EU Lawmakers Raise Alarm at Lack of Commitment to Enforcing Clinical Trial Data Transparency

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BRUSSELS—At a meeting in the European Parliament today, a multi-stakeholder panel of European Union (EU) lawmakers, officials, academics and civil society called for decisive action to ensure greater transparency of clinical trial data.

Despite the European Commission's Clinical Trial Regulation to improve transparency and accountability entering into force in June 2014, implementation is being dogged by a lack of commitment from various quarters.

Michèle Rivasi MEP (Greens), called on stakeholders to "respect and fully implement the legislation on clinical trials transparency". She emphasised:

"Public health requires transparency, the most complete transparency possible. We, politicians, citizens and patients, cannot accept that clinical studies remain confidential, unreported or subject to trade secrets. We all know that opacity or lack of information do not favour the general interest, particularly in the health domain or when commercial interests are at stake."

Meanwhile, recent developments at the European Court of Justice could imperil the European Medicines Agency's (EMA) access to documents policy (policy 0043), hindering access to Clinical Study Reports. These reports inform decision-making on market approval, medicines pricing and reimbursement, and clinical practice and are critical to ensure patients safety. Transparency is therefore essential for a wide range of parties, including policymakers, public health bodies, the research community, healthcare professionals and patients and a responsibility for all concerned parties.

Karla Soares-Weiser, Editor in Chief at Cochrane Library that compiles studies for researches, healthcare professionals, patients and policy makers from all over the world, said:

"The availability of clinical trial data is essential for Cochrane to produce high quality and relevant systematic reviews. Without this, we risk to base our reviews on partial data and to exaggerate benefits of a health intervention or underestimate its possible harms. Good health care decision making by policy-makers as well as patients will be hindered."

Health Action International (HAI) Senior Policy Advisor Jaume Vidal, added:

"It is a shared responsibility of all involved to ensure that commercial interests do not

jeopardise patient safety—curtailing access to clinical trial data would do just that. At a time where the calls for greater transparency grow louder at the global level, the EU cannot relinquish its leadership position and must reignite the discussions on how to make the Clinical Trial Regulation operational, effective and non-reversable."

Today's event was organised by Health Action International and TranspariMED, and hosted by Michèle Rivasi MEP (Greens, DEVE/ENVI). The panel discussion involved representatives from European Commission, European Medicines Agency (EMA), Cochrane Collaboration, Transparency International Health Initiative and Prescrire.

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