Recommendations on a New Model for the Provision of Scientific Advice

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Safe and effective medicines that benefit patients
Drug development requires appropriate scientific standards to ensure safe and effective medicines that benefit patients and a high level of human health protection required by the article 168-1 of Treaty on the functioning of the European Union. These requirements should be defined and made available to drug developers via a public debate.

To inform drug developers about scientific and procedural requirements, the European Medicines Agency (EMA) provides scientific advice (SA) to companies. This activity is supported by European regulation. However, the current model of confidential SA to individual companies does not seem to be the best use of this instrument, but rather results in a number of problems…

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