



Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Austrian
Federal Office for
Safety in Health Care
BASG

Translation by AMVS GmbH

Communication from the Federal Office for Safety in Health Care concerning the obligations of the manufacturers placing safety features pursuant to Delegated Regulation (EU) 2016/161

Referring to the provision of Article 14 of Delegated Regulation (EU) 2016/161 concerning the obligation of the manufacturers placing the safety features to verify that the two-dimensional barcode carrying the unique identifier complies with Articles 5 and 6, is readable and contains the correct information, the Federal Office for Safety in Health Care (*Bundesamt für Sicherheit im Gesundheitswesen*, BASG), after consulting with Austrian Medicines Verification System GmbH (AMVS), respectfully requests compliance with the following procedures.

- Paying particular attention to checking the completeness of the uploaded data in the repository prior to the first delivery to Verifying and Dispensing Locations.
- Recommendation to perform random checks of the uploaded data for correctness (batch number, expiry date).
- Taking into account the observations set out under 2.23 in the Q & A document of the European Commission concerning the particular requirements relating to the characters used in batch IDs and serial numbers.
- Proactive cooperation with AMVS upon occurrence of alert messages, especially as regards ruling out technical errors and process errors in accordance with the information regarding the start phase operations.

BASG respectfully expresses thanks for taking into account the above points which are intended to warrant the effective and efficient functioning of the system!

For the Federal Office for Safety in Health Care

Reichhart Thomas
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