade protectionism is not a substitute for better world food agricultural policies that aim towards environmental sustainability, domestic food security and better productivity. But evidence on the impact of subsidies is indeed a bit more mixed especially given the widespread reliance of many poor countries on lower priced food imports. From a food security perspective, the greatest concern about the economic partnership agreements, are tariff standstills, that disallow countries to raise tariffs if food imports threaten long term viability of important domestic agricultural production; the ban on export predictions and export taxes which could slow the export of food during periods of shortages; limits on the size of remedies available under the safeguard clause, which restricts it now to a period of 200 days only; and a failure to prohibit the use of export subsidies by EU partners which poorer ACP countries simply cannot afford for their own producers. This unfair competition has been raised on a number of occasions by the former UN specialist, Jean Ziegler. Moreover, given that many ACP countries have high levels of under-nourishment that range from 16 % in the Pacific to over 30 % in other ACP regions, this is a justifiable cause for public health concern. Ziegler also queried whether eliminating tariffs on EU imports might jeopardize government funding for social programmes and thereby threaten governments abilities to meet their obligations in terms of economic, social and cultural rights, including the right to food. This is an even more fundamental issue of whether trade trumps rights, or according to many international legal scholars, rights should trump trade.

This now brings me to the issues of trade and health services. The proponents who argue that trade and health services through trade treaties should be able to increase access to services, argue whether or not it does so. All depends on the regulatory structures that are put in place to manage the impacts of increased commercial presence in health services, and this might be true. But as far back as 2000 the World Health Organization was arguing that very few countries had any strategies to do this effectively and the harm caused by market abuses is extremely difficult to remedy after the fact. The health systems » knowledge network of the WHO's Commission on Social Determinants of Health and its review on the global literature on this topic essentially concluded that there are too many market failures in more privatized systems that lead to inequities and access. The policy advice to move towards greater access is to move from risk pooling towards more universal and progressively tax funded systems, with extreme caution in contracting private providers and where there is private insurance, restrict it to top ups for the wealthy. Furthermore, the final report of the Commission was even a little stronger in terms of its caution, essentially saying that if governments want to trade a little in health services, do not lock it in with the trade treaty as it will prevent them ever going backwards on their commitments.

Presently, the level of these commitments under GATT remains fairly low, but developing countries did make a disproportionate share of such commitments in 1995. Because there is no cost free way of governments to change their minds, this led to cause for cancelling all existing GATT developments on health and other important health related services and to remove these from the scope of subsequent negotiations. Now that is a pretty strong recommendation to make; but contrary to the intent of that recommendation and the evidence that lies behind it in terms of equitable access, present EU practices and free trade agreements do include putting service trade in some of the sectors strongly linked to health, particularly education with ten free trade agreements but also three free trade agreements that specifically represent health services. Although, few of these offer specific or enforceable conditions, they are considered as a signal of the EU's interest in expanding substantially binding committees in such services. The EU has also placed services negotiations within the

EPA's even if it did not have to do so to be WTO compliant, and many of the APC countries did not want this to occur.

The one completed cariforum Agreement contains commitments to liberalize services and telecoms, in banking, in retailing and courier. While health and important health determining services have not been committed under this particular partnership agreement, several Caribbean and African countries have already scheduled liberalization in these sectors under the 1995 GATT's. Since private health insurance is scheduled under banking or financial services, the cariforum EPA, which does commit to banking services and any others in the future that might be modelled on it, will have implications for commitments in this sector (banking or financial services) to any future extension of public health insurance monopolies.

The other major area of concern that has been well documented and discussed is around intellectual property rights. Suffice it to say that despite the fact that TRIPS permits exceptions, and limits to patents for public health needs, including compulsory licensing and parallel importing, and despite a reaffirmation of these flexibilities in the 2001 Doha declaration, there has only been a limited uptake of these provisions by developing countries, due partly to ongoing pressure from patent holding pharmaceutical companies, and sometimes their governments, when countries attempt to use these flexibilities. This variability in terms of use of these flexibilities is underscored by the recent seizure by European port authorities of so called counterfeit Indian generic medicines bound for other countries. It is important to recognize that the term counterfeit under TRIPS does not mean a false label, bogus, or unsafe drug, but simply a trademark or potential trademark violation; a definition that is being incorporated into some developing countries' anti-counterfeit legislation, which arguably threatens their obligations under the right to health, or right to life. It is also interesting to point out that the RAND Corporation review of intellectual property rights and development that it did for the UK, basically found that although it was a bit mixed with respect to intellectual property rights and other forms of technology transfer in terms of access to help technologies or essential medicines, was profoundly and unequivocally negative. One of the major concerns here is with not so much the economic partnership agreement, but the EU's free trade agreement negotiations with India, which will include data exclusivity, patent protection and order measures that go beyond the requirements in TRIPS itself. This has many medical groups concerned about the negative impact this will have on the production of generic drugs for poorer countries around the world. The EU, even within the EPA's, has basically without introducing a specific language, called for more stringent intellectual property rights in the negotiations. As of late 2008, most of the ACP's have agreed to pursue ongoing negotiations around strengthened intellectual property rights. The only completed EPA is with the CARIFORUM, while avoiding TRIPS+ in health technologies, it contains extended IPR provisions related to copyright that affects digital or internet access to knowledge which could in effect reduce access for students and researchers. Unlike WTO rules which have exceptions that allow educational institutions to make copies of digital information, the EPA treaty does not have such exceptions and it could prevent legitimate access. This could widen the persisting digital divide between the EU and ACP's and could dampen educational opportunities with these countries with knock-on effects on health and development, and it could also add to the push factors, driving skilled workers, notably skilled health workers, to the EU, USA and Canada.

Significantly, the cariforum EPA references that the IPR provisions should not impede in any way access to medicines. But concerns exist over strengthened enforcement provisions, including seizure of goods and use of precautionary measures and injunctions of « possible » rather than actual infringements of intellectual property rights plus expansion of these to third parties who are not themselves infringers. These measures are consistent with the EU's very controversial policy on counterfeit products that is not required under WTO rules.

To return to government procurement, this is an optional agreement under the WTO, not required for inclusion at all in an economic partnership agreement. Nonetheless, the completed cariforum EPA contains a short chapter on government procurement that

promises to offer to EU companies national treatment in bidding of all forms of government contracts. Given the relatively high percentage of Gross Domestic Product generated by government spending in higher income countries with an increasing amount of that spending through contracts, this is a future growth area for private investors and providers. Similar to the WTO agreement on government procurement, when such provisions are enacted in cariforum, it would prevent effective ACP governments from giving any preferential treatment to domestic providers in their allocation of tax revenue spending. All such contracts would have to be based solely on the principle of open and effective competition. While that may save public revenue if more competitive suppliers are able to provide much needed service at a dramatically lower cost, it will also impose the cost of any development of that capacity within the country. It is somewhat ironic that the protections for domestic supply was paramount in the USA's recent « buy American » provisions to its tax funded counter cyclical spending package.

I would like to close by talking about the environment aspect, because if we assume that EPA's do in fact increase growth, development and trickle down health, which is a rather large assumption, what of the environment externalities given that the environment will shortly supplant the triple crises of food, fuel and finances as the major cause of poverty and poor health. There is fairly abundant evidence to suggest that trade liberalizations are associated with legal and illegal depletion of essential natural resources. Let us look at the implication that Africa should develop its economies first by increasing agricultural productivity and export, and then look at diversification. Agricultural productivity demands water, and Africa is already water scarce. Indeed, there is an estimate that we will experience environmental scarcities by 2025 with at least 1.8 billion refugees seeking essential environmental goods. Another of course is, that what drives global production and global trade is energy and transportation and these are the two sectors that are contributing most to greenhouse gas emissions and all perils of climate change.

Just over a year ago, the UK Sustainable Development Commission essentially challenged that there is no ecologically sustainable scenario of continually growing incomes for a world of 9 billion people, which is an important point to remember. Underneath all assumptions of the economic partnership agreements excluding the details of all the specific trade treaty clauses, resides the assumption of growth and continuing production and consumption. But we know that this is not environmentally feasible, it just will not work. In this particular report, they try to look at how model economic growth could allow for some degree of sustainability. In the first model of low growth and sustainability it would require huge forms of national and global wealth redistribution, not through economic transactions but from political decisions of governments. It would also assume a large downward shift in work time so that more people would work less for reasonable incomes to avoid massive amounts of unemployment. The second model demanded a clear break from a non-fossil fuel economy. So what to do ?

I will now conclude with a few thoughts about the economic partnership agreements. The first is that there should be clear linkages *ex ante* between the European Union trade agenda and its development agenda. There are needs to be broad public and parliamentary commitment to partnering countries on the content of the trade negotiations. We should undertake « right to health » impact assessments and adopt models proposed by the UN Special Rapporteur on this right and incorporate the right to food, water, housing, education and other obligations binding governments under human rights covenants. We should also do a « right to development impact » assessments where we could disaggregate the gains and losses by different social groups within countries as to whether or not derogation from trade rules would be essential for countries to meet their obligations under human rights and under the millennium development goal targets. We should do an environmental impact assessment of the long term effects of increased trade flows in terms of fossil fuel use or energy and resource flows in terms of production.

More immediately, in terms of the EU and the economic partnership agreement : compensation for losers within countries, compensation for countries for lost tariffs and other trade related revenues, financial support for measures to stabilize small agricultural producers affected by global commodity fluctuations, and for countries to move up the value chain from primary goods to manufactured products. As well, the EPA's could add enforcement language to what is right now the best hortatory definition of sustainable development that overarches these agreements, hence a language to the effect that the EU and the ACP members could retain both the right to regulate trade and investment in order to advance human, cultural, economic, social, health and environmental best interest of their respective populations and of future generations. Once that is placed inside the treaties, to ensure a dispute panel process made up of individuals concerned with policy choices that allow states to achieve those goals related to sustainable development and human rights rather than simply complying with the obligations of increased trade liberalization.

Uiteenzetting door de heer Juan Garay, *Health team coordinator, DG Development, European Commission*

Coherentie tussen het Europees ontwikkelings- en handelsbeleid

Exposé de M. Juan Garay, coordinateur de l'équipe santé, DG Développement, Commission européenne

Cohérence entre les politiques européennes du commerce et du développement

I was working as a Bureau District Officer in central African countries before joining the Commission eight years ago. Previously I was a District Medical officer in Zimbabwe in a hospital which covered a large district. In the 1990's we were facing the very dramatic AIDS pandemic with 80 % of the patients dying in this 150 bed hospital, where I was often the only doctor. We had no drugs to cure AIDS, so we developed all types of measure to try to have palliative human care and at that time I came across a letter of Marleen Temmerman to The Lancet. She wrote about the right not to know your HIV status. From my remote district hospital without electricity, I took my pen and wrote a response. It was a very difficult time as we were facing the tragic situations of patients and families being basically sentenced to death due to the AIDS infection. Then in 1996 at a Congress in Vancouver it was very clear that there was a way to treat and prevent death of all these patients. Then through MSF particularly, I got quite involved in trying to address how access to medicines was a very important equation of our efforts to promote the « right to health ».

So I am here to inform you of what we are envisaging in terms of one of the challenges which is to have a greater link between health, development and trade, while mentioning other important areas of coherence. Beforehand, I have two other limitations that I would like to share with you. First of all I am a public health physician, so I intend to know about health issues, I could not convince my DG Trade colleagues to come and explain in greater detail what is happening with EPA's, with bilateral trade agreements and with India in relation to the recent press releases around the concerns. I do have some information on these issues, but I could not bring the colleagues dealing directly with the Caribbean trade relations. So even with these limitations, I dared to come to explain why I think we are entering into a new way of looking at health both from this communication and from what the Council's conclusions will very soon reflect as the EU policy on global health. Let me give you a very short overview of the way we see the health challenges today in developing countries.

