''Can we afford our medicines?
The access to medicines crunch in Europe"
European Parliament (room A3G-3), 12 November 2014, 12:30-15:00

Welcoming remarks by **Kostas CHRYSOGONOS (GUE/NGL, EL)**

Affordable access to medicines: the situation on the ground

Introduction by **Beatriz BECERRA BASTERRECHEA (ALDE, ES)** *@beatrizbecerrab*

Moderated by David Hammerstein @DaHammerstein, Senior policy advocate, TACD

- ✓ **François Berdougo** @FBerdougo, Secretary General of the Harm Reduction Working Group of Médecins du Monde @MdM_France
- ✓ **Gonzalo Fanjul** @GonzaloFanjul, Policy Director, IS Global Barcelona Institute for Global Health @ISGlobalorg
- ✓ **Rohit Malpani** @MSF_access, Director, Access Campaign, Médecins Sans Frontières (MSF)

Q&A session

What can we do about the high cost of medicines?

Introduction by **Michèle RIVASI (Greens/EFA, FR)** *@MicheleRivasi*

Moderated by Ellen 't Hoen @ellenthoen, Medicines Law & Policy.

- ✓ **Jamie Love** @jamie_love, Director, Knowledge Ecology International (KEI) & U.S. Chair of the Intellectual Property Committee, TACD
- ✓ **Teresa Alves**, International Policy Adviser, La Revue Prescrire,
- ✓ Prof. dr. **Graham Dukes**, University of Oslo

Q&A session

The European Commission was represented by DG SANCO & DG Enterprise

Concluding remarks by **Nessa CHILDERS (S&D, IE)** *@nchildersMEP*

You can see & download speakers' slide presentations at http://tacd-ip.org/archives/1238. The webstream of the whole event is here: http://greenmediabox.eu/en/ct/62-Can-we-afford-our-medicines- & at http://82.197.155.96/gmbox/39/src/20141112_medicines_or.mp4. Join the discussion on twitter using **#a2mEurope**. For any questions, email a2m.Europe@gmail.com. Please see end of this report for additional sources of useful information.

Detailed summary

Kostas Chrysogonos (GUE/NGL, EL) welcomed everyone and explained that this event is necessary because the lack of access to medicines is a reality in many EU Member States today. Health services need to be reformed, he agreed, but not in a violent and irrational way. He continued by giving the example of the Greek situation with a number of citizens' not receiving social security or access to healthcare, although they had paid their contribution to the social system for many years. It is not about excluded people or migrants, but people who used to work and are now unemployed. This is the case for many families in Greece which cannot be provided vaccination or access to treatments. The horizontal ***budget cuts*** excluded a big part of the population from health services, he explained, but this was also the case for other countries. There are cuts in the health service sector, and in the meantime, funds and resources are reduced drastically. Health products are no longer available as public goods but commercial products. Medical innovation is currently based on patent monopolies; a system no longer working. There were dis-functionalities before the crisis, administrative burden and reforms are necessary, he agreed, but the way they are doing them is wrong. This is all about cuts in spending. The reform should be the result of a social dialogue, not imposed by politicians, especially in countries under Troika supervision and not imposed by external actors. The subsidiarity principle should be taken into account. The needs of society and for adequate systems should correspond to modern needs without excluding citizens. He hoped that this meeting would allow for the undertaking of effective action.

Beatriz Becerra Basterrechea (ALDE, ES) began by explaining that she was a new MEP and did not know many things about medicines or research. She was not a doctor or a scientist, but she thought she was good with diagnosis. Health is not a luxury but a basic right, she stated. The question is about how to guarantee that right. ***Public funding*** must serve public interest. The crisis and imposed measures on budgets had dramatic consequences on access to medicines and should be the starting point for the rethinking of new models of public health pricing and medical innovation. It is not acceptable that millions of EU citizens are not receiving the highest quality life-saving medicines because governments cannot pay for the skyrocketing costs for the best treatments. The current model of medical innovation and pricing does not work. It has failed to promote real innovation and has become far too expensive for most of the world including many Member States, mentioning the case of hepatitis C treatments. The ***patent monopolies*** model was supposed to be an incentive for generating innovation but has turned out to be an obstacle. Its objective, of producing affordable useful products needed by societies, has failed. Public investment means 85 per cent of medical research must result in 85 per cent ***public return*** for public health instead of the **privatization of knowledge** by means of patent monopolies, she explained. Health innovation should develop products and services that are affordable and accessible. There is no doubt of the right of companies to have a profit, but life and death is a general interest issue and not just a business. New models are needed to break monopolies and push medicines towards real health needs and not just blockbuster profits.

