



Press release
22 October 2014

Medicines are not just a commodity: Decision to leave responsibility for medicinal products with Health Commissioner welcomed

In early September 2014, when presenting his team for the new EU Commission, President Juncker announced his decision to move competence for medicines and medical devices from the Health Commissioner to the Commissioner for internal market and industry. The news prompted a public outcry. Numerous civil society organisations, Members of the European Parliament and Health Ministers from several Member States expressed their astonishment and concern, and called on Mr Juncker to abandon this portfolio change (1-5).

Mr Juncker initially rejected these pleas, insisting that he had included “*A Deeper and Fairer Internal Market with a Strengthened Industrial Base as a priority in [his] Political Guidelines*” (6). On 22 October 2014 however, Mr Juncker reconsidered and decided to leave competence for medicinal products with the Health Commissioner (7).

A positive sign, which should be more than symbolic. We hope that Mr Juncker’s change of heart is a sign of a change in priorities, rather than a strategic political move. We hope that Mr Juncker realised that EU policy on pharmaceuticals and health technologies should be driven first and foremost by the promotion and protection of health and patient safety.

Moreover, lessons should be learned from the experience of recent years. In December 2009, the relocation of medicinal products to the Health Commissioner was an advance, at least in principle, but in practice it was not enough to realign EU policies with public health. For instance, recent negotiations over the EU Clinical Trials Regulation and the saga of the European Medicines Agency (EMA)’s policy on increased access to clinical data have shown that the EU Commission remains reluctant to accept greater transparency. Progress was only achieved thanks to the mobilisation of civil society organisations, healthcare professionals, consumers, independent researchers, Members of the European Parliament, the EU Ombudsman and the Ministers of Health of Member States (8,9).

Put health first. We sincerely hope that Mr Juncker’s decision to leave medicinal products under the responsibility of the Health Commissioner means that, in the future, public health and patient safety will have priority over the short-term competitiveness of the medical products industry, particularly in cases where patients’ needs do not coincide with the interests of industry (1).

We therefore call on the new Commission, and particularly on the new Health Commissioner Dr Vytenis Andriukaitis, to tackle the following public health priorities:

- Ensure greater **transparency of clinical data**, including **pharmacovigilance** data (a) (10); anonymised individual patient data (“raw data”) should be made available, to allow reanalysis of the results of clinical trials (9); the EMA must be compelled to set up, without further delay, a public online **register of documents** held by the agency (b) (9);
- Demand **robust evaluation of new drugs before marketing authorisation** is granted, notably by requiring comparative trials against a reference treatment in order to demonstrate whether the new drugs adds any added therapeutic value (therapeutic progress), rather than supporting initiatives that aim to deregulate the system, such as the EMA’s controversial “adaptive licensing” pilot project (11);
- Reinforce the **independence of Drug Regulatory Agencies and free them from pharmaceutical company influence** (by allocating public funds for their activities to replace the current fee-for-service system, and by eliminating conflicts of interest and revolving door practices) (12,13);
- Defending **EU citizens’ right to obtain compensation for harm** caused by medicinal products or medical devices: medicines and medical devices are not mere commodities, but products which inherently carry high risks and should therefore be outside the scope of Directive 85/374/EEC on liability for defective products (14,15).

We also urge the new EU Commission to **ensure that the US/EU Transatlantic Trade and Investment Partnership (TTIP)**, currently under negotiation, does not lower European safety standards, impede transparency, impose greater protection of intellectual property (IP) rights, or further expand monopoly protection, thus keeping the price of new pharmaceutical products high and jeopardising access to medicines in Europe and beyond (16).

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a- EMA policy on access to pharmacovigilance data is unsatisfactory (ref. 10). Moreover, the EU Commission's proposal for a directive on trade secrets, published in November 2013, currently under discussion in the EU Parliament, poses a real threat to transparency, since it could undermine the advances in clinical data transparency established in the recently adopted Regulation on clinical trials.

b- The EMA should have established such a register more than ten years ago, in compliance with Regulation (EC) 1049/2001.

References:

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- 13- HAI Europe, ISDB, MiEF "Final proposals on pharmacovigilance: Some progress, but a missed opportunity to genuinely strengthen patient safety" Joint press release; 7 December 2010: 2 pages.
- 14- "Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products" *OJ L 210*, 7 August 1985, p. 29–33.
- 15- Le Pallec S "'Gueules cassées du médicament": d'épreuves en épreuves" Speech at *Prescrire's "Pilule d'Or"* event; 29 January 2014: 4 pages + video (14 minutes, in French).
- 16- HAI Europe and Oxfam "Europe seeks to expand big pharma monopoly at expense of poor people, warn NGOs ahead of TTIP talks" Joint press release 29 September 2014. <http://haieurope.org>: 2 pages.

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

MiEF. The Medicines in Europe Forum (MiEF) was launched in March 2002 including more than 70 member organisations in 12 Member States, representing four key players on the health field, i.e. patient groups, family and consumer bodies, social security systems, and health professionals. It is a testament to the importance of European medicines policy. Medicines are not merely consumer goods, and the European Union represents an opportunity for European citizens to seek further guarantees of efficacy and safety. Contact: pierrechirac@aol.com

NCC. 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