

# DEUTSCHE GESELLSCHAFT FÜR KINDER- UND JUGENDMEDIZIN e.V.



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## Public consultation on PIP guideline

Dear Ladies and Gentlemen,

The German Society of Pediatrics and Adolescent Medicine (DGKJ) thank you for the opportunity to comment the PIP guideline.

The guideline can be considered very important for pharmacovigilance. However, the entire text could profit very much - while finishing and accepting the PIP guideline - from a more realistic concept that takes into account a proper dealing with the remaining uncertainties in pharmacovigilance/toxicity.

In particular, a concept for post-marketing safety in the relevant age-groups and for the relevant indications would be very helpful, if it is based on current law. To be more precise: The compliance check could, for example, include a check of prior safety update reports and a successful upset of a focused pro-active pharmacovigilance concept.

As pharmacovigilance will mainly start after checking and labelling, a reliable structure to grant post-marketing control of remaining uncertainties might be a suitable compromise.

We have made more specific comments directly within the attached file.

We would be very happy if you would consider our comments as helpful for improving the PIP guideline.

Do not hesitate to contact us in case of further questions and/or comments.

Yours sincerely

Prof. Dr. Norbert Wagner  
President

Prof. Dr. Fred Zepp  
Chairmann of the Committee on Drug Safety in Children