Panel 1: Affordable access to medicines: the situation on the ground

David Hammerstein, senior policy advocate, TACD, introduced the panel and listed some of the keywords which might underpin this first session. Most notably, he drew attention to ***transparency***, transparency of prices and transparency of clinical trials. How many times do we have to pay is also a question. Are public investment protected to give back ***public return*** in form of public health and access to medicines? Another keyword is ***efficiency***, with the question, are systems efficient, could they be more efficient by sharing knowledge, by sharing results and data? Hammerstein then raised the issue of unethical practices, competition issues touching upon the entry of generic onto the market and the relationship between doctors and pharmaceutical companies.

The monopoly issue is often linked to not fueling innovation but preventing it, he said. Monopoly is not a good word in this house, he added, and they have to be broken up. However, this has not been considered

about the pharmaceutical sector in his opinion. Some people think there is a monopoly position in the production of R&D, with the marketing and selling of the products.

Hammerstein disagreed the EU lacked competence, and suggested it was about EU measures of fiscal austerity, of transparency, IPR policies, EU innovation and research policy and investment, non-discrimination and basic fundamental rights. No studies have been done on the health impact of the Greek budget cut measures, despite massive cuts. No provisions exist of how we are going to pay the price of best treatments for many medicines. There is no sharing of knowledge of Health Technology Assessments, he continued. No price caps are considered as the example of roaming in the EU. Solutions will come from civil society, experts and politicians, he added. Access to medicines and healthcare is the best policy. If it does not work for all, it is not working at all, he concluded.

François Berdougo, Secretary General of the Harm Reduction Working Group of Médecins du Monde began his presentation by giving a few highlights on the work of Médecins du Monde. Médecins du Monde documented the negative consequences of healthcare budget cuts in Greece on healthcare system and universal access to care. This includes an increase in users' charges and the loss of healthcare coverage for approximately three million people. Médecins du Monde action worldwide focuses on programmes for drug users and their low access to life saving drugs. They defend the rights of drug users to access harm reduction services and show how the policies are feasible through programmes in different regions. Moreover, even in high income countries access to HCV treatments for injecting drug users remains low. Berdougo then went on to speak about the high level prices of HCV medicines, focusing on the example of ***Sofosbuvir***. He explained that Sofosbuvir has strong therapeutic value and causes low side effects. However, in order to achieve universal access, affordable drugs are needed. Prices levels accepted in the US or considered in France are unbearable for many healthcare systems in a period of budget cuts. These price levels have consequences on access to drugs, he continued, leading to ***treatment rationing***. He further illustrated his comments by comparing the necessary budget to treat all HCV patients with fibrosis stage F2 and above, being higher than the 2014 annual budget of Paris public hospitals. That situation has led to restricted recommendations of use by the High Authority for Health, because of the financial burden the French State would have to face, Berdougo said. In order to respond to risks of treatment rationing, Médecins du Monde built a coalition made of patient organisations, medical NGOs and found allies in healthcare professionals, economists and researchers. This coalition had been heard by the pricing commission, for the first time. It was the first time ever that civil society has been heard by this official state body. He reiterated that one of the key demands is for the French state to issue a ***compulsory-license for Sofosbuvir***. Today, a debate exists in France on the issue of pricing criteria, new models of pharmaceutical innovation and research funding as a result, he said. He continued by mentioning the lessons learnt from the HIV issue and underlined that when there is competition from ***generics***, prices can be driven down. He also noted the possibilities for governments to use the flexibilities offered by the TRIPS agreement, notably with regard to compulsory licenses or patent opposition**.** ***Compulsory licensing*** has been used by high income countries, he noted. He urged the institutions to push for a compulsory license, and if pricing negotiations between Gilead and the French government were to fail, for the government to use TRIPS flexibilities to achieve public health outcomes. They now promote a change of the legislation related to drug evaluation and pricing. He concluded by explaining that they will continue to promote a debate on medical innovation models driven by health needs and will try to put this issue higher up on the agenda. He stressed that implementing a compulsory license should be an option and not a dream.

