TTIP & access to clinical trial data

TACD – TTIP and its impact on access to knowledge, and access to and affordability of medical technologies

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Health Action International (HAI) is an independent, global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy.

Health Action International (HAI) Europe

- Non-profit global network
- Established in 1981
- Comprising consumers, public health NGOs, healthcare professionals, researchers
- HAI Europe: European office, based in Amsterdam
- Working to increase access to essential medicines and improve their rational use through research and evidence-based advocacy
- Position funded by the Executive Agency for Health and Consumers (EAHC), Open Society Foundations (OSF), Camino Foundation
- NGO independent from corporate funding and sponsorship

TTIP & public access to clinical trial data

- Transatlantic Trade Agreement (TTIP):
  - Global standard for future FTA
  - Strong (de)regulatory dimension
  - Concerns over impact on health protection standards, including public access to clinical trial data

- **Transparency** of **clinical trial data** crucial to:
  - **Protection of public health**
  - Advancement of **biomedical science**
  - **Ethics**

Secrecy of clinical trial data: An enduring practice

- Civil society long-term call for transparency of medicines safety and efficacy data (Uppsala Declaration, 1996)
- Problem:

  - Little access to clinical trial data

  - Deficiencies in the model for reporting scientific research

Only about half of abstracts presented at conferences are later published in full *(Scherer et al.,2007).*

Studies with positive results are more likely to be published *than those with negative results (Song F. et al., 2010).*

Study publication bias leads to overestimation of treatment effects*. (Dwan K. et al., 2008).*

Reporting bias is widespread in the medical literature *(McGauran N. et al., 2010).*

Access to clinical trial data in EU: Positive developments

- European Ombudsman (2010) recommendation to EMA on clinical trial data disclosure (*Complaint 2560/2007/BEH)*
- EMA opens up policy on access to documents (2010)
- EMA working towards proactive publication
- New Clinical Trials Regulation – published EU OJ 27.05.14
- Pro-transparency requirements by medical journals (e.g., BMJ)

TTIP: A threat to trial data transparency? (I)

- PhRMA – Comments on TTIP submitted to USTR (10.03.13)

  *''Another **issue of concern to the industry is the EMA's current and proposed data disclosure policies** (…) PhRMA and its members **urge the U.S. government to engage with the EU in every available venue** to ensure responsible data sharing (…)''*

- AmCham – Position on TTIP (14.-03.13)

  *'' Failing to **protect confidential commercial information contained in regulatory submissions** is inconsistent with the **EU's treaty obligations contained in TRIPS**. The **US** should **raise trade-related concerns with these EMA policies in the context of the TTIP discussions** (….)''*

TTIP: A threat to trial data transparency? (II)

- Trade secrets to be included in TTIP IP Chapter
- EC proposal for a directive on trade secrets (28.11.13)
- EFPIA statement on trade secrets directive – 28.11.13

  "***Almost every aspect of the drug development process*** *involves the generation and application of substantial amounts of technical information and* ***know-how****, including the (...)* ***clinical trials phase***."
- Exchange of CCI and trade secrets information between EMA-FDA – regulatory chapter (EU official position on pharmaceuticals)

EMA: Shift in clinical trial transparency policy

- EMA announces out-of-court settlement with AbbVie despite positive ruling on interim measures (03.04.14)

- EMA shift in transparency policy (May 2014)

Restrictive ToU: users to acknowledge that trial data is protected by ***copyrights*** *and* ***proprietary rights***

CSR sections considered 'open access' now likely to be CCI

- EMA Executive Director's reply to European Ombudsman in the context of the Ombudsman's enquiry (22.05.14)

"(…) Commission's clear message that we would also have to assure compliance with national and international obligations (…) included but not limited to the ***TRIPS Agreements*** *and* ***copyright laws****".*

Uphold open access to clinical trial data

- EU and US to uphold that **clinical trial data** is a **public good**
- **Public health overrides any consideration on CCI**
- **TTIP not to** include any provision that can **restrict disclosure of clinical trial data**
- **Refrain from giving away rights** to pharmaceutical companies which are **not firmly established in law**
- **TRIPS** to be **read in the context of Doha Declaration** on the TRIPS agreement and public health

Public access to clinical trial data to be enshrined in law

- **Public access to medicines safety and efficacy data**, including pharmacovigilance data, to be **enshrined in law**
- **No to self-regulation**

  It cannot be left to companies to decide on their discretion when, how, to whom and to which extent clinical trial data should be disclosed.

References

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