



AWTTC

All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

USE OF PHARMACEUTICAL COMPANY DATA



Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group



Introduction

The All Wales Therapeutics and Toxicology Centre (AWTTC) and the Pharmaceutical Industry acknowledge that early information sharing will support timely implementation of National Institute for Health and Care Excellence (NICE) and All Wales Medicines Strategy Group (AWMSG) guidance on the use of medicines.

The protection of confidential pharmaceutical company information will be ensured, in particular information that is shared early as commercial-in-confidence (CIC) or academic-in-confidence (AIC).

For the purposes of this document, CIC refers to information provided in confidence relating to the commercial interests of the owner of the information, and AIC refers to information provided in confidence in circumstances where disclosure could prejudice future publication of the information in a scientific context.

Overarching principles

1. AWTTC will adhere to the principles and requirements of data protection legislation, in particular the UK General Data Protection Regulation (UK GDPR), the Freedom of Information Act 2000 and the Data Protection Act 2018, when dealing with information received from a pharmaceutical company.
2. AWTTC will store any confidential information received from pharmaceutical companies securely within the in-house medicines access database and on Microsoft SharePoint, in line with [NHS guidance](#) and hosted by Cardiff and Vale UHB.
3. The medicines access database is password protected and only accessible to designated staff via the Welsh NHS network. An authorisation system is used to validate and track access to that data.
4. Only those who require use within their professional remit have access to the confidential information, and such numbers will be kept to a minimum.
5. Individuals with access to such confidential information sign a confidentiality agreement. All access to such confidential information is auditable.
6. The AWTTC Vault is an essential tool for distributing meeting papers and ensuring that only authorised personnel have access to sensitive information. The Meeting Confidentiality Statement, used by committee members for accessing papers on the Vault, details confidentiality requirements and disposal instructions for confidential information. This platform is also vital for managing confidential documentation and facilitating the secure sharing of commercially sensitive information by pharmaceutical companies with AWTTC. Our operations, including data usage, are meticulously designed to align with evidence-based medicine practices and adhere to stringent data protection standards. We prioritise the security of sensitive data by employing this system, which complies with the Common Law Duty of Confidentiality and GDPR. This commitment ensures that all data are managed with the utmost integrity and security.
7. AWTTC will not release any confidential information into the public domain without the agreement of the data owner. In circumstances where AWTTC wishes to publish data regarded by the owner as CIC or AIC, both AWTTC and the data owner will negotiate in good faith to seek a mutually acceptable solution. Negotiations will recognise both the need for AWMSG to support its recommendations with evidence and the data owner's right to publication. The data owner will retain the right to make a final decision in relation to the release of confidential information into the public domain.

Principles related to specific information types

Horizon scanning and financial forecasting

AWTTC will use UK PharmaScan to gather information on medicines expected to be available in the future.

Pharmaceutical companies may be requested to provide information supplementary to that in UK PharmaScan, as needed, to facilitate timely access to NICE- and AWMSG-approved medicines. Where no UK PharmaScan record exists, pharmaceutical companies will be requested to provide the information that would otherwise have been obtained via UK PharmaScan alongside any necessary supplementary information. Guidance on this provision of information will be available from AWTTC. Timely company engagement is especially crucial for Wales to facilitate making new medicines available to patients within 60 days of the NICE Final Draft Guidance (FDG) publication or a Final Evaluation Determination (FED) in line with the Welsh Government New Treatment Fund policy.

Information provided to AWTTC in relation to horizon scanning and financial forecasting will be maintained in strict confidence and stored securely within their in-house database. Access to AWTTC's horizon scanning reports and financial forecasting spreadsheets will be through Microsoft SharePoint as a secure platform. This platform can only be accessed by a minimal appropriate number of named NHS in Wales health board and trust employees, including senior pharmacists and leads from the All Wales Medical Genomics Service, National Pathology Programme, Medicines Value Unit and NHS Wales Joint Commissioning Committee. These health board and trust individuals will be made aware that information included within AWTTC's horizon scanning report is confidential and intended only for those specifically authorised to access it for financial and service planning. Personnel employed by organisations within the NHS in Wales who have access to the AWTTC horizon scanning and financial forecasting reports will sign a confidentiality agreement each year (Appendix A).

