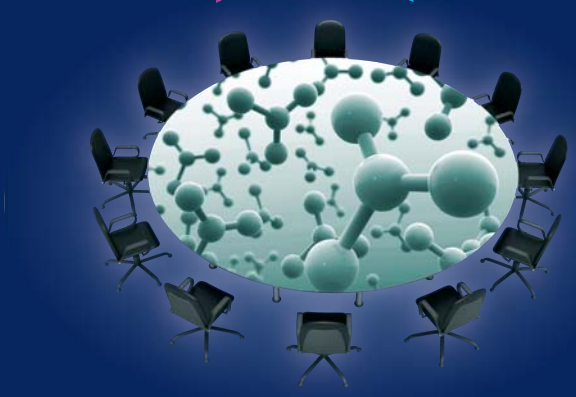
NanoMed

A report on the nanomedicine environment

ECONOMIC
REGULATORY
ETHICAL & SOCIAL
PATIENTS
PUBLIC COMMUNICATION



NanoMed Round Table

SEVENTH FRAMEWORK PROGRAMME

Overview

Nanomedicine is the application of nanotechnology in medicine and healthcare, at the molecular level. To put this in context, the molecules in our bodies and the structures inside our cells operate at the scale of about 100 nanometres or less - a nanometre is one-billionth of a metre.

Although very promising, nanomedicine may add new dimensions to many ethical, societal and economic issues. For the promises to be realised and to achieve the maximum benefit of nanomedical innovations for everyone, the way has to be paved for a safe, integrated and responsible approach to nanomedicine. This will also be a necessary condition for the sustainable competitiveness of nanomedical research and development in Europe, and of its healthcare industry. It is therefore of primary importance to understand the possible impacts and consequences of nanomedicine in advance.

The NanoMed Round Table brought together expert stakeholders from across Europe within five Working Groups, each of which considered a specific field highly relevant to decision-making regarding nanomedical innovations.

The Groups' key findings were as follows:

- **Patients' Needs** – **Our research shows that patients want nanomedicine and they want to know more about it from reliable sources. The European Commission, national governments, and trade and research associations all have a role to play in ensuring dialogue with, and information provision to, patients.**

- **Ethical and Societal Aspects** - **Ethical engagement with nanomedicine needs to begin with the very concept of 'nanomedicine', a word that now groups diverse research activities together. Nanomedical researchers, physicians, patients, and policy makers will all benefit when, on the basis of philosophical and social analysis, the programme and purpose of nanomedicine are better understood and more clearly defined.**

- **Economic Impact** - **Reliable data is needed to predict the impact of nanomedicine on healthcare costs and benefits, and market growth. This information is required to enable the EMEA to make decisions on early interventions and national authorities to make reimbursement decisions.**

- **Regulation** - **A proactive regulatory system is required that ensures better coordination and harmonisation of regulatory procedures, early dialogue with users and stakeholders, and takes account of the economic cost implications of regulation. Given its recently enhanced role, it seems reasonable to suggest that DG SANCO should take the lead in encouraging European level regulatory bodies to achieve this aim. At Member State level, national governments should encourage national regulatory bodies to take similar action.**

- **Communication** – **The European Commission should provide credible and accessible sources of balanced information about nanomedicine, to facilitate understanding and dialogue.**

Nanomedical applications are not just a theoretical possibility – for example, the Round Table has identified forty-five products that are already on the market . However, the field of nanomedicine is still a relatively new one. This means that as this report is published, Europe is at an ideal moment to consider the impacts and consequences of nanomedicine, as well as action required as a result.

Several factors serve to underline the particular relevance and timeliness of this report. The recently enhanced role of DG SANCO, and the European Commission's anticipated strategic Action Plan for Nanosciences and Nanotechnologies 2010-2015, rank among these. Another factor is the scale and depth of impact that nanomedicine may deliver, which should not be underestimated. Nanomedicine is enabling us to take a significant step forward in understanding and treating disease, by shifting attention to the molecular level.

As well as adding another layer to healthcare, nanomedicine also presents us with arguably the best case study of changing business models in terms of the move from curative to preventive medicine. In the context of health being viewed increasingly as 'well-being' rather than 'absence of disease', nanomedicine may have much to contribute.

Nanomedicine is also covering new ground in that it is combining many previously unconnected disciplines, such as economics, supply chain and insurance, to name but a few. This convergence of different fields means that we need to be very clear about where and how we start thinking about the impact of nanomedicine.

