Peter Liese (EPP) **Cristian Silviu Buşoi (ALDE)** **Margrete Auken (Greens/EFA)**

TRANSPARENCY IN MEDICAL RESEARCH TO PROTECT PUBLIC HEALTH: Opening up EU clinical trial data for safe and effective medicines

"*Doctors can have no idea about the true effects of the treatments they give. Does this drug really work, or have I been deprived of half to the data? No one can tell. Is this expensive drug really worth the money, or has the data simply been massaged? No one can tell. Will the drug kill patients? Is there evidence that it is dangerous? No one can tell. This is a bizarre situation to arise in medicine, a discipline in which everything is supposed to be based on evidence*".
Dr. Ben Goldacre in The Guardian, 25-9-2012

The European Parliament is presently considering the Clinical Trials Regulation (http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm#rlctd). This proposal is an opportunity to reinforce high ethical standards, comprehensive safety reporting systems and to promote open access to clinical studies reports and data – all of which can safeguard public health. Opening up access to medical research data is one way to promote ethical and efficient new medicines in the EU.

At this event, academic, experts, policy makers, EU regulators and the European Commission will give their opinions on this subject which directly affects the health of all of us.

Date: Tuesday, November the 13th
Time: 12h30 - 14h00
Room: Members' Salon private dining- room, European Parliament, Brussels

#PharmaData

Organized with support from

Trans Atlantic Consumer Dialogue & Health Action International Europe

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Programme

12h40 - 12h45: **Opening by MEP Margrete Auken**

12h45 – 12h55: **Dr. Ben Goldacre**, medical doctor, epidemiologist, author of Bad Science and Bad Pharma:
"*How patients and the public are harmed when trial data is withheld*"

12h55 – 13h05: **Prof. Dr. Peter Gøtzsche**, medical doctor and Director of the Nordic Cochrane Centre:
"Open access to all data is a moral obligation towards the patients"

13h05 – 13h15: **Prof. Dr. Trudo Lemmens**, Scholl Chair in Health Law and Policy, University of Toronto, and Visiting Professor, HeLEX Centre, University of Oxford:
"*Clinical Trial transparency and human rights*"

13h15 – 13h20: **Response by MEP Cristian Silviu Buşoi**

13h20 – 13h25: **Response by Mr. Stefano Soro**, Head of Unit, Medicinal products – quality, safety and efficacy European Commission DG SANCO

13h25 – 13h30: **Response by Mr. Fergal O'Regan**, Adviser to the European Ombudsman

13h30 – 13h55: **Open discussion with speakers and respondents**

13h55 – 14h00: **Conclusions by MEP Peter Liese**

Please register by sending an email before November the 2nd to katrina@haieurope.org

Note - to get access badge to the European Parliament, please, include the following information: full name, date of birth, nationality, type of ID (passport, ID, driving license) and ID number.
In case of any special food requirements, please, mention it in the registration mail.