Gonzalo Fanjul, Policy Director, IS Global Barcelona Institute for Global Health made a presentation on the impact of austerity policies on health and access to medicines. He began by mentioning a UNICEF campaign launched a couple of weeks ago on the impact of the crisis on children in the period 2008-2012 showing an increase in child poverty and capacity of families to cope with unexpected expenses. Fanjul explained the effect on mental health, nutrition patterns and lifestyle. Austerity seemed to be at the core of the problem, although it was not the only reason. He continued by explaining the two phases of fiscal response to the

crisis. 2007-2009 showed an increase in social spending which reversed for the period 2010-2012 with the introduction of austerity. The impact has been extensive, diverse and likely to have long lasting effect on the right to health of EU citizens, he remarked. Health services were eroded with diverse intensity. It is still too early to speak about the broader consequences due to the lack of data, but Fanjul explained that they can already observe a ***huge increase of mental health disorders***, as well as HIV and malaria outbreaks in Greece while waiting lists are expanding in many countries. There is also an increase in out of pocket expenses and restriction of coverage. Vulnerability appears to be a more difficult indicator to capture, however, indicators of fear of vulnerability have risen by 300 per cent in Spain due to the disappearance or weakening of traditional safety nets. Lessons learnt from the previous crises were of an increase of drug and alcohol abuse problems, psychological problems and long term effects of unhealthy behaviours in unemployed families. Coming back to the Spanish example, he raised the issue of nutrition patterns of children in school and malnutrition which were happening in critical periods of child development. The future impact on health capacity and productivity of the economy were easy to expect, he added. All of these factors raised the questions on how they were dealing with the crisis and the extent of how countries were following austerity policies. He then followed up on possible alternative reactions, comparing Greece and Spain with the Icelandic case. He further mentioned the possibilities raised by the WHO in times of austerity on health priorities and protection and vulnerability of groups, and on the debate with regard to efficiency and equity. Who is to be blamed, Germany, the Troika? Presenting a graph on the drivers of increasing inequality, he noted that the market was one of them, while transfers and taxes had also contributed to inequalities during the crisis.

Hammerstein suggested when people said that banks were too big to fail; he thought instead the emphasis should be that there are people who are too weak to fail.

Rohit Malpani, Director, Access Campaign, Médecins Sans Frontières (MSF) started with a presentation of MSF action worldwide and the access campaign launched in 2009. They observed that medicines are often unaffordable, not suited for conditions on the ground, or do not exist because the innovation system is not working in providing incentives. Lessons from the access campaign are that ***generic competition*** is a successful way to improve access to medicines, having led to a decrease of the cost of HIV medicines for example. Evidences are here showing that only generic competition leads to price reduction. This is also relevant for western countries, he added. The absence of generic competition shows unaffordable prices. The situation with new HIV/AIDS medicines which are under patent and monopolies make treatment unavailable for MSF and similiar organizations. There are therefore concerns about the economic sustainability of treatments, he continued, and not only concerning HIV/AIDS but for hepatitis C and other diseases.

The solution MSF promotes is the need for government to take action through ***TRIPS provisions***. MSF is working in advocating for the use of these flexibilities. But EU countries and pharmaceutical companies are challenging the use of these safeguards and flexibilities in trade agreements. What the EU is pushing for instead is ***tiered pricing*** which, simply put, is offering different prices based on the perceived ability to pay of states. This is not a good strategy, he continued, as it allows charging whatever price companies wish. There are many problems: Industry is allowed to make decision about who pays what price, based on arbitrary criteria, such as GNI, not taking into account internal social differences. There is no sensitivity to economic and social factors and many patients are still left behind. Other concerns touch upon the lack of transparency of the prices paid in different jurisdictions. Therefore, governments cannot negotiate prices in an informed way. There is also no information, no transparency on research and development costs, he explained. Tiered pricing is arbitrary and irrational, he continued, and as well you often see countries paying different prices although ranking with the same GNI per capita.

The challenges today are what can be done to make changes. One way in the EU is the use of ***TRIPS flexibilities and price controls*** or to take other measures to increase transparency. They have to consider more deep changes to the current system not only looking at marginal changes but ***systemic changes***.

Today's innovation is based on ***patent monopolies***. The cost of R&D is not linked to the price of the medicines, he said. Contesting ***the myth of the cost of R&D*** of medicines, he further referred to a statement made by GSK CEO on the cost of medicine development, being more about hundred million dollars than billions. MSF pleaded for developing a system that not only allowed for the development of affordable medicines but medicines that were needed. The ***crisis today is not only of access, he insisted, but of innovation***. This is a challenge for the EU, giving the example of tuberculosis, antibiotics and Ebola. MSF asks for a system not driven by profit but health needs, new ways of creating incentives which delinks R&D costs from the end price. This could be through ***new models of R&D***:

- Innovation prizes
- Patent pooling & equitable licensing
- Open data
- Collaborative data sharing.