In the last decade, we have become familiar with the « right to health » within the Millennium Development Goals, as these are the wider agreements around the need to progress in some of the clearer health challenges. This has opened many interesting opportunities but it also restricts the views on the essential values of health particularly around the rights to health. If we put both in combination and do not forget with the MDG's the very important principles from the rights to health, from all the legal frameworks and international agreements since the Human Rights Charter, and we do not forget the Primary Health Care Principles from 1978 in Alma Atta, then we can enter the new decade with clearer and more effective ways to promote and protect the rights of health.

In terms of the MDG's you know that in September we will review their progress and everything around development policies, analysing what are the new initiatives to boost MDG progress.

Briefly, on health MDG's there is clear evidence that under-five mortality has been greatly reduced in many regions of the world. Even not adjusting for demographic growth, the number of children dying today is much lower than the numbers of 1980, 1990. In the last decade there has been a net 2 million reduction in child death. Clearly this has happened, but it is uneven progress where in regions such as the Sub-Saharan Africa it has been very limited and even more astonishingly with cases related to the HIV/AIDS pandemic, under-five mortality rates are higher today than the year 2000. So there is uneven progress and the health gaps from the previous century and now are greater for the under-five and they are also increasing within countries where we know

from various reports and studies that the gaps of the under-five mortality between the rich and poor are closely correlated to income quintiles. As for MDG 5 we thought the situation was different, we used to say that the half million pregnant women dying every year had been a stagnant figure for the last decade and that there had been very negligent progress on MDG 5. Recent data tell us that maternal mortality has been reduced in certain regions of the world and there are a number of analyses explaining why and what are the success factors. In a very interesting parallel way, if we break down the progress of reduction on maternal deaths by regions, Sub-Saharan Africa is again the worst off track. In fact in southern Africa and west Africa the mortality rates are greater today than in 2000.

As for MDG 6, the progress is much more difficult to measure as HIV/AIDS continues to be one of the major health challenges in the world and it has triggered throughout the decade many of the international agreements. While the number of people in treatment, thanks to advocacy with the right approach, has gone from virtually nil to over 3 million, many of the other concerns around HIV/AIDS have not made any significant progress or have yet to be seen. In fact the MDG target of holding back the epidemic is very far from being reached and particularly prevention services are still covering a very low percentage of the population. It is even more difficult to know how the epidemic is behaving as the prevalence is now conditioned and influenced by the coverage of treatment. April 25th is Malaria World Day and later in the year the EU Parliament will discuss the progress of Malaria. I will personally take part.

There are many discussions in the UN and in 2011 there will be a high level conference on non-clinical diseases that cannot simply be excluded because they are not an MDG on its own. The burden of non-clinical diseases is growing. This now brings me out of the MDG analysis which gives a very mixed picture, especially for Sub-Saharan Africa and other countries and regions of the world. This leads me to try not to look at the MDG's alone, and particularly not the health MDG's. When we look at MDG 4 we have learned more and more that we can never address under-five mortality unless we address MDG 1 and MDG 7. The most important attributable risks for health are beyond the health sector, they are to do with nutrition, with access to water and good sanitation among others. One of the most important areas of discussion in the MDG 5 now in council is deeply related to gender equality and women's rights, so there is no way that the health sector can alone address the challenges of MDG 5. Consequently, MDG's should no longer act in silo's and in fact during this decade the centre of urgency of children and women dying and of patients with HIV/AIDS dying, while there were effective treatments in the world, has led us to look at health with a sense of urgency. We have reacted to health by looking at the emergency problem, trying to tackle this issue, trying to confront the need for treatment and based on solidarity values to react to the urgent needs of people who are at risk. We can no longer look at the different health MDG's in isolation nor look at the health MDG's in isolation from other MDG's.

In the last five years, after a decade that was mainly dominated by a disease approach, a lot of the initiatives, NGO's, the programmes in countries and national strategies are fragmented by operations, programmes and projects looking at one disease or one group of diseases and trying to tackle them in parallel, all of which have meant huge opportunity costs. Moreover, in the second part of the decade while keeping on the large resource mobilization, the large political involvement, awareness and decisions on tackling some of the most urgent diseases, the EU has been attempting to look at the structural problems undermining progress on health, not in MDG 4 nor in MDG5, but in the wider picture of health. In 2005 we started looking at one of the main bottlenecks of progressing in health, which was the crisis of human resources for health in developing countries. We picked this as a high priority because it was where the EU could have the greatest added value. We are very conscious that a lot of the benefits we have in our social protection in Europe have to do with the benefit of having skilled migrant workers working in our national health systems, and from the analysis of 2005 it was very clear that this was an essential policy to be developed. Interestingly, in Manchester we found that there were more doctors from Malawi than in the whole of Malawi and while we made a lot of efforts in development aid, support and policies and co-operation with Malawi to progress on health services, which is in fact one of the

countries showing the most promising progress on health, our EU net effect on Malawi was indeed negative.

With these concepts in mind, we have for the last year been trying to bring the development efforts from the EU into a more coherent approach with other internal policies, to avoid having a progressive interest with a net negative impact on the lives of citizens in the developing countries as mentioned previously. We started a year ago with a wide consultation, with a lot of very interesting information and we have had seven Global Health Policy Forums where we have tried to open the door to all stakeholders related to global health, NGO's, academic institutions, agencies, experts, European parliament groups, member states, and throughout this year we have been developing this communication, which I will now present on the main elements which will open up a new way of addressing health challenges.

We are at the moment discussing the Council conclusions and we hope they will be ready for adoption and signature by all EU member states on May 10th 2010. So I will share with you what the draft Council conclusions are likely to be in order to reassure you that there is a EU commitment to a more coherent approach. The communication refers basically to the core principles around health which are common to our EU internal health policies, agreed by our health ministers in the EU and should therefore apply to everything we do in external relations. There are four principles agreed by health ministers in 2005, and they relate to solidarity, universality, equity and quality of care. So if we apply these principles to our external action and try to see two things : what is the picture in health in the partner countries and the world as a whole, and what are the main determinants of those health indicators. Thirdly, what is the main EU added value to see where we could improve on our coherence in addressing health ?

In the communication there are four main objectives. One relates to increasing the governance, the structure of health governance in the world. As I have already mentioned, over the last decade the health aid architecture has mobilized many resources and has clearly rendered very significant results, although with some uneven consequences as the example given. The health governance in parallel to this wide fragmentation is now very clearly challenged in the WHO, and the World Health Assembly. We will discuss these issues in May in the World Health Assembly, which to be honest, has been very weak and its main decisions at global level and at local level have not been so clearly guided, but influenced by the power relations of large global health initiatives and significantly by the international financing institutions. There is a need to increase a more democratic and effective governance around health and as EU collectively, we have a first challenge to try to give the UN and in this case the WHO, a clearer role and clearer capacity in the mandate of guidance and main governance issues around global health.

The second objective concerns the progression of universal coverage of health services. This has a lot to do with the principles of solidarity, equity and universality of quality care. We know that the access to these services has not progressed very much, with the exception of some diseases in the least developed countries such as Sub-Saharan Africa. If we go in greater detail, the access to services is more inequitable and in many countries has a lower coverage than in the year 2000, and we need to see how from our development aid we can be more consistent in working with partner countries in increasing this coverage. The three main strategies that we will try to implement, have to do with increasing the equity of our support to health in developing countries. At the moment, the global aid architecture and EU aid architecture are not clearly correlated with countries in greatest need. For capita health aid that the EU and the global international community provide is very uneven and is not correlated with GDP, is not correlated with human development indexes, nor with the financial gaps that countries have.

Whichever threshold we agree on, it is necessary to have enough public funding, financing, to have equitable health services. We do not have a correlation between the financial needs of countries and the level of per capita aid. In the EU we are now discussing very concrete measures to better map and forecast what the EU is planning

or is able to do in supporting health efforts in developing countries, and to try to concentrate on the countries with greatest need and to those countries that are giving more attention to health and social sectors.

The second strategy is to strengthen health systems. As the aid architecture of the past decades has concentrated on diseases, it is very clear that in some regions in the world a child could more easily die from diarrhoea than from AIDS or malaria. We need a very clear effect on which disease you have and how your right to health is protected and promoted globally. Also, we require comprehensive health care for patient centred services that respond to patient needs and not to the priorities that are often decided in New York, Geneva or Brussels. We based a lot of our analyses in a very important resolution by the World Health Assembly that was adopted last year in 2009, resolution 6212, on primary health care and strengthening health systems, bringing back the principles of primary health care that have been lost over the last decade, of inclusive leadership, universality and patient centred approach. By strengthening health systems we know how we are going to do it and that the only clear and sustainable and effective way in which the EU can support comprehensive health systems is by applying the Aid Effectiveness Principles to the health sector. These principles have to do with supporting countries and their institutions with a very open and clear process of dialogue and mutual accountability in having the responsibility of protecting the citizens » right to health. So we want to have our EU aid going through programme based approaches, using country systems, but also including the participation of all stakeholders, notably civil societies in the design, documentation and monitoring of those health strategies.

The third element has to do with making better and greater use of global health knowledge. It has a lot to do with coherence because it is related to the global strategy and plan of action on public health innovation and intellectual property rights, on how to better address the market failures leading to; lack of investments, lack of development and lack of access to medicines which are most needed in developing countries.

I will now concentrate on the elements of coherence, on the new communication and on this new EU policy that is about to be adopted. In many countries, if we increase our levels of ODA, which is one of the commitments clearly made in many of the European Council conclusions, to the health sector and do it in a more equitable way by addressing countries in greatest need and with a more systematic approach, this will give rise to strong health systems delivering universal and equitable care. The Fair Finance Commitments are also included in this communication and will be developed further but if we do not address our trade policies, our migration policies and other policies, the EU net effect on the health in many partner countries might be indeed negative.

In the very vast list of factors that influence health we had to choose which critical policies might negatively influence health and also choose those that had the greatest potential for positive synergies in promoting health. We concentrated on five key priority elements for the overall policy coherence for development which was adopted on the 20th of April. The five priority issues are trade, financing, migration, food security, and environment and climate change. We believe that addressing these five areas in a more consistent way will lead to a far more coherent approach to health.

I would like to briefly mention the clear commitments we have made on coherence in relation to trade. In the opening of the 4.3 Chapter; what the Commission requests that the EU now adopts in the Council conclusions is to ensure that all relevant internal and external policies contribute to promoting equitable and universal coverage of quality health services. In order to do so the impact assessment of the relevant policy areas should analyse the effects of policy options on global health. This is in fact very strong language and it will mean a lot of work. We will be questioned and scrutinized on how we are complying with this commitment. On trade it is very strong and sane that the EU should work to ensure more effective use of TRIPS' provisions to increase the affordability and access to essential medicines. In fact in some ways the Council's

conclusions, after reflection on all the consensus that these commitments had to meet, is even a bit more ambitious, not just to promote access to essential medicines but medicines for all.

The second commitment says that the EU should support the priority actions identified in the global strategy and the plan of action on public health innovation and intellectual property. Among the hundred or so measures there are many important actions that the international community should be serious about. We hope that the communication will influence EU positions in the next Health Assembly to give far greater support to this growing strategy.

The third commitment states that these two previous commitments should address the challenges expected after 2016 when the TRIPS framework comes into force in least developed countries.

The most important commitment has been taken on by all the member states whereby the EU should continue to ensure that EU bilateral agreements avoid clauses which undermine access to medicines. We will need to work a lot to and have a closer scrutiny on bilateral trade agreements, on EPA's and look in greater detail on how these commitments can lead to a greater coherence of health, development and trade.

