Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the National Institute for Health and Clinical Excellence (NICE) on guidelines for the release of company data into the public domain during a health technology appraisal

Principles

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1. NICE and ABPI acknowledge that: o it is in the interests of patients generally, and the consultees in each technology appraisal specifically, that all relevant information about technologies being appraised be put in the public domain; o NICE is under obligations of transparency and fairness to, amongst others, patients and other consultees in conducting each technology appraisal; and o the rights of the owners of the data provided to NICE must also be respected.
2. For the purposes of this Agreement:
o Commercial in confidence information is information provided in confidence relating to commercial interests of the owner of the information
o Academic in confidence information is information provided in confidence in circumstances where disclosure could prejudice future publication of the information in a scientific publication. It would be expected that any information marked as academic in confidence is going to be published at some stage and that a timeline for publication can be given.
3. The amount of information submitted on an 'in confidence' basis should be kept to a minimum. The whole submission may not be marked as confidential. It is likely to be unacceptable to mark complete sections as confidential. Only information that is genuinely confidential, such as actual numbers, should be marked as in confidence. NICE will only treat information in confidence if the material is in fact commercial in confidence or academic in confidence.
4. When marking data as confidential, companies should indicate if this status will apply at the time NICE anticipates publication/presentation of the data. The last opportunity for companies to review the confidential status of information is at the time of commenting on the Assessment Report (in the MTA process) and two weeks before the first Appraisal Committee meeting (in the STA process).
5. For all unpublished clinical data submitted as academic or commercial in confidence the minimum that should be made available for release is

	that which normally would be included in a CONSORT (or PRISMA) compliant abstract (http://www.consort-statement.org/?o=1011) and be suitable for public disclosure. An equivalent approach is required for all data and studies which underpin and are included in economic analyses and models, and for the economic model included in the submission if that is marked academic or commercial in confidence.
6.	In circumstances where NICE wishes to publish data regarded by the data owner as academic or commercial in confidence, both NICE and the data owner will negotiate in good faith to seek to find a mutually acceptable solution, recognising the need for NICE to support its recommendations with evidence and the data owner's right to publication. However the data owner retains the right to make a final decision in relation to the release of confidential information into the public domain.
7.	Presentation of evidence on the clinical and cost effectiveness of a technology in an Appraisal Committee meeting held in public prior to receipt of marketing authorisation is permissible. Such presentation does NOT constitute a breach of the Code of Practice for the Pharmaceutical Industry as the term 'promotion' in the Code does not include information provided to national public organisations such as NICE, provided the information is factual, accurate and not misleading.
8.	Academic in confidence information may be presented during the public sessions of Appraisal Committee meetings. However, the data owner retains the right to make a final decision in relation to the release of confidential information into the public domain.
9.	For commercial in confidence information the owner retains the responsibility for its release into the public domain. It is recognised that, with the exception of presentation of data at Appraisal Committee meetings, the data owner retains the right to make a final decision in relation to the release of confidential information into the public domain
10.	NICE will normally disclose in full economic models provided by manufacturers/sponsors to NICE as part of an STA submission (or used or developed by the Assessment Group as the model of choice in an MTA) and the data on which such models are 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 company. Model structures will not be accepted as confidential information, and by submitting a model the manufacturers/sponsor will be taken to have agreed that the model structure may be put into the public domain.
11.	If NICE is challenged that confidential information it has received should be released in the interests of fairness, during an appraisal, at appeal, through judicial review, or otherwise, data owners must on request promptly reconsider whether it is in fact necessary to maintain confidentiality. NICE does not intend to make repeated requests for a prima facie tenable claim of confidentiality to be abandoned or modified, and it will

	accept the data owner's judgement in that regard. Nor can NICE "second guess" the motives of a data owner. If a data owner would not agree to the specific request for disclosure made, but would agree to some more limited disclosure (for example to a "confidentiality club",) then it is asked itself to suggest the disclosure it would find acceptable, rather that to wait for NICE to propose the specific formula it may have in mind and discuss and agree a potential solution with NICE. If disclosure is not possible the data owner must be prepared to assert publicly that the information is considered to be confidential, and must submit evidence giving the justification for maintaining confidentiality in defence of NICE's maintenance of that confidentiality. In the absence of any such assertion and evidence, NICE shall be entitled to conclude that the information is no longer confidential.
12.	It is acknowledged that the principles in this document apply to licence extensions as well as new chemical entities and that the key date for release of information in the public domain by NICE is the receipt of marketing authorisation for the technology.

Guidelines

Data	Position
Clinical and economic data	The amount of information submitted on an in confidence basis should be kept to a minimum. The whole submission may not be marked as confidential. 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. Incremental costs, quality adjusted life years and cost effectiveness ratios are not expected to be marked as provided 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, is not regarded as commercial or academic in confidence to the extent that it has already been placed in the public domain.
Unpublished data	<u>Study design</u> The ABPI Code of Practice requires companies to register their clinical trials in line with the IFPMA Joint Agreement published in January 2005 and recently updated (see Clause 21.3 of the Code). The Joint Agreement invites companies to register all their clinical trials from the beginning of Phase II onwards at the inception of the trial on a publically accessible website such as http://clinicaltrials.gov. It is a potential breach of the ABPI Code of Practice if companies fail to register their trials.
	<u>Unpublished results</u> Companies will authorise NICE to quote publicly from either a full report or an abstract of unpublished trials, where the date of release, by NICE, of data from such reports/abstracts is not less than 12 months after the sign-off by the company of the trial report. NICE will seek the express permission of the company before placing any data in relation to unpublished trials in the public domain. The data owner retains the right to make a final decision in relation to the release of confidential information into the public domain. This12 month restriction shall be the subject of negotiation in good faith between NICE and the company in the event that the licensing authority "fast tracks" any application leading to NICE seeking earlier publication.
Price	
	Information on the NHS list price may only be marked as