For all of these reasons, not taking action now would be a wasted opportunity. By doing nothing, we would significantly risk blocking the development of innovative procedures in Europe, to the detriment of European research and development, the healthcare industry, and, most importantly, patients.

It's never too early to act until it's too late.

[1] US National Institutes of Health: http://nihroadmap.nih.gov/nanomedicine

[2] The European Medicines Agency, whose "main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use": www.ema.europa.eu

[3] The European Commission Directorate General for Health and Consumers

* Ref. Economic Impact Working Group

Summary of Recommendations

Communication and Dialogue About Nanomedicine

The European Commission should:

- establish a platform to provide credible and accessible sources of balanced information on the methods, benefits and risks of nanomedicine.
- investigate funding opportunities for EU level trade and research associations to produce lay information using stakeholder dialogue on nanomedicine research.
- support patient organisations to investigate whether nanomedicine is currently/potentially useful in treating their condition (with a view to their providing balanced information to patients if so), and provide funding to identify and understand the issues that it raises for them.
- develop communication guidelines for the various nanomedicine stakeholders, and provide good practice examples.

The European Commission, national governments, industry and independent grant organisations should allocate a significant percentage of financial resources in the field of nanomedicine to public communication.

The European Commission and national funding agencies should integrate public involvement in decision making on priorities in research funding and encourage, train and reward scientists in public engagement activities.

Patient organisations should be involved in the work of the European Technology Platform on Nanomedicine and the "NANOfutures" European Technology Integration and Innovation Platform in Nanotechnology initiative, and be encouraged to participate in governmental stakeholder fora. Patients' involvement in EU and national policy making processes should also be institutionalised.

Parliamentarians at EU and national level should conduct multi-stakeholder hearings, to deliberate in a comparative manner the value of basic nanomedical research for prevention, diagnosis and therapy of disease.

The Potential and Implications of Nanomedicine

The European Commission and national governments should:

- integrate the deliberation of ethical and societal issues with consideration of the feasibility of particular developments in nanomedicine.
- encourage social science and humanities research that goes beyond the risks and benefits of medical innovations to include the consideration of promises, hopes and anxieties.
- support the development of a broader range of methodologies for research on the environmental, health and social implications, and on the ethical, legal and social aspects, of nanomedicine.

Promoting Nanomedicine Research

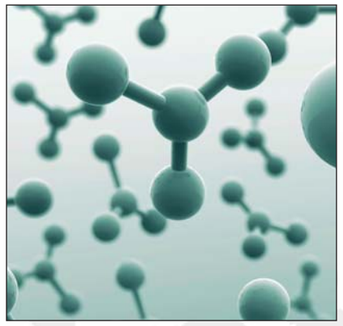
The European Commission and national governments should:

- together with the European Science Foundation and the European Research Council, initiate a deliberative process about the possibly distinctive features of nanomedicine that include its social and ethical dimensions. This process should inform the setting of EU Framework Programme and national research agendas.
- in consultation with patient organisations, continue to discuss priorities for nanomedicine and fund their research and development, encouraging the integration of national nanomedicine strategies to ensure complementarity.
- establish partially public-funded technology-specific reference centres linking early development with clinical research and clinical practice.

Ensuring a Supportive Regulatory Environment for Nanomedicine

The European Commission should:

- establish and promote supporting mechanisms that boost the effectiveness of the existing regulatory framework, especially by harmonising regulatory procedures on reporting and data collection.
- ensure the proportionate responsiveness of regulatory policies through engagement and partnership with users and stakeholders, as well as taking into account factors that differ between Member States (e.g. national regulatory infrastructures and cultures), and monitoring health and environmental impact.
- support institutional mechanisms that facilitate a common perspective regarding clarity, objectivity and common practice for credibility and authority.
- Regulators should take into consideration the economic implications of regulation for nanomedicine and the funding support needed for access to regulatory expertise and extra compliance investment, especially for SMEs.



Nanomedicine in Healthcare Systems

Companies and clinicians should produce data based on well-defined criteria of cost-effectiveness for the economic evaluation of nanotechnology-based innovations in clinical trials and health technology assessment studies.