Medicines assessment

See Appendix B for detailed guidelines on managing data types.

AWTTC acknowledges that, while it is generally in the interests of patients for all relevant information about medicines being assessed by AWMSG and its sub-groups, the Licensed One Wales Medicines Assessment Group (LOWMAG) and the One Wales Medicines Assessment Group (OWMAG), to be in the public domain, the rights of the data owners must be respected, as noted in point 7 of Overarching Principles.

The amount of information submitted 'in confidence' by a pharmaceutical company, as part of a medicine assessment, should be kept to a minimum. The whole submission may not be marked confidential, and it is generally not acceptable to mark complete sections as confidential. Only information that is genuinely confidential, such as data values, should be marked as 'in confidence', and AWTTC will only treat information in confidence if the material is stated as CIC or AIC. When marking data as confidential, pharmaceutical companies should indicate if this status will apply at the time AWTTC anticipates presentation/publication of the data. The last opportunity for pharmaceutical companies to review the confidential status of information included in the draft Evidence Summary Report (ESR) is prior to the LOWMAG meeting.

AWTTC will not release any information provided to it during an AWMSG appraisal or a medicine's assessment prior to the launch of the relevant medicine into the UK market.

AWTTC will not publish any confidential information associated with medicines which are being assessed via AWMSG's processes for the assessment of licensed and off label medicines.

AWTTC will normally disclose a short description of the economic model provided by the pharmaceutical company in their submission and the data on which the model is based. Exceptionally, data within a model can be treated as confidential if they contain or make practical the reverse engineering of confidential data inputs which are credibly specified as confidential by the pharmaceutical company. Model structures will not be accepted as confidential information and by submitting a model the pharmaceutical company will be taken to have agreed that a description of the model structure may be put into the public domain.

It should be noted that AWTTC's critique of the clinical and economic evidence, as summarised in the ESR, is owned by AWTTC, and pharmaceutical companies must recognise the need for AWMSG to support its recommendations with evidence and may not mark complete sections of the ESR as confidential. Only information in the ESR that may legitimately be marked as confidential will be identified as such.

Information in the ESR will be disclosed to AWTTC staff involved in the assessment and relevant committee members via AWTTC's Vault. All committee members access meeting papers via AWTTC's Vault and are required to sign a confidentiality statement which prohibits unauthorised disclosure of sensitive or private information shared between parties. By signing a confidentiality statement, members demonstrate a commitment to safeguarding all sensitive and commercial information shared during meetings. Pharmaceutical companies can be assured that any confidential data or materials are handled with the utmost care, strictly protected from unauthorised disclosure, and securely disposed of after use.

The pharmaceutical company will have the opportunity to check and comment on the evidence status report before it is shared with committee members. Any information highlighted as 'commercial in confidence' will be redacted before it is uploaded to the AWTTC website.

Commercial access arrangements

Medicines will normally be evaluated at the list price that is agreed with the Department of Health and Social Care. During the health technology assessment process, there are opportunities for commercial engagement between companies and the NHS to improve the value proposition of a medicine. For products undergoing a NICE evaluation, the NHS in Wales will align their own commercial agreements with NHS England (refer to CASWG Flow Chart). AWTTC requires companies to share the commercial, budgetary and planning information already provided to NICE so that AWTTC can support health board and trust implementation of NICE guidance within 60 days of FDG/FED publication. Providing the relevant information required to successfully implement a commercial arrangement associated with NICE and AWMSG appraisal recommendations will ensure that the medicine can be made available across the NHS in Wales. AWTTC requests that pharmaceutical companies email NHSWales.CA@wales.nhs.uk for discussion on anything in relation to commercial arrangements.

