



## STATEMENT

17 December, 2014

For immediate release

### **EU trade secrets directive threat to health, environment, free speech and worker mobility**

#### ***Multi-sectoral NGO coalition calls for greater protections for consumers, journalists, whistleblowers, researchers and workers***

AMSTERDAM—We strongly oppose the hasty push by the European Commission and Council for a new European Union (EU) directive on trade secrets<sup>i</sup> because it contains:

- An unreasonably broad definition of “trade secrets” that enables almost anything within a company to be deemed as such;
- Overly-broad protection for companies, which could sue anyone who “unlawfully acquires, uses or discloses” their so-called “trade secrets”; and
- Inadequate safeguards that will not ensure that EU consumers, journalists, whistleblowers, researchers and workers have reliable access to important data that is in the public interest.

Contrary to the Commission’s goals, this unbalanced piece of legislation would result in legal uncertainty. Unless radically amended by the Council and European Parliament, the proposed directive could endanger freedom of expression and information, corporate accountability, information sharing—possibly even innovation—in the EU.

Specifically, we share great concern that under the draft directive:

- **Companies in the health, environment and food safety fields could refuse compliance with transparency policies even when the public interest is at stake.**

**Health:** *Pharmaceutical companies argue that all aspects of clinical development should be considered a trade secret.<sup>ii</sup> Access to biomedical research data by regulatory authorities, researchers, doctors and patients—particularly data on drug efficacy and adverse drug reactions—is critical, however, for protecting patient safety and conducting further research and independent analyses. This information also prevents scarce public resources from being spent on therapies that are no better than existing treatments, do not work, or do more harm than good.<sup>iii</sup> Moreover, disclosure of pharmaceutical research is needed to avoid unethical repetition of clinical trials on people.<sup>iv</sup> The proposed directive should not obstruct recent EU developments to increase sharing and transparency of this data.<sup>v</sup>*

**Environment:** Trade secret protection can be used to refuse the release of information on hazardous products within the chemical industry. Trade secret protection may, for example, be invoked by companies to hide information on chemicals in plastics, clothing, cleaning products and other items that can cause severe damage to the environment and human health. They could also use the directive to refuse disclosing information on the dumping of chemicals, including fracking fluids, or releasing toxins into the air.

**Food safety:** Under EU law, all food products, genetically modified organisms and pesticides are regulated by the European Food Safety Authority (EFSA). Toxicological studies that the EFSA relies on to assess the risks associated with these products are, however, performed by manufacturers themselves.<sup>vi</sup> Scientific scrutiny of the EFSA's assessments is only possible with complete access to these studies. Companies argue, though, that this information contains confidential business information and strongly oppose its disclosure.<sup>vii</sup> It is essential that the risk assessment work of public bodies is properly monitored by the scientific community. All data that these public bodies use must therefore be exempt from the scope of the directive.

➤ **The right to freedom of expression and information could be seriously harmed.**

Under the proposed directive, whistleblowers can use undisclosed information to reveal misconduct or wrongdoing, but only if "...the alleged acquisition, use or disclosure of the trade secret was necessary for such revelation and that the respondent acted in the public interest". Unfortunately, though, determining whether disclosure was necessary can often only be evaluated afterwards. In addition, it remains unclear whether many types of information (e.g., plans to terminate numerous employees) qualify as "misconduct" or "wrongdoing". This creates legal uncertainty for journalists, particularly those who specialise in economic investigations<sup>viii</sup>, and whistleblowers.<sup>ix</sup>

➤ **The mobility of EU workers could be undermined.**

The proposed directive poses a danger of lock-in effects for workers. It could create situations where an employee will avoid jobs in the same field as his/her former employer, rather than risking not being able to use his/her own skills and competences, and being liable for damages. This inhibits one's career development, as well as professional and geographical mobility in the labour market.<sup>x</sup>

In addition, despite the Commission's desire for a "magic bullet" that will keep Europe in the innovation game, closed-door trade secret protection may make it more difficult for the EU to engage in promising open and collaborative forms of research. In fact, there is a risk that the measures and remedies provided in this directive will undermine legitimate competition—even facilitate anti-competitive behaviour.

Unsurprisingly, the text is strongly supported by multinational companies. In fact, industry coalitions in the EU and the United States (US) are lobbying, through a unified Trade Secrets Coalition, for the adoption of trade secret protection.<sup>xi</sup> In the US, two new bills are pending before Congress.<sup>xii</sup> If passed, these texts would allow trade secret protection to be included in the Trans-Atlantic Trade and Investment Partnership (TTIP)—something that will be incredibly difficult to repeal in the future through democratic processes.<sup>xiii</sup> Given that TTIP is expected to set a new global standard, its potential inclusion of trade secret protection is particularly worrisome.

