

Scottish Medicines Consortium (SMC) Position Statement on the Use of Artificial Intelligence (AI) in Medicines Submissions

Guidance for pharmaceutical companies submitting evidence to SMC

October 2026

Introduction

The Scottish Medicines Consortium (SMC) acknowledges that artificial intelligence (AI) is becoming increasingly embedded across the lifecycle of medicines, including in their development and in the preparation of submissions to regulators and Health Technology Assessment (HTA) bodies.^{1, 2} This means that SMC is increasingly likely to assess submissions that have been supported, in whole or in part, by AI tools.

Scottish and wider United Kingdom (UK) public sector guidance is clear that AI tools should be used lawfully, ethically and responsibly, with appropriate governance, assurance and meaningful human control.^{3, 4} In this context, SMC has developed this position statement to ensure that the use of AI in medicines' submissions is consistent with Scottish public sector values and underpinned by clear guiding principles, including transparency, validation, accountability and expert oversight.^{3, 5}

This position statement aligns with key principles published by other international HTA agencies and bodies involved in the generation and development of guidance to analyse and evaluate evidence in healthcare.^{1, 2, 6-10}

Purpose and scope

In this position statement SMC lists key expectations for pharmaceutical companies on the use of AI in medicines submissions to SMC. It aims to support transparency, consistency and responsible practice where AI has been used in the generation, analysis, reporting, drafting or quality assurance of any evidence material submitted to SMC.

This position statement is intended primarily for pharmaceutical companies that submit evidence to SMC. It provides guiding principles on the use of AI in submissions, while supporting innovation where AI can add value in a proportionate and responsible way. It will also assist SMC staff and committee members by setting out a consistent framework for considering when AI has been used in a submission.

This position statement applies to AI used in relation to the development of evidence and documentation for submissions to SMC. This may include AI used to support literature review activities, evidence synthesis, data extraction, analysis of clinical or real-world data, economic modelling, drafting of submission content, or quality assurance of documents and outputs, or the generation of synthetic data and simulated patient cohorts.

This statement does not provide detailed methodological guidance on the acceptability of individual AI tools or specific algorithms, nor does it replace existing SMC submission requirements, methodological standards or governance processes.

The use of AI does not remove the responsibility of companies to ensure that all submitted evidence is accurate, robust, transparent and fit-for-purpose.

As the use of AI evolves and its governance improves, this position statement will be reviewed and updated in response to developments in policy, regulation and practice.

Definition of AI

Within this position statement, AI refers to machine-based systems that infer from the input they receive how to generate outputs such as predictions, analyses, content, recommendations or decisions. AI systems can vary in their level of autonomy and adaptiveness after deployment. This position statement uses the term broadly to include, where relevant, methods such as machine learning (ML), Deep learning (DL) natural language processing (NLP), Neural Networks (NN) and generative and agentic AI when used to support the generation, analysis, reporting or quality assurance of evidence within submissions.¹¹ A glossary is provided in appendix 1.

Guiding principles on the use of AI

SMC supports the responsible use of AI where it adds value to the development, analysis, reporting or quality assurance and drafting of evidence submitted for the assessment of medicines. SMC considers that any use of AI in medicines submissions should be guided by the following principles. A proportionate guidance on how to disclose AI use is provided in Appendix 2.

1. Transparency and disclosure

Submitting companies should be transparent about whether, where and how AI has been used in the preparation of a submission package. Transparency is needed to allow scrutiny of the role of AI in evidence generation and to support confidence in the robustness of AI-supported submitted material.

SMC recognises that transparency should be proportionate and should not require disclosure of proprietary information beyond what is needed to support assessing the impact of AI use on the submission.^{2, 7, 9, 10, 12}

What this means in practice (SMC expectations):

- **Clear disclosure of AI use:** Submitting companies should clearly state whether AI has been used in preparing the submission and highlight the parts that were AI-supported or generated. This includes the purpose for using AI and whether it contributed to evidence generation, analysis, drafting, summarising, quality assurance or another task.^{7, 12, 13}
- **Proportionate description of the method used:** Submitting companies should provide enough information to allow SMC to understand how the AI tool or method was used and what influence it had on the output, and where relevant, how the outputs were checked for accuracy.^{2, 6, 10}
- **Prompt transparency:** For natural language processing and generative AI, the prompt is considered part of the methodology. Where AI has been used for analytically important tasks (such as evidence synthesis, data extraction, economic modelling), companies should be prepared to provide the exact prompts or instructions or methodological frameworks used.

