31 March 2016

Submission to the European Ombudsman public consultation on the transparency of trilogues

At present there is very limited, if any, access to documents related to Trilogue Meetings. Trilogues are meetings held between representatives of the European Parliament, Council and European Commission to discuss policy and legislative proposals.

The transparency requirements of European Institutions are enshrined in the EU freedom of information Regulation (Regulation 1049/2001) which governs public access to documents of European Union’s institutions and agencies. The accountability and public scrutiny of European institutions and agency’s decisions are only possible when the public has access to both the body of evidence and the rationale on which decisions are based.

Under Regulation 1049/2001 European citizens are entitled to access any documents produced or received by European institutions, especially when an overriding public interest is at stake (article 2.3 of EC Regulation 1049/2001). This includes access to information about ongoing discussions on legislative proposals and their content.

A concerned citizen, member of the public, has no possibility whatsoever to follow up the discussions, or to be informed about ongoing debates within Trilogue Meetings. This makes it very difficult for citizens to determine which document to request, leading to endless exchanges with the institutions before documentation is provided.

This lack of information for the public ends up privileging commercial parties who have greater economic and human resources to monitor ongoing debates - even when not sitting at the trilogue table – and influence European Commission officials, Members of the European Parliament and representatives of Member States. This further contributes to a greater asymmetry in participation in EU decision making.

Most notably, within health policy-making, there is a sharp divide between the available resources of public interest groups and those of private interest, as shown in a 2012 report by HAI and CEO, which stated:

“... the pharmaceutical lobby is spending more than €40 million annually to influence decision making in the European Union (EU) – of which nearly half is spent by drug manufacturers on in-house lobbyists. A large share of the industry however, doesn’t declare how much it spends.”

“civil society organisations active on EU medicines issues, on the other hand, spend a combined €3.4 million per year.”}
In order to reduce this immense disparity and to level the playing field in favour of public interest, we would recommend setting up a register of Trilogue documents which would contain:

- A full list of all documents publicly available, properly indexed (per topic and date)
- Calendars for Trilogue meetings (forecast and actual meetings held), as well as a timeline for the decision-process;
- Agendas of Trilogue meetings, with links to any documents or reports being discussed;
- Lists of participants in Trilogue meetings, including observers and their CVs and declarations of interests;
- Detailed minutes of Trilogue meetings, including any informal vote with detailed information on any major and minor disagreements among stakeholders present; as well as access to presentations shared at the meeting, additional reports or background information.

**Endorsing organisations**

**HAI.** Health Action International is a non-profit organisation comprising a European network of consumers, public interest NGOs, health care providers, academics, media and individuals working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. More info: www.haiweb.org. Contact: ancel.la@haiweb.org

**ISDB.** The International Society of Drug Bulletins, founded in 1986, is a worldwide network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of the pharmaceutical industry. Currently ISDB has about 80 members representing 41 countries around the world. More info: www.isdbweb.org. Contact: press@isdbweb.org

**MiEF.** The Medicines in Europe Forum was launched in March 2002 and reaches 12 European Member States. It includes more than 70 member organisations representing the four key players on the health field, i.e. patient groups, family and consumer bodies, social security systems, and health professionals. Such a grouping is unique in the history of the European Union and is testament to the importance of European medicines policy. Contact: pierrechirac@aol.com

The **Nordic Cochrane Centre** is part of the Cochrane Collaboration, an international not-for-profit international network of more than 30,000 dedicated people from over 100 countries preparing, maintaining and promoting the accessibility of systematic reviews of the effects of health care. More information: www.cochrane.org. Contact: pcg@cochrane.dk

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