Brussels, 19 July 2019

Response from the European Association of Hospital Pharmacists (EAHP) regarding the feedback of the European Medicines Agency (EMA) on inconsistencies of the stability data of cancer drugs in different European countries

Dear Mr García Burgos,

Thank you very much for the consideration of EAHP's request in relation to the inconsistencies of the stability data of cancer drugs across Europe.

EAHP is aware of the differences between the centralised procedure and products authorised via national procedures. The problem faced by hospital pharmacists is however linked to the lack of any information regarding the shelf life in the context of compounding in aseptic preparation units at the hospital pharmacy.

Hospital pharmacists feel that there is a missing liability for pharmaceutical companies to present extended in-use stability data together with the application for EU approval of their products. The lack of such data leads to high amounts of discard which has a serious impact on hospital resources and the environment.

For instance, the summary of product characteristics (SmPC) for Durvalumab (Imfinzi®), Atezolizumab (Tecentriq®) and Nivolumab (Opdivo) indicates a 24-hour stability period across European countries. However, monoclonal antibodies of this type have almost always a good extended physical-chemical stability under controlled conditions (such as absence of light, cooling and smooth handling). This has already been established in regard to Nivolumab (Opdivo) for which independent scientific data about extended stability exists. This information has however not been considered since the original data is still provided in the SmPC. Hospital pharmacists consequently feel that there is a tendency towards the inclusion of an arbitrary 24-hour limit on the shelf life of a product in the SmPC even though the product could still be safe and stable to use days later.

Furthermore, EAHP would like to bring to your attention problems caused for hospital pharmacists due to the lack of drug solution density information. Data specifying the density of a drug solution is frequently being used, in particular in the hospital pharmacy for the compounding of intravenous medications. The accuracy of the gravimetric method, which is applied by hospital pharmacists in such cases, depends on an accurate determination of the density of the drug solution being used. Unfortunately the SmPC rarely includes this data, forcing hospital pharmacies to contact the manufacturers directly. This approach is often time consuming and the quality of the data received can vary considerably. The inclusion of data specifying the density of a drug solution in the SmPC would increase patient safety.

EAHP understands that EMA cannot engage in discussions linked to wastage and healthcare resources, however we would appreciate hearing your thoughts about the possibility to request further information regarding the extended in-use stability data of a medicinal product and the density of a drug solution, preferably as a mandatory part of the SmPC.

Best regards,

Petr Horák
President
European Association of Hospital Pharmacists (EAHP)

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