EUROPEAN HEMATOLOGY ASSOCIATION

The Hague, November 16, 2018

HMA/EMA Task Force on the Availability of Authorised Medicines
Via e-mail: AAMTFSecretariat@ema.europe.eu

EHA statement following the Nov. 9 HMA/EMA workshop on availability of authorised medicines

The European Hematology Association (EHA), as representative of hematology professionals across Europe, would like to express its appreciation to the HMA/EMA Task Force on the Availability of Authorised Medicines for taking the lead in addressing an issue which it has rightly recognized as being of great importance to all stakeholders in healthcare. We appreciated the opportunity to participate in the November 9 workshop, and we gladly take advantage of the possibility to share some follow-up thoughts and concerns.

In hematology, as in many other disciplines, we see that the unavailability of medicines has a negative impact on the quality and cost of treatments and on (equal) patient access to the best possible care.

EHA therefore lauds your efforts to map the breadth and depth of the problem, collect input from all relevant stakeholders and initiate actions to address the issues. In particular, we welcome the acknowledgement that the causes of shortages are manifold and diverse and that reporting and communication need to be improved.

In our view, it is of key importance that:

1. Any new or harmonized reporting system should not be limited to collecting information about availability as such (which drugs, where, how much, how long) but also on identifying and registering the causes of shortages.

2. In considering short-term ways of coping with unavailability of medicines, it needs to be kept in mind that, whereas in some therapeutic areas shortages can be solved by 'simply' resorting to alternatives (which may be more expensive but is just as safe and effective), in hematology (and oncology) the alternative is almost always worse.

3. Special attention is given at EU level to the availability of drugs for rare diseases, heavily affected by high prices, cost-benefit considerations, market distortions and inequalities in purchasing power between countries.[1]

4. Governments act in accordance with their responsibility to ensure their citizens' right to health and (access to) healthcare, laid down in the EU Charter of Fundamental Rights. One way of doing this is by making market access for pharmaceuticals conditional on continuity of supply, including a mandatory fallback plan in case of supply disruptions. Reporting of supply disruptions by manufacturers should be obligatory. The principle

[1] Luzzatto et al., *Outrageous prices of orphan drugs: a call for collaboration.* Lancet 2018; 392: 791–94

should be that shortages without proper fallback scenario are unacceptable and should lead to penalties for the manufacturer.

5. The broader international context is taken into account. Collaboration between EU regulators and their counterparts in the US and elsewhere will be required to address the causes and consequences of supply and market issues that extend beyond Europe.

EHA thanks the Heads of Medicines Agencies and the European Medicines Agency for their leadership on this important issue and look forward to future opportunities to contribute to the collaborative search for solutions.

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