



to: Jean-Claude Juncker, President of the European Commission
 cc: Dr Vytenis Andriukaitis, Commissioner for Health and Food safety
 Elżbieta Bieńkowska, Commissioner for Internal Market, Industry, Entrepreneurship and SMEs
 Ladislav Miko, Acting Director-General of DG SANCO
 Daniel Calleja Crespo, Director-General of DG ENTR
 Glennis Willmott, Rapporteur on Medical Devices
 Peter Liese, Rapporteur on IVD Medical Devices
 Members of the European Parliament (IMCO, ENVI, ITRE Committees)

Brussels, 11 December 2014

New structure of the European Commission – Pharmaceutical Products and Health Technologies

Dear President,

We followed attentively your speech before the European Parliament of 22 October 2014, where you stated the following: *“Responsibility for medicines and pharmaceutical products will stay with the Directorate-General for Health because I agree with you that medicines are not goods like any other. The relevant policy will be developed jointly by Vytenis Andriukaitis and by Elżbieta Bieńkowska, who showed her incredible talents in her hearing.”*

We very much welcomed your decision. We indeed believe that medicinal products cannot be regulated as any other good. Policies and legislations related to medicinal products should always be led by public health as well as patient safety objectives. Economic interests should in no way be the main driver in this field.

We however still have serious concerns in relation to the portfolio for health technologies, which encompasses medical devices. Looking at the decision issued on 1st November 2014 on the organisation of responsibilities of the Members of the Commission ([C\(2014\) 9000](#)), it appears that

Unit SANCO B2 (Health Technology and Cosmetics) will be moved to DG ENTR. As for medicinal products, we believe that the Health Directorate-General is best placed to ensure health technologies are regulated in the interest of patients' safety and public health. Pharmaceuticals and health technologies are of equal importance in the provision of care and should not be treated differently.

Over the past years, numerous scandals and controversies over faulty medical devices have shown the need to maintain a health and safety perspective over an economic growth perspective¹. Ensuring that these technologies are efficient and safe to use is of utmost importance and we insist that this competence is left in the hands of Dr Vytenis Andriukaitis, Commissioner for Health.

We already raised our concerns jointly with other European Health NGOs in an [open letter](#) addressed to you on 28 October 2014. We reiterate our plea to keep the portfolio of health technologies in the Directorate-General for Health. We call on your Commission to put the health of European citizens before economic interests.

Sincerely,

Dr Katrín Fjeldsted
CPME President

RA Birgit Beger
CPME Secretary General

List of signatories in alphabetical order:



AGE Platform Europe is a European network of more than 150 organisations of and for people aged 50+ representing directly over 40 million older people in Europe. Our work focuses on a wide range of policy areas that impact on older and retired people. These include issues of anti-discrimination, employment of older workers and active ageing, social protection, pension reforms, social inclusion, health, elder abuse, intergenerational solidarity, research, accessibility of public transport and of the build environment, and new technologies. AGE Platform Europe takes also active part in several EU projects. The purpose of our work is to voice and promote the interests of the 190 million inhabitants aged 50+ in the European Union and to raise awareness of the issues that concern them most.

www.age-platform.eu

¹ D. Cohen, «Out of joint – The story of the ASR », BMJ, 2011, n°342
Meier, Berry (2012): Hip Implants U.S. Rejected Was Sold Overseas, New York Times
Scientific Committee on Emerging and Newly Identified Health Risks, The Safety of PIP Silicone Breast Implants, 1st February 2012, p. 9, 23, 27
BEUC Medical Devices testimonies <http://www.beuc.org/Content/Default.asp?PageID=2141>
Les prothèses mammaires implantables PIP - État des lieux, ANSM, Avril 2013



The **Association Internationale de la Mutualité (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.

www.aim-mutual.org



BEUC, the European Consumer Organisation has a membership of 40 well-respected, independent national consumer organisations from 31 European countries (EU, EEA and applicant countries). BEUC acts as the umbrella group in Brussels for these organisations and our main task is to represent our members and defend the interests of all Europe's consumers.