MSF has developed a neglected diseases initiative pushing for the development of treatments for these diseases, making sure they are affordable. R&D has a cost, he agreed, and requires investment and risk. But the current system is not working for patients in the EU nor for the ones MSF is treating around the world. They hoped from today's discussion to look at new models going beyond the patent system.

Hammerstein thanked MSF and said they were probably the ones that knew the situation on the ground the best. How can we ensure pharmaceutical R&D and social systems were health driven and not market driven, he asked.

Margrete Auken (Greens/EFA, DK) was shadow rapporteur on the clinical trials regulation and was calling for full ***transparency***, she explained, with regard to the results and data of the trials once the marketing authorisation had been granted. There has been a big battle with the pharmaceutical industry over this. She also criticised the cost arguments. They have to be stronger and get rid of conflicts of interest of those prescribing medicines. Referring to Denmark, she said that the authorities do not call for a ban on conflict of interest but only declarations. They must be clearer that good administration means no conflict of interest.

Hara Georgiadou, Bridging Europe asked whether the 300 billion euros promised by President Juncker gave a place to health.

Marianella Kloka, Advocacy officer, Greek NGO PRAKSIS made a remark on transparency. They were at the beginning of the year invited by the WHO and the Greek ministry of health to contribute to the elaboration of ***health indicators*** to assess the outcomes of austerity measures and policy on health issues. They had no other communication since then even if promised with the results. Nevertheless, they have themselves started to monitor the situation, and have conducted research on beneficiaries of medicines for hepatitis C and vulnerable populations. Results show that visits to the doctor (for hepatitis C positive patients) decreased to 85 per cent from 2009 and onward, access to medicines (not innovative) was reduced to 65 per cent. They are talking about new innovative medicines today and they all want them, but she underscored what was happening with the current medicines.

Nikolas Tsemperlidis, representative from a Greek union of consumers raised the issue that access to medicines was connected to many parameters. This has to be connected to the social security systems, to income, competitiveness and entrepreneurship and people who serve medical societies. The representative then questioned the funding scheme of the ***European Medicines Agency***, where 80 per cent is coming from the pharmaceutical industry while the US FDA model finds only 20 per cent. He pleaded for more in terms of transparency about what expert, what company, what financial interests, who is consulted. Moreover,

approval should not only mention a majority in favour but declare who voted against. Finally, when it comes to temporary approvals, he asked, how are they given, whether there are limits. He concluded that the results of publicly-funded research should be available to the public for the common good.

Panayiotis Kouroumplis (Greek MP, leading opposition centre-left party SYRIZA) said that interests are important and influence decisions. The responsibility of civil society is important. If we decide to give up our rights to other people we will get the consequences. All today's issues have to do with human dignity and access to medicines, he said. Nobody, without exception should depend on money to get access and stay alive. We need to find ways in order to react, and ways to develop another kind of thinking for all the people concerned by the issue, he concluded. He called for governments to consider issuing compulsory licenses.

Dr Eleni Alevritou, President, Greek Consumers Association EKPIZO said that her organisation is not exclusively dealing with medicines. Because of the situation in Greece they have decided to look at this area. She felt rather optimistic because of the presence of experts from different groups of the Parliament. The Parliament can today see excellent examples of the work of NGOs, she added.

Fanjul explained that in Spain as the result of fiscal constraint, they introduced prescription by active ingredients. This has been one of the main drivers of bringing down the pharmaceutical cost of the government back to the 2002 levels. What this means is that they should force the why not principle. In other words, when it comes to the issue of the use of compulsory licenses, governments should have to respond "why not?" at first and not "why?" If there are policy alternatives in these areas, why are they not implemented? That is what civil society should demand from governments.

Berdougo responded on transparency and conflict of interest. MDM made progress in France in highlighting ***conflicts of interests*** between patient groups & pharmaceutical companies, but at the moment they have to progress on transparency of financial relationship between health professionals and the pharmaceutical industry. They have to ***educate a lot of stakeholders about the R&D issue***. A lot of physicians, politicians do not know about alternative models of R&D and research funding. This is important that politicians have these kinds of ideas as 10 per cent of MPs in France are actually health professionals. Nevertheless, they are brainwashed by pharma rhetoric. We have to change that, he concluded.