I would like to finish with the last few issues which I consider are important to coherence and trade, and health the development. Genetic competition and rational use of medicines are of major importance to ensure the sustainability of health care systems and the EU should also work at regional and global level to eliminate trade in falsified medicines. The EU should also further address the problem of illicit drugs and its effects on health and consider addressing the crucial effects of tobacco and alcohol.

All these challenges have had to be summarized in ten pages, and the Council conclusions in two pages. The Council conclusions to be adopted very soon will reflect these EU commitments using a strong language to ensure that the bilateral agreements are fully supportive of these objectives for health.

Uiteenzetting door mevrouw Valbona Muzaka, *lecturer in Global Politics, School of Social Science/Politics, University of Southampton*.

Intellectuele eigendomsrechten en toegang tot medicijnen

Exposé de Mme Valbona Muzaka, *lecturer in Global Politics, School of Social Science/Politics, University of Southampton*

Les droits de la propriété intellectuelle et l'accès aux médicaments

Basically, intellectual property rights are usually seen as a competitiveness issue or a commercial issue as far as the EU and the US are concerned, versus public good or in this case public health and access to medicines. In my view, the idea that states can compete the way companies compete is a nonsensical idea but it is a discussion that we are having at the moment. What I am trying to say is that the EU and the US, plus various business actors who rely on strong intellectual property rights frame them as a competitiveness issue, so we need the intellectual property rights to move forward.

First of all I would like to give an overview of the pharmaceutical research and development. Without understanding how the research process takes place we cannot understand the arguments being put forward by the pharmaceutical companies. There are three things I want to draw your attention to. The first is that there are hundreds and thousands compounds being tested routinely by pharmaceutical companies and by biotech companies. So we have Phase I of drug discovery and Phase 2. Between Phase 2 and Phase 3 a pharmaceutical company applies for a patent before it starts testing on humans. The clinical testing on humans takes place in Phase 3 which might take as long as eight years — the industry says —, and after a successful drug has been discovered or developed there is the Phase 4 which refers to marketing approval.

The reason I am giving all this background is to highlight three points.

First of all, patent application takes place a long time before the drug actually reaches the market; it could be between two to ten or twelve years. This is why a lot of the pharmaceutical companies, and now the EU and the US negotiators when they go to the developing countries say you have to grant patent extensions because it takes so long for the drug to come to the market.

Another element that I want to draw your attention to is in regards to the clinical testing, basically Phase three. There is a lot of data produced by the pharmaceutical company during this phase and the TRIPS Agreement says that the governments should make sure that this data is not used unfairly; protection against unfair use. What is happening with the free trade agreements is that both the US and EU are asking for data exclusivity.

The third element that I would like to underscore is the fact that marketing approval and patent granting are given by different agencies, so the agent that gives the patent looks into the application and makes sure that the application is novel, and a new discovery that fulfils the presentability criteria. A company can have a patent but the drug may not be approved on the market, so the marketing authorities are different and usually public health authorities that look into the drug and decide whether it does what it says it should do. More recently there has been a move to link the patenting approval and the marketing approval together. There are some requests, though admittedly not by the EU but by the US in most cases, to say to the marketing approval body that you cannot approve a generic drug if there is still a patent pending or in force for that particular drug. Thus we have yet another layer of a public authority that has to enforce private property rights. Therefore, this is the reason why I wanted to explain to you this pharmaceutical development process.

A list is given of the top twelve pharmaceutical companies led by Johnson & Johnson and it indicates where these companies and their headquarters are located and their revenues of 2009.

The pharmaceuticals industry today is highly internationalized which means that it has access to policy makers in the US, in Europe and in Japan. Its interests and demands are seen today as being paramount not only for the industry per se but to Europe itself

and to the US economy. The pharmaceutical market was estimated in 2007 to be around 663 billion US dollars and has grown from around 400 billion dollars in 2002. Although this might sound like an impressive figure, 80 % of these pharmaceutical sales actually take place in Canada, US and Europe. According to the pharmaceutical industry, to bring a new medicine to the market takes not only about twelve years but costs about one billion US dollars. This is a figure that comes from the industry which obviously has got the incentive to inflate it and although we do not actually have access to the pharmaceuticals » books per se, there have been some studies that have put the figures at a much lower level.

All the pharmaceutical research and development process are based on the system of patents and the patent allows them to take whatever the market can give them in terms of income for about twenty years normally, but as I mentioned earlier the patent is issued some time before the drug does reach the market. This kind of arrangement fails patients across the world and especially in developing countries in three important ways.

Firstly, although over the last two decades we have seen the growth in the protection level of pharmaceutical intellectual property rights, we have not seen a growth in innovative capacity. The industry was producing about 93 new chemical entities in the 1970's, this fell to 48 in the 1980's and fell even further to 27 in the year 2000. So although we are granting more in the protection of intellectual property rights the industry itself is not becoming more innovative. What they are getting very good at is playing the intellectual property rights system. It is a process called « evergreening », so you tweak a little bit a particular drug or you use it for something else that it might be useful for and you get another patent. It is not unusual for a drug to have tens and hundreds of patents protecting various elements of it. In this sense the intellectual property rights system is not really working and there is a growing awareness even within the industry that it is not particularly working and this impacts on everyone.

The second element is that most pharmaceutical companies will invest in drugs for which there is a market and not for a drug for which there is a need. Only around 5 % of R&D actually goes towards cures for diseases that affect patients that have no purchasing power, to diseases such as malaria, tuberculosis etc. So this intellectual property rights system is indeed letting patients down.

Finally, the third element is that a patented drug is a lot more expensive than its generic version. On average a generic drug costs about 40 % to 80 % less than a patented medicine. Moreover, if we look into the health care budget of most developing countries you can see that the share they spend on purchasing medicine is a lot higher than it is for developed countries. Routinely on average, developed countries spend about 17 % of their total health care budget on purchasing medicine, but this share could go up to 60 % for developing countries.

So there are three ways that intellectual property rights can have an effect on medicine. One of the first that comes to the fore is price, secondly the fact that most investment goes towards medicine for which there is a market and not necessarily a need and finally that we see fewer new drugs reaching the market rather than more.

Briefly, I will now refer to a graph that was taken from the WHO website which highlights the point that was made by previous speakers that it is wrong to think that people in Africa, Asia, Latin America or other developing countries only need access to drugs that deal with communicable diseases. This is not true, it is clearly shown in this graph that both group 1 — communicable diseases —, and group 2 — non-communicable diseases — are spread across the developing and the developed world.

A lot has been said about the free trade agreements that EU and the US are signing to narrow down TRIPS' flexibilities, but TRIPS itself has changed the scene and narrowed down the space that governments had to deal with public health problems. It introduced pharmaceutical patents for about 20 years. Before that, countries had shorter patents and in some countries there were no patents whatsoever for pharmaceutical products. TRIPS itself is not an agreement that is concerned with public health but with protecting

private rights. There is an element in the agreement, article 8, which stipulates that the agreement should be implemented in a way that does not have an unfavourable impact on public health. However, this is not binding, it is in the preamble of the agreement.

Since TRIPS came into force in 1995, a lot of efforts have been made by various state actors and non state actors to narrow down the few flexibilities that the TRIPS agreement contained. There is unilateral pressure coming from the US and from the EU to narrow down provisions afforded in the form of technical assistance coming from the WTO or WIPO to most developing countries. In most cases it came in the shape of readymade intellectual property laws that did not necessarily take into account public health needs or development needs. Only countries that have good intellectual expertise like Brazil and India have been able to take advantage of TRIPS and to balance the intellectual property rights' provisions in their laws.

In 2001 there was the Doha declaration on TRIPS and public health which re-instated the TRIPS flexibilities but unfortunately this was mainly at the level of principles and in practice a lot of things have been taking place which has meant that the declaration has not been respected. There has been a lot of pressure even after the declaration when countries use the TRIPS flexibilities; one example was where Thailand and Brazil used compulsory licensing in 2006 and 2007 respectively and came under heavy criticism both from the US and the EU. When countries of middle income with quite a huge pharmaceutical market use these flexibilities they tend to come under pressure.

There are countries that use more strict criteria and are more careful in giving patents. Today there is the case of Novartis at the High Supreme Court in India and one by Bayer also in India; in the first case the patent was not granted and in the second it was granted but generic companies are producing a generic version. So we have a direct conflict between companies and the Indian courts here. In addition, this unilateral pressure continues to be used with the example of US special 301 section where a lot of countries get listed there if their intellectual property rights are not adequate or improper from US perspective. The EU has introduced its own version of the « watch list », although it goes to great lengths to say it is not to impose trade sanctions on countries but to simply highlight problems particularly with enforcement and then to find ways to cooperate with the countries to bring the intellectual property rights laws up to standard, according to the EU perspective.

There is also a new intellectual enforcement agenda. In 2008 there were at least 19 cases of generic seizure in European ports of drugs usually going from India and China to Brazil and other countries and a few more seizures in 2009, but not yet any in 2010. Besides this, there is the infamous Anti-Counterfeiting Agreement that is being currently negotiated with a lot of discussion about the impact it will have on copyright and internet users and importantly on the impact it might have on the access to medicine.

Until 2008 all free trade agreements, without any exceptions, whether signed by the US or the EU, contain TRIPS Plus obligations and provisions in one way or another. TRIPS Plus refers to either further increasing the level of intellectual property rights protection or introducing new forms for intellectual protection that TRIPS itself does not contain. There are five areas that are important in terms of access to medicines; one of which refers to pharmaceutical data protection or data exclusivity, which is a hot issue. Referring back to my explanation on the pharmaceutical R&D process in which pharmaceutical company produces data by doing clinical trials. TRIPS says that this data should be protected as it is submitted to the marketing approval authorities, should be submitted for marketing purposes and should be protected against unfair use. The US protects the data for five years and the EU for eight to ten years. The result is that a patent which might not be granted still has its data protected so generic companies cannot access this data to be able to produce a generic version of the drug. Another problem might be that one country decides to issue a compulsory license and it says to the generic company that it can produce the drug if it wants, however, if the data is protected by another layer of protection the generic company may not be able to use it. The bottom line is that it delays the introduction to generic drugs.

Another aspect is patent term extension which is something that comes up in the US and now also in the EU agreements. As it takes about eight to ten years before the drug can come onto the market, a lot of countries want to extend the patent by two to five years. The problem with this is that when a bilateral trade agreement or a free trade agreement has been signed, what might be unreasonable delay for a developed country, could be reasonable for developing countries that have not got the capacities and do not choose to channel them all into a marketing approval process. So there is a conflict in terms of what is a reasonable or unreasonable delay. The other points are; linking marketing approval with patents, limiting the grounds that compulsory license can be issued, although TRIPS itself does not, and putting limitations on parallel imports.

Focusing more specifically on the European Union there are two key documents. The first is the 2000 Lisbon agenda which has the aim of making the EU one of the most competitive economies in the world with innovation and intellectual property coming at the very top in terms of strategies and the second is the 2006 Global Europe agenda which refers specifically to trade, to push in areas where there is no agreement at the multilateral level. Most of the free trade agreements signed by the EU and US are TRIPS Plus and also WTO Plus in areas such as investments, services and procurement etc. The EU is also signing agreements with certain African countries; with ASEAN, particularly Singapore and Vietnam; with several countries in Central America; there have been negotiations with Mercosur, but they have stalled; with Canada and finally there is an agreement with India which is currently being negotiated.

Basically, this agreement between India and the EU is very important as India is seen as the pharmacy of the world, especially for developing countries. Certain reports indicate that up to 90 % of AIDS drugs that are used in developing countries come from India. Even the US President Programme uses a lot of generic drugs coming from India. In 2005 India had to change its patent law which is when TRIPS became applicable to it and other developing countries. As a result India has been able to incorporate quite a few of the TRIPS flexibilities especially to the type of patents given and to whom. Indeed there is a possibility for a patient group to challenge a patent on several grounds, so India is seen as an important player in the generic medicine game.