The NHS in Wales Commercial Medicines Access Reference Tool (CMART) has been developed by the Commercial Medicines Access Team (CMAT). CMAT consists of staff from AWTTC and NHS Wales

Shared Services Partnership (NWSSP). CMART is managed by CMAT within AWTTTC to support the health boards and Velindre NHS Trust in the management of medicines available with a commercial access arrangement. A commercial arrangement may be a simple or complex Patient Access Scheme (PAS), Commercial Access Agreement (CAA) or Managed Access Agreement (MAA). It is hosted and secured within the NHS in Wales and accessed using password and two-factor authentication via Microsoft SharePoint, also known to the pharmaceutical industry as 'The commercial in confidence Vault'.

CMART access is restricted to two nominated and authorised individuals per health board/trust within the NHS in Wales. These authorised providers and commissioners have access to the CIC information for specific medicines in order to support implementation and ensure they are procuring from the correct supply route at the correct price. Access permissions must be requested by the Director of Pharmacy and the nominee must complete a confidentiality agreement (see Appendix A) which stipulates that the information contained is needed for their professional role and cannot be disclosed to any third party without the specific permission of NHS organisations in Wales or the relevant manufacturer, unless under a legal obligation to do so. AWTTTC annually collects and reviews information on use of the CMART, and user authorisation will be revoked if it is believed information has been accessed or used inappropriately; further substantive action may also be taken if needed. AWTTTC will inform the relevant pharmaceutical company of any substantiated concerns.

To ensure the information in the CMART continues to be accurate and up to date, CMAT will track the appraisal process undertaken by NICE and AWMSG and collate the necessary details required to maintain the tool. Specific information regarding the commercial agreement will not be uploaded to CMART until the confidential pricing details have been confirmed by the pharmaceutical company.

Once the FDG or FED is published by NICE, or an AWMSG recommendation is published, the information will be made available via CMART. Early engagement with AWTTTC is essential to ensure this can align with the date of the published guidance and facilitate the requirements and timings of the New Treatment Fund.

The process of agreeing a commercial arrangement for use in organisations across the NHS in Wales is via the Commercial Arrangement Scheme Wales Group (CASWG) and AWTTTC provides secretariat support. Commercial information is stored securely within the Cardiff and Vale NHS local network specifically for AWTTTC. The local network is further restricted to only AWTTTC staff who work within CMAT. Members papers for CASWG are also shared via the Vault and are read only. Members papers are removed from the Vault at the end of each meeting and are not retrievable from this source. Further information relating to the process for commercial arrangements, including CASWG, can be found on the AWTTTC website.

Freedom of information requests

Freedom of Information requests are managed by the Freedom of Information Office at Cardiff and Vale Health Board. The officers will collaborate with the information owner to ensure that each request complies with the Freedom of Information Act 2000. Confidential or commercially sensitive information will not be disclosed under any circumstances.

Consequences of a confidentiality breach

In the unlikely event that AWTTTC breaches commercial confidentiality the pharmaceutical company will be informed at the earliest possible opportunity. Early communication will allow the pharmaceutical company the opportunity to take appropriate steps to mitigate the impact. AWTTTC has established an internal process for reporting incidents, including breaches of commercial confidentiality. This procedure enables us to thoroughly evaluate the circumstances surrounding the incident and implement preventative measures to avoid future occurrences.

References

SMC. 2018. Release of Company Data Agreement between the ABPI and the Scottish Medicines Consortium (SMC), which is part of Healthcare Improvement Scotland (HIS), on guidelines for the release of company data into the public domain during SMC assessment. Available at: <https://scottishmedicines.org.uk/media/3572/20180710-release-of-company-data.pdf>. Accessed April 2025.

NICE. 2023. NICE health technology evaluations: the manual Available at: <https://www.nice.org.uk/process/pmg36/chapter/developing-the-guidance-2#information-handling-general-considerations>. Accessed April 2025.