Malpani said that a lot of research ***is currently funded by public funds***. Why are we not demanding more public investment? EU investment should be with a **strings *attached in transparency, affordability and access***. An important question is about what we are getting in return. A lot of public investment is made by Member States, and one of the most promising vaccines on Ebola was a decade ago handed over to the private sector. A substantial amount of money has been put into accelerating the development of three vaccines. What are we getting for the investment?, he asked. In terms of access on hepatitis C: new medicines can be affordable. The cost of producing them could be less than 200 dollars (as opposed to current 55.000$ price tag) with enough economies of scales in market places. We could be 18 months away from getting low cost hepatitis medicines on the market. "Why not?" he asked.

<u>Panel 2: What can we do about the high cost of medicines?</u>

Ellen't Hoen moderator, Medicines Law and Policy said that she would like this panel to focus on solutions. She then invited Michele Rivasi (Greens/EFA, FR) to give an introduction.

Michele Rivasi (Greens/EFA, FR) explained the reasons why she was interested in the issue. As a biologist, her first approach to medicines issues came with the H1N1 pandemic when she criticised the alarmist decisions made by the WHO, as well as the conflicts of interest within the WHO and Member States pushing for the purchase of vaccines. At the time, there were differences of prices among countries and the result was that there had not been more death in countries having bought and used the vaccines than in others.

She was also shadow rapporteur on the pharmacovigilance proposals, where the role of the EMA was looked at, and today thanks to the work of the European Parliament, experts' declaration of interest has to be given. She further explained that she commissioned a study comparing prices of medicines in the EU, and the first results were that you find huge differences between countries (Italy, UK, France) due to different price strategy.

Rivasi then went on to speak about innovation, mentioning the case of Sofosbuvir and explaining that ***there is not so much innovation coming from big pharmaceutical companies nowadays, but that companies prefer buying innovative SMEs,*** increasing prices as each EU Member States is responsible for the price of medicines. This is very important because today it is about Sofosbuvir but there are also similar problems with breast cancer and hormonal cancer medicines. The problem can be seen in Greece where people cannot afford their medicines anymore. Tools are available, she explained and there must be an alternative to the patent system and exclusivity. She finally recalled that she posed the question in plenary and was answered that prices are a Member State's competence. But each Member State has the possibility to make use of ***compulsory licensing*** and to open the license, asking other laboratories to develop the medicine and reduce its price. She is not against pharmaceutical laboratories, she explained, but there is an issue between public and private research. 1.8 billion euro is given by the EU to the ***Innovative Medicines Initiative (IMI)*** but without ***conditionality***, she said. Public interest should come first, and she pleaded against the renationalisation of health. We have to act together to move forward, she concluded.

Jamie Love, Director, Executive Director, Knowledge Ecology International (KEI) & U.S. Chair of the Intellectual Property Committee, TACD made a presentation on implementing ***delinkage***. He first agreed with previous speakers on the use of compulsory licenses. His presentation first explained the three main sources of funding for biomedical R&D, namely 1) grants from governments and charities; 2) profits from selling products protected by legal monopolies, the patent system is the most famous among them and 3) the drug tax credit offered by the US for the execution of clinical trials. Love continued by presenting figures (please consult respective slides) on the R&D investment from the private sector in comparison to global sales between 2004 and 2010, and illustrated his point with the case of cancer treatment R&D spending in Europe in 2009. After showing a graph on the relative spending on drugs and relative mortality rates for all cancers, showing a differential access and outcomes between countries with higher and lower income, he came with the idea of eliminating monopolies on cancer drugs and fund R&D with a combination of grants and three types of innovation prizes: ***End product prizes; Open source dividend; Milestone prizes***. Furthermore, he developed on the EU example of an EU wide Cancer innovation fund and a plurilateral cancer innovation fund. He concluded on the role of Europe as supplier of innovation under the delinkage model, explaining that a greater reliance upon grants would first enhance the role of universities and SMEs in supplying innovation. Second the de-emphasis of marketing monopoly would create more competitive opportunities for SMEs in manufacturing and distributing. Last, new inventions can be patented, and patents can be fully exploited in foreign countries.

Teresa Alves, International Policy Adviser, La Revue Prescrire gave a presentation on "Stopping the spiral of exorbitant prices". She began by introducing the publication Prescrire produced by medical professionals and financed from subscription only. They are a member of the international society of drugs bulletins and conduct drug reviews, looking at products and attributing ratings. More specifically, they assess, whether innovative medicines bring an advantage, harms reactions, efficacy and convenience for patients. They also make comparisons with existing products. Alves then went on to speak about results obtained between 2000 and 2013 to illustrate the ***crisis of innovation***. The majority of new medicines add nothing new, are not responding to medical needs, according to their research. 14 per cent of them are even worse in safety and efficacy, bringing no advantage/benefit. She noted that over the past 13 years, 65% of all new medicines have had no real added therapeutic value. Less than 20 per cent of new medicines have some possible therapeutic added-value. These results are consistent with those of many other institutions and research centres.

