

ANM Shared Understanding on Operationalizing the Appropriate Use of AI in Pharmaceutical Regulatory Roles

The environment surrounding pharmaceuticals development is undergoing significant change and increasing complexity due to advances in innovative technologies and diversification of modalities. Regulators are rapidly required to manage this new wave in appropriate manner. Artificial intelligence (AI) is expected to support the evaluation and analysis of evidence or information across the pharmaceutical product lifecycle, including nonclinical, clinical, manufacturing, and post-marketing safety activities. At the same time, the development, implementation, and operation of AI are complex, and appropriate governance is indispensable to ensure the accuracy and reliability of outcomes.

In addition, as regulatory authorities within the region differ in their legal systems, technical expertise, IT infrastructure, and data environments, it is more practical—rather than establishing binding and uniform rules at this stage—to first develop a shared understanding and shared language, and to promote convergence in operational practice through mutual understanding and capacity building.

Based on this recognition, we, the ANM participating authorities, confirm the following shared understanding regarding the appropriate use of AI in pharmaceutical regulatory roles.

1. Foundational understandings

The requirements relating to the quality, efficacy and safety of medicinal products belong to regulatory science-based considerations. The use of AI does not relax these requirements; rather, it should reinforce them from the perspective of securing patient safety.

Consideration and use of AI should be proportionate and risk-based, depending on the context of use and associated risks. Governance of AI should extend beyond initial deployment and cover the full lifecycle, including operation, maintenance, and updates.

Collaboration among authorities does not undermine each authority's mandate, authority, or final decision-making. Within the bounds of applicable national laws and requirements for handling confidential information, priority is placed on establishing shared understanding and shared language.

This shared understanding is non-binding. Each participating authority may refer to it in accordance with its own laws and regulatory frameworks.

2. Shared terminology and core principles

As ANM, it is beneficial to advance a common set of terms and a structured framing of the following core principles:

- Context of Use: purpose, role, scope of application, decision points, human involvement/oversight, limitations

- Data governance: data provenance, overview of preprocessing, considerations regarding representativeness and bias, documentation and traceability

- Approaches to validation: alignment with the context of use and fit-for-use, evaluation metrics, basic concepts for internal and external validation

- Lifecycle management: performance monitoring, re-evaluation, general considerations for updates/changes, attention to drift

- Transparency and accountability: provision of necessary and sufficient information to relevant stakeholders (context of use, performance, limitations, updates, etc.)

- Regulatory workforce competency needs be recognized as a core principle: regulatory professionals who oversee or rely upon AI-assisted outputs should possess sufficient competency to critically evaluate, challenge, and take accountability for those outputs, in alignment with recognized frameworks (such as the WHO Global Competency Framework for regulatory authorities).

Note: The above is an outline of issue areas and does not prescribe submission formats or levels of requirements.

49 **3. Way forward**

50 Under the ANM framework, the shared vocabulary and issue framing will be refined in a stepwise manner through
51 workshops, case sharing, and related activities.

52 With reference to international discussions and trends in standardization, ANM-shareable reference materials (reference
53 outlines) will be updated as necessary.

54 Participating authorities with established digital regulatory infrastructure are encouraged to contribute implementation
55 case studies (including pilot AI deployments, lessons learned, and competency-building experiences) in order to accelerate
56 the development of practical, evidence-based reference materials under the ANM framework.