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P R E S S R E L E A S E

EMA implementation of transparency regulations called into question

Amsterdam 11th October – A broad definition of commercial confidentiality is the key barrier to public access to information on the safety and effectiveness of medicines, leaving European citizens at greater risk for otherwise preventable harm.

The 2003 EU pharmaceutical legislation reform called for an improvement in the transparency of regulatory procedures and decision-making. Subsequently, the European Medicines Agency (EMA) has held an open consultation on *Principles to be applied for the Deletion of Commercially Confidential Information for the disclosure of EMA documents*.

The EMA consultation document proposes a broad definition of commercial confidentiality based on effects of disclosure on companies' commercial interests, without any explicit exclusion of data on a product's safety and effectiveness. This is inconsistent with the provisions on transparency within EU pharmaceutical legislation and is unacceptable from a public interest perspective. It is crucial that the definition of commercial confidentiality be explicitly limited to information that is unrelated to a product's safety and effectiveness.

Reports of laboratory, animal and clinical studies submitted to the EMA to establish a medicine's safety and effectiveness for market authorisation are not yet publicly available. European Public Assessment Reports provide only summary information about the evidence that has been submitted to the regulator. HAI Europe argues that access to such data is a prerequisite to public health and trustworthy communication.

"If only partial scientific information is made public, prescribing and drug use decisions will be misinformed, not adequately informed. We know from recent experience that these misinformed decisions have serious consequences: for example, thousands of heart attacks and deaths from rofecoxib (Vioxx) use might have been prevented had there been full public access both to pre-market data on rofecoxib's cardiac adverse effects and to full data on outcomes of the VIGOR trial", said Barbara Mintzes, HAI Europe's consultant and researcher at Therapeutics Initiative, University of British Columbia.

HAI Europe therefore recommends the adoption of a precise and limited definition of commercial confidentiality and regulatory procedures that make transparency the norm and secrecy the exception.

HAI – Health Action International (HAI) is an independent, global network of over 200 consumer, health, development and other public interest groups involved in health and pharmaceutical issues in 70 countries worldwide. HAI works to increase access to essential medicines and improve their rational use. HAI actively promotes a more rational use of drugs and believes that all drugs marketed should meet real medical needs, have therapeutic advantages, be acceptably safe and offer value for money. More info: www.haiweb.org