



## Establishing a Science-based Societal Learning Mechanism and understanding of nanomedicine



### Key Points

- In order to **enable responsible innovation** in nanomedicine, the regulatory framework should facilitate a **scientifically based societal learning process**, i.e. by being flexible enough to allow society to acquire, exchange and accumulate knowledge and experience in dealing with a new technology.
- For effective implementation of the existing regulatory framework, there is a need for **better coordination and harmonisation of regulatory procedures**, especially those on **reporting and data collection**.





## Summary and Recommendations

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### Key Points (cont.)

- Essential to the responsiveness of the regulatory framework are early dialogue with users and stakeholders, and differentiated considerations taking into account factors such as national regulatory infrastructures and cultures.
- Regulatory policy for innovative medical products must take into consideration the economic implications of regulation.



## Boosting the effectiveness of existing regulation

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- Better coordination and harmonisation of existing regulatory procedures is urgently needed to facilitate data collection and improve regulatory clarity.
- Priorities are **the clarifying of the regulatory pathway for 'combination products'** (which bear the features of different medical products and even food or cosmetic products), **defining common terminology and relevant data**, and **promoting data collection efficiency**.



## Recommendation 1

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- At the current development stage, regulatory policy should focus on promoting the harmonisation and responsiveness of **existing regulatory systems**.
- The European Commission should establish and promote supporting mechanisms that boost the **effectiveness and responsiveness of the existing regulatory framework**.



## Recommendation 2

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The European Commission should strengthen its efforts to:

- clarify the regulatory pathway and classification of combination products in the EU, and
- actively seek international collaboration to improve consistency between different jurisdictions.



The European Commission should devote efforts to:

- defining common terminology and relevant data in nanomedicine,
- actively supporting the clarification of data requirements concerning safety, efficacy and clinical endpoints for the evaluation of the effect of the products.



The European Commission should:

- take advantage of the merits of recent medical product regulation initiatives (e.g. seek international collaboration in establishing common reporting schemes to promote the efficiency and effectiveness of product authorisation),
- use the Cross-border Healthcare Directive to facilitate data collection on common clinical issues and boost expertise for the clinical application of nanomedicine.



**Recommendation 5**

The European Commission should:

- establish and promote **early dialogue with the different stakeholders** on regulatory issues concerning nanomedicine;
- ensure the **regulatory framework** for nanomedicine is **grounded in users' experience**.

**Recommendation 6**

- **Patients' involvement** in the nanomedicine policy making process should be **institutionalised at both EU and national levels**.



The European Commission should:

- facilitate the accessibility of regulatory expertise by **establishing user-friendly mechanisms**, which
- **encourage early dialogue with regulatory bodies** and regulatory partnership

in order to **facilitate consensus on data requirements**.



The European Commission should:

- Consider the appropriate application of the **subsidiarity principle** in regulating nanomedicine, taking into consideration **national regulatory infrastructures and cultures**. The need for capacity building at national level should also be addressed in EU regulatory policy;
- ensure regulatory policies take into account factors such as the situation in different Member States, different sizes of companies and different types and applications of nanotechnologies.



The European Commission should:

- ensure continued efforts to address and monitor the health and environmental impact of nanomedicine, including
- improving awareness of environmental, health and safety issues of nanomaterials, both in hospitals and in nanomedicine companies.



The European Commission should:

• **support institutional mechanisms that facilitate a common perspective** with respect to clarity, objectivity and common practice for credibility and authority, e.g. **joint efforts on development of testing protocols, standards and best practice.**



### **Economic implications**

Regulators should take into consideration the economic implications of regulation for nanomedicine, including:

- impact on timeline, insurability
- funding support needed for access to regulatory expertise
- extra compliance investment, especially for SMEs and academic institutions.



## **NanoMed**

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**Stewart Brand, editor of Whole Earth Catalog, recently summed up our mishandling of modern biotechnology:**

**"The environmental movement has done more harm with its opposition to genetic engineering than with any other thing we've been wrong about.**

**We've starved people, hindered science, hurt the natural environment and denied our own practitioners a crucial tool."**

**Let's try to avoid repeating these mistakes with nanotechnology and nanomedicine.**

