EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mr Horák
President
EAHP
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18 February 2019
EMA/37979/2019

Subject: ASK-50569 Inquiry

Dear Mr Horák,

Thank you for your letter dated 18 January 2019 regarding inconsistencies in the in-use stability data for parenteral oncology medicines and whether there is any ongoing initiative at EMA to address such inconsistencies in Europe, with a view to reduce expenditure and avoiding wastage of cancer medicines across Europe.

EMA has published two guidance documents aiming at harmonizing the requirements and assessment of in-use stability of pharmaceuticals (CPMP/QWP/2934/99) and the shelf-life for sterile products for human use after first opening or following reconstitution (CPMP/QWP/159/96 Corr).

The stability information included in the SmPC is always based on stability data presented by the company applying for marketing authorisation. Oncology medicines are currently approved in the EU via EMA, through the so-called centralised procedure, which results in a single marketing authorisation valid in the entire EU. All medicines authorised centrally via EMA have the same product information and the same conditions for use, which apply equally to all EU countries. Before EMA was established in 1995, approval of oncology medicines was done by individual EU Member States via national procedures. Therefore, inconsistencies in the product information may apply to medicines which have not been approved via EMA and could be due to differences in the supporting data presented at the time and to differences in the national evaluations of these medicines.

As discussed during our recent teleconference, it would be helpful if you could provide us with the examples you are referring to in your letter. This will help us to evaluate whether any action is needed to address the issue you raise.

EMA acknowledges that the in-use shelf-life of medicines is an important factor affecting the use of the product and applicants should provide appropriate stability data in this regard. Such data aim at supporting the described posology applied for by the company.

Your letter and the paper you reference also touch upon the proposal to make better use of oncology medicines by extending their in-use shelf-life and thus reducing waste. These measures are proposed to contain the rising cost of cancer medicines for healthcare systems, and to prevent shortages.

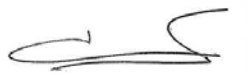
As you are aware, EMA is not directly involved in policies regarding healthcare costs, neither in commercial decisions regarding procurement of medicines or which presentations companies should market. EMA does however have a remit to determine appropriate presentations for paediatric use to ensure that appropriate dosage requirements can be met, e.g. in line with the paediatric development guideline:

https://www.ema.europa.eu/documents/scientific-guideline/guideline-pharmaceutical-development-medicines-paediatric-use_en.pdf

With regard to shortages, we would like to highlight that companies have an obligation to ensure continued supply of the market. EMA is also working with stakeholders in the context of the Heads of Medicines Agencies/EMA task force on the availability of medicines. The Agency also remains committed to the wider discussion on improving patients' access to medicines, and as such this is highlighted as a key priority in EMA's vision for the future.

In this context, we count on EAHP's continued collaboration to further discuss measures that can help improve availability of medicines in the EU. Also, as discussed at the teleconference, we take this opportunity to encourage EAHP's to help us shape EMA's regulatory science strategy and other EMA initiatives, such as the initiative on electronic product information, with the hospital pharmacists' perspective.

Kind regards



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