NICE. Agreement between the ABPI and NICE on guidelines for the release of company data into the public domain during a health technology appraisal. Available at: <https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/Guidelines-for-the-release-of-company-data-into-the%20public-domain-during-a-health-technology-appraisal.pdf>. Accessed April 2025.

Appendix A. Confidentiality agreement

AWTTC Horizon Scanning Repository in SharePoint

CONFIDENTIALITY AGREEMENT (Cancer Medicines) 2025

"Confidential Information" means all confidential and commercially sensitive information held within the Cancer Medicines horizon scanning repository folder

By signing this agreement for the defined workspace **cancer medicines** I agree:

- To keep all Confidential Information strictly confidential and not disclose it to any other person (other than to appropriate NHS employees within my organisation who need to know the Confidential Information for the purposes of horizon scanning and/or service planning).
- To apply the same security measures and degree of care to the Confidential Information as I apply within my own organisation, providing adequate protection from unauthorised disclosure, copying or use.
- Not to disclose any Confidential Information to any third party without the prior consent of AWTTC and, in the event that such disclosure is permitted, ensure that the third party is fully aware of and complies with this agreement as if they were a party to it.

I acknowledge:

- That any breach of confidentiality could cause NHS Wales, AWTTC and the User' Organisation harm that is irreparable.
- The importance of maintaining confidentiality of the defined workspace, and that if I breach any terms of the confidentiality agreement AWTTC shall be entitled to refuse to provide me with access to the defined workspace or any Confidential Information in the future, whether relating to this or any other matter.
- That publication of any Confidential Information is strictly prohibited.

HORIZON SCANNING workspace in SharePoint hosted by AW TTC

CONFIDENTIALITY AGREEMENT (non-cancer medicines) 2025

"Confidential Information" means all confidential and commercially sensitive information held within the workspace.

By signing this agreement for the defined workspace **non-cancer medicines** I agree:

- To keep all Confidential Information strictly confidential and not disclose it to any other person (other than to appropriate NHS employees within my organisation who need to know the Confidential Information for the purposes of horizon scanning and/or service planning).
- To apply the same security measures and degree of care to the Confidential Information as I apply within my own organisation, providing adequate protection from unauthorised disclosure, copying or use.
- Not to disclose any Confidential Information to any third party without the prior consent of AW TTC and, in the event that such disclosure is permitted, ensure that the third party is fully aware of and complies with this agreement as if they were a party to it.

I acknowledge:

- That any breach of confidentiality could cause NHS Wales, AW TTC and the User' Organisation harm that is irreparable.
- The importance of maintaining confidentiality of the defined workspace, and that if I breach any terms of the confidentiality agreement AW TTC shall be entitled to refuse to provide me with access to the defined workspace or any Confidential Information in the future, whether relating to this or any other matter.
- That publication of any Confidential Information is strictly prohibited.

HORIZON SCANNING workspace in SharePoint hosted by AW TTC

CONFIDENTIALITY AGREEMENT (financial forecasting) 2025

"Confidential Information" means all confidential and commercially sensitive information held within the workspace.

By signing this agreement for the defined workspace **financial forecasting** I agree:

- To keep all Confidential Information strictly confidential and not disclose it to any other person (other than to appropriate NHS employees within my organisation who need to know the Confidential Information for the purposes of horizon scanning and/or service planning).
- To apply the same security measures and degree of care to the Confidential Information as I apply within my own organisation, providing adequate protection from unauthorised disclosure, copying or use.
- Not to disclose any Confidential Information to any third party without the prior consent of AW TTC and, in the event that such disclosure is permitted, ensure that the third party is fully aware of and complies with this agreement as if they were a party to it.