www.beuc.org



The **Council of European Dentists (CED)** is a European not-for-profit association which represents over 340,000 practising dentists through 32 national dental associations and chambers from 30 European countries. Its key objectives are to promote high standards of oral healthcare and effective patient-safety centred professional practice across Europe, including through regular contacts with other European organisations and EU institutions. CED is registered in the Transparency Register with the ID number 4885579968-84.

www.eudental.eu



The **Standing Committee of European Doctors (CPME)** aims to promote the highest standards of medical training and medical practice in order to achieve the highest quality of health care for all patients in Europe. CPME is also concerned with the promotion of public health, the relationship between patients and doctors and the free movement of doctors within the European Union. CPME represents the National Medical Associations of 27 countries in Europe and works closely with the National Medical Associations of countries that have applied for EU membership as well as specialized European medical associations. To achieve its goals, CPME co-operates proactively with the Institutions of the European Union.

www.cpme.eu



The **European Association of Hospital Pharmacists (EAHP)** is an association of 34 national organisations that represents and develops the hospital pharmacy profession at the European and international level in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting. This is achieved through science, research, education, practice, as well as sharing best-practice and responsibility with other healthcare professionals.

www.eahp.eu



The **European Federation of Nurses Associations (EFN)** was established in 1971. The EFN represents over 34 National Nurses Associations and its work has an effect on the daily work of 6 million nurses throughout the European Union and Europe. The EFN is the independent voice of the nursing profession and its mission is to strengthen the status and practice of the profession of nursing for the benefit of the health of the citizens and the interests of nurses in the EU & Europe.

www.efnweb.be



The **European Heart Network (EHN)** is a Brussels-based alliance of heart foundations and likeminded non-governmental organisations throughout Europe, with member organisations in 24 countries.

The EHN plays a leading role in the prevention and reduction of cardiovascular diseases, in particular heart disease and stroke, through advocacy, networking, capacity-building and patient support, so that they are no longer a major cause of premature death and disability throughout Europe.

www.ehnheart.org



The **European Patients' Forum (EPF)** was founded in 2003 to ensure that the patients' community drives policies and programmes that affect patients' lives to bring changes empowering them to be equal citizens in the EU. EPF currently represents 64 members, which are national coalitions of patients organisations and disease-specific patient organisations working at European level. EPF reflects the voice of an estimated 150 million patients affected by various chronic diseases throughout Europe. EPF's vision for the future is that all patients with chronic and/or lifelong conditions in the EU have access to high quality, patient-centred equitable health and social care.

www.eu-patient.eu



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. EPHA is a member of, among others, the Social Platform, the European Public Health and Agriculture Consortium (EPHAC), the Health and Environment Alliance (HEAL), and the EU Civil Society Contact Group.

www.epha.org



ESIP represents a strategic alliance of over 40 national statutory social security organisations in 16 EU Member States and Switzerland. ESIP's mission is to preserve high profile social security for Europe, to reinforce solidarity based social insurance systems, and to maintain European social protection quality.

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



HOPE, the European Hospital and Healthcare Federation, is an international non-profit organisation, created in 1966. HOPE represents national public and private hospital associations and hospital owners, either federations of local and regional authorities or national health services. Today, HOPE is made up of 35 organisations coming from the 28 Member States of the European Union, Switzerland and the Republic of Serbia. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.

www.hope.be



PGEU is the European association representing community pharmacy. Our members are the associations and chambers of pharmacists from 34 European countries comprising over 400.000 community pharmacists.

The PGEU's mission is:

- To promote and develop cooperation in Community Pharmacy among the European nations;
- To advocate for the contribution community pharmacists make to health systems and to public health through the provision of health services and the promotion of the rational and appropriate use of medicines;
- To ensure our vision of Community Pharmacy is reflected in EU policy and legislative developments.

www.pgeu.eu



The **Smoke Free Partnership** is a strategic, independent and flexible partnership between Cancer Research UK, (www.cancerresearchuk.org), the European Heart Network (www.ehnheart.org) and Action on Smoking and Health (UK) (www.ash.org.uk). Together, we aim to promote tobacco control advocacy and policy research at EU and national levels in collaboration with other EU health organisations and EU tobacco control networks. SFP is registered on the EU's Transparency Register under 6403725595-50.

www.smokefreepartnership.eu