I would like to highlight the three key area that relate to access to medicine.

One is patent extension which I mentioned earlier. The EU is asking in its draft article 9.3 a five year extension to make up for the fact that it takes a long time for the marketing approval authorities to go through a file. This means that the patent is valid for a further five years and generics cannot be on the market until patent expiry. This has implications for the internal market but also the world market for generics.

The second key element is data protection which refers to the data produced during the clinical testing. The EU model protection is up to ten or eleven years, so it is asking the Indian counterpart to do the same, although this has not been accepted by the Indians whatsoever. The last agreement with the EU and South Korea placed the protection at five years.

Finally the third element relates to intellectual property rights enforcement for which the EU is one of the main advocates and is trying to incorporate it in the TRIPS Plus Agreement with regard to India. This will have an impact not just on border measures but on import, export and medicines in transit as such. Quite interestingly though, issues that are important to the opinion are found in the agreement, but issues such as traditional knowledge and generic resource sharing which India is big on in multilateral agreements, do not get a mention in this particular agreement.

Overall, to bring this to an end there is a push or commitment to treat intellectual property rights as a competitiveness and commercial issue. This in itself is wrong because intellectual property rights are not only linked to trade but are linked to so many other areas which are important from a public health perspective. They are linked to education, to bio-diversity, to human rights, and to development. There is a relentless push to frame the high intellectual property rights as a competitive and commercial issue which is very one-sided at the expense of developing countries.

As I have said from the beginning this whole patent for medicine model might actually not be working any longer. This model is about 500 years old, emerging in Venice and then developed from the 15th century onwards, so it is time to rethink the intellectual property rights system itself. But even if we decide to keep the system we are stuck with, it is worth revisiting the whole reasoning and justification behind it. It is supposed to be a balance and supposed to be rights that provide enough incentive for innovation while also providing access to this innovation. If pharmaceutical companies want to have global patents, then the other half is that they should make sure there is access to this medicine globally. You cannot have one half without the other if we really want to have a balance in the intellectual property rights regime.

Uiteenzetting door de heer Rangarirai Machemedze, *Health and Trade specialist*, Seatini/Equinet, Zimbabwe

Kan het recht op gezondheid gevrijwaard worden in het economisch partnerschapsakkoord tussen de Europese Unie en de landen van oostelijk en zuidelijk Afrika (ESA) ?

Exposé de M. Rangarirai Machemedze, *Health and Trade specialist*, Seatini/Equinet, Zimbabwe

Le droit à la santé peut-il être préservé dans les accords de partenariat économique entre l'Union européenne et les pays de l'Afrique de l'Est et du Sud (ESA) ?

Thank you for inviting me to share with you the very issues that are currently at the heart of our own economies in terms of negotiations taking place between the EU and the African, Caribbean and Pacific countries. I do hope that by coming here my expectations of putting across the issues to the Belgian Senate will ensure that it would take them seriously within the EU Parliament as these issues are going to go through the process of ratification. This is not only important for us in Africa, but also for the EU countries themselves.

I will start with a brief background on Economic Partnership Agreements (EPA) to be able to show where exactly we are today. Economic Partnership Agreements are by nature legal and technical instruments, but more importantly they are political instruments. The relationship between Africa and the EU regarding trade has been for a very long time guided by the Lomé Conventions where African countries supplied goods and raw materials in the form of quotas, such as sugar, beef, veal, bananas, etc. But because most African countries are members of the WTO — as is the EU — the WTO does not allow discrimination of other members which resulted in some countries within the WTO bringing the issue of EPA relations between ACP countries in the EU to the WTO District Settlement Body, saying that their relationship was being discriminated against. The WTO ruled that the EU and the ACP (African, Pacific and Caribbean countries) had to bring their trade relations into conformity with the WTO. This meant the re-negotiation of trade relations, hence the so called economic partnership agreements that are being currently negotiated between the ACP and the EU.

This is where we are coming from.

The new trade arrangements that are being negotiated, are different from the old arrangements in that the new are supposed to be reciprocal in nature, meaning that if African countries are getting market access to the EU market, the same should apply to the EU, meaning they should also get market access for their goods and services to the African markets.

Regarding the question that has been presented to me, whether the right to health can be assured in the economic partnership agreements between the EU and the countries of Eastern and Southern Africa, I have to take a rather radical stand.

The quick answer is certainly no. Given the offensive interest that the EU has been showing in the negotiations so far, it is very difficult for us to conclude that the right to health will be guaranteed in the economic partnership agreements. About eight countries in Eastern and Southern Africa have signed the interim partnership agreements that have been put on the table. The other countries have not signed. The reason for not signing is that they are not happy with the provisions in these agreements.

Moreover, for the eight countries that have signed, including my own country Zimbabwe, if you were to ask officials and trade ministers as to why they signed the agreement they would say they wanted the aid that had been promised in the economic partnership agreement without looking necessarily at the other provisions that are detrimental to the various sectors of the economy, including the health sector. They would also say that they signed the agreements simply because they thought they would benefit developmentally from them. Those that were following the negotiations can testify that as soon as the Interim Economic Partnership

Agreements were initialled, in December 2007, just one month later, the very same countries came back to the EU asking to re-negotiate the terms of these agreements. What they signed they are not going to benefit from. There are over twenty clauses within the EPA's that have since been put on the table for re-negotiation with issues relating to export taxes, standstill clauses, etc.

Nevertheless, the Cotonou Agreement is the umbrella agreement that is the legal basis for negotiating other agreements and, if we look at article 19.2, this is a very important provision with regards to the right to health which reads : « Cooperation shall refer to the conclusion of the United Nations' conferences and to the objectives, targets and action programmes agreed at international level and to their follow up as a basis for development principles. Cooperation shall also refer to the international development cooperation targets and shall pay particular attention to putting in place qualitative and quantitative indicators of progress ». This article mandates the parties to observe the international instruments in the implementation of the Cotonou Agreement. Most of the indicators on MDG's are not going to be met by 2015 and even the Review Conference that is coming to New York in September has been told that not all the targets will be met.

Regarding the issues of the right to health, these become lost in the midst of negotiating the economic partnership agreements which in essence create a free trade area and in a free trade area there are quite a number of issues that go beyond simple trade concerns. The fact that the economic partnership agreements are supposed to be WTO compatible means that those countries which are going to sign them must change their national laws to incorporate the agreements. Moreover, these WTO agreements are legally binding on national economies. So there are virtually a lot of issues that have been raised, especially on agriculture which we know very well affects to a large extent health issues, the so called social determinants of health, issues around nutrition and around food security coming from the Agricultural Agreement that is going to be negotiated in the EPA's.

There is also a provision to discuss the intellectual property rules. Besides the issues on access to medicines, they touch on the issue of farmers » rights with respect to saving seeds for them to be able to grow food for nutrition purposes which affect health. As you may know, seeds have been commercialized, but seeds are considered as a technology hence the application of intellectual property rights. Farmers are expected to buy seeds every season and, under the intellectual property rights rule, if they buy seeds for growing maize or corn, they are not allowed to save the seeds for the next season. All this is affecting the efforts being made to ensure the right to health.

Negotiations on EPA's are going to include issues around health services, some of which are basically health delivery services which are also going to be put on the table for negotiation, especially the role of private companies. In most African companies health services are a prerogative of local authorities and to a large extent of governmental authority, but their provisions under these authorities are actually threatened by the services negotiations that are going to take place under the WTO. Where countries are required to offer sectors for investments, the health sector is the most targeted in terms of investment. There are counter arguments to say that if the health services provisions are put under the domain of private companies their quality will increase, but it is not just the question of quality that we are talking about, it is also the question of accessibility and affordability. Many people may not be able to afford the services and hence this will affect their accessibility to health services.

There are a number of international instruments that the parties that are going to negotiate the international agreements need to look at before they really sign full and comprehensive EPA's. Most of these international instruments are UN Charters which talk about the right to protect health.

Specifically, there is the Charter of the United Nations, article 55 of 1945 and the Universal Declaration of Human Rights of 1948, article 25, which talk about health issues. The International Covenant on Economic, Social and Cultural Rights of 1976, article 12, has also to be read to ensure that what we are negotiating comply with this

article. There are the Convention on the Rights of the Child of 1990, the Convention on the Elimination of all Forms of Discrimination Against Women of 1981, the African Charter on Human and Peoples » Rights of 1986, article 16, which also talk about health. Then there is the European Social Charter of 1961, and the Abuja Declaration in terms of financing health from the African point of view of 2000 and 2001 where it said that fiscally 15 % of the national budgets should go towards health. In terms of regional agreements there is also the SADC Protocol on health of 1999 (Southern African development Community) and then there is the Common Market for Eastern and Southern Africa Treaty of 1993, articles 110 to 111, which all talk about the need to protect health and to regard health as a fundamental human right that must be protected in the international instruments.

If we go back to my earlier point of departure, the Cotonou Agreement states clearly that we should recognize the provisions of these international instruments. That has to be taken seriously taken into account.

Then there are the various national constitutions that protect health. As you know, the constitutions take precedence over international treaties. As example : the Constitution of Malawi, the Constitution of Ethiopia, the Constitution of Uganda all provide for the protection of health.

So in the final analysis, these conventions, treaties and constitutional provisions create obligations to be discharged by the state parties. Therefore, in this regard, the parties to the negotiations in Eastern and Southern Africa as well as the EU must ensure that whatever they are going to come up with at the end of the day does not breach the provisions of these international treaties, and that is critical as we are all members of the United Nations and thereby we have to abide by the declarations we have set for ourselves.

I would like to quote the Charter of Fundamental rights of the European Union of 2000, article 35, which talks about health care in which it says everyone « has the fundamental right to access to health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities ». Now I am putting it to you to say that if this article applies to the individuals of the European Union, then surely any attempt by the EU to force other countries to sign agreements and in this case the Economic Partnership Agreements, violates the spirit of this article. Outside the presence of the EU it will certainly be tantamount to genocide and history will certainly judge the EU for deliberately flaunting the national agreements in the name of the selfish interests that have been elaborated in the Lisbon Treaty of 2006.

With regards to what can be done, I am addressing this house to say that we have certain statistics that can guide our own decisions that we have to take regarding economic partnership agreements and their ratification and to whether we should proceed with the negotiations. The 2008 WHO report brought out some very interesting statistics on the state of health in Sub-Saharan Africa.

There are five points I would like to highlight.

The first is that the GDP per capita Growth in Sub-Saharan Africa fell in most years from 1980 to 1994, leaving little room to expand the access to health care, or to transform health systems. If we are to go back to the period that is being referred to, it is the period in which African countries were implementing structural adjustment programmes, and by the way economic partnership agreements are just an extension of structural adjustment programmes. There is no difference, it is only in the writing otherwise the conditions are the same as the conditions in structural adjustment programmes championed by the IMF and the World Bank.

Secondly, by the early 1990's, Zambia's public health budget was cut by two thirds because structural adjustment programmes were saying for austerity purposes that The

Zambian government must cut expenditure, resulting in the health sector being most affected, followed by the education and agricultural sectors.

Thirdly, during the same period funds available for operating expenses for the expanding government workforce dropped by as much as 70 % in countries such as Tanzania. For Sub-Saharan Africa the 1980's and the 1990's were a period of managing shrinking government budgets and disinvestments in the health sector. This is how the WHO brought out all these issues and it concluded by saying that public health care delivery has been commercialized as informal payment systems, and cost recovery systems have shifted the cost of services to the users in an attempt to compensate for the chronic underfunding of the public health sector and the fiscal stringencies of structural adjustment. This is what the World Health report concluded. In like manner the economic partnership agreements further exacerbate the problems as shown above.

