How long is the Arm of “Big Pharma”?
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This event at the European Parliament involved the European Medicines Agency (EMA) and was co-hosted by WEMOS (an independent civil society organization based in the Netherlands, whose aim is to improve public health worldwide). The afternoon consisted of two panels, the first was composed of: Noel Wathion (Deputy Executive Director of the European Medicines Agency), Martin Seychell (Directorate-General for Health and Food Safety [European Commission]), and Fergal O’ Regan (Head of Inquiries and Coordination Unit of the European Ombudsman).

On the second panel were: Yannis Nastis (Policy Manager for Universal Access & Affordable Medicines of the European Public Health Alliance), Dick Bijl (President of the International Society of Drug Bulletins (ISDB)(representative of WEMOS)), and Silvio Garattini (Director of the Mario Negri Institute for Pharmacological Research). The keynote speech was offered by MEP Bart Staes (Rapporteur Discharge Agencies), and the event was hosted by MEP Dennis de Jong.

One intent behind this event was to discuss and understand how the European Medicines Agency (EMA) tackles the idea of transparency, and how the EMA is addressing and minimizing ‘conflicts of interest’. An additional focus was on a discussion of EMA’s openness/willingness to work toward greater attention, time, and allocation of resources to the idea of ‘added therapeutic value.’ This added therapeutic value could be applied to new medicines and independent clinical research as a precursor to decisions made on marketing authorization and acceptance of new pharmaceuticals; added therapeutic value could also aid in assessing, monitoring, enforcing safety, standardization, and accountability for those pharmaceuticals that are already approved and on the market.
**Dennis de Jong**, (MEP; host), reminded the attendees/audience/listeners that it is almost impossible to escape any conflict of interest/have 0% conflict; he stated that such conflicts are present in all industries and are not just limited to Pharma. He stated, for example, that there is inherent conflict within the agriculture, tobacco, and food industries, amongst others. Mr. de Jong therefore highlighted that the best bet is to do what it is possible to minimize conflicts of interest, and to continually evaluate and improve areas where conflicts may be more significant and/or potentially more problematic and prone to effecting outcome, patient-rights, and heath and treatment options, etc.

**Noel Wathion**, (Deputy Executive Director of the European Medicines Agency), discussed this notion of ‘conflict of interest’ further. He stated that while intimate contact between the EMA and pharmaceutical companies are necessary in order for the EMA to work efficiently and carry out its purpose as a functioning body, there are procedures in place that ensure that single-entities or parties cannot directly influence decision-making within the EMA. More concisely, he stated that there is collegial decision making whereby “no one person can influence an entire scheme.” For example, there are peer-reviewed procedures and rules of engagement that the pharmaceutical industries must abide by, and there is a transparency of assessment reports and meeting agendas, etc.

**Martin Seychell**, (Directorate-General for Health and Food Safety [European Commission]), also stated that it is important to continually work towards increasing and maintaining a high level of transparency of interaction with the Pharma industry, and to uphold and strive towards an equally high level of integrity and ethics in conditions and interactions with the pharmaceutical companies and the Pharma representatives.

**Fergal O’ Regan**, (Head of Inquiries and Coordination Unit of the European Ombudsman), built upon this theme of transparency, highlighting that it is necessary to have transparency because it helps to “build trust.” Interestingly, he also said that transparency is not necessarily as important as being ‘perceived’ as transparent. Mr. O’Regan also spoke about necessity of the perception of the “independence of [the European] Medicines Agency.”

Prior to the second panel of speakers taking the floor, commentary was accepted from the audience. Questions were posed, some seemingly rhetorical, such as
why many of the positions and people appointed to the EMA’s “expert panels” are continually and directly from the pharmaceutical industry. Members of the audience wanted to know how and if this improves or hurts trust and credibility of the EMA? (The audience members were quite a diverse group, and included patient advocates, health interest groups, pharmaceutical associations, and journalists.)

To begin the second panel, **Yannis Nastis**, (Policy Manager for Universal Access & Affordable Medicines of the European Public Health Alliance), first started by saying that while he believes that the EMA is the “success of the EU,” he also finds it important to understand and review the idea of the ‘regulator.’ He stressed that because the EMA has extensive economic and policy reach—and therefore potential ramifications in its actions—it is important for them to not only think proactively but make recommendations that are in line with such responsibility. Furthermore, he noted that he believes the ‘adaptive pathways’ is one area where the EMA has stumbled. One question that Mr. Nastis raised that was interesting and could be given further attention in the future was: “Who is the ‘client’ of the EMA?...Who does the EMA ‘work for’?”

**Dick Bijl**, (President of the International Society of Drug Bulletins/ ISDB, representative of WEMOS), raised the extremely significant issue that new drugs entering the market have not necessarily proven to have any additional therapeutic value that would set them apart from the drugs that already exist on the market. **This concept of “additional therapeutic value” is an extremely important** one because the EMA is introducing new drugs/pharmaceuticals to an already-saturated market (as is the case with the high amount of antidepressants or contraceptives on the market)—and no added benefits of these ‘new drugs’ may be brought to the table. This not only floods the market unnecessarily, but also further exacerbates the gap between diseases that have little-to-no pharmaceuticals available for them and conditions, ailments, diseases for which there are already a superfluous amount of pharmaceuticals devoted.

**Silvio Garattini**, (Director of the Mario Negri Institute for Pharmacological Research), added to and agreed with the comments of Mr. Bijl. Mr. Garattini, like many others, spoke about the presence of representatives of Pharma companies within the EMA expert panels, etc. He also spoke about the increased
dependence upon pharmaceutical money by the EMA, which in-and-of itself is a conflict of interest and can have sway over decision-making in ‘accelerated approval’ for drugs that have not yet reached the Phase III clinical trial stage. Mr. Garattini also strongly advocated for the need to improve legislature; he stressed that there should be the category of 'added therapeutic value’ added to and included within new legislature.

As mentioned earlier, the general themes of the event covered the topics of increased transparency, minimizing conflicts of interest, and additional therapeutic value. To conclude this report by elaborating on the theme of additional therapeutic value: One very significant point that was raised by Mr. Bijl was that: **new drugs entering the market have only to show that they are not worse than what is already existing.** Thus, an important suggestion was made — and reinforced by some other panelists such as Mr. Garattini as well as many members of the audience— to engage in “**comparative trials**” not just placebo trials. Comparative trials measure and pit drugs against one another rather than measure drugs against a placebo. An increase in the use and implementation of such comparative trials could be vital, and results could most likely increase the safety and effectiveness of pharmaceuticals across the board— something that would therefore operate in the greatest interest of the public and within the Public Health sphere.