	commercial in confidence prior to the price being agreed with the Department of Health. Pricing information will not be released, by NICE, into the public domain before the price has been agreed with the Department of Health and made publically available. Therefore, final guidance and appraisal consultation documentation can only be released with full disclosure of the list price of the technology. If the final list price has not yet been determined at the time of evidence submission, companies will provide to NICE, and the academic group commissioned to carry out the evidence review, the expected list price or a range of prices within which the final list price is likely to fall. Where the company plans to delay the availability of the product to the NHS to a time significantly beyond marketing authorisation (that is, the 'launch' date is not equal to the marketing authorisation date), and that delay has an impact on the availability of the final list price, NICE should be informed at the earliest opportunity.
Economic analysis	
Published	Any information once published, even in abstract form, is not regarded as commercial or academic in confidence to the extent that it has already been placed in the public domain.
Unpublished	Companies will generally authorise NICE to quote publicly from either a full report or an abstract of unpublished analyses, where the date of release, by NICE, of data from such reports/abstracts is not less than 12 months after the sign-off by the company of the report on the economic analysis. NICE will seek the express permission of the company before placing any data in relation to unpublished analyses in the public domain. The data owner retains the right to make a final decision in relation to the release of confidential information into the public domain. This 12 month restriction shall be the subject of negotiation in good faith between NICE and the company in the event that the licensing authority "fast tracks" any application leading to NICE seeking earlier publication.
Economic model	In the case of both STAs and MTAs, companies shall agree to their economic models being available in executable electronic form for the academic group and for other consultees and commentators to test their reliability and robustness, and, in the case of the academic group, to suggest alternative approaches if they think fit. The creator/commissioner of an economic model shall continue to own all intellectual property rights in it, and the model will only be released by NICE to consultees and commentators to enable third parties to engage with an

	appraisal. Exceptionally, NICE may agree to keep some or all of the economic model confidential if: • the company informs NICE that the model contains specified confidential data inputs, which are not redactable without loss of functionality of the model; • the company is prepared to assert, publicly and without any caveats, that the economic model contains confidential data inputs that cannot be redacted without severely limiting the model function; • the company is prepared to submit evidence to that effect in defence of NICE's maintenance of confidentiality in the event that NICE is challenged on that basis. If all of the above conditions are not met NICE will not agree to keep the model confidential. Even if NICE agrees to keep a model confidential, the company agrees to keep the requirement for confidentiality under review. Specifically, in the event of a request for disclosure of the material from one or more consultees, NICE will seek permission to release the material and the company will consider granting such permission. NICE will ensure that the same arrangements apply to models produced as part of a NICE health technology assessment by Assessment Groups
Implementation	
Budget/resource impact (including marketing/sales forecasts)	Companies are encouraged to supply data on uptake of their products in the NHS from any projections they have prepared, at their own discretion, indicating which data should remain as commercial in confidence.
Regulatory	
Licensed indication	Companies are requested to provide to NICE the text of the licensed indication for which regulatory approval is being sought in the UK. This information will be treated as commercially confidential, if the Company requests this.
Timing	Companies are requested to provide to NICE (expected) timing of steps for regulatory approval in the UK: particularly, and if applicable, the date of CHMP opinion, the date of receipt of marketing authorisation and any delay incurred at clarification. Companies are also requested to state whether the date of 'launch' of the product in the United Kingdom is different from the date of the marketing authorisation. The launch date will be treated as commercially confidential if the Company requests this.
SmPC & EPAR	Whilst both the final SmPC and final EPAR are public documents, draft versions will not be published because changes may take place right up to the date of regulatory

	approval. The final SmPC and EPAR are available in the public domain and cannot be regarded as commercial or academic in confidence.

Implementation

It is recognised that the implementation of this agreement will be predominantly a matter of interest between the individual marketing authorisation holder and NICE. It is also recognised that the interests of the pharmaceutical industry encompass both manufacturers of products under appraisal, and manufacturers of products which may be displaced as a result of an appraisal. NICE expects companies to try to act reasonably, and not, for example make demands as a manufacturer of a competing product which they would object to as a manufacturer of a new product. Where disagreements arise NICE may, on occasion request the ABPI to assist in finding a mutually agreeable solution.

NICE accepts an obligation of confidentiality in relation to commercial in confidence information and academic in confidence information supplied to it during a health technology appraisal. If NICE receives a request for disclosure of such information pursuant to the Freedom of Information Act 2000 it will consult the owner of the information in question in a timely fashion to enquire if the information remains commercial in confidence or if the owner is content for the information to be released

This agreement supersedes the previous agreement issued in October 2003 with effect from 1 May 2011.

Note on patient access schemes and flexible pricing arrangements

A separate agreement will be drawn up to address the arrangements for patient access schemes and flexible pricing.