PRESS RELEASE

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Providing scientific advice to pharma industry undermines independence of regulatory authorities

Confidential discussions between pharma, EMA and health technology assessment bodies threatens independence of pricing and reimbursement decisions

BRUSSELS—Health Action International Europe, the International Society of Drug Bulletins, the Medicines in Europe Forum and the Association Internationale de la Mutualité have criticised the European Medicines Agency (EMA) for providing confidential "advice" to pharmaceutical companies on their development plans for new medicines in exchange for fees—a potentially harmful practice that the EMA is now trying to extend to national health technology assessment (HTA) bodies in the European Union (EU).

The coalition of medicines advocates made the criticism in a joint response to the EMA's public consultation on its 'Best practice guidance for pilot EMA HTA parallel scientific advice procedures'.

"There is immense potential for conflicts of interest to arise when the EMA, through its Committee for Medicinal Products for Human Use, provides advice about specific pharmaceutical products in exchange for fees, then later decides the marketing authorisation for these products," said Ancel.la Santos Quintano, policy advisor with Health Action International. "This dubious practice should be ended; not refined and broadened to HTA bodies."

HTA bodies are widely consulted throughout the EU. They determine the 'therapeutic added value' and appropriate level of financial reimbursement for new medicines. If a new medicine provides no additional therapeutic value in comparison with safer and cheaper well-established treatments, yet receives authorisation from drug regulatory agencies, HTA bodies can recommend that it does not receive reimbursement. This limits European patients' exposure to potential avoidable adverse drug reactions and helps minimise Member States' healthcare expenditures.

"When the EMA and national HTA bodies sell scientific advice to pharmaceutical companies to aid in drug development, they essentially become co-developers of medicines and financially dependent on the pharmaceutical industry," said Joerg Schaaber, president of the International Society of Drug Bulletins. "Establishing financial and business ties with the pharmaceutical industry undermines the independence of HTA bodies, as well as the critical roles that both the EMA and HTA bodies have in protecting public health."

HAI Europe, ISDB, MiEF and AIM are also concerned that the EMA describes the scientific advisory process between it, HTA bodies and the pharmaceutical industry as "confidential" in its draft guidance document.

"Public institutions, such as the EMA, must at all times be transparent and accountable," said Pierre Chirac, coordinator with the Medicines in Europe Forum. "Advice to pharmaceutical companies by drug regulatory authorities and HTA bodies is not only unnecessary if scientific data is robust and clinical trials are designed to address legitimate public health needs, but dangerous because of its potential to result in regulatory capture, particularly when the process is conducted in secrecy."

Instead of providing customised advice to pharmaceutical companies, the coalition of medicines advocates recommend that the EMA continues developing guidelines that help drug manufacturers make development decisions that address genuine public health needs. It also urges HTA bodies, in their development of in-depth reviews, to refuse early discussions about drug development with the EMA and pharmaceutical companies and instead require full access to clinical trial data and complete assessment reports for medicines.

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The complete joint consultation response by HAI Europe, ISDB, MiEF and AIM is available at http://haieurope.org/wp-content/uploads/2014/07/2014_ParallelScientificAdvice_FINAL.pdf.

The EMA has provided scientific advice for a fee to the pharmaceutical industry since 2005. The same practice was applied to HTA bodies in 2010 under a pilot project. In March, 2014, the EMA also launched an 'adaptive licensing' project, which "builds on existing regulatory processes and intends to extend the use of elements that are already in place, including scientific advice."

The EMA's public consultation on 'Best practice guidance for pilot EMA HTA parallel scientific advice procedures' closed on 14 July.

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About us:

Health Action International (HAI) Europe
HAI Europe is a non-profit, European network of consumers, public interest NGOs, healthcare 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 information: www.haieurope.org.

Medicines in Europe Forum (MiEF)
The MiEF is an informal network. It was launched in March 2002 and reaches 12 European Member States, including more than 70 participating organisations representing the four key players in the field of health (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. More information: http://english.prescrire.org.

International Society of Drug Bulletins (ISDB)
Founded in 1986, ISDB is a worldwide network of bulletins and journals regarding drugs and therapeutics that are financially and intellectually independent of the pharmaceutical industry. Currently, ISDB has approximately 80 members in 41 countries around the world. More information: www.isdbweb.org

International Association of Mutual Benefit Societies / Association Internationale de la Mutualité (AIM)
AIM is a group of autonomous, not-for-profit health insurance and social protection bodies that operate on the principle of solidarity. Currently, AIM's membership consists of 42 national federations representing 25 countries. In Europe, they provide social coverage against sickness and other risks to more than 160 million people. AIM strives, via its network, to make an active contribution to the preservation and improvement of access to health care for everyone. More info: www.aim-mutual.org.

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