

EAHP Opinion on Unmet Healthcare Needs

Being unable to access quality care when needed is oftentimes categorised as having an unmet healthcare need. Another type of unmet need relates to an existing medicinal product that might not meet the specific demand of an individual patient and thus does not offer a major therapeutic advantage to him or her. Yet another condition that could be classified as unmet would be the lack of a satisfactory method of diagnosis, prevention, or treatment. Based on these different types of unmet medical and healthcare needs it can be concluded that no uniform concept exists. Consequently, some needs of patients cannot be adequately addressed by hospital pharmacists.

For the European Association of Hospital Pharmacists (EAHP) it is of utmost importance that a clear pathway to address unmet healthcare needs is devised.

The unmet need definition proposed by the European Commission in its revision of the general pharmaceutical legislation¹ is in the view of EAHP insufficient to fully address the entire problem in the EU. For EAHP it would be important to not only focus on unmet medical needs but to widen the definition also to healthcare needs which are not always met equally in all Member States.

An "unmet healthcare need' encompasses

- 1. A condition that is complex and/or affects a small patient population and for which no satisfactory method of diagnosis, prevention or treatment exists in Europe
- 2. Differences between the health care services deemed necessary to deal with a particular health problem and the actual services offered to an individual

To determine the unmet healthcare needs created by the absence of treatment or the lack of satisfactory treatment of an individual patient a process rooted in scientific evidence must be designed collaboratively by the European Medicines Agency, patients, and healthcare professionals. This process should be adaptive due to the variety of diseases that exist, and it should also be capable of supporting the assessment of innovative treatment solutions.

Role of the hospital pharmacist to address unmet healthcare needs

- 1. No approved treatment
 - a. Ensuring hospital pharmacy involvement in clinical trials and research
 - b. Increasing clinical trials for special populations
 - c. Investigating compounding possibilities to meet needs
 - d. Offering access through compassionate use
 - e. Providing pharmaceutical advice for off-label treatment
- 2. Provision of treatment
 - a. Supporting the efficient use of resources
 - b. Offering reconciliation and review processes at admission, an in-patient period and at discharge ofpatients with concise and curated medication lists
 - c. Ensuring the safe supply of medicines and medical devices deemed suitable for addressing the unmet healthcare need
 - d. Being part of the multidisciplinary treatment team by providing pharmacotherapy
 - e. Increasing the availability of hospital pharmacy-led home care services

¹ A medicinal product shall be considered as addressing an unmet medical need if at least one of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:

⁽a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality;

⁽b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.