Table 1. Criteria for assessing whether to include regulatory data of a drug or biologic in a Cochrane review (not in order of priority)

Criteria	Description of criteria
1	Monetary cost of the intervention on the healthcare budget (i.e. considering both the price of a course and the number of people in the population that are being - or will be treated)
2	Burden of disease of the indication this product is meant to treat/prevent
3	Number of people using or likely to use the product
4	Product new to the market
5	Product from a new drug class or has a new mechanism of action
6	Has important interactions with other drugs (e.g. drug-drug interactions)
7	High proportion of RCTs evaluating this product are industry funded
8	Prominent claims of safety and/or efficacy advantage of this product over currently available treatments
9	High degree of media attention surrounding this product
10	High proportion of trials of this product are unpublished
11	Post-marketing surveillance has identified safety concerns
12	Important or standard outcome measures (also known as 'endpoints') have not been published
13	Concerns regarding a lack of published data on potential harms of the product
14	Marketing authorization based on surrogate outcomes (rather than clinical outcomes)
15	When protocol(s) are publicly available
16	When statistical analysis plan(s) publicly available
17	Known errors or concerns about trial publications of this product
18	Important discrepancies between the journal publication and the trial registry entry