

Deliberations during EU Health Council in Luxembourg concerning medical devices regulation
AIM: Patient safety must prevail over industrial interests

"Patient safety of medical devices must prevail over industrial interests" says Christian Zahn, President of the international association of healthcare payers AIM, on the occasion of the agreement today by the Employment, Social Policy, Health and Consumer Affairs Council on the substance of its negotiating stance on two draft regulations concerning medical devices and in vitro medical devices.

The AIM President invites the Council and the European Parliament to step up efforts to bring patient safety to the heart of the Medical Devices Regulation, instead of the competitiveness of the industry and instead of focus on early access to the market for new medical devices.

"High risk medical devices should go through a similar approval process as currently exists for pharmaceuticals. Only on that basis we can protect patients from defective and dangerous products", explains Zahn. In the future, breast implants, cardiac catheters or artificial knee or hip joints should be tested and approved in accordance with uniform criteria, and only by one European approval authority, for example the European Medicines Agency (EMA). A secure authorization process includes thus the proof of the risk-benefit ratio based on clinical studies, more transparency through the establishment of a central database and the introduction of compulsory liability insurance.

The current authorization procedure by private, so-called "Notified bodies" is by far not sufficient to eliminate the main problems in the current approval of high-risk medical devices. This became also clear with the 2012 test performed by two British newspapers. Approvals were given to fictitious hip producers by various "notified bodies", although their prostheses contained toxic substances according to the submitted files. *"The few more obligations for the notified bodies as now suggested by the Council, do not ensure greater patient safety. Both Council and the Parliament should rethink their positions and promote a safe and effective licensing procedures, based at the EMA"* adds Zahn.

About AIM



AIM is the umbrella organisation of health mutuals and health insurance funds in Europe and in the world. Through its 61 members from 27 countries, AIM provides health coverage to more than 200 million people in Europe alone, through compulsory and/or complementary health insurance and managing health and social facilities. AIM strives to defend the access to healthcare for all through solidarity, based and not-for-profit health insurance. Its mission is to provide a platform for members to exchange on common issues and to represent their interests and values in the European and international Institutions. More information? Contact: Menno Aarnout (menno.aarnout at aim-mutual.org]