So what can we do given this situation ? I believe it is not too late as the EPA's will come for ratification. It is certainly within your means to question, even the Belgian state itself, on their role in the EPA's negotiations. Of course the EC is leading the negotiations, but Belgium is a member of the EU and must seize the power to also question whether these agreements are going to be beneficial to the very countries that are going to be part of this negotiation, not only to the countries but most importantly to the impoverished people of Africa, Caribbean and the Pacific. Surely Belgium cannot be seen to be complacent to the impoverished peoples of Africa through these near colonialist policies in the form of economic partnership agreements. Frankly speaking, it is not only going to be the health sector that will be affected by these agreements but a lot of other areas, one of which is regional integration which has already become their first casualty. The fact that some countries have signed the EPA's and others have not or others have just initialled points to the fact there has been the Balkanization or fragmentation of African countries, has to be taken into account.

It only takes us to go two weeks back in time, to the problems with the volcanic ash here in Europe, to understand what I am talking about. African countries cannot depend on one market. Due to the structural adjustment programmes the Kenian farmers are being forced to grow flowers for export rather than to grow food and as a consequence of the volcanic ash, they were losing two million american dollars a day by not being able to transport their flowers to the European market.

There is no doubt that the interests of Africa and its citizens are the legitimate sequel of a developmental process that is shaping our lives, our future, our livelihoods and that of our children which lie in the following areas : a healthy and productive workforce, access to the means of production, good quality jobs, a fair and equitable distribution of the wealth, a good education system and an excellent infrastructure. I have presented this list just to show you what these economic agreements are going to negatively affect, and when I talk of infrastructure it includes hospitals and clinics which are very essential to the realization of health, including even education.

Trade liberalization, which is at the center of the economic partnership agreements, can only be beneficial in the presence of certain prerequisites which include social safety needs, the need to have a domestic regulatory framework, the relevant and communication infrastructure.

Gedachtewisseling | **Échange de vues**

Mrs Seco Gérard (Artsen zonder Grenzen). — I would like to thank all the speakers for their very interesting presentations in which we obtained more evidence about the negative impact some of those trade agreements can have on issues like access to medicines. Access to medicine is something that we at MSF have been looking at for several years now and we are actually very worried about the EU-India Trade Agreement, fearing that we may fall back to the situation we were in, in early 2000. As it has been referred to by some I believe, in the early 2000's organizations like MSF, ministries of health and donors were feeling rather powerless to address HIV/AIDS because the treatments were much too expensive. Thanks to the legislation in India at the time, competition could take place between producers and the prices went down. That allowed organizations like us and others to start addressing the crisis of HIV/AIDS. The crisis however, is far from being over and what we see is that we are being confronted with trade agreements as the one between EU and India which may impact on drugs again, reducing competition among producers and resulting in higher prices. This is all happening in a background where the crisis is far from being over, where there is a back-tracking of donors regarding HIV/AIDS willing to give less to mechanisms like Global Fund and it is not only about HIV/AIDS. Indeed any new drug to treat any other diseases such as diabetes and hypertension would be submitted to the same rules. So we have to keep all these issues very strongly in mind as the trade agreements will affect any kind of health problem we want to address. Many countries still have a lot to do regarding the Health MDG's and many are in fact backtracking.

The evidence is clearly there, but the people negotiating these trade agreements are doing so with a competitiveness agenda and not looking at the negotiations from a public health point of view. MSF has brought this to the attention of Mr De Gucht and has sent letters to Mr Vanackere, without receiving any response, so I now address Ms Temmerman as you are in position to put this on the agenda and to ask Belgium as a European Member state — and importantly as having the next European Presidency — how they are ensuring that those trade agreements will not affect access to medicines. There is a simple way of doing this, i.e. to take away the clauses that have been explained by the different experts here : extension of patent, tax exclusivity, counterfeiting and border measures. So I hope you will ask this and receive some answers in return.

Mrs Dot Keet. — I am from South Africa and I would like to add one point to Mr Machemededze's presentation about the role of the various international institutions by underscoring a few points about the WTO. The EU claims to be acting in these free trade agreements in conformity with WTO rules and regulations. However, there is nothing in the WTO that requires reciprocity between the developed, developing and under developed countries. Secondly, the EU has forced many least developed countries into signing these reciprocal trade liberalization agreements, which is in defiance of WTO special deferential treatment for LDC's. Furthermore, the EU is also ignoring the fact that in the WTO governments are adopting very cautious positions relating to services' liberalization and are demanding various exemptions and special provisions for least and lesser developed countries. By moving outside of the WTO, the EU is putting itself in a more favourable powerful position in relation to these countries than they are within the WTO framework, where normally they can act together. It is also in the WTO, which the EU is ignoring, that the least developing countries have demanded that investment liberalization, tight free market competition policy, the opening up of government procurement to European companies, be kept out of the WTO. Once again the EU is outflanking that resistance and tackling these countries in small groups, or individually so that the EU can impose conditions on them. These are called the New Generation issues and the EU is going well beyond what is even being discussed in the WTO through these economic partnership agreements. So there are very serious challenges ahead.

There is one point I would like to talk about which is global Europe. We are very aware, and on this ground a country like South Africa has refused to enter into such agreements with the EU which include a most favoured nation clause under WTO terms. This means that if a country signs an agreement with larger countries such as China, India or Brazil, they have to extend the same terms to the EU. This is in defiance of the attempts

of these countries to diversify their trade, aid, technology and investment relations with other countries to reduce their dependence on the EU. So there are all these dimensions of the WTO that the EU claims to be following but in fact it is adopting highly tendentious and questionable positions in defence of the interests of European corporations.

M. Bert De Belder (Intal). — I have a question for Professor Labonté. Are other trade policies possible since we have been discussing the potentially negative impact of current EU trade policies and we are currently in a serious world economic crisis in which people can challenge current models of economic development, and international trade ? Are there any alternatives from which we can learn such as the trade of countries as Brazil, India or China with other third world countries or trade within the ALBA countries in Latin America ? Do they use qualitatively different trade policies with their trading partners from the south and are there things we can learn from them and propose to the EU to incorporate in their trade policies ?

Mrs Jane Nalunga (SEATINI). — I have some comments and one specifically to Professor Labonté. In his concluding remarks he talked about compensation to the losers. I was very surprised, given the way his presentation was progressing because he said the policies are wrong, the systems are wrong and that they just cannot work. So how can you give compensation or a safety net for the majority of people who are the losers ?

Then I would like to make a comment to Mr Juan Garay regarding the MDG's. When you look at the most important success factor or the limited success of MDG's in Sub-Saharan Africa it is mainly because of the direct aid to health services and to the other sectors like education. Without that direct aid there would not have been any success in the MDG's, so here we raise the issues of sustainability. How do we sustain MDG's in particular when we only look at the outside injection of aid into these sectors ? We should look not only at the overall economy and devotement of the country but at all these issues we have been talking about. If the systems and policies are wrong, how can we achieve the MDG's if they are just being sustained by direct injection of aid from outside ?

Professor Ronald Labonté. — I would like to reiterate the points that the Senate should in fact try to debate about these particular problems. First of all, there is one thing to recall in terms of the EU's interests in these particular negotiations; it is a way to ratchet up into multilateral agreements. The developing countries do not want to negotiate all these side issues on a multilateral basis and in some point in time, particularly through these bilateral agreements, but many poor or lower income developing countries, which are also WTO members, have agreed to them under some duress or without fully acknowledging what the implications were. In many cases they thought this was the best way to improve their development assistance relationships. It will now be impossible to withhold all these issues from the WTO and it is a backward manoeuvre.

In relation to the whole issue about coherence, and looking at other trade policies that might be possible I was very pleased to hear that the EU is trying to look at coherence. But as long ago as the late 1960's, with the Pearson Commission on Official Development Assistance, it was noted that the trade policies could almost immediately undermine, whatever benefits that might arise from overseas development and official development assistance. Although there is this dated attempt to be coherent in relationship on trade to health, it still restricts that coherence to health services, intellectual property rights and access to essential medicines. We have heard that the EU is not even complying with that particular set of policies. In my presentation I was essentially arguing that we have to be much broader in terms of understanding how trade can negatively affect health through various developments and social determinants of health pathways.

Moving on to the issue of compensation, I do agree that compensation is problematic as it does not challenge the fundamental paradigm, but we have to think of what can be put on the table at this particular time. If we look at compensation — and this takes me back to coherence and development assistance —, there is a very serious concern that more and more assistance could go through the EU Development Fund into aid for trade. Either if it tries to achieve this compensation or to give the ACP countries more assistance for technical developments to be able to compete in a global economy, that

could easily crowd out some of the traditional development assistance for health, education and for essential public infrastructures.

In terms of what other trade policies might be able to offer us, regional agreements, which are agreements between countries of similar size or economic development, are probably one of the best ways in which economic growth can be more sustainable and more equitable. When we look at the Mercosur Agreement or the other agreements of South America we still run into some juggernauts like Brazil, Argentina and Chile dominating the economic relations, although there have at least been stated efforts through the « United States of the South » to try to become more coherent around social policies as well as economic trade policies. I still believe that the best option in terms of arguing for changes in trade policies is to change the nature of the dispute settlement and of the binding language. The countries pushing trade liberalization on a competitiveness basis still argue that the actual reasons they are doing so, is to improve sustainable development, reduce poverty, and improve conditions for people in developing worlds. They have stated this as the overarching principle but without any enforcement. Therefore, put it into enforcement language and forcible language, put in place a dispute panel process that allows for adjudication of derogation of any existing trade policies by developing countries, to be able to achieve those particular aims.

M. Juan Garay. — I will try to answer briefly to the four questions that I have directly identified to the concerns on the EU trade policies and their undermining effects on developing countries. Firstly, I did foresee that there would be questions and concerns on the EU-India bilateral trade agreements. The information I have is a very early draft, which is a starting point but which is clearly evolving. As yet we cannot inform of the actual content of the agreements. However, many of the concerns of MSF and other organizations are being considered. There are also arguments on how patent restoration or data exclusivity that are being tabled by the Indian side, may have possible effects on innovation for their Pharma industry. But I am sure that the negotiations will lead to a far less concerning content in terms of access to medicines. We are now already using the communication to have a more in-depth dialogue with the DG Trade. We have further opened up the dialogue to start applying the commitments to have greater coherence on development and trade, and in relation to the health values to allow access to medicines.

I am not qualified to answer whether the EU is complying with the WTO, but I have been informed that with TRIPS and WTO everything that has been negotiated in the bilateral trade agreements is in compliance. However, I will not go into this argument but I will submit it to DG Trade. I can only restate that this new communication which I will be co-ordinating, and the Council conclusions which are about to be adopted, will bring in mechanisms to see how all these bilateral trade agreements do not have clauses that undermine the access to health services and to medicines. These are new times and we will try to make everything clear and concrete, and all your concerns, recommendations and insights will be important to us.

On the sustainability of aid, I explained earlier how the fragmentation of aid particularly in the health sector has been developing over the last decade. What we do know is that aid on itself can never be sustainable. Project aid and tackling short term and partial needs, even when they are priority needs in partner countries, is even less sustainable. One of the things that we are really convinced about is that applying aid effectiveness commitments are very important in bringing fairer relations to our development policy, bringing more alignment and more predictability of our aid. This is more beneficial to policies in countries being long term, helping them to build up policies in human resources and policies in access to health services etc. Consequently, by bringing in more compliance aid effectiveness commitments can lead to less dependency.

There has been another communication that has been recently adopted on fiscal policies and development, which I feel is very important to take into account. It has a section on how fiscal policies, including relations with international financial institutions, should not undermine and should be in line with securing sufficient public

financing for social sectors. Those are elements which I think will help reduce dependency and therefore have more sustainable development.

Dr. Valbona Muzaka. — One of the steps that could be taken short term is to extend a moratorium to further expanding intellectual copy rights protection to find out what is actually happening with TRIPS itself to see what implications it has. This is just a short term step that the EU could take.