The European Commission should:

- together with national governments, promote and support projects in partnership with key stakeholders, to assess the cost-effectiveness of nanomedical innovations as early as possible.
- launch a health economics project to assess the economic impact and emergence of new cost models relating to nanotechnological innovations in preventive medicine and the monitoring of chronic diseases.
- provide funding to examine access issues relating to nanomedicine products.
- support further research to work with bodies representing clinicians to gauge awareness of novel possibilities arising from nanomedicine and incorporate these into clinical practice.
- National reimbursement agencies and public and private insurers should establish a European working group to consider the future impact of innovative approaches in healthcare systems with nanotechnology as a case study.

Nanomedicine in a Global Context

The European Commission should:
share the NanoMed Round Table's conclusions with international expert groups to improve European and international strategies for maximising the positive economic impact of nanomedicine together with national governments, involve low-income countries in developing a fair and sustainable global policy on benefit sharing in nanomedicine.

Patient Views and Understanding of Nanomedicine

Report of a Pilot Study by the Patients' Needs Working Group of the NanoMed Round Table

Summary and Recommendations

KEY POINTS

Patients have relatively low levels of knowledge and awareness of nanomedicine, but they would like more information.

Despite this low level of knowledge there are high levels of support among patients for nanomedicine products and research.

Patients have clear views on how and from whom they would like to receive this information.

Patients do not think that nanomedicine is inherently unsafe, but there is a lack of clear understanding about the potential safety aspects.

Nanomedicine is an opportunity that patients want to see embraced. Equally, there is a significant and time-critical opportunity to inform patients about it.

Patients' Awareness of Nanomedicine

There is low awareness and knowledge of nanomedicine among patients and patient organisations, even in condition areas where it is being used. The overwhelming majority of patients would like to receive more information on nanomedicine, ideally via the internet, from patient organisations and/or clinicians.

Recommendation 1
The European Technology Platform on Nanomedicine and "NANOfutures" European Technology Integration and Innovation Platform in Nanotechnology, together with the European Patients' Forum, should explore the involvement of patient organisations in the work of the Platforms, to provide input from patients' perspective and improve patients' understanding of nanomedicine. For these reasons, patient organisations' views should also actively be sought as part of any other nanomedicine strategy development at EU level.

Recommendation 2
The European Commission has produced much useful information on the internet on nanotechnology aimed at the general public, e.g. short films, leaflets and brochures. It should organise the production of similar lay information on nanomedicine, which could be used by patient organisations, clinicians and the media.

Recommendation 3
European-level trade and research associations should produce lay information using stakeholder dialogue on nanomedicine research. National-level trade and research associations should disseminate this information in their country's language(s) to patient organisations, media and bodies representing clinicians. The European Commission should investigate what existing programmes should or could fund this, and/or develop new funding streams where required, e.g. science and society programmes or European Science Foundation.

Recommendation 4
Patient organisations should be supported by the European Commission to investigate whether nanomedicine is currently or potentially useful in treating their condition, and if so to enable engagement in nanomedicine with a view to providing balanced information to patients and carers.

Recommendation 5
The European Commission, working with the European Patients' Forum, should identify and engage with patient organisations that already communicate to their members on nanomedicine, and work with them to produce a 'best practice' case study and toolkit (e.g. FAQs, webpages, short files) to help guide and support other patient organisations.

Patient Support for Nanomedicine

The majority of patients view nanomedicine as a technology that could address many unmet medical needs and they support nanomedicine research.

Recommendation 6
The European Commission and national governments in consultation with patient organisations should continue to discuss priorities for nanomedicine and fund their research and development. To ensure complementarity and avoid duplication, the European Commission should encourage the integration of national nanomedicine strategies.

Safety and Risk

Patients do not view nanomedicine as inherently unsafe, but there is a lack of clear understanding about the potential safety aspects that may be unique to it. This should be addressed through appropriate safeguards and the communication of information. Patients have mixed views on whether nanomedicine is different from other new types of medical research.

Recommendation 7
Where governments have organised stakeholder fora to discuss the potential risks and benefits of nanotechnologies including nanomedicine, they should encourage patient organisations to participate. Where such fora do not exist, governments should urgently consider establishing them.

Recommendation 8
The European Commission should provide funding for focus groups and other participatory methods (e.g. citizen conferences, interviews, surveys) in a number of European countries, to identify and understand the spectrum of issues that nanomedicine raises for patients and their families.

Access and Clinical Preparedness

Further research is desirable on access to nanomedicine products and clinical preparedness.

