View from the inside - the pharmaceutical industry

Bringing medicines to *life*

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Our Shared Aim

To provide the highest quality evidence base possible to Appraisal Committees to support making the right decisions about medicines for NHS patients

- *which touches the lives of each of us*

Background

- Evidence base for medicines is changing with UK regulatory authorities permitting new medicines to be made available to patients earlier with a consequent reduction in the evidence base

- Pharmaceutical pipeline is changing with medicines now targeted at smaller numbers of patients with a different evidence base

- Important to have *appropriate* challenge of the evidence (clinical and cost-effective) in the context of uncertainty

- Many stakeholders involved

Potential inefficiencies and challenges

- Volume of clarification questions issued by ERGs – are all of these required? What are the key issues?
- Clarification questions need to be answered in a two week period – although a process issue, the volume of requests in combination with short turnaround can prove challenging
- Rational, level of appropriateness or importance of the question is often unclear
- Additional analysis or reworking of existing data sets – this can be quite complex if there need to be a rework of source clinical data (appreciate that the same individuals are also working on the regulatory filings in different countries)
- ERG sometimes conduct new analysis with little time for parties involved to fully consider the quality or implications of the work meaning that AC may make decisions based on information that has not been subject to review and quality control issues

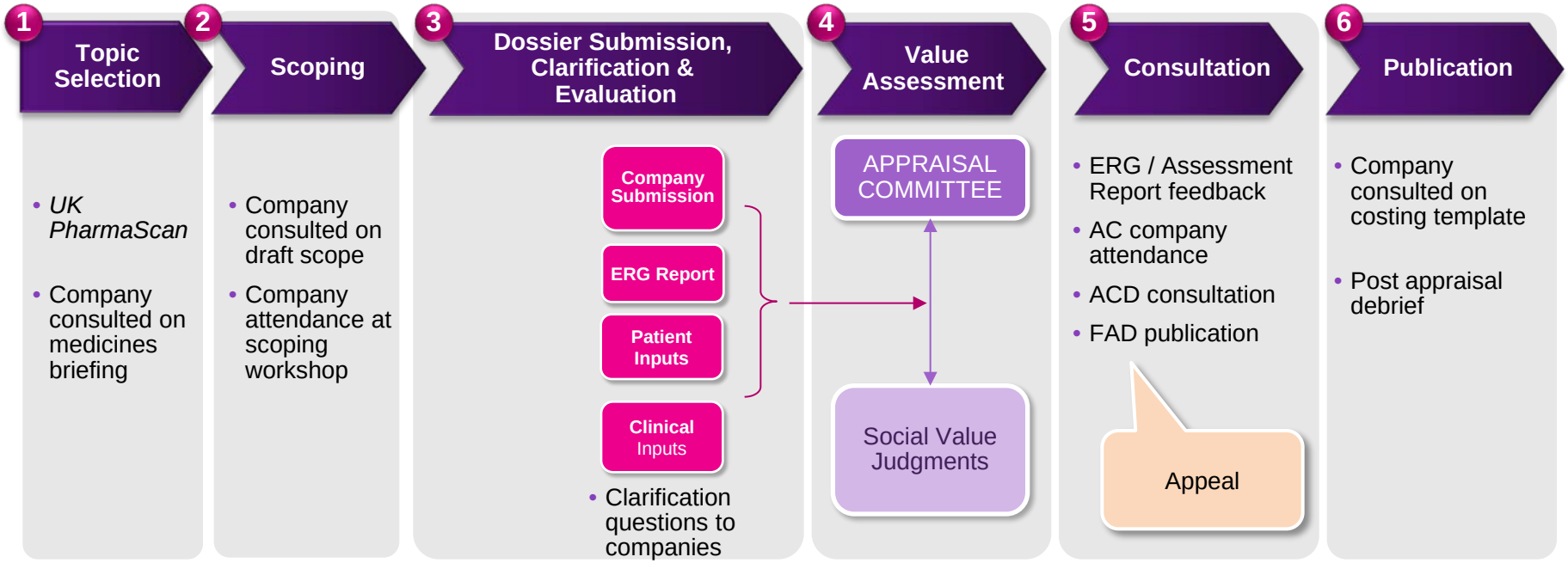
Predictability and consistency

- While we appreciate the need for TAR groups to remain autonomous, they often adopt their own evidence evaluation leading to inconsistency unpredictability between the groups
- Model modifications / analyses by ERGs is sometimes not shared with manufacturers
- Committees making decisions based on information that has not had appropriate review

Proportionality & Targeting

- The scope given to ERGs when critiquing company submissions can mean the ERGs pursue a wide range of avenues of enquiry
- Clarification questions from ERGs can be difficult to understand and lead to significant additional work for companies and TAR groups

Earlier and more meaningful dialogue between ERGs / TARs and companies would be helpful across the process



View from industry

Solutions

- ERG attendance and active participation in the decision problem meeting
- Earlier and greater engagement and dialogue between ERGs and manufacturers would improve process efficiency throughout
- Meeting or TC with manufacturer & NICE after the clarification questions are issued
- Clear rules of engagement could be developed to address concerns that increased dialogue might compromise independence
- Process for quality control with two way feedback