

DGAI Präsident ♦ Direktor der Klinik für Anästhesiologie  
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81377 München

Addressed to NASC Representatives and  
European Representatives WFSA

ESA Council Members and Presidents of  
Societies are in copy for information.

P R Ä S I D E N T

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Munich, 23<sup>th</sup> of February 2018

### **Pharmacovigilance procedure regarding volume replacement therapy with hydroxyethyl starch (HES)**

Dear Colleagues,

The German Society of Anaesthesiology and Intensive Care (DGAI) is very concerned about the current pharmacovigilance procedure regarding hydroxyethyl starch (HES)-containing solutions.

On 08th January 2018, the Pharmacovigilance Risk Assessment Committee (PRAC) of the European Medicines Agency (EMA) recommended the suspension of the marketing authorisation of this - from our point of view - very important and clinically valuable medicinal product.

This committee opposes not only against the recommendation of its own independent medical expert committee, but also against the recommendation of important anaesthesiology societies like the DGAI (German Society of Anaesthesiology and Intensive Care Medicine) and the European Society of Anaesthesiology (ESA).

The final decision is now to be taken by the European Commission, which will vote about this procedure in one of its next meetings.

The DGAI is not aware that any anaesthesiology society is promoting the suspension of the HES marketing authorisation. Thus, we would like to ask you to make an impact through your local authorities on the decision taken by the European commission. Moreover, we would like to suggest publishing an article which critically discusses the decision of the EMA in the EJA (see attachment). This Artikel will be sent to the European Commission and the EMA.

We therefore kindly hope that you accept this proposal. Due to the time pressure, we are thankfully looking forward to receiving your appreciated feedback until the 28<sup>th</sup> of February 2018.

Best regards,

A handwritten signature in blue ink, appearing to read 'B. Zwißler', enclosed in a thin black rectangular border.

Prof. Dr. med. Bernhard Zwißler  
President of the DGAI