We urge the Council and the European Parliament to radically amend the directive. This includes limiting the definition of what constitutes a trade secret and strengthening safeguards and exceptions to ensure that data in the public interest cannot be protected as trade secrets. The right to freely use and disseminate information should be the rule, and trade secret protection the exception.

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*HAI Europe is a non-profit, 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.*

### **Corporate Europe Observatory (CEO)**

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*CEO is a research and campaign group working to expose and challenge the privileged access and influence enjoyed by corporations and their lobby groups in EU policy making.*

### **Medicines in Europe Forum (MiEF)**

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*MiEF was launched in March 2002 and reaches 12 European Member States. It includes more than 70 member organizations representing the four key players on the health field: patient groups, family and consumer bodies, social security systems and health professionals. It is a unique group and a testament of the importance of European medicines policy. Medicines are not mere consumer goods, and the Union represents an opportunity for European citizens to seek further guarantees of efficacy, safety and pricing.*

### **EUROCADRES (Council of European Professional and Managerial Staff)**

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*EUROCADRES is the trade union voice of almost six million professional and managerial staff. We are one of three recognised European cross-sectoral social partners representing employees and participating in the European cross-sectoral social dialogue.*

### **Commons Network**

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*The Commons Network is a non-profit organization and think-tank promoting access to knowledge and other social and ecological causes from the perspective of the commons. Based in Berlin and Brussels, we engage in policy formulation as well as public debate, promoting the public good through commons-based solutions.*

### **GeneWatch UK**

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*GeneWatch UK is a not-for-profit organisation that aims to ensure genetic technologies are used in the public interest. It supports access to environmental information and government and corporate transparency so that the public can have a say about genetic technologies ranging from genetically modified crops and foods to human genetic databases.*

### **La Quadrature du Net**

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*La Quadrature du Net is a non-profit association that defends the rights and freedom of citizens on the Internet. More specifically, it advocates for the adaptation of French and European legislation to the founding principles of the Internet, most notably the free circulation of knowledge. As such, La Quadrature du Net engages in public-policy debates concerning, for instance, freedom of expression, copyright, regulation of telecommunications and online privacy.*

### **Center for International Environmental Law (CIEL)**

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Since 1989, CIEL has worked to strengthen and use international law and institutions to protect the environment, promote human health, and ensure a just and sustainable society.

### **Article 19**

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*ARTICLE 19 is an independent human rights organisation that works globally to protect and promote the rights to freedom of expression and information. Its mission is to promote, protect, develop and fulfill freedom of expression and the free flow of information and ideas in order to strengthen global social justice and empower people to make autonomous choices. Its global headquarters is in London, UK and has regional offices in Bangladesh, Brazil, Kenya, Mexico, Myanmar, Senegal and Tunisia.*

### **Association Internationale de la Mutualité (AIM)**

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*AIM is a grouping of autonomous, not-for-profit health insurance and social protection bodies that operate on the principle of solidarity. Currently, AIM's membership consists of 61 organizations in 27 countries. In Europe, they provide social coverage against sickness and other risks to more than 230 million people. AIM strives via its network to make an active contribution to the preservation and improvement of access to health care for everyone.*

### **Public Citizen, US**

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*Public Citizen is a non-profit, consumer rights advocacy group and think tank based in Washington, D.C., United States. Public Citizen's Global Access to Medicines Program works with partners worldwide to improve health outcomes and save lives, through use of pharmaceutical cost-lowering measures including generic competition. We help civil society groups and public agencies overcome patent-based and other drug monopolies.*

### **Cochrane Collaboration – Nordic Cochrane Centre**

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*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.*

### **International Society of Drug Bulletins (ISDB)**

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*ISDB, 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 in 41 countries around the world.*

### **Knowledge Ecology International (KEI) Europe**

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*KEI Europe is a Swiss association formed in November 2013 focusing on the management of knowledge, including innovation and access to knowledge goods.*

### **European Public Health Alliance (EPHA)**

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*EPHA is a change agent—Europe's leading NGO advocating for better health. We are a dynamic member-led organisation, made up of public health NGOs, patient groups, health professionals, and disease groups working together to improve health and strengthen the voice of public health in Europe.*

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<sup>i</sup> European Commission. Proposal for a Directive on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure. COM(2013) 813 final. November 28, 2013. Available at: [http://ec.europa.eu/internal\\_market/iprenforcement/docs/trade-secrets/131128\\_proposal\\_en.pdf](http://ec.europa.eu/internal_market/iprenforcement/docs/trade-secrets/131128_proposal_en.pdf).

