May 17, 2019

RE: Request to start an investigation into the factors leading to medicines shortages

Dear Commissioner Andriukaitis, dear Ms Bucher,

Recent studies, such as the 2018 Medicines Shortages Survey of the European Association of Hospital Pharmacists (EAHP)¹ and an investigation by France Assos Santé into the recurring difficulties of access to certain vaccines and medicines by French citizens², have shown that the problems caused by medicines shortages all across the European Union continue to accumulate. The undersigned associations are extremely concerned by this development, in particular since the quality and safety of care is significantly affected. Patients are at risk of suffering deterioration in their health status if they cannot receive their prescribed medicines in a timely manner. Simultaneously, the amount of time that different healthcare professionals are able to spend with patients is reduced by the increased necessity of investing more and more working hours into the management of shortages.

As representatives of organisations of patients, consumers, healthcare professionals and public health advocates, we consider that the mandate of the European Commission to assist in alleviating medicines shortage problems includes, but also goes beyond, facilitating best practice-sharing. Given that medicines shortages are impacting patient care in all Member States, a strong EU commitment under the leadership of the European Commission is needed to contain the problems and ensure remedy, as acknowledged by the European Commission itself in its contribution to the informal

EU27 leaders’ meeting in Sibiu (Romania) on 9 May 2019. Such engagement should be carried out in coherent addition to the efforts by the joint task force of the Heads of Medicines Agencies and the European Medicines Agency on the availability of authorised medicines for human and veterinary use.

The undersigned associations request the European Commission to start an investigation into the factors leading to medicines shortages to provide clear and transparent information on the root causes of these problems, including on responsible entities and affected population groups, to healthcare professionals, patients and the general public. Further evidence on EU’s medicines shortage crisis should also inform the planning of the activities of the Directorate General for Health and Food Safety during the next legislative period.

We, the undersigned associations, solicit a meeting at your earliest convenience to further discuss this investigation request.

Yours sincerely,

Signatory organisations (in alphabetical order)

• AFA – Crohn RCH France
• AFH – Association française des hémophiles
• AGE Platform Europe
• AIDES
• Alterconsumo
• Amalyse
• APAA - Autoimmune Diseases Patient Association Romania
• ARAS – Asociatia Romana Anti-Sida
• ASPLA - Asociatia Prietenii lui Adrian
• BAPD – Bulgarian Association for Patients’ Defense
• CHV – Collectif Hépatites Virales
• DECO PROTESTE
• EAHP – European Association of Hospital Pharmacists
• EAP – European Academy of Paediatrics
• EATG – European AIDS Treatment Group
• ECL Access to Medicines Task Force
• EFCCA – European Federation of Crohn’s & Ulcerative Colitis Association
• EHC – European Haemophilia Consortium
• EIW – European Institute of Women’s Health
• EKPZ – Consumers’ Association “The Quality of Life”
• EPHA – European Public Health Alliance
• Épilepsie France
• France Assos Santé
• France Lymphome Espoir
• Give Life Foundation
• HAIE – Health Action International
• OCU - Organización de Consumidores y Usuarios
• ORS – Romanian Health Observatory
• Prescrire
• Test Achats
• TRT-5

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3 Europe in May 2019: Preparing for a more united, stronger and more democratic Union in an increasingly uncertain world (p.33).