



Brussels, 25 February 2019

**The European Association of Hospital Pharmacists (EAHP), the European Hospital and Healthcare Federation (HOPE), the European Social Insurance Platform (ESIP), the International Association of Mutual Benefit Societies (AIM), Prescrire and the Standing Committee of European Doctors (CPME) call for timely application of the new rules on medical devices and complete transparency concerning high-risk medical devices with public access to Eudamed.**

Since 2012, the co-signing organisations have advocated for strengthening the rules governing market access for medical devices, better market transparency and improved patient protection. Some have argued, in particular, for an independent centralised authorisation system for high-risk medical devices.

**The implant files scandal is yet another warning of the urgency of the situation and of the weaknesses of the existing legislation, at the expense of patients' safety.**

Although we regret the lack of ambition of the requirements adopted in the 2017 Regulation, as stakeholders advocating in the interest of public health, **we call on the European Commission not to delay the implementation of the new Regulations on medical devices** and to seek **the highest level of transparency regarding high-risk medical devices.**

The new Regulations on medical devices and in-vitro diagnostic medical devices that were adopted in 2017 are at least a step in the right direction. In particular, the new notification process for notified bodies by the Member States, the new scrutiny mechanism for the certification of medical devices and the setting up of a European database on medical devices (Eudamed) should improve the safety of medical devices.

However, **these provisions far from guarantee the same level of safety as those for pharmaceuticals, even though medical devices may carry the same level of risk for patients.** They also fall short of guaranteeing full transparency of information concerning high-risk medical devices.

Timely implementation of the new rules will allow for an evaluation of their adequacy as regards solving the identified problems and for the identification of areas in need of improvement. Only once they are properly evaluated, will we be able to consider, the adoption of any further measures where needed.



In addition, **we call on the European Commission to implement the highest level of transparency (especially concerning Eudamed), as public access to information on high-risk medical devices is key to ensuring traceability, vigilance and surveillance.**

We remain committed to this issue and are ready to provide our support to the European Institutions where needed.

The co-signing organisations

*The European Association of Hospital Pharmacists*

*The European Hospital and Healthcare Federation*

*The European Social Insurance Platform*

*The International Association of Mutual Benefit Societies*

*Prescrire*

*The Standing Committee of European Doctors*



**AIM** Healthcare and social benefits for all



### **About the European Association of Hospital Pharmacists (EAHP)**

The European Association of Hospital Pharmacists (EAHP) is a not-for-profit organisation that defends the interests of more than 22.000 European hospital pharmacists from its 35-member associations. EAHP works to develop knowledge on hospital pharmacy to ease the improvement of care and outcomes for patients in the hospital setting. The Association achieves this through science, practice, research, education, as well as sharing best-practice and responsibility with other healthcare professionals.

### **About the European Hospital and Healthcare Federation (HOPE)**

HOPE, the European Hospital and Healthcare Federation, is a European non-profit organisation, created in 1966 representing national public and private hospital and healthcare associations and hospital, health and social care services owners. With 36 organisations from the 28 Member States of the European Union, Switzerland and the Republic of Serbia, HOPE covers almost 80% of hospital care and is also active in the healthcare and social fields.

### **About the European Social Insurance Platform (ESIP)**

The European Social Insurance Platform (ESIP) represents 50 national statutory social insurance organisations (covering approximately 250 million citizens) in 16 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security. For more information visit [www.esip.eu](http://www.esip.eu).

*Note: ESIP members support this position in so far as the subject matter lies within their field of competence.*

### **About the International Association of Mutual Benefit Societies (AIM)**

The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuels and other not-for-profit healthcare payers. It has 59 members from 29 countries in Europe, Latin America and Africa and the Middle East. 32 of its members, from 19 countries, are based in the European Union. AIM members provide compulsory and/or supplementary health coverage to around 240 million people around the world, including close to 200 million people in Europe, on a not-for-profit basis. Some AIM members also manage health and social services. Collectively, they have a turnover of almost €300 billion.



### **About Prescrire**

Prescrire is a non-profit continuing education organisation, committed to better patient care. Prescrire provides independent, reliable information on treatments and therapeutic strategies, in order to support informed decisions. Prescrire is entirely financed by its subscribers, and accepts no advertising or other external financial support. For more information, please visit <http://english.prescrire.org> or <http://prescrire.org>. Contact: [rkessler@prescrire.org](mailto:rkessler@prescrire.org).

### **About the Standing Committee of European Doctors (CPME)**

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. CPME is committed to contributing the medical profession's point of view to EU institutions and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.