I acknowledge:

- That any breach of confidentiality could cause NHS Wales, AW TTC and the User' Organisation harm that is irreparable.
- The importance of maintaining confidentiality of the defined workspace, and that if I breach any terms of the confidentiality agreement AW TTC shall be entitled to refuse to provide me with access to the defined workspace or any Confidential Information in the future, whether relating to this or any other matter.
- That publication of any Confidential Information is strictly prohibited.

Commercial Medicines Access Reference Tool (CMART) confidentiality agreement.

CONFIDENTIALITY AGREEMENT

Access to Medicines – Commercial in Confidence workspace in NHS Microsoft 365 hosted by AWTTTC.

"Confidential Information" means all confidential and commercially sensitive information held within the workspace.

By signing this agreement for the defined workspace I agree to:

- Keep all Confidential Information strictly confidential and not disclose it to any other person (**other than to appropriate NHS employees within my organisation who need to know the Confidential Information**).
- Not to reproduce, disseminate, copy, disclose, modify, distribute and/or adapt in whole or in part any Confidential Information in any way.
- Apply the same security measures and degree of care to the Confidential Information as I apply within my own organisation, providing adequate protection from unauthorised disclosure, copying or use.
- Not disclose any Confidential Information to any third party without the prior consent of AWTTTC and, in the event that such disclosure is permitted, I shall ensure that the third party is fully aware of and complies with this agreement as if they were a party to it.

I acknowledge:

- That any breach of confidentiality could cause NHS Wales, AWTTTC and the User' Organisation harm that is irreparable.
- The importance of maintaining confidentiality of the defined workspace, and that if I breach any terms of the confidentiality agreement, AWTTTC shall be entitled to refuse to provide me with access to the defined workspace or any Confidential Information in the future, whether relating to this or any other matter.
- That publication of any Confidential Information is strictly prohibited.

Appendix B. Guidelines on managing data types

Data type	Position
Clinical and economic data	The amount of information submitted on an 'in confidence' basis should be kept to a minimum. It is unacceptable to mark the whole submission, complete sections and/or full tables as confidential. Only information that is genuinely confidential should be marked as such. Incremental costs, quality adjusted life years and cost effectiveness ratios are not expected to be marked as 'in confidence'. Results of evidence synthesis exercises or further calculations can only be marked as confidential if they would allow back calculation to the original confidential information or would disclose other confidential information.
Clinical trial evidence	
Published data	Any information once published, even in abstract form, can no longer be regarded as confidential
Unpublished data	Study design: ABPI policy encourages voluntary registration of specified information relating to the protocols of phase III trials involving patients in the UK.
	Results: Pharmaceutical companies will authorise AWTTTC to quote publicly from either a full report or an abstract of unpublished trials, where the date of release by AWTTTC of data from such reports/abstracts is not less than 12 months after the sign-off by the company of the trial report. This 12-month restriction shall be the subject of negotiation in good faith between AWTTTC and the pharmaceutical company in the event that the licensing authority 'fast track' any application.
Price	
	Pricing information will not be released by AWTTTC into the public domain before product launch in the UK. It is acknowledged that final pricing is often only determined immediately prior to launch. Net pricing details, such as those associated with a commercial arrangement, will not be released into the public domain.
Economic analysis	
Published	Any information once published, even in abstract form, can no longer be regarded as confidential.
Unpublished	Pharmaceutical companies will authorise AWTTTC to quote publicly from either a full report or an abstract of unpublished analyses, where the date of release, by AWTTTC, of data from such reports/abstracts is not less than 12 months after the sign-off by the company of the analysis. This 12-month restriction shall be the subject of negotiation in good faith between AWTTTC and the company in the event that the licensing authority 'fast track' any application leading to AWTTTC requiring earlier publication.
Economic model	Pharmaceutical companies shall normally agree to their economic models being available in electronic form for the purposes of an AWMSG appraisal. The model will be supplied in confidence and held as such by AWTTTC.
Budget impact	Pharmaceutical companies are encouraged to supply data from any projections they have prepared, of uptake of their products in the NHS, at their own discretion, indicating which data should remain as CIC.