Assessor's comment:
Solicited AEs were not more frequent in the concomitant versus staggered groups.

No deaths occurred in this study.

No SAEs related to the vaccines were reported. No (S)AEs led to discontinuation of the study.

Otherwise similar event rates were seen for solicited local and systemic events as already known from other trials with this vaccine.

No safety issues are identified.

The safety profile remains unchanged.

Discussion on clinical aspects

For both safety and immunogenicity the results of this study confirm the information known and already reflected in the product information.

Overall, this study does not add new information regarding the immunogenicity and safety. The benefit-risk profile remains unchanged.

CHMP overall conclusion and recommendation

☒ **Fulfilled:**

No regulatory action required.