Alves then argued that clinical research mainly funded by companies does not enough focus on unmet needs; aims to obtain a ***marketing authorisation without the need to prove therapeutic advance***; and clinical trials tend to be used as marketing tools. At the same time, marketing approvals are given faster and faster; often based on weak evidence, with often insufficient post marketing risk minimisation measures and dangerous drugs being approved and subsequently withdrawn. She expressed serious concerns over the EMA's adaptive licensing project which in her opinion can have dangerous implications for patients.

With regard to high medicine prices she explained that prices are often ***negotiated in opacity*** and not frequently based on real cost of production which remains unknown. There is also a disconnection between the drug price and its therapeutic value. She further explained that influential oncologists have described current prices of cancer medicine as "astronomical, unsustainable and even immoral". These prices therefore put universal access and health protection systems at risk. Furthermore, money spent for expensive drugs with little added-value is money wasted for what is really needed by society.

Teresa Alves then illustrated her presentation with the case of Sofosbuvir treatment against hepatitis C. While Prescrire recognises that the new medicine offers an advantage, she noted the essential contribution of ***publicly funded research*** for its development. Furthermore, she compared estimated production cost of 100 USD per patient to the ***84.000 USD cost per patient per treatment***. She said that the clinical trials were just enough to obtain the marketing authorisation and that there is little data about long term adverse drug reactions and drug interactions. The company justifications for this high price are about expected savings in medication use, transplants and hospitalisation, she explained. However, Alves highlighted that this ***forecast has been contested*** and that these savings would be obtained in 20 years if severely-ill patients were to be treated. She further noted that Sofosbuvir is under a ***voluntary licence*** in 91 countries but stated that this might simply be a window-dressing exercise since numerous other countries are excluded. Finally, Alves explained the high price Gilead paid to buy Pharmasset, the developer of the drug, in 2011 for 11bn dollars, and the need to recoup investment. She emphasized that Gilead paid 139$ per stock in 2011 for Pharmasset, while Pharmasset's value in 2005 was only 5$ per stock.

Alves presentation concluded with suggestions about what is needed. First is to rethink the R&D system, with ***more research into unmet medical needs, more comparative clinical trials to demonstrate therapeutic advance compared to existing medicines, more publicly funded research and to set prices that reward real innovation***. This would also mean to refuse exorbitant prices, use flexibilities such as compulsory licences, and demand ***evidence of therapeutic advance as criteria in marketing authorization***. Finally, that would also mean opening the "black box", with ***transparency and access to clinical, regulatory and pricing data, allow independent analysis and information sharing, encourage public scrutiny and identify real innovation***.

Prof. dr. Graham Dukes, University of Oslo said that there is waste of money that could be used for good purposes. High medicine prices are demanded and accepted because of the widely propagated belief that the industry is committed to high research costs and that research record is proven successful. However, when in the US, the Security and Exchange Commission examined drug companies data, it found out that on average, only some 13 per cent of company revenues were spent on research while 48 per cent went on administration, marketing and profits. He continued by giving the example of an American firm that argued before a Dutch court that the cost of cancer drugs reflected research expenditure, while it actually happened that the costs had been supported by US public funds. The Dutch court accepted the claim that it would be seriously disadvantageous if a generic company was allowed to produce the same drug at a lower price. The legend that drugs cost a lot to develop is, amongst others, propagated by the ***Tufts Center for the Study of Drug Development*** which has the purpose of providing the drug industry with arguments to justify prices when dealing with the authorities. It has produced highly biased reports over the years. In his view, this Centre should have been closed down ages ago by an honest industry. The best and most sensible and successful critical approach of pricing is the one existing in Australia, Prof. Dukes continued. Producers were

obliged to price the products at the same level of that of existing generic or other drugs long on the market, unless be proven that the products was better, safer or had other advantages. It brought down and kept low prices, but had to be abandoned following elections when an industry-sympathetic lobby acquired power. Using American data in matters of drug pricing and costs can be useful but it would be better to have EU data, he explained. We could, in a number of countries, secure reliable data of the cost to develop drugs and how companies are spending their money. More transparency is needed on the way money is used and how it could be improved. Prof. Dukes then underlined the possible merits of pooled procurement, a system that could have two or three countries working together.