2. Human oversight and accountability

Use of AI does not remove the responsibility of companies for the accuracy, completeness and appropriateness of the evidence submitted to SMC. Human oversight, or human in-the-loop, should be maintained and documented throughout any AI-assisted process.^{2, 6, 7, 9, 13}

What this means in practice (SMC expectations):

- **Human review and verification:** AI use should not replace expert judgement. SMC expects that all AI-supported output(s) included in a submission will have been reviewed and verified by appropriately qualified individuals.
- **Reporting of human oversight:** Companies should explain clearly how human oversight of AI-supported outputs was undertaken and whether inaccuracies, major mistakes or hallucinations were found and amended.
- **Accountability:** Companies remain fully responsible for checking, reporting and amending factual errors, omissions, fabricated references, or outputs inconsistent with underlying evidence.^{2, 7-9, 12}

3. Scientific rigour, validation and reproducibility

The use of AI should not undermine established methodological standards. Any AI-supported approach used in generating, analysing or reporting evidence should be scientifically sound, appropriately validated, and suitable for its intended purpose.^{6, 7, 12, 14}

What this means in practice (SMC expectations):

- **Validation of outputs:** Companies must explain how AI use was validated (eg, data calibration, benchmarking against conventional methods, repeated testing) and why it is fit-for-purpose.^{6, 12, 14}
- **Existing submission standards apply:** AI may assist in generating material, but it does not in itself confer validity. Standard SMC requirements for robustness and completeness remain fully applicable.^{6, 7, 12, 14}
- **Model version and timestamps:** Generative AI models are updated continuously. To ensure scientific rigour, companies must explicitly state the exact version of the model used and the date(s) it was accessed or run.
- **Synthetic data and digital twins:** The generation of synthetic patient data or simulated patient groups to strengthen control arms (especially in rare diseases) requires high scrutiny. Companies must provide rigorous validation of synthetic cohorts against real-world data and ensure transparent disclosure of generation methods.²

4. Proportionate, risk-based and fit-for-purpose use

SMC considers that the acceptability of AI use in a submission should be considered in relation to its context of use and potential impact.^{6, 10, 12}

What this means in practice (SMC expectations):

- **Proportionate fit-for-purpose use:** Use of AI for administrative purposes or drafting a summary requires less scrutiny. However, using AI in evidence generation, analysis, or modelling will require detailed justification. The level of documentation and validation must be proportionate to the risk that errors, hallucinations, or bias could affect the submission and or evidence presented.^{6, 10, 12}

5. Data quality, governance and confidentiality

Data used to develop or apply AI methods in support of submissions should be relevant, reliable and appropriately governed.^{6, 7, 9, 10, 12, 13} Submitting companies remain responsible for ensuring that their use of AI is aligned with information governance requirements, including confidential and commercially sensitive information.

What this means in practice (SMC expectations):

- **Governance and security:** Companies should ensure that the use of AI is consistent with legal, ethical, and governance requirements.^{6, 13, 15} SMC expects caution where externally hosted or publicly available tools are used to process confidential or commercially sensitive information. Data practices must be secure, ethical, and aligned with treating data as a high-quality asset.¹⁶
- **Integrity of source material:** The origins and quality of data must be evaluated and reported, particularly when outputs rely on published literature or internet materials that may contain incomplete or outdated information.

6. Ethics, bias and relevance to the Scottish context

Companies should consider whether the use of AI raises ethical concerns, introduces or amplifies inequity or bias), or limits the applicability and generalisability of evidence to the relevant population.^{8, 10, 12, 15}

What this means in practice (SMC expectations):

- **Bias mitigation:** Companies must consider if AI introduces bias in training data, selectively covers evidence, or limits coding performance.
- **Local relevance:** Companies must ensure that AI-supported outputs remain highly relevant to NHSScotland practice, treatment pathways, and the specific patient population affected. Where risks to local relevance are identified, companies must explain how they were mitigated.