More long term the EU and other actors like the US need to question what it means to be competitive. As I said in my presentation, competitiveness for nations makes no sense. Nations, states, the EU are no companies, and they do not compete as companies do. It has become a common sense that the EU has to become competitive, but I would like to see the EU and the Commission questioning what that means and have a long term view for every agreement they enter into, to question what the social purpose is of this agreement. If the answer is simply more income for EU business or for EU citizens, surely that is very short-sighted if it means that people across the world are not being well fed, not having food security, nor health care etc. Surely this is not what the EU stands for and certainly not what the future the EU wants to be part of. It becomes a completely unstable world. So it is important just to have this long term view of what the social purpose of the EU trade policy is, and if it turns out that it is only meant for EU citizens and EU companies, it is certainly dangerous.

Mr Rangarirai Machemedze. — I have two issues; the first refers to TRIPS on how trade agreements will not affect access to medicines. If we go back to the WTO, there was a very big battle to fight for life-saving drugs especially around HIV/AIDS, tuberculosis and malaria which led to the adoption of the use TRIPS flexibilities with regards to licensing and parallel importation, which is why most countries have managed to issue licenses and are able to get drugs from India and Brazil. But the problem at the moment regarding this flexibility is for us to have a permanent amendment of the TRIPS agreement, to have two thirds of the WTO membership put their signature onto this amendment. As from 2004 when this was adopted, we have had very few countries that have put their signature to the permanent amendment of the TRIPS agreement. This is also an issue that we have to raise with the Belgian parliament, to talk to the other members. With regards to the African members, only two countries have put their signatures to it, Mauritius and Rwanda. Therefore, we may run the risk of renegotiating this particular provision.

Secondly, with reference to the issue on WTO compatibility and reciprocity, in fact under the WTO they actually state that the developing and developed countries must respect the concept of less than four reciprocity in negotiating these agreements. This is a way of ensuring special and deferential treatment in recognizing that the countries are not on the same level of development. There are other developing countries from the south which should be treated with special and deferential treatment.

Mrs Temmerman. — Before closing the session, I would like to address the question raised by MSF. I can only assure you that we have been working on this topic within the commission. In May 2009 the plenary Senate adopted the Resolution on Global Social Health Protection. We will definitely continue to discuss the matter, but as the politics is rather unclear right now I cannot guarantee who will be in the commission and how this will evolve in the future.

I would like to close the session by thanking all the speakers and those who have been with us all the afternoon, listening and participating actively to the debate. I would also like to thank the administrative and supporting services of the senate. Before leaving may I remind you of the four principles that all of the speakers have mentioned this afternoon : of solidarity, equity, universality and global health quality, which are very important values.

De voorzitter-rapporteur,	*La présidente-rapporteuse,*
Marleen TEMMERMAN.	Marleen TEMMERMAN.

Trade Liberalization and Public Health

Ronald Labonté
Canada Research Chair
Globalization/Health Equity
University of Ottawa
Institute of Population Health

rlabonte@uottawa.ca
www.globalhealthequity.ca

Introduction

- Trade is as old as human societies
- Beyond village barter, power and elite interests enter
- History of forced openings (Britain and 18th century China, the USA and 19th century Japan)
- History of coerced openings (Latin America and Africa, structural adjustment programs)

Two Questions

1. How does trade improve development and health?

2. How will the Economic Partnership Agreements affect development and health?

Background: Comparative Advantage?

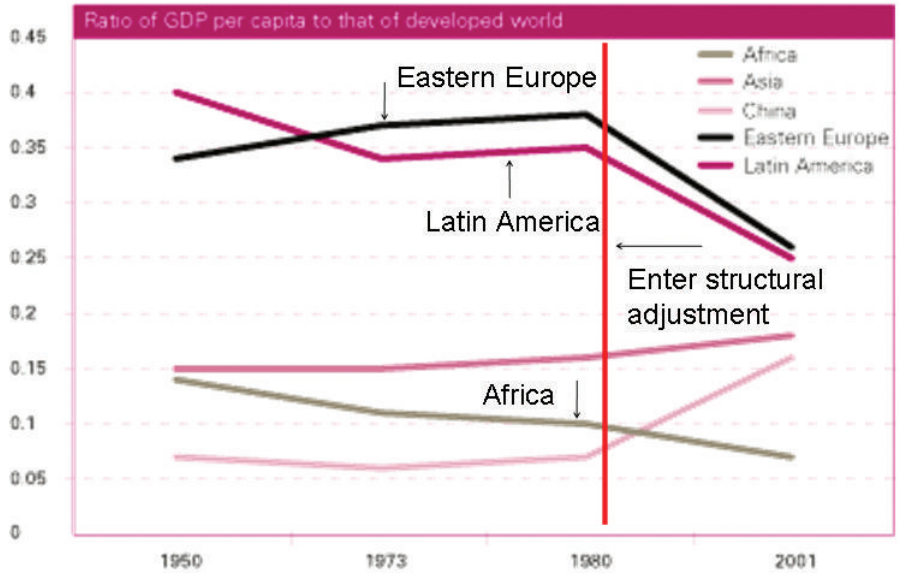
Then	Now
Finished goods traded across borders	Most trade intra-firm between branches in global production chains
Capital was immobile	Capital is hypermobile
Difference top and bottom country quintiles by wealth was 3:1	Difference top and bottom country quintiles by wealth ~ 300:1
Displaced agricultural workers migrated to 'new world'	Migration by skill-level and need with increasing barriers to lesser-skilled from liberalized developing countries

One billion new low-wage workers from India and China removes that one comparative advantage for newly integrating countries

Pro-Trade/Health Argument

Liberalization	➔ Increases Growth
Increased Growth	➔ Increases Wealth
Increased Wealth	➔ Decreases Poverty
Decreased Poverty	➔ Increases Health
Increased Health	➔ Increases Growth

Growth for some, not for others



World Economic and Social Survey 2006, UN DESA

Poverty reduction minimal

- Poverty at $1.25 day down by 505 million since 1981; but up by 123 million excluding China
  - Decreases in some parts offset by increases in others
- Poverty at $2.50 day up by 402 million; and by 745 million excluding China
  - Global poverty at these rates now number 3.2 billion

Chen, S. & Ravallion, M. (2004). "How Have the World's Poorest Fared since the Early 1980s?" The World Bank Research Observer, vol. 19, no. 2, pp. 141-169.
Chen, S. & Ravallion, M. (2008). The Developing World Is Poorer Than We Thought, But No Less Successful in the Fight against Poverty, Policy Research Working Paper 4703. Washington, DC: World Bank.

Trading our way to better health through poverty reduction?

"it is hard to maintain the view that expanding external trade is…a powerful force for poverty reduction in developing countries"

Ravallion, M. (2006). "Looking beyond averages in the trade and poverty debate," *World Development*, vol. 34, no. 8, pp. 1374-1392.

Average tariffs recovery: Low and middle income countries

- Middle income countries: 40% – 60%
- Low income countries: 0% – 30%
- For 28 low income countries:
  - 6 replaced lost tariffs
  - 10 partially replaced tariffs
  - 12 replaced no lost tariffs
- Tariffs account for 10% – 50% of all public revenue in the world's 53 poorest countries

Source: Labonté, R et al. *Globalization and Health: Pathways, Evidence and Policy*. London: Routledge. 2009.

Trade Openness and Health

- Openness associated with improved infant mortality and life expectancy at birth
  - Holds for developing but not developed countries
  - Not growth but health technology, public health knowledge and foreign assistance exchange between high- and low-income trading countries
- Study pre-dates WTO and bilateral/regional trade agreements
  - Impact of extended IPRs on technology diffusion?

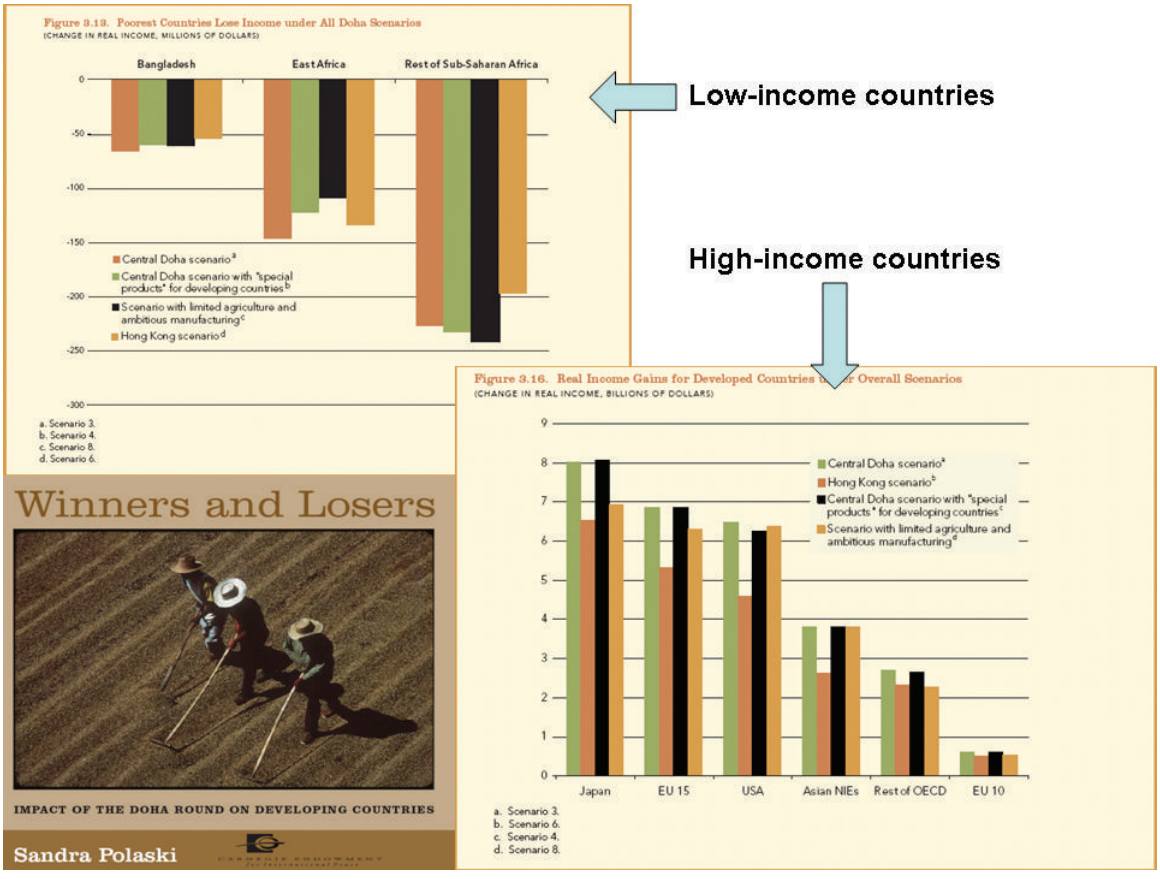
Source: Owen, A.L. & Wu, S. (2007). "Is Trade Good for Your Health?" *Review of International Economics* vol. 15, no. 4 pp. 660-682.

Developing countries falling further behind: Doha 'Development' Round

Projected to 2015:

- **Benefits:**
  - US$79.9 billion to developed (high-income) countries
  - US$16.1 billion to the rest, a figure that amounts to about a penny a day for people in developing countries
- **Costs:**
  - NAMA tariffs losses under high-income country proposals
  - US$38 billion for developed nations
  - US$63.4 billion for developing ones

Sources: Sundaram, J. and Arnim, R. 2009. "Trade Liberalization and Economic Development," Science 323. Gallagher, K. P. 2007, Measuring the cost of lost policy space at the WTO, IRC Americas.