Recommendation 9
The European Commission should provide funding for a project examining access issues relating to nanomedicine products (diagnostic and therapeutic).

Recommendation 10
The European Commission should support further research to work with bodies representing clinicians and other healthcare professionals to: a) gauge awareness of novel possibilities arising from nanomedicine and incorporate these into clinical practice, and b) assist CPD/CME (Continuous Professional Development/Continuing Medical Education) to anticipate novel possibilities and formulate appropriate responses.

The full report and annexes can be viewed and downloaded at www.nanomedroundtable.org

Summary and Recommendations

KEY POINTS

Ethical engagement with nanomedicine begins with the very concept of 'nanomedicine', a word that now groups diverse research activities together. Nanomedical researchers, physicians, patients and policy makers will all benefit when, on the basis of philosophical and social analysis, the programme and purpose of nanomedicine are better understood and more clearly defined.

The discussion of ethical and societal questions about nanomedicine must be informed by consideration of the feasibility of nanomedicine applications.

As well as the significance of nanomedical innovations, promises, hopes and anxieties should also be considered.

Low-income countries must be involved in the development of fair and sustainable global policy on benefit sharing in nanomedicine.

Approaching Nanomedicine: Ethical and Societal Issues

Questions which hitherto have become central to reflection on nanomedicine include:

The 'right not to know' – The development of nanotechnologically-enabled diagnostic tools is likely dramatically to widen the gap between diagnostic capability and available therapies. What rights and means do citizens have not to know, or make known, the results of diagnostic tests?

The ethics of human enhancement - How should we determine the permissibility and regulation of interventions that could be applied beyond the therapeutic contexts to enhance individuals' physical and mental capabilities?

Demographic effects - The Nano Cancer Initiative of the US National Institutes of Health has claimed that, by 2015, no one will suffer or die from cancer. Although this seems unrealistic, such a drastic decrease of mortality would have a considerable impact on social security systems.

Such questions focus on applications (e.g. new diagnostic tools or brain-machine interfaces) which are envisioned by various promoters of nanomedicine and which resonate powerfully within popular culture. Their discussion relies upon the assumption that such applications are realistic in the short or medium term.

Recommendation 1

Since the discussion of implications of hypothetical but unlikely products is unhelpful, the European Commission and national governments should integrate the deliberation of ethical and societal issues with consideration of the feasibility of particular nanomedicine developments. This requires assessment of the visions driving nanotechnological developments, as well as historically and theoretically informed analyses of the cultural tendencies, societal aspirations, and commercial trends that influence nanotechnology for medicine and health.

Recommendation 2

The European Commission and national governments should support the development of a broader range of methodologies for research on the environmental, health and social (EHS) implications and the ethical, legal and social aspects (ELSA) of nanomedicine.[1] This requires the explicit formulation of the criteria used to determine what is relevant for public deliberation.

Scientific and Technological Ambitions of Nanomedicine

Nanomedical research is hugely ambitious. In the search to understand and treat disease, it shifts attention beyond the cellular to the molecular level, and seeks to control a pathway from the molecular level right up to patients' and physicians' daily routines. Analysis of the scientific and technological ambitions of nanomedical research directs us to a view of nanomedicine as, primarily, basic research on the understanding, diagnosis and treatment of disease.

Moreover, the lack of a clear-cut definition of 'nanomedicine' could be an opportunity to configure nanomedical research so as to mark a departure from 'business as usual'. Some prominent actors in the field suggest that the novelty of nanomedicine is its adoption of a 'bottom-up' approach which draws on principles of self-organisation and on systems theory more generally. Accordingly, nanomedicine might be defined, for funding purposes, as medical research grounded in systems biology. The notion of the system encompasses many orders of magnitude, from the molecular level all the way up to societies and healthcare services, so this definition affords a unique opportunity to incorporate ethical and societal perspectives into the research process.

Recommendation 3

The European Commission's Research Directorate-General, the European Research Council and the European Science Foundation together with national funding agencies and research ministries, should initiate a deliberative process about the possibly distinctive features of nanomedicine that include its social and ethical dimensions. This process might include the development of roadmaps and should inform the setting of EU Framework Programme and national research agendas, and engage the scientific communities and their governing bodies, including academies of science.

