REMOTE RP ACTIVITIES

According to the introduction in the EU GDP, anyone who carries out wholesale activities in the union must hold a wholesale distribution authorisation in a member state and must comply with the principles of and guidelines for GDP. From this follows that wholesale activities carried out in a country outside of the union is not bound by these guidelines and falls outside of the jurisdiction of the member states.

Therefore, any RP activities being carried out by a person localised and employed in a country outside of the union should not be accepted.

This is, however, not clearly stated anywhere in the guidelines, neither in existing human or veterinary guidelines nor in the proposals for Pharmaceutical Regulation or Directive. And it is a recurring observation made in GDP inspections performed by NOMA that certain RP activities are delegated to employees located outside of the EU/EEA, especially post-Brexit.

The Q&A of the EU GMP clearly states that QP certification / confirmation should take place within the EU/EEA (or Northern Ireland) in all cases.

We hereby suggest that a revision on the questions and answers document (Q&A) of the EU GDP include the following:

Q: Are remote activities by the RP (i.e. when not at the authorised site address specified on the WDA) allowed?

A: Remote activities could be allowed if accepted by the national competent authority where the authorised site is located. Some competent authorities may have specific requirements regarding this. Wholesalers and RPs should ensure that they comply with any applicable local requirements. In order to determine what requirements apply, wholesalers should consult with their national competent authority.

Q: Where remote RP activities are allowed, what conditions should apply?

A: RP activities should take place within the EU/EEA (or Northern Ireland) in all cases.