EPAs and trade in goods

- Annual revenue gain full EPA implementation: € 12.7 million
- Annual tariff loss: € 550.0 million
- Promised annual EU AfT: € 300-400 million
  - Not legally binding in EPAs
  - For trade development and infrastructure not lost tariffs revenue replacement
  - Could crowd out other health and health-related development assistance
- Potential negative impact on health and social protection spending

Source: C Stevens et al, *The new EPAs: comparative analysis of their content and the challenges for 2008, Final Report* . London: ODI.

EPAs and long-term development

Recent history indicates that new trade preferences granted to the ACP have been quite quickly extended by the EU to other suppliers. The competitive advantage of DFQF (duty-free quota-free) is likely to be eroded in the same way…It would be optimistic to expect the benefits (of greater EU openness resulting from the EPAs) to last for much more than a decade.

Source: C Stevens et al, *The new EPAs: comparative analysis of their content and the challenges for 2008, Final Report* . London: ODI.

Economic and employment insecurity

- Trade/financial liberalization associated with greater economic and labour market insecurity
- These insecurities associated with greater chronic and infectious disease
- Liberalization-related labour market polarization pronounced in Latin America and the Caribbean
- Increased women's employment in EPZs and export industries has contributed to gender empowerment, but exploitative conditions, unsafe conditions, few or no family benefits and lack of labour rights compromise potential health gains and lead to negative health outcomes
- Women occupy lower paid, less desirable jobs while bearing disproportionate share of responsibility for unpaid work in the household

Source: Labonté, R et al. *Globalization and Health: Pathways, Evidence and Policy*. London: Routledge. 2009.

Trade in health-damaging goods

- Liberalization in tobacco trade increases consumption and related diseases
- FCTC does not address trade and its domestic provisions now subject to an investor/state dispute under a bilateral investment treaty (BIT)
- Liberalization in alcohol trade increases consumption and related diseases
  - EU *pisco* dispute with Chile
  - EU new dispute with the Philippines
  - EU pursuing full GATS liberalization in advertising (including alcohol)
- Liberalization in food trade increases obesogenic food environments
  - FDI in food through liberalization changing availability
  - Food trade may worsen food security

Sources: Labonté, R. *Trade, Growth and Population Health: An Introductory Review.* University of Ottawa, Institute of Population Health 2010; and Labonté, R. et al, *Trade and Chronic Disease* (forthcoming)

Food trade and food security

- Openness to food imports can destroy less efficient and unsubsidized small-scale producers
- EPA safeguards for food security weaker than those in WTO
- EPA concerns:
  - tariff standstills
  - ban on export restrictions and export taxes
  - safeguard period of 200 days only
  - failure to prohibit EU use of export subsidies

Trade in health services

- **Pro:** Increase FDI should produce a net health gain if private providers and insurers properly regulated
- **Con:** "few countries have developed adequate strategies to regulate the private financing and provision of health services," and "the harm caused by market abuses is difficult to remedy after the fact" (World Health Organization *World Health Report 2000*)

Health Systems Knowledge Network, WHO Commission on Social Determinants of Health

Market failures in more privatized systems lead to access inequities

Evidence-based policy advice to promote access equity:

- Move from risk-pooling towards universal, progressively tax-funded system
- Caution in contracting private providers (provider competitive model) and careful monitoring of equity impacts
- Where private insurance exists, restrict to luxury top-ups for wealthy

WHO Commission on Social Determinants of Health Final Report

Until governments have demonstrated their ability to effectively regulate private investment and provision in health services in ways that enhance health equity, they should avoid making any health services commitments in binding trade treaties that affect their capacities to exercise domestic regulatory control. It is not clear that any government, anywhere in the world, has met this test.

IPRs and health

- TRIPS has raised price of drugs, even in developing countries
- IPRs *may* benefit developing country growth though technology transfer (though directional causality not known) but singularly negative for essential medicines
  - No new drug or health innovation in developing countries
  - Increase in drug costs (India 2005 TRIPS compliance, targeting drugs for developed country markets)
  - Differentiated market pricing has not worked
- EU counterfeit (?) 'anti-counterfeit' policy
- EU TRIPS+ (data exclusivity)
  - Concerns highest with EU FTA with India, the pharmacy of the developing world

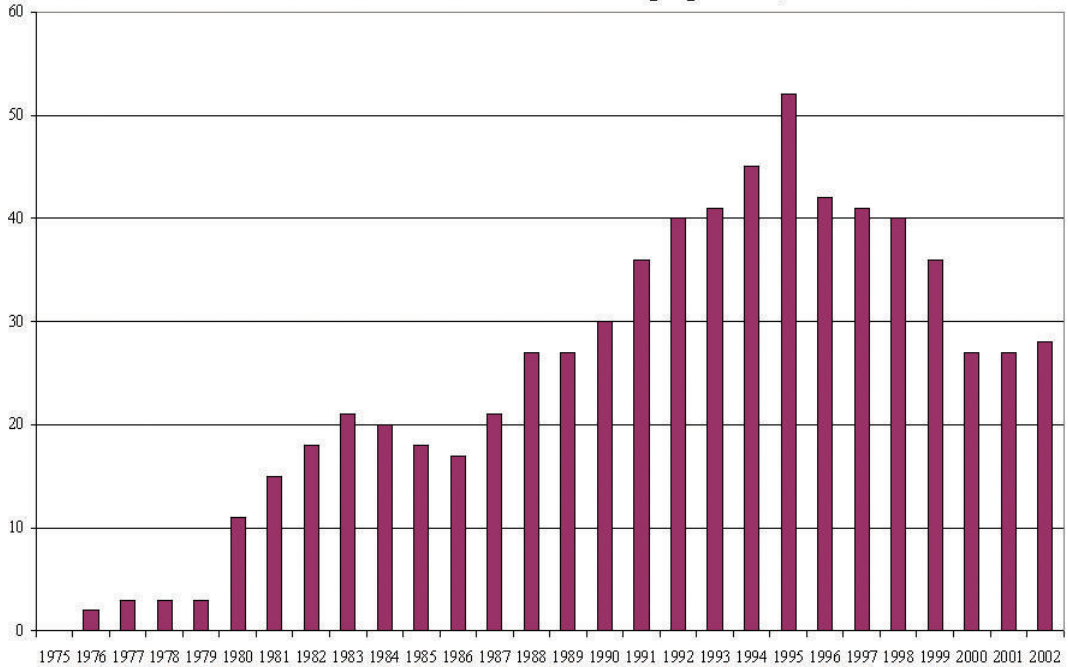
IPRs, EPAs and health

- CARIFORUM EPA
  - Provisions to ensure there is no impediment to access to medicines
- TRIPS+ on digital and internet copyrights (no exceptions for educational use):
  - Decrease educational opportunities, increase educational costs with negative health externalities
  - Add to push factors for skilled workers, notably health workers, migrating to EU, USA and Canada
  - Under EPA 'most favoured nation' provision (not required for WTO compliance) this TRIPS+ provision extends to *all* WTO member states

Government procurement

- Optional under WTO, why in EPAs?
- CARIFORUM EPA promises to offer to EU companies 'national treatment' in bidding on all forms of government contracts, a substantial future growth area for private investors and providers
- All contracts would have to be based on open competition, precluding use of government contracts for local economic development or other health-related (e.g. social inclusion) purposes

Number of financial crises by year, 1971 - 2002



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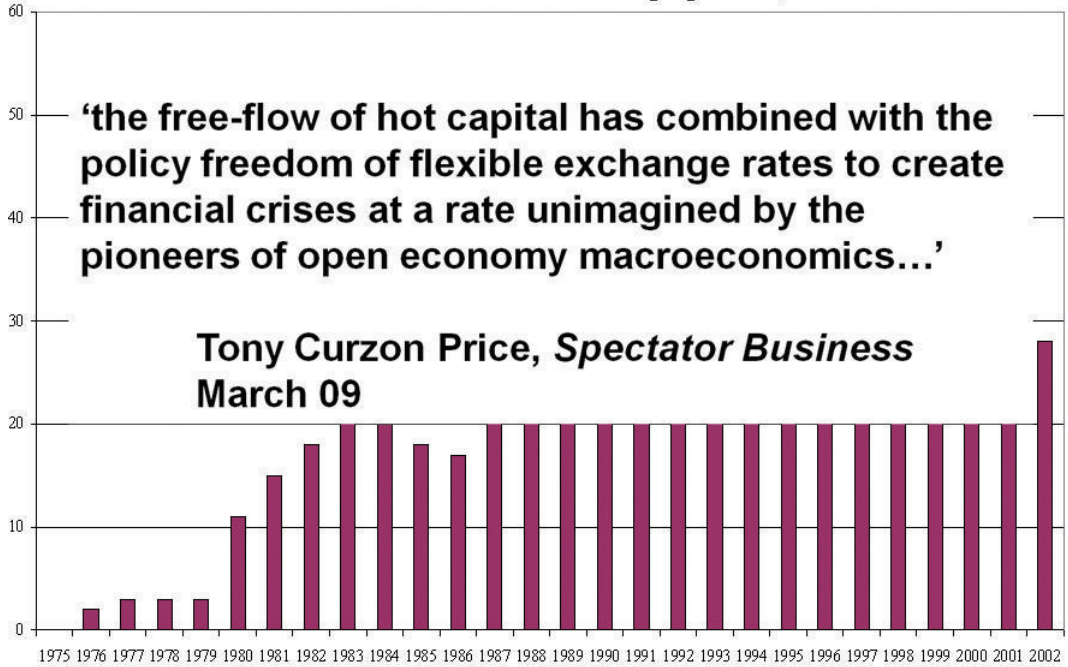


Source: Labonté, R et al. *Globalization and Health: Pathways, Evidence and Policy*. London: Routledge. 2009.

Health Consequences of the Crisis: Low-Income Countries

- Increase in those living below the extreme ($1.25/day) poverty level: 50 – 200 million by 2009/2010
- For 390 million poorest Africans, a 20% drop in income
- Increase in global unemployment: 55 million
- Increase in child mortality: 200,000 to 400,000 excess deaths
- Increase in child labour and in domestic (often women-directed) violence
- Decrease in remittances and in health/social protection spending
- Decrease ($300 billion, or 25%) in financial flows to developing countries

World Bank. The Global Economic Crisis: Assessing Vulnerability with a Poverty Lens, 2009; Marmot M, Bell R. How will the financial crisis affect health? *BMJ* 2009;338:858-60; International Labour Organization. *Global employment trends 2009*. Geneva: ILO, 2009; Overseas Development Institute. *Children in times of economic crisis: Past lessons, future policies*. Background Note. March 2009.

EPA and investment

- CARIFORUM EPA
  - Positive
    - Commitments to labour, environmental and anti-bribery good practices
    - No investor/state provisions
  - Negative
    - Prevents any performance requirements in investment (removes policy lever for local development)
    - Forbids capital controls/repatriation (removes policy lever for effective taxation and avoidance of capital flight)
    - Could still be liable to investor/state suits under 179 ACP BITs and 'forum-shopping'

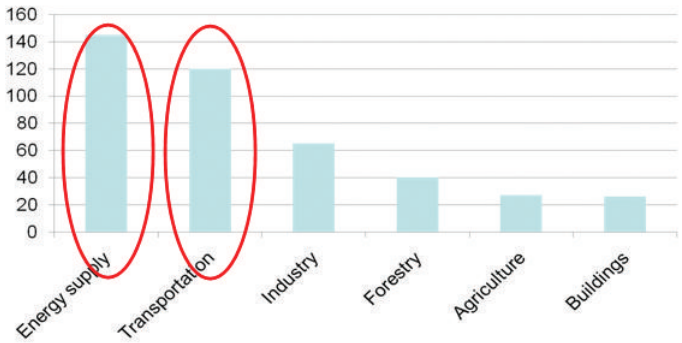
For every $100 in global economic growth, only $1.30 trickles down to the poorest 20%, less than half that trickled down in the 1970s.