Nanomedicine is the subject of high expectations and considerable public investment, but has yet to prove itself. In order to assess the value of basic nanomedical research, we might ask where a nanomedical approach is most productive and beneficial for researchers, healthcare systems and societies.

Recommendation 4

Parliamentarians at EU and Member State level should conduct multi-stakeholder hearings that encompass public and world health advocates and patient groups. The aim should be to deliberate in a comparative manner the value of basic nanomedical research for prevention, diagnosis and therapy of disease. Scientific input should be provided from fields as diverse as medical anthropology, international law, bioethics and cancer research. Such hearings will focus and strengthen nanomedical research and raise public awareness of its possibilities and expectations.

Changing Conceptions of Medicine and Health

Health used to be defined as 'normal functioning', or as the absence of disease, but is now increasingly viewed as 'well-being', or as living to the fullness of one's capacities. Irrespective of whether and when nanomedical research lives up to its scientific and technological ambitions, it is already a part of these developments. A host of issues arises where commercial interests and medical research intersect. Nanotechnologically-enabled diagnostic tools, for example, expand possibilities of self-diagnosis and self-treatment, contributing to a reorganisation of medical expertise. At the same time, the marketing of diagnostic capabilities empowers individuals but also exploits their vulnerabilities and anxieties.

Recommendation 5

The European Commission and national governments should encourage social science and humanities research that goes beyond the risks and benefits of medical innovations to include the consideration of promises, hopes and anxieties. Such research should assess the emerging divisions of roles and responsibilities between patients, physicians, hospitals, e-health information systems, insurers and consumers. It should also identify safeguards that could and should be provided by public health care systems.

If health is defined as the absence of disease or as normal functioning, it is an unevenly distributed public good. However, when it is defined more broadly as living to the fullness of one's capacities, the gap between rich and poor countries widens further, broadening responsibilities and opportunities for benefit sharing.

Recommendation 6

The European Commission and national governments should create ways of involving low-income countries in the development of a fair and sustainable global policy on benefit sharing in nanomedicine. Avenues for this might include international organisations such as UNESCO[2] and bodies which work towards and monitor the implementation of the United Nations Millennium Development Goals[3].

The full report and annexes can be viewed and downloaded at www.nanomedroundtable.org

1 This includes calls for research on foresight and technology assessment of nanomedical developments, as well as the design and evaluation of public engagement exercises.
2 United Nations Educational, Scientific and Cultural Organization
3 www.un.org/millenniumgoals

Economic Impact

A Report by the NanoMed Round Table Economic Impact Working Group

Summary and Recommendations

KEY POINTS

Reliable data is needed to predict the impact of nanomedicine on healthcare costs and benefits, and market growth.

If urgent action is not taken, the current lack of data and economic models will hinder the development of nanomedicine in Europe.

Early health economics assessment is crucial to recognise the potential applications of nanomedical innovations as early as possible and therefore enable maximum patient benefit.

The future impact of nanotechnology innovations in healthcare systems, and their added value in preventive medicine should be assessed.

Action is required to ensure the effective organisation of nanomedicine in Europe and Europe's competitiveness in the face of worldwide competition.

The Importance of Assessing the Economic Impact of Nanomedicine

The potential of nanomedicine to diagnose, treat and prevent diseases has been recognised, but its cost-effectiveness is not well developed in the public framework. Since each Member State applies different reimbursement rules, the lack of data and economic models will hamper the development of nanomedicine in Europe.

How Should the Economic Impact of Nanomedicine be Evaluated?
Nanotechnology will be considered in health economics only if it brings significant added therapeutic value. Data on clinical effectiveness must therefore be acquired prior to any attempt to evaluate economic significance. Societal and economic criteria (going far beyond the cost of treatment) also need to be taken into account.

Measuring and Maximising the Positive Economic Impact of Nanomedicine

Addressing the Current Lack of Data

Up to now health economics studies do not cover innovations coming from nanotechnology, so data regarding the economic assessment of nanotechnological innovations in the healthcare sector is scarce.

Recommendation 1
Companies and clinicians should produce data based on well-defined criteria of cost-effectiveness for the economic evaluation of nanotechnology-based innovations in clinical trials and health technology assessment studies.

Early Health Economics Assessment

Early medico-economic assessment is critical to recognise as early as possible (ideally at the pre-clinical stage) the potential applications of nanomedical innovations; this enables assessment of maximised therapeutic value for patients.

