TRANSPARENCY INTERNATIONAL Deutschland e.V.

Die Koalition gegen Korruption.

Transparency International Deutschland e.V.
Alte Schönhauser Str. 44
D – 10119 Berlin

To Health Canada

250 Lanark Avenue

Graham Spry Building

AL.2007A

Ottawa, Ontario

K1AOK9

Dr. med. Angela Spelsberg, S.M.
Leiterin der Arbeitsgruppe Gesundheitswesen
Geschäftsstelle
Alte Schönhauser Str. 44
D-10119 Berlin
Tel.: (+49) (30) 54 98 98 0
Fax: (+49) (30) 54 98 98 22
E-Mail: aspelsberg@transparency.de
www.transparency.de

Berlin, den 24. Mai 2016

Re: Comments on March 10, 2016 Health Canada Draft Guidance Document, "Disclosure of Confidential Business Information under Paragraph 21.1(3)(c) of the Food and Drugs Act"

Dear Madam or Sir,

We are writing to you as representatives of non-governmental organisations in Europe, the U.S., and Canada endorsing the full disclosure of clinical trial data.

With the Berlin Declaration 2012[1],[2]supported by four thousand institutions and individuals from the public sector[3], we have committed ourselves to protection of health and well-being of the people in Europe by granting transparency to clinical trial data submitted for drug licensing and also for post-marketing surveillance.

We do not agree that clinical trial data can be declared confidential business/commercial information or business or trade secrets. Data obtained in clinical research during the process of drug development, licensing and postmarket are not to be viewed as commercial goods because they not only involve efforts and intellectual property of the manufacturer but also of many human beings participating in clinical trials who consent to the contribution of lives, time, efforts, tissues, and well-being. These contributions may not be regarded as property of the sponsor of clinical trials but as a common effort in the spirit of improving our knowledge and ability to treat medical conditions jeopardizing health.

The European Union has passed clinical trials regulation in 2014[4],.to create the legal basis for proactive disclosure of clinical trial data by the regulatory authorities in Europe.[5] We consider this a major achievement towards better health and integrity of research on marketed medical products. However, we are aware that manufacturers and other interest groups oppose EMA's effort by arguing that their intellectual property rights granted in trade agreements like WTO, TRIPS, as well as in CETA and TTIP documents are curtailed.

[1] http://www.bmj.com/content/345/bmj.e7303/rapid-responses
[2] https://www.transparency.de/Berliner-Erklaerung-2012.2330.0.html
[3] http://www.theglobalipcenter.com/clinical-data-and-disclosure-policies-the-european-union-member-states-and-international-best-practices/
[4] http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32014R0536&from=en
[5] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2014/10/WC500174796.pdf

By freedom of information act rulings in Germany we were able to obtain not publicly available contracts on post-marketing or phase-IV clinical trials. These contracts between doctors and sponsors oblige the doctors to maintain strict data confidentiality on all observations including serious adverse events (SAEs) occurring during the trial and granting substantial honoraria at the same time. This is in our eyes a violation of professional conduct rules as well as a gateway to misconduct and underreporting of adverse events of marketed drugs. Transparency and unrestricted access to the data submitted to regulators for independent scrutiny are therefore crucial. We demand from regulatory bodies to no longer declare clinical trial data as confidential business information (CBI) as regulators are not only responsible for drug licensing but also for drug safety, and their primary responsibility is to the public, not industry.

History shows that while regulators have a mandate to promote and protect the health of their citizens, they cannot do so singlehandedly, and healthcare decisions are driven by a myriad of decisions informed by evidence. If that evidence, in the form of clinical trial data, are not available to individuals from the public sector, non-governmental organisations like our own, health advocacy groups, and the general public, Health Canada will fail to achieve its mandate to promote and protect the health of Canadians. We therefore urge you to:

- Expand your notion of who can get access to information under 21.1(3)(c). Current wording in the Draft Guidance Document (section 3.2 and section 8) is restrictive and puts unreasonable barriers in front of individuals, patient groups, and other organisations from the public sector wishing to access information;
- Eliminate the currently proposed complex “considerations” regarding the purpose of disclosure (section 3.3). Individuals, patient groups, and other organisations should not be required to have formal research plans like those of scientific investigators, and it should be noted that the European Medicines Agency does not require a reason for disclosure of clinical trial data under its Policy 0043. The requirement under 21.1(3)(c) that “disclosure is related to the protection or promotion of human health or the safety of the public” does not require lengthy documentation and can be safely assumed given the identity of the requestor as an individual, patient group, or organisation from the public sector.

We fully endorse a statement Dr. Peter Doshi shared with us, stating that:

"Information about a drug’s safety and effectiveness should be understood as clinical – not business – information. However, unless and until this is clarified by regulations or compelled by a Court decision, I request that you use the power to disclose confidential business information under section 21.1(3)(c) of the Act.”

Yours sincerely

Angela Spelsberg, MD, SM

Chair, Working Group on Health

Transparency International Germany

Mark Harrington

Treatment Action Group

261 5th Ave., suite 2110

New York, NY 10016 USA

+1 212 253 7922 p

mark.harrington@treatmentactiongroup.org

www.treatmentactiongroup.org

David Carmichael

Canadians for Vanessa's Law
2443 Montagne Avenue

Oakville, Ontario Canada L6M 0J5

Telephone: 905-847-9368

Anne Rochon Ford
Project Lead: Nail Salon Workers Project (NNEWH - York U)
www.nnewh.org
tel: 416-651-7218 / 416-712-9459
annerf@sympatico.ca / annerf@yorku.ca

Prof. Dr. med. Thomas Lempert
Neurology First

Thomas.lempert@schlosspark-klinik.de

Telefon +49 (0)30 3264-1158

http://www.neurologyfirst.de

Vera Sharav,

President,

Alliance for Human Research Protection

verahsharav@gmail.com

Dr Shyamala Nataraj

Forum for Medical Society in Mumbai

A coalition of medical and non medical individuals and NGOs in developing countries

nataraj.shyamala@gmail.com

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Initiative unbestechlicher Ärztinnen und Ärzte

info@mezis.de

www.mezis.de

Drug Safety Canada

Terence Young, MP