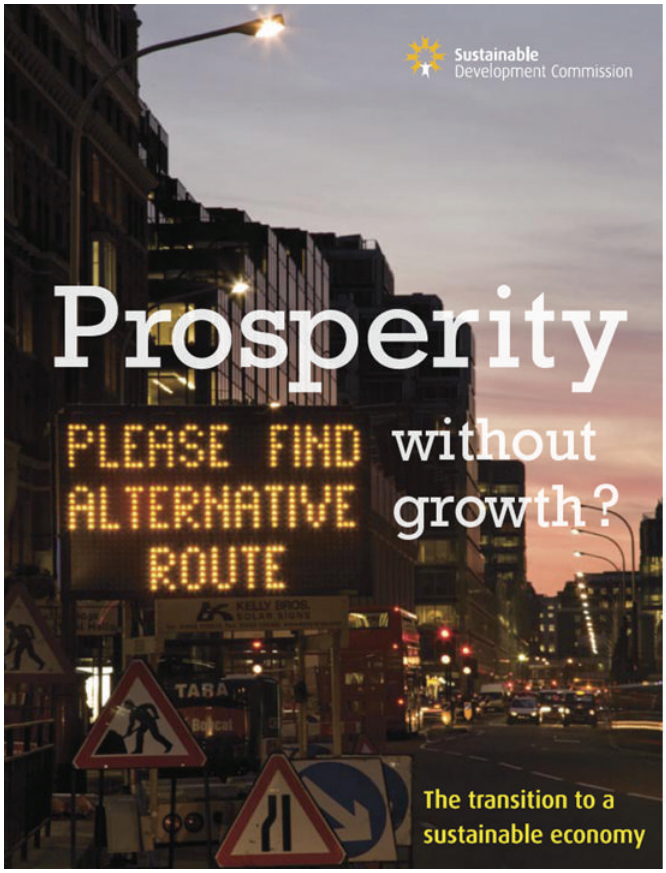
Export led growth (business as usual) requires consumption levels primarily by higher-income groups that are already environmentally unsustainable

Woodward, D. & Simms, A. 2006, *Growth is Failing the Poor: The Unbalanced Distribution of the Benefits and Costs of Global Economic Growth, ST/ESA/2006/DWP/20*, United Nations Department of Economic and Social Affairs, New York, 20.

Growth is Not Working

Percent changes in GHG emissions 1990-2004 by sector





The truth is that there is as yet no credible, socially just, ecologically sustainable scenario of continually growing incomes for a world of nine billion people.

UK Sustainable Development Commission, *Prosperity without Growth?* 2009

What to do?

- Ensure clear linkages *ex ante* between the EU trade agenda and its development agenda
- Ensure *ex ante* broad public and parliamentary engagement in partnering countries on the content of trade negotiations
- Right to health impact assessment of EPAs, adopting models proposed by UN Special Rapporteur on this right and incorporating the right to food, water, housing, education and other obligations binding on governments under International Human Rights covenants
- Right to development impact assessment of EPAs, disaggregating by social groups
- Environmental impact assessment of long-term effects of increased trade flows (fossil fuel use) and energy and resource flows (production) of trade-related economic growth

What to do?

- Compensation for losers within countries (income supports, education, re-skilling or up-skilling, other social protection measures) and to countries for lost tariffs or other trade-related revenues
- Financial support to measures to stabilize small agricultural producers affected by global commodity fluctuations and to countries to move up the 'value-chain'
- Add enforcement language to the hortatory definition of sustainable development over-arching the EPAs; that EU and ACP members would retain 'the right to regulate trade and investment in order to advance human, cultural, economic, social, health and environmental best interests of their respective population and of future generations'
- Ensure a dispute panel process made up of individuals concerned with policy choices that allow states to achieve the goals of sustainable development and human rights obligations

IPRs and Pharmaceutical R&D

The Pharmaceutical R&D process

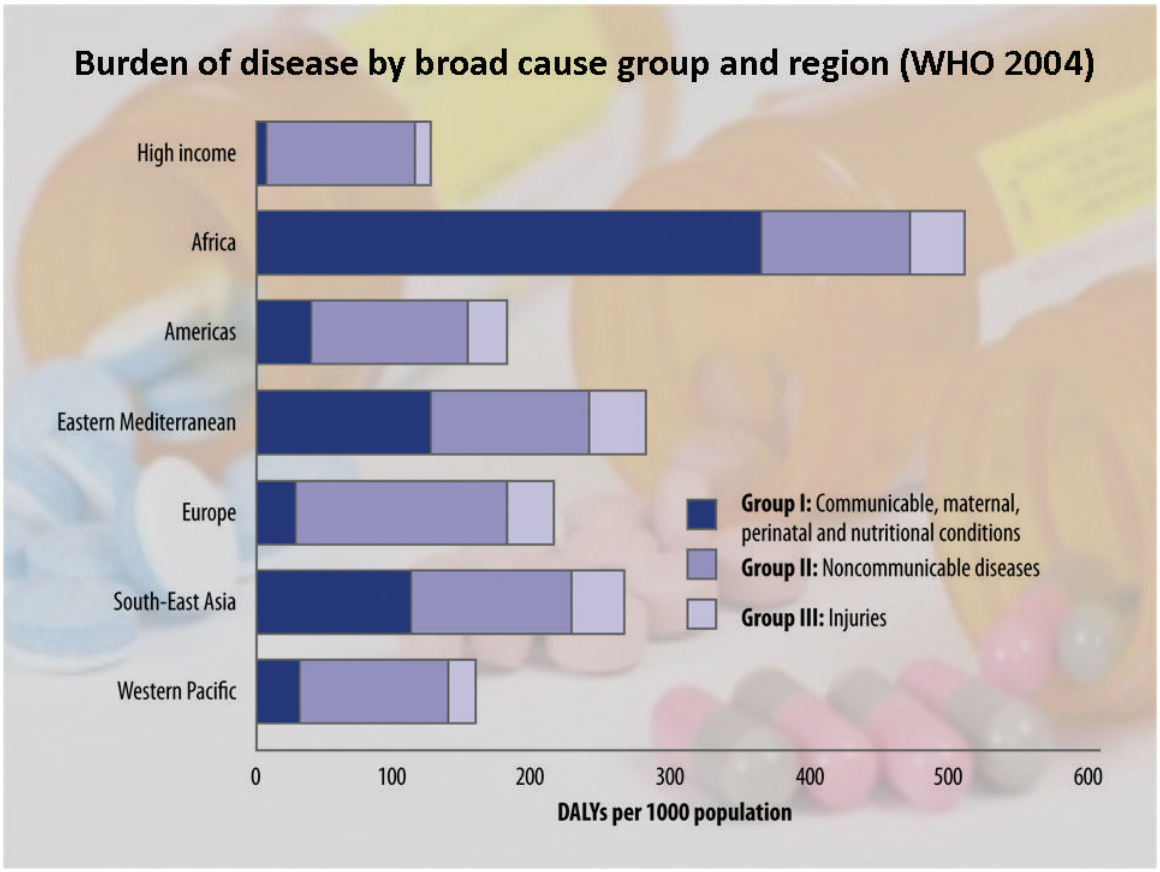
Phase I Drug Discovery	Phase II Pre-clinical testing	Patent Application	Phase III Clinical testing	Phase IV Market approval
Around 10,000 compounds screened	Around 250 compounds tested in-vitro and animals to assess the chemical, biological and toxicological properties of the compound		Around 5 compounds enter clinical trials stage: **S1-**the drug is tested for safety, safe dose range and mechanism of action in 20 to 100 *healthy* volunteers **S2-**the drug is tested on 100 to 500 volunteer *patients* to establish that the drug effectively treats the disease. **S3-**the drug is tested in large trials with 1,000 to 5,000 *patients* in hospitals and clinics to determine effectiveness, to identify long-term effects, toxicity etc.	Only 1 successful drug Market approval from health regulatory bodies
2 years	1-2 years		6-8 years	1-2 years

Top 12 pharma companies

Rank	Company	Total Revenues (US$ m)
1	Johnson & Johnson (US)	63,749
2	Pfizer (US)	48,296
3	GlaxoSmithKline (UK)	44,654
4	Roche (Switzerland)	44,267
5	Sanofi-Aventis (France)	42,179
6	Novartis (Switzerland)	41,459
7	Astra Zeneca (UK)	31,601
8	Abbot Laboratories (US)	29,529
9	Merck (US)	23,850
10	Wyeth (US)	22,833
11	Bristol-Myers Squibb (US)	21,366
12	Eli Lilly (US)	20,378

Some pharmaceutical data

- Global pharmaceutical market estimated around US$ 663 billion in 2007
- 80% of global pharmaceutical sales in the US, Canada and EU in 2007
- According to industry, a new medicines costs around US$ 1 billion and takes around 12 years
- Less innovative: number of NCE per year has fallen from around 93 in 1960s, to 48 in the 1980s and 27 in 2000s
- Only around 5% of pharmaceutical R&D goes towards cures for diseases such as malaria, TB and others confined to patients with no purchasing power
- Cost of medicine around 17% of health care budget in most developed countries but up to 60% in the rest of the world



TRIPs and access to medicines

- TRIPs brought a sea change in IPRs for pharmaceuticals with important implications for access to medicines
  - Pharmaceutical patents (Length /Type)
  - Pharmaceutical data protection
  - Compulsory licensing
- TRIPs not concerned with public health *per se;* recognised in principle (Art 8), but measures cannot be inconsistent with TRIPs provisions
- From 1995 onwards, there have been continuous efforts to narrow down TRIPs flexibilities through:
  - Unilateral pressure
  - Legal interpretation of TRIPs provisions at the multilateral level
  - Technical assistance and design of IP laws at the domestic level
- 2001 Doha Declaration reaffirmed TRIPs flexibilities but the battle continues

The battle continues

- Continuous pressure when flexibilities are used
  - Compulsory licenses in Thailand and Brazil (2006, 2007)
  - Patentability criteria in India; Novartis and Bayer court cases
  - US Special 301 list (from 2000 onwards, half of countries listed due to 'inadequate' IP protection for pharmaceuticals)
  - EU introduced its 'watch list' version in 2006
- The new IPR enforcement Agenda
  - Generics and counterfeits: seizure of drugs in transit in Europe (20 cases during 2008)
  - Anti-Counterfeiting Agreement (ACTA) negotiations

The battle continues

- All US and EU PTAs/FTAs signed up to 2008 contain TRIPs plus obligations
- TRIPs Plus provisions for pharmaceuticals in Preferential/Free Trade Agreements:
  - Pharmaceutical data protection (exclusive right model, 5yrs or more)
  - Patent term extensions
  - Patent linkage (linking marketing approval to patent status)
  - Limiting the grounds for issuing compulsory licenses
  - Parallel importing (system of IP exhaustion)

Current EU negotiations

- Two key documents: 2000 Lisbon Strategy and 2006 'Global Europe':
  - Economic Partnership Agreements with certain African countries
  - FTA with ASEAN (Singapore and Vietnam)
  - FTA with Central American countries
  - FTA with MERCOSUR (stalled)
  - FTA with Canada
  - FTA with India

EU-India negotiations (2007-)

- India seen as the 'pharmacy of the world'; reportedly, around 90% of generic AIDS drugs used in developing countries come from India
- India amended its patent law in 2005 to comply with TRIPs
- Balanced provisions with safeguards against unnecessary patents; patient groups can challenge patents
- Key issues:
  - Patent extension, 5 years (draft Art.9.3)
  - Data protection, EU model 11 years, not accepted by India (draft Art.10)
  - IPRs enforcement provisions (draft Art12-28) beyond TRIPs, applicable to imports, exports and goods in transit
  - TK and genetic resource sharing not included