

**Written Comments to the OECD Chemicals Committee**

March 2026

OECD Draft 2027-2030 Environment Health and Safety Programme

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General Comments

The pharmaceutical sector welcomes the OECD's continued efforts to advance global harmonisation in chemical safety assessment and risk management, particularly under the 2027-2030 Environment, Health and Safety Programme. The focus on New Approach Methods (NAMs), data standardisation, and international cooperation represents an important step toward more efficient, science-based, and sustainable regulatory systems.

Clarification of Scope - Nonclinical vs Chemical Assessment

Throughout the programme, the OECD discusses the application of New Approach Methodologies (NAMs) and its potential role in establishing test guidelines for both nonclinical safety studies and chemical assessments. We strongly urge the OECD to delineate clearly between these two applications, as they operate under distinct regulatory and legislative frameworks across various jurisdictions. Furthermore, we emphasize the criticality of clarifying that regulatory bodies do not mandate adherence to the forthcoming OECD test guidelines for all NAMs utilized in nonclinical safety studies and chemical assessments as a prerequisite. Given the inherent complexity in our development pipelines, some of these assessments will be developed for highly specific contexts of use that may not be conducive to standardization at the OECD level.

1. Support for Global Harmonisation and Use of Existing Frameworks

We strongly support initiatives that enhance international alignment, including the development of OECD Test Guidelines, Harmonised Templates, and the reinforcement of the Mutual Acceptance of Data (MAD) system. These efforts are essential to avoid fragmentation and duplication across jurisdictions.

However, it is critical that new OECD initiatives fully consider and build upon existing regulatory frameworks, particularly the EU REACH Regulation, which already provides a comprehensive and complex system for chemical safety assessment. Any new approaches should be carefully aligned to avoid duplication of requirements, inconsistencies, or parallel systems that could increase regulatory burden without added value.

2. Avoiding Additional Administrative Burden

The global pharmaceutical sector operates within an already highly regulated environment: on one side, the pharmaceutical regulatory framework is based on strict requirements to ensure safety,

efficacy and quality of our medicinal products globally (i.e. pharmaceutical legislations, and Good Laboratory and Manufacturing Practices) ; on the other, our industries must navigate the overlap with other framework, such as the environment landscape globally, adding the complexity of non harmonized approaches (i.e. EU and other countries REACH framework, Extended Producer Responsibilities and Packaging related requirements, etc).

In this context, we emphasise that:

- New tools, reporting formats (e.g. expanded OHTs), or data requirements should **not introduce additional administrative complexity**.
- Efforts should prioritise **streamlining and interoperability with existing systems** (e.g. IUCLID-based processes).
- Digitalisation and machine-readable data formats should **reduce—not increase—reporting burden**.

3. Gradual and Flexible Implementation of NAMs

We strongly support the development and use of NAMs, including in vitro and in silico methods, and are actively contributing to the transition away from animal testing.

However:

- NAMs should **not become mandatory in the absence of validated guidelines and regulatory acceptance**, particularly under EU REACH where guidance is still evolving.
- Implementation should follow a **phased, flexible timeline**, allowing industries to adapt processes without disrupting ongoing development and regulatory submissions.
- The use of NAMs should remain **context-specific and fit-for-purpose**, taking into account sectoral applications and regulatory requirements.

4. Ensuring Scientific Robustness and Regulatory Reliability

For the pharmaceutical sector, **scientific reliability and predictivity** are essential to ensure patient safety, environmental protection, and business continuity.

Therefore:

- NAMs, IATA, and computational models must demonstrate **robust validation, reproducibility, and clear applicability domains**.
- Integration of NAMs into regulatory decision-making (e.g. via IATA) should be based on **sound scientific evidence and transparent criteria**, as also highlighted in the OECD programme.
- Any uncertainty associated with NAM outputs must be clearly characterised to **avoid delays in hazard assessment and regulatory approvals**.

5. Avoiding Delays in Chemical and Pharmaceutical Development

Timely hazard and risk assessment is critical across the pharmaceutical lifecycle—from early development to manufacturing and post-market phases.

We therefore stress that:

- New methodologies must **enhance efficiency rather than slow down assessments**.
- Parallel acceptance of traditional and novel methods may be necessary during transition phases.
- Regulatory guidance should ensure that the use of NAMs does **not introduce bottlenecks or uncertainty in decision-making**.

6. Sector-Specific and Use-Based Approach

A “one-size-fits-all” approach is not appropriate across all chemical sectors.

We recommend:

- A **tailored, sector-specific implementation** of OECD recommendations, reflecting the unique characteristics of pharmaceuticals (e.g. controlled use, benefit-risk considerations).
- Consideration of **specific exposure scenarios, lifecycle stages, and regulatory frameworks** applicable to pharmaceuticals.
- Development of guidance in close collaboration with industry stakeholders to ensure practical applicability.

7. Safe and Sustainable Innovation (SSIA) and PFAS

We support the OECD’s work on Safe and Sustainable Innovation and on priority substances such as PFAS.

However:

- Transition strategies toward safer alternatives must be based on **comprehensive scientific and socioeconomic impact assessments**.
- Substitution should follow a **risk-based and evidence-driven approach**, avoiding unintended consequences or regrettable substitutions.
- Collaboration with industry is essential to ensure **feasible and effective implementation**. Under the EU Horizon Plan, the IHI PFAS initiative has been initiated this year to reunite EU cross-stakeholders in identifying solutions for the PFAS transition (including substitutions and emission mitigation measures). The OECD should partner with the public private initiative for efficient continuation of the effort.

8. Data Standardisation and Research Data Guidance

We support the expansion of OECD Harmonised Templates and guidance on research data.

To maximise impact:

- Standardisation efforts should focus on **interoperability with existing systems** and usability for regulators.
- Requirements for non-guideline studies should remain **proportionate and flexible**, to encourage innovation while improving regulatory uptake.
- Guidance should ensure that research data can **progressively contribute to regulatory frameworks without imposing excessive burdens**.

9. Collaboration and Co-Development

Finally, we emphasise the importance of **early and continuous collaboration between regulators, industry, and scientific experts**.

Successful implementation of OECD initiatives will depend on:

- Transparent dialogue and consultation
- Joint development of guidance and case studies
- Sharing of best practices and lessons learned (i.e. EU NAMS roadmap)

Conclusion

The pharmaceutical sector remains committed to supporting the OECD's vision for modernising chemical safety assessment and promoting sustainable innovation.

We advocate for a **science-based, proportionate, and pragmatic transition**, ensuring that new approaches:

- Build on existing frameworks,
Maintain high standards of safety and reliability,
Avoid unnecessary regulatory burden,
- Minimize the cost increase and time loss for generating corresponding endpoint data and
- Enable continued innovation and timely access to safe products.

Specific Comments

- **Paragraph 37-38:** Reference is made to "serious conditions." In line with the language in Section 901 of FDASIA, suggest adding "life-threatening." Proposed Recommendation or Specific Text Change: For serious or life-threatening conditions