

## Board of Member States

### Statement on European Reference Networks (ERNs) and industry

November 2016

In recognition of the importance of industry in improving our knowledge of rare conditions and developing clinical tools and therapies, the Board of Member States agrees with engagement between ERN members and industry where appropriate, for example in clinical trials and research projects.

However, there is no legal provision for the involvement of external stakeholders, including industry, in the operation and governance of ERN. To address this issue and to steer ERN in their thinking on engagement with industry, the Board of Member States offers the following guidance:

- \* Conducting some aspects of research and in particular clinical trials will be an integral task of ERNs which may require collaboration with industry. This requires defining in advance the relations with industry so that they will be organised in an open and transparent manner. In particular, access to the data from registries and biobanks has to be carefully defined respecting the patients' rights and relevant national and European legislation.
  - \* A complete transparency policy should apply to the relationship between ERNs and industry.
  - \* Industry stakeholders cannot have a place in the governance structure of an ERN.
  - \* There must be no industry funding of any operational ERN activity (e.g. activities such as, but not exclusive to: the management and running of the network, meetings of the members, development of diagnostic guidelines etc.)
  - \* Each designated ERN should establish a charter endorsed by all its members, to define its own Conflict of Interest Policy and ensure disclosure of all financial and non-financial conflicts of interest before any engagement commences.
  - \* Conflict of interest policy must respect relevant national and European legislation and follow the recommendations and guidelines developed by independent organisations and recognised bodies.
  - \* Each Healthcare provider (HCP) must respect and follow the national legislation relating to conflict of interest.
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