

Final Version 131103

Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the Scottish Medicines Consortium (SMC) on guidelines for the release of company data into the public domain during a health technology appraisal

Principles:

1. SMC and ABPI acknowledge that while it is in the interests of patients generally for all relevant information about products being appraised 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 product(s) into the UK market
3. Any reference in this Agreement to abstracts shall assume the adoption of the CONSORT rules for trial reporting and abstracts in relation to clinical trials, and an equivalent standard for reporting economic models.
4. In circumstances that warrant publication of data regarded by the data owner as confidential, or the non-publication of data normally available for publication in accordance with these guidelines, both parties 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 determine a global publication strategy.
5. It is recognised that in all cases the data owner retains the right to make a final decision in relation to the release of information held in confidence into the public domain.
6. It is acknowledged that the principles in this document apply to licence extensions as well as new chemical entities.

Data	Position
Clinical trial evidence	
- published	Any information, once published even in abstract form, can no longer be regarded as commercial in confidence but only to the extent that it is already in the public domain
- unpublished - design	ABPI policy encourages voluntary registration of specified information relating to the protocols of phase III trials involving patients in the UK and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 SAMM studies relating to that product
- results	Companies will authorise SMC to quote publicly from either a full report or an abstract of unpublished trials, where the date of release, by SMC, of data from such reports/abstracts is not less than 12 months after the sign-off by the company of the trial report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 company in the event that the licencing 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.

Draft SmPC & EPAR	Whilst both the SmPC & 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 the last minute
Final SmPC & EPAR	Public documents
Economic analysis	
- published	Any information, once published even in abstract form, can no longer be regarded as commercial in confidence but only to the extent that it is already in the public domain.
- unpublished	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.
- model	Companies shall normally agree to their economic models being available in electronic form for an independent academic group for the purposes of a SMC appraisal. The model will be supplied in confidence and subject to suitable intellectual property protection. The terms of Principle 4 above shall specifically apply to any decision about availability of economic models. Similar arrangements apply to models produced as part of a SMC assessment, by agreement with the model developers.
Budget/resource impact (including marketing/sales forecasts)	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 commercial in confidence.