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European Medicines Agency

Highlights 1st EMA-Active Pharmaceutical Ingredients Committee (APIC) bilateral meeting

Chair: Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introductions

The chair welcomed the delegation highlighting the importance of bilateral exchanges, in addition to APIC's active participation in other EMA fora, including the Industry Standing Group (ISG), Quality Working Party (QWP), Quality Innovation Group (QIG) and Good Manufacturing Practice (GMP) / Good Distribution Practice (GDP) Inspectors Working Group (IWG). APIC's important role in advocating for the quality and safety of active pharmaceutical ingredients (API) and intermediates was highlighted.

APIC reaffirmed its commitment to actively contributing to relevant EMA groups and to strengthening its advocacy efforts to promote the use of compliant API in medicinal products, thereby supporting continued assurance of product quality and patient safety.

2. APIC introduction and mission

APIC provided an overview of the structure and activities of both the European Chemical Industry Council (CEFIC) and APIC, highlighting their key missions and ongoing work through dedicated task forces and working groups aimed at promoting global harmonisation, sustainability, and patient safety.

EMA welcomed the information shared and encouraged APIC to further strengthen its participation in relevant EMA fora, where topic-specific discussions and exchanges can take place.

3. APIC's perspective on current priority topics

APIC shared its perspective on key topics highlighting points to consider reflecting the specificities of API manufacturing.

- Inspection reliance: APIC raised the need to clarify perceived differences in the regulatory oversight of EU and non-EU API manufacturers. EMA highlighted that the EU framework applies

multiple complementary controls to ensure that active substances, whether manufactured in the EU or imported into the EU, are in compliance with EU GMP standards. The complementary framework was outlined, which includes the legal responsibility for manufacturers to operate according to GMP and those of the Qualified Person to verify active substances manufacturing compliance with GMP, but also risk-based inspection programmes, measures introduced by Directive 2011/62/EU, such as written confirmation and inspection requirements for exporting third country authorities as well as the international information-sharing programmes. It was also noted that expected revision to the EU pharmaceutical legislation will also cover the system of supervision of GMP compliance.

- Re-use of solvents: APIC sought clarification on the registration and validation requirements applicable to recovered solvents, highlighting both operational constraints faced by API manufacturers and industry's objective of reducing the carbon footprint through the use of solvent recovery and re-use during manufacturing processes. EMA acknowledged that APIC provided comments during the public consultation on the draft revised Chemistry of active substance guideline and confirmed that an overview of comments received will be published in due course. EMA noted that the objective of the revision was to include learnings from the Lessons learnt from presence of N-nitrosamine impurities in sartan medicines and that solvent recovery and re-use practices were identified as one of the root causes. While the guidance recommends that recovered materials be re-used within the same process and that their use in the final manufacturing steps be avoided, alternative approaches may be acceptable, provided that they are supported by a robust risk assessment and appropriate scientific justification (subject to assessment). APIC was encouraged to continue technical discussions with QWP (primarily via the annual meeting of QWP with interested parties). and to participate to Annex 15 public consultation once this is launched.
- Nitrosamines: APIC provided an overview of their nitrosamine task force activities and highlighted some challenges experienced by manufacturers including evolving acceptable intake limits, acceptance of purge-factor approaches, confirmatory testing requests, limited supplier transparency, application of less-than-lifetime limits and implementation timelines after limit revisions. EMA confirmed that global alignment remains the objective of ongoing ICH M7 work and invited APIC's active contribution to the discussions. It was clarified that competent authorities may requires additional data and confirmatory testing when the presented risk assessments are not sufficiently supported by scientific data or robust scientific rationale. APIC was invited to bring specific examples to the QWP. Manufacturers and marketing authorisation holders were encouraged to ensure adequate level of transparency in terms of information sharing and to approach the relevant competent authority in case of issues complying with the general guidance on N-nitrosamines.

4. APIC position on the reformed EU legislation

API welcomed the reformed EU legislation and presented its perspectives and proposals on implementation of the Active Substance Master File (ASMF) certification requirements, highlighting several considerations relevant to API manufacturers.

EMA welcomed the extensive feedback provided and confirmed that the implementation of the ASMF certification framework is a priority area. The Agency noted that the final legislative texts, as well as relevant delegated acts, are still pending. EMA also reiterated its commitment to maintaining an open dialogue with stakeholders throughout the implementation process through the established engagement mechanism, including ISG and industry stakeholder platforms, and dedicated communications channels such as the Agency corporate website, EMA Industry Highlights newsletter).

5. Conclusions and next steps

The bilateral exchange provided a valuable opportunity to discuss issues affecting this important API manufacturing sector, complementing the more in-depth technical discussions held within relevant expert groups.