<sup>ii</sup> See the European Federation of Pharmaceutical Industries' press release stating that "Almost every aspect of the drug development process involves the generation and application of substantial amounts of technical information and know-how, including the preclinical chemistry, manufacturing and control process as well as clinical trials phase." (Available at: <http://www.efpia.eu/mediaroom/129/44/EFPIA-welcomes-the-Commission-39-s-Proposal-on-the-protection-of-undisclosed-know-how-and-business-information-quot-Trade-Secrets-quot>).

<sup>iii</sup> See for more information: HAI Europe Policy Paper. 'Protecting citizens' health: Transparency of clinical trial data on medicines in the EU'. Oct. 2013, p. 5. Available at: [http://haieurope.org/wp-content/uploads/2013/10/HAI\\_Protecting-citizenshealth-transparency-of-clinical-trial-data-on-medicines-in-the-EU.pdf](http://haieurope.org/wp-content/uploads/2013/10/HAI_Protecting-citizenshealth-transparency-of-clinical-trial-data-on-medicines-in-the-EU.pdf).

<sup>iv</sup> See Lemmens T and Telfer C "Access to Information and the Right to Health: The Human Rights Case for Clinical Trials Transparency" (September 22, 2011). American Journal of Law and Medicine 2012; 38 : 63-112. Available at SSRN: <http://ssrn.com/abstract=1932436>

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<sup>v</sup> The new EU Clinical Trial Regulation and the European Medicines Agency (EMA) 2014 access-to-data policy ensure that detailed clinical data (in the format of clinical study reports) will be pro-actively published in a public database within 30 days after the marketing authorisation decision or the application's withdrawal (ref. <http://english.prescrire.org/en/79/207/46302/3839/3303/SubReportDetails.aspx>).

The EU has further committed to open access to research publications and increased access to research results partly funded by EU biomedical R&D grants: See for the whole package of Horizon 2020: [http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference\\_docs.html#h2020-legal-basis-fp](http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#h2020-legal-basis-fp) (More specifically see: H2020 rules of participation and H2020 Regulation of Regulation of Establishment).

<sup>vi</sup> One of the EFSA's most interesting objectives is to make its scientific opinions "reproducible" by others, a key validation criteria in scientific methodology.

<sup>vii</sup> The EFSA has recently launched a [Transparency Initiative](#) to improve its credibility, and is considering providing independent scientists with access to this data. For more information see: <http://www.efsa.europa.eu/en/consultationsclosed/call/140717.htm>. Unfortunately, this objective has been strongly criticised by the manufacturing industries (chemical, pesticide, seed, biotech, and additives), which argue that this toxicological data contain "*confidential business information*" that "*should be protected from all disclosures and misuse at all times*". These industries openly threatened the EFSA with legal action should the Authority decide to publish this data. The EFSA would probably have a solid legal defense for such action because ensuring food safety serves as a strong justification. But this situation may change if the current directive on trade secrets covers such essential data.

<sup>viii</sup> Orange M "Secret des affaires: un projet de directive organise l'omerta" 2 avril 2014 ; [www.mediapart.fr](http://www.mediapart.fr) Mauduit L "[En France,] Les socialistes préparent l'omerta sur la vie des affaires" 22 juillet 2014. [www.mediapart.fr](http://www.mediapart.fr).

<sup>ix</sup> Eurocadres opinion paper 20 October 2014 "An EU regulation on Trade Secrets" [http://eurocadres.eu/IMG/pdf/20141020\\_trade\\_secrets.pdf](http://eurocadres.eu/IMG/pdf/20141020_trade_secrets.pdf).

<sup>x</sup> Ibid endnote ix.

<sup>xi</sup> In the EU, a so-called "Trade Secrets & Innovation Coalition" is pushing for this directive. This coalition is even registered in the EU Transparency register under this name, see:

<http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=956363012640-91>. This coalition includes Alstom, DuPont de Nemours, General Electric, Intel, Michelin, Air Liquide, Nestlé and Safran, who work together with the pharmaceutical and the chemical industries (see also <http://www.ip-watch.org/2012/07/16/industry-groups-press-for-eu-us-action-on-trade-secret-protection>).

<sup>xii</sup> House Bill: Trade Secrets Protection Act of 2014 (H.R. 5233) -- <https://www.congress.gov/bill/113th-congress/house-bill/5233> and Senate Bill: Defend Trade Secrets Act of 2014 (S. 2267)-- <https://www.congress.gov/bill/113th-congress/senate-bill/2267/text>.

<sup>xiii</sup> The US has made no secret of its explicit wish for strong language on trade secret protection in this agreement: see also [http://transatlantic.sais-jhu.edu/publications/CRS\\_TTIP\\_report\\_Feb\\_2014.pdf](http://transatlantic.sais-jhu.edu/publications/CRS_TTIP_report_Feb_2014.pdf), p 35.