7. Clarification and Communication when needed

SMC does not expect routine pre-submission discussion or engagement with companies because AI has been used in a submission. However, where companies are considering novel, substantial or methodologically important uses of AI that are likely to affect evidence generation, analysis or interpretation, an initial enquiry through existing SMC routes may be helpful. SMC may also seek additional clarification during assessment where this is needed to understand the methods or outputs used in a submission.^{1, 10, 13, 15}

What this means in practice (SMC expectations):

- **Initial communication where needed:** Where AI use is novel or methodologically important, companies may enquire with SMC through existing communication channels^{6, 10, 12}

Clarification during assessment: SMC may request further information from companies, during the assessment process to understand AI-supported methods, outputs or their impact on the submission.

Appendix 1. Glossary

Algorithm

A set of instructions a computer follows to perform a task, solve a problem or generate an output. Algorithms underpin all AI systems.⁵

Artificial intelligence (AI)

Technologies used to allow computers to perform tasks that would otherwise require human intelligence, such as recognising patterns, processing language, generating content or making predictions.⁵

Agentic AI

AI systems that can make decisions and take actions with limited human input in order to achieve a stated objective.¹⁴

Bias

Systematic error or distortion in data, model design or outputs that can lead to inaccurate, unrepresentative or potentially inequitable results.³

Context of use

The specific purpose for which an AI model or output is being used, including the question it is intended to address and the setting in which it is applied.¹³

Deep learning

A more advanced form of machine learning that uses many layers of neural networks to identify complex patterns in large amounts of data.¹⁵

Digital twin

A virtual representation of a real-world asset, entity or process such as a patient profile, biological pathway.¹⁷

Explainability

The extent to which the reasoning, behaviour or outputs of an AI system can be understood and explained to those using or reviewing it.⁶

Generative AI

A type of AI that can generate new content, such as text, images, audio, video or code, based on patterns learned from training data.¹⁴

Human-in-the-loop

An approach in which human judgement, review and intervention remain part of the AI process, for example when checking, refining or approving outputs.^{9, 10}

Large language model (LLM)

A type of AI model trained on very large amounts of text data to understand and generate language-based outputs.^{9, 14}

Machine learning (ML)

A type of AI that learns patterns from data and uses those patterns to generate outputs such as predictions, classifications or recommendations.⁵

Natural language processing (NLP)

A field of AI concerned with analysing, interpreting and generating human language. LLMs are one form of NLP.^{9, 14}

Neural network

A type of computational model, loosely inspired by the structure of the human brain, that learns by adjusting connections between layers of processing units.^{5, 14}

Prompt

The instruction or input provided to an AI system to generate a response or output.¹⁵

Synthetic data

Artificially generated data that mimics the statistical properties, structures and patterns of real-world data without containing any personal identifiable information. It is used to simulate patient cohorts and strengthen control arms in clinical studies.¹⁸

Transparency

Clear reporting, in this context used in relation to whether AI was used, how it was used, and what effect it had on the output or process.⁶

Validation

The process of assessing whether an AI model or output performs adequately and is suitable for its intended purpose.¹³

Appendix 2. Suggested disclosure items when AI has been used in submissions to SMC

If AI has been used in the preparation of a submission, submitting companies are encouraged to provide a proportionate description of its use. The purpose of this appendix is to support transparency and consistency in reporting. The level of detail should be proportionate to the nature, scale and extent of AI use within the submission.

A. Scope and use

- In which specific sections of the submission, analyses or documents was AI used?
- For what purpose was AI used within the submission?
- Was AI used for administrative or drafting support, or analytically significant tasks (eg evidence synthesis, data extraction, economic modelling, synthetic cohorts)?

B. Tool and data sources

- What type of AI tool (eg LLM, ML, NLP) or method was used?
- What specific platform name, model version was used and when it was accessed?
- What datasets or source materials (eg published literature, proprietary data) were 'fed into' the AI tool or method, and how was their quality and relevance assessed?
- Were any publicly available or externally hosted AI tools used? If yes, how were confidentiality and data security maintained?

C. Validation and fitness for purpose

- How was the AI method or tool assessed as suitable for its intended purpose?
- What known risks or limitations (eg hallucinations, made-up references) were identified, and how were these addressed?

D. Human oversight and accountability

- What level of human review was applied to verify accuracy, consistency, and completeness of the AI outputs?
- Who retained final responsibility for approving the AI-generated contents submitted to SMC?

E. Impact and relevance to NHS Scotland

- Did the use of AI influence the results presented in the submission?
- Were any important assumptions or decisions informed by AI-supported outputs? If yes, how were they reviewed and justified?
- Where relevant, how was the AI-supported work assessed to ensure it remains applicable to NHSScotland practice and the Scottish patient population?

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