

Open Medical Science For Better Health-Care For All Making FP9 Work For The Public Interest Meeting Report

November 29th 16:00 – 18:30 – European Parliament in Brussels
Room: Paul-Henri Spaak P1C051
Commons Network and Universities Allied for Essential Medicines (UAEM)

Supported by MEPs: Lola Sánchez Caldentey, Guillaume Balas, Margrete Auken, Michèle Rivasi

Agenda

1. Introductions: tour de table: In maximum two sentences tell us what needs to be done to improve evidence based medicine for public health needs?
2. What measures can be taken at different levels (EU, national, local, universities) to reduce industrial conflicts of interest?
3. How can open science be successful, fair to all (including young researchers) and transformative?
4. What changes need to take place in systematic reviews of medical treatments to assure better information for patients, doctors and health-care managers?
5. What changes do we need in our biomedical innovation model to assure affordability, universal access and efficacy? What are alternatives to our present model based on patent monopolies?
6. What are the next steps?
7. Conclusions

Participants

NAME	ORGANISATION	POSITION
Margrete Auken	European Parliament	MEP
Dick Bijl	International Society of Drug Bulletins	President
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Peter Grabitz	UAEM	Student Leader Berlin
David Hammerstein	Commons Network	Director
David Healy	Bangor University	Professor
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Anna Peiris	UAEM	Student Leader London
Nicole Skoetz	Cochrane Cancer	Senior Editor

Improving medicine for public health needs – overview of "what needs to be done"

- Greater challenge of non-factual information that is put out through official channels, using *valuable data*
- *Effective science*, correct *dissemination of information* and correct *assessment of public decision*
- Need for *independent committees* instead of having the same people doing policy and making decisions if the research is good enough
- *Everything about clinical trials should be as blinded as possible* (data, what when wrong, why people dropped out) to avoid bias
- Need *personal and sustainable medicines* instead of Evidence Based Medicine (EBM) – *EBM is anti medical*
- To have *patient relevant questions, and patient relevant outcomes*. And investigative trials not funded by pharmaceutical industry
- Place the *interest of the patient in first place* - clinical trial *outcomes measures* in place of statistical measures
- *Empower the citizens/patients with databases*; subject-driven data and medical data; integrated validate for studying cause and effects
- *De-link the finance of research from finances progressively*, Open science and cooperation
- Focus on *transparency* would resolve other issues, such as COI, etc.
- Move from transparency and *focus on COI*, and also what are we doing with this conflicts - *ban those involved in COI*
- COI declaration for decision makers is *not enough, industry must not be there*
- *Establish and publish the unacceptable list of biases, protect whistleblowers, fund drug safety research* (with open democratic force), split the function of authorisation of putting drugs on the market

Conflicts of interest (COI), oversaturation of data and guidelines

The discussion focused on various forms in which COI may appear. It is therefore important to diagnose firstly financial but also other conflicts of interest. It was pointed out that the whole major problem is to merely focus on financial COI while missing the big picture. Some worse research occurs where there is not a financial COI, but another COI - organisations that push soft power (i.e. influenza). Nonetheless, there is a difference between financial COI and other biases, as the financial COI is so great. It is something that can be controlled through public regulation.

Problem that arises is how can we be sure that everything that the public has done is good and independent? We need to bear in mind that public is also politically influenced. When data comes from industry it should subject to further scrutiny, and go under audit.

However, there are different examples, i.e. Sleeping Sickness, supported by industry and the protection of the public interest was not in private hands. We have to be as rigorous ourselves, that we should expect that from others.

There are also many other ways of COI, and other business influences. Today the academic scientific publishing journal COI does not affect transparency - such as the U.S. where the Sunshine Act has not have a huge impact.

The second issue is oversaturation of the data which leads to less effective decisions in practice. This has somewhat become the issue of Cochrane centre and other publishers where quantity has, unfortunately, become dominant - more you publish and more you make. This leads to focusing on gaining high income to have very good editing, and to coordinate the peer review.

The third issue is problematic guidelines for practitioners. Most doctors will be fired if they do not follow these guidelines that are based on, often problematic, systematic reviews. Practice is also dictated by how the local structure is set up and not fully in the hands of practitioners. There is no current alternative apart from taking personal risk of not following these guidelines which is extremely difficult and not a systemic approach.

New approaches in policy

The discussion moved from particular problems to a wider alternative setting in medical policy.

The inputs focused on the question whether to have the idea of having a completely different system (with no monopolies or patents), instead of reforming it. What would a completely different system look like (in concrete terms) and how long do we (including patients) want to wait? What steps can we do to increase access to medicines in the short-medium term? We need some incremental steps that could be a basis to start moving towards complete alternative models. Suggestions included creating PP Report, diagnosis and remedies - immediate policy actions mainly focused on pricings, which is an obvious big problem.

One of the attempts of a completely new R&D comes from DNDi:

- a. First step: Provide short term solutions (attacking price, and creating new formulations)
- b. Medium-Long: Disrupting the system, and have evidence that the way the system has ben disrupted is working
- c. We are looking to the wrong cultural institutions that benefit from the R&D System, but we are not looking the low and middle-income countries as agents to test new models. Instead looking at the as recipients. It is unlikely that those who profit from the system will be the ones who provide the radical change.
- d. So look to other actors who are interested in developing their own R&D. There are countries that are writing the policies now, as to how their systems are designed – i.e. Egypt

This referred to a debate at recent WTO with Egypt, China, Indonesia, etc., about use of anti-competition laws. These countries were more in favor of modifying legislation. There are elements of the necessary changes, and

different schemes, which can define the model and the next steps. We have to look with other allies, not just within the EU but also with the ones that are able to advance quicker.

Disagreement was pointed out here, as access to medicines is valuable for developing countries, but not the West where we need to think about *Polypharmacy* because very few people are dying from being on too many medicines, not from being on too little. Therefore, we should get rid of control trials as a gateway for getting industry on the market. Also, patents aren't the issue - they do not determine the price (i.e. Valium) - it is marketing that drives the power.

Managing patents

Strong patents and data exclusivity were identified as large obstacles to a fair system. This links to the profits of pharmaceutical companies based on patents where their financial benefits were doubled. Next to this, it was pointed out that more money goes to marketing than to research. As industry has a lot of power, at the same time when we are having this meeting, they are having a number of meetings with MEPs and other policy makers. It was concluded that although getting rid of patents won't change things overnight, the way they are used needs to be changed.

What are the next steps? Do we need any extra coordination on a European level?

One of the proposals was starting centers for Evidence Based Medicines as a response to the crisis in the Cochrane center. I.e. first centre in the world in Oxford (Karl Henegan) and another one in Germany, which would open up a space for criticising Cochrane center.

Disagreement about EBM points out that EBM is concentrated on short-term and adverse effects. And for solutions, we need to think about the long-term effects, decades afterwards and not the short-term effects of medicines and vaccines.

Finally, it was highlighted that there is ample change to work on EBM, and it is becoming easier to read it than the systematic review. After this has been done a couple of times, it will show the need for a network that is not just people doing, but also people who could get funding.

Another suggestion was to find a way that could create an alternative network. I.e. an alternative to publishing.

Final points were that effectiveness is crucial; we need to do something more efficiently and built on the successes we have. There has been landmark decision by Federal court of Canada to grant access to regulators, not just one of two trials, but all of the data. So we are moving forward. We are at a crisis point, challenge is that we have provided the right technical solutions and need to stop turning to technical answers and get into democratic answers.