Recommendation 2
The European Commission and national governments should promote and support projects in partnership with health economists, technology developers, clinical researchers, healthcare providers and patient associations, with comparisons across Europe, to assess the cost effectiveness of nanomedical innovations as early as possible.

Reimbursement Issues

When added therapeutic value is clearly demonstrated, e.g. in the case of unmet medical need, reimbursement generally occurs. However, nanotechnology is most often considered as one innovation among others, without recognising its deep impact on the definition of medical practices.

Recommendation 3
National reimbursement agencies, along with public and private insurers, should establish a European working group to consider the future impact of innovative approaches in healthcare systems across Europe, taking nanotechnology as a case study.

Preventive Medicine and Monitoring of Chronic Disease

Nanotechnology applications may offer new solutions for preventive medicine and the growing need for diagnostic and monitoring tools. The added value of nanotechnology for consumer-driven markets in healthcare and well-being must also be considered.

Recommendation 4
The European Commission should launch a health-economics project to assess the economic impact and emergence of new cost models relating to nanotechnological innovations in preventive medicine and the monitoring of chronic diseases.

Effective Organisation of Nanomedicine in Europe

This is critical to avoid false investments, optimise clinical benefits and therefore to maximise economic impact.

Recommendation 5
The European Commission and national governments (especially health and research ministries and bodies) should establish technology-specific reference centres linking early development with clinical research and clinical practice. These centres should be partially publicly-funded.

Worldwide Competition in Nanomedicine

Europe's competitiveness must be ensured at every level of nanomedicine investment, from basic research to reimbursement.

Recommendation 6
The European Commission should share the conclusions of the NanoMed Roundtable with international expert groups in order to improve European and international strategies for maximising the positive economic impact of nanomedicine.

The full report and annexes can be viewed and downloaded at www.nanomedroundtable.org

Regulatory Aspects

A Report by the Regulatory working party of the NanoMed Round Table

Summary and Recommendations

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.

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

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
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
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.

Recommendation 3
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 effect of the products.

Recommendation 4
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), and use the Cross-border Healthcare Directive to facilitate data collection on common clinical issues and boost expertise for the clinical application of nanomedicine.

Ensuring the Responsiveness of Regulatory Policies

This requires, among other measures, meaningful engagement with users and stakeholders.

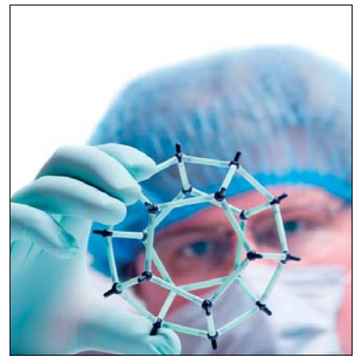
Recommendation 5
The European Commission should establish and promote early dialogue with the different stakeholders on regulatory issues concerning nanomedicine, and ensure the regulatory framework for nanomedicine is grounded in users' experience.

Recommendation 6
Patients' involvement in the nanomedicine policy making process should be institutionalised at both EU and national levels.

Recommendation 7
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.

Recommendation 8
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 to 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.

Recommendation 9
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 (EHS) issues of nanomaterials, both in hospitals and nanomedicine companies.



Establishing Mechanisms of Credibility for Responsible Innovation

Mechanisms that offer credibility and authority are needed to support and encourage responsible practice in the development of innovative products.

Recommendation 10
The European Commission should support institutional mechanisms that facilitate a common perspective with regard to clarity, objectivity, and common practice for credibility and authority, e.g. joint efforts on development of testing protocols, standards and best practice.

The Economic Implications of Regulation

The cost of accessing regulatory expertise and meeting regulatory requirements can present significant barriers to bringing innovative nanomedicine to market.

Recommendation 11
Regulators should take into consideration the economic implications of regulation for nanomedicine, including impact on timeline, insurability and the funding support needed for access to regulatory expertise and extra compliance investment, especially for SMEs and academic institutions.

The full report and annexes can be viewed and downloaded at www.nanomedroundtable.org

Public Communications

A Report by the NanoMed Round Table Communication Working Group

Summary and Recommendations

KEY POINTS

Public engagement and deliberation about nanomedicine at all levels is fundamental if we as a society want to profit from the hopes and promises invested in nanomedicine.

Credible and accessible sources of balanced information must be provided, together with fora to debate and discuss questions about needs, risks, benