Healthcare Improvement Scotland | SMC Advice on new medicines

Release of Company Data

Agreement between the Association of the British Pharmaceutical Industry (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

NHS SCOTLAND

Published July 2018

www.scottishmedicines.org.uk

Principles

1. SMC and ABPI acknowledge that, while it is in the interests of patients generally for all relevant information about medicines being assessed by SMC to be put into the public domain, the rights of the owners of the data must also be respected.

2. SMC has made a commitment not to release into or use in the public domain any information provided to it during an SMC appraisal prior to the launch of the relevant medicine(s) into the UK market.

3. For the purposes of this Agreement, commercial-in-confidence (CIC) information is information provided in confidence relating to the commercial interests of the owner of the information and Academic-in-Confidence (AIC) 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 AIC is going to be published at some stage and that a timeline for publication can be given.

4. The amount of information submitted 'in confidence' by pharmaceutical companies should be kept to a minimum. The whole submission may not be marked confidential and 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', and SMC will only treat information in confidence if the material is in fact CIC or AIC.

5. When marking data as confidential, pharmaceutical companies should indicate if this status will apply at the time SMC anticipates presentation/publication of the data. The last opportunity for pharmaceutical companies to review the confidential status of submitted information, to the extent it is incorporated in the draft Detailed Advice Document (DAD), is at the time of commenting on the draft DAD following the New Drugs Committee (NDC) meeting. However, when undertaking such review pharmaceutical companies must apply Principle 4 above.

6. For all unpublished clinical data submitted as AIC or CIC, the minimum that should be available for release is that which normally would be included in a CONSORT compliant abstract and be suitable for public disclosure. An equivalent approach is required for economic data and models if marked AIC or CIC.

7. In circumstances where SMC wishes to publish data regarded by the data owner as AIC or CIC, both SMC and the data owner will negotiate in good faith to seek to find a mutually acceptable solution, recognising the need for SMC 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.

8. AIC information may be presented verbally during the public sessions of the SMC 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 CIC information, the data owner retains the responsibility for its release into the public domain and retains the right to make a final decision in relation to the release of information held in confidence into the public domain.

10. SMC will normally disclose a short description of the economic models provided by pharmaceutical companies in their submission 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 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.

11. It should be noted that SMC's critique of the clinical and economic evidence, as summarised in the final DAD, is owned by SMC and pharmaceutical companies may not mark complete sections of the DAD as confidential pursuant to Principle 4 above. Only information in the DAD, which may legitimately be marked as confidential, based on application of the Principles set out in this document, may be identified as such.

12. It is acknowledged that the principles in this document apply to licence extensions as well as new chemical entities.

Guidelines

Data	Position
Clinical and economic data	The amount of information submitted on an in confidence basis should be kept to a minimum, applying only to information that is genuinely confidential. It is unacceptable to mark the whole submission, complete sections and/or full tables as confidential. 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, can no longer be regarded as confidential but only to the extent that it is already in the public domain
Unpublished data	<u>Study design</u> ABPI policy encourages voluntary registration of specified information relating to the protocols of phase III trials involving patients in the UK and the current publication status three months after marketing in the first major market and prospective registration of phase IV and PASS studies relating to that product
	<u>Unpublished results</u> Pharmaceutical companies will authorise SMC to quote publicly from either a full report or an abstract of unpublished trials, where the date of release by SMC 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 SMC and the pharmaceutical company in the event that the licensing authority “fast track” any application.
Price	
	Pricing information will not be released by SMC into the public domain before product launch in the UK. It is acknowledged that final pricing is often only determined immediately prior to launch.

SPC and EPAR	
Draft	Both the SPC & EPAR are public documents and will come into the public domain only by the regulatory authority. A draft version cannot be published as changes may take place even in indication right up to a late stage.
Final	Public documents
Economic analysis	
Published	Any information, once published even in abstract form, can no longer be regarded as confidential but only to the extent that it is already in the public domain.
Unpublished	Pharmaceutical companies will authorise SMC to quote publicly from either a full report or an abstract of unpublished analyses, where the date of release, by SMC, 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 SMC and the company in the event that the licencing authority "fast track" any application leading to SMC requiring earlier publication.
Economic model	Pharmaceutical companies shall normally agree to their economic models being available in electronic form for the purposes of a SMC appraisal. The model will be supplied in confidence and held as such by the SMC provided always that Principle 10 above shall specifically apply to any decision made by SMC about availability of economic models.
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.

You can read and download this document from our website.
We are happy to consider requests for other languages or formats.
Please contact our Equality and Diversity Advisor on 0141 225 6999
or email contactpublicinvolvement.his@nhs.net

Scottish Medicines Consortium
Healthcare Improvement Scotland

Edinburgh Office
Gyle Square
1 South Gyle Crescent
Edinburgh
EH12 9EB

0131 623 4300

Glasgow Office
Delta House
50 West Nile Street
Glasgow
G1 2NP

0141 225 6999