Prof. Dukes then raised the issue of ***uncritical prescribing***, with some doctors over-prescribing due to the pressure of commercials or patients, who believe that they have to come back from the doctor with a prescription. The commercial person is of no need, a financial burden on the community, he said. The result of its work is in over prescribing and waste. There is a solution tried on small scales, the employment of persons sent out by authorities or impartial bodies. They are credible and successful. Commercial detailing would be prohibited and then taken over by employing people providing unbiased, reliable information. Doctors do need information like this. At least, this could provide a mean of keeping the doctors properly informed. The approach is popular among doctors and highly appreciated. As for the patients' pressure, there is no quick solution but it is a matter of education. But this belief needs to be progressively eradicated.

Ellen 't Hoen asked about better transparency of pricing in the EU and the role of the European Commission. Considering the suggestion made this afternoon regarding new models for R&D, would it be possible with the resources of the Commission spent on the pharmaceutical industry to pilot these new models and try them?, she asked. Moreover, she asked what role the Commission can play in ensuring transparency in drug pricing.

Thomas Heynisch Deputy Head of Unit, Food and Healthcare Industries, Biotechnology, DG ENTR said that on drug pricing, article 168 of the Treaty gave clear responsibility to Member States when it comes to management of health care. This is the basic line. Recalling the question on transparency, he explained that the remit of the Commission services was limited. There is only one available instrument and that is the ***Transparency Directive***. The Commission appreciated the support from the Parliament when trying to amend the Directive, however it is currently stuck in the Council. ***Generics*** can play a major role in reducing cost, everybody agrees, and the Commission called for speedy pricing and reimbursement decision for generics, but with no endorsement from Member States so far. Everybody agrees too that the linkage between intellectual property and pricing and reimbursement decisions are not conducive to ***early access***. This was also in the Transparency Directive. Heynisch continued on the issue of ***biosimilars***, which can play a major role in driving down treatment costs. The Commission is trying to promote the acceptance of biosimilars as a way to have high quality medicines available in Member States while respecting Member States role and the roles of the value chain including prescribers. He noted that the last presentation referred to the question whether prescribers are informed about the properties of biosimilars. With regard to ***orphan drugs*** that tend to be costly, the role of Member States is again clear. DG ENTR launched a working group to promote cooperation among Member States, but noted that Member States are equally defending their turfs. One of the concrete outcomes was that the Commission managed to convince several member states to engage in further activity. It fosters the cooperation among member states.

On non-availability of medicinal products in Member States, this requires a detailed analysis. They had a working group and after having conducted a survey with competent authorities, it appears that is not the costly products that seem to be in needs, the problem coming from the availability of low cost products.

On ***adaptive licencing***, there are concerns, but the phenomenon to push for ***off-label use*** comes because of cost containment. Adaptive licensing if done properly requires the involvement of the authorities. On the

Innovative Medicines Initiative, he explained that the funds are not available to big pharmaceutical companies but SMEs and academia. He stressed that public money is not going to big pharma.

He agreed that they should have a closer look at alternative models and they want to have a comprehensive approach. He encouraged interested parties to ask the Commission to have a closer look at these models. Recently, they asked participants in the Rome meeting to come with concrete priority topics-deadline is the end of this month. The Commission is open to suggestion on areas where the Commission should be more active.

Nessa Childers (S&D, IE) summed up the meeting as she had to join the plenary session. She began by saying that the situation in Ireland wasn't fine, especially in the case of health services. Access to healthcare and pharmaceuticals was not good in the first place even before the crisis she explained. There are long waiting lists in public health services for diagnoses. ***Access to healthcare is a public good, she stated, this is also a human right***. On the Member State competence claim, she responded that in a country like Greece, it is no question that this is a breach of rights set in the Treaty. Breach of human rights is not a competence of Member States, it has to do with the whole of Europe. Mr Berdougo explained that the wide coalition built achieved results. She then explained that one thing worked in politics, it is fear of politicians that they would lose their seat. Civil society also has to expose the power of lobbyists. She called for a wide coalition in the health area, so that governments would begin to reinvest money, which had been taken out of the system. She concluded by ***insisting on the question of human rights and the breach of the Charter of Fundamental Rights in Greece when it came to access to public health services***.

Dirk Van Den Steen, Team leader Healthcare systems unit, DG SANCO explained that the Commission did understand that there is a problem, this is why the Commission put out a Communication on Health Systems where medicines are singled out as a specific area where there are concerns. This is Member States' territory so the Commission could support Member States that proposed initiatives such as the one from France. He further indicated that the Commission supported the work of the Council reflection process on responsible health system and that the health programme included an action on reference pricing. This is one way of helping the debate. They had similar initiatives in the new health programme looking at pricing models. The Commission looked forward to the outcome of the discussion in the working party on pharmaceuticals and medical devices on innovation for the benefit of patients that should see ***council conclusions in December 2014***.

Merel Philippart, Universities Allied for Essential Medicines (UAEM) asked why society is dependent on pharma companies, while most innovative medicines are a result of ***publicly funded research***. She said that society pays twice both for the research but also for the high prices. Why can't states ***fund their own production***? she asked.

David Preece, European Association of Hospital Pharmacists (EAHP) said that the problem of ***shortages*** was affecting access in hospitals for new innovative as well as generic medicines covering a wide area. They would issue a report in the coming week.
A representative from the **European Haemophilia Consortium** asked the European Commission representatives whether the legal instrument of ***joint procurement*** had already been used and were there plans to use it for hepatitis C treatment or other diseases.

Evangelia Kikeleki, member of the EESC also member of a consumer organisation spoke on behalf of the consumers against the transfer of responsibilities for medical devices from DG SANCO to DG ENTR. Juncker said that health was not for sale and could not belong to DG ENTR. She also asked about the risks brought about by the current discussion on TTIP.
A representative of the European association of pharmacists commented on the absence of debate on the impact of TTIP on access to medicines.

A representative from the European Platform for Patients' Organisations, Science & Industry asked the question whether there are enough patients involved. He said he had not heard anything on bringing orphan drugs to the patients as well as on the EU/US agreement (TTIP).

Prof. Dukes replied on own R&D that it has been done to a small extent, mentioning centres in San Francisco and Strasbourg working on drugs set aside by big companies. These groups are promising. Other proposals have been made to establish further groups, he indicated. It can be done but so far only on small scale.

Alves on TTIP referred to a paper published by a coalition of NGOs. There are a lot of strings attached, putting access to medicines and health at risk. She agreed that TTIP is a clear and present danger.

Love thought that TTIP was a threat to health in Europe. What is needed is to demand for negotiations not to be secret while it was not for a lot of lobbyists in the US. On patient groups, he explained that in the US, the typical situation was that ***patient groups were focusing on reimbursement policies and to make sure people were covered, but not challenging prices directly***. He also mentioned that in many cases patient groups are heavily influenced by big pharmaceuticals. He criticized the Commission for not stepping up the fight against the high prices of innovative drugs. The EU has an interest to protect itself from high prices of cancer drugs, he added.

Heynisch assured everyone that the European Commission never had the intention to jeopardise access to medicines in Europe. Certain requests with regard to including pricing and reimbursement issues in the TTIP negotiations are not endorsed by the Commission as they had to have a closer look at the different healthcare systems on both sides of the Atlantic. The incompatible approach to coverage and financing does not make a convincing argument in engaging in discussions on this within TTIP because it might end up with a one-way street.

Additional sources of information:

- ✓ **TACD resolution on access to medicines (A2M), November 2014**
  http://tacd.org/new-resolution-on-access-to-medicines/

- ✓ **TACD, HAI Policy Paper "Time for the EU to lead on innovation: EU policy opportunities in biomedical innovation and the promotion of public knowledge goods"**
  http://haieurope.org/wp-content/uploads/2012/04/HAI-Europe_TACD-EU-Innovation-Paper.pdf

- ✓ **Update: TTIP Civil society response paper to Big Pharma wish list**
  http://commonsnetwork.eu/new-coat-ttip-civil-society-response-paper-to-big-pharma-wish-list/

- ✓ **HAI Europe Recommendations: Keys to improving access to, and the rational use and good governance of, medicines in Europe**
  http://haieurope.org/wp-content/uploads/2014/10/HAI-Europe-recommendations-to-improve-A2M.pdf

- ✓ **Trading Away Access to Medicines (Revisited) – New report from HAI Europe and Oxfam**
  http://haieurope.org/wp-content/uploads/2014/09/Trading-Away-Access-to-Medicines-Revisited.pdf

- ✓ **Europe for access to medicines & public health care-10 commitments for the new European Parliament, November 2014**
  http://saludporderecho.org/wp-content/uploads/2014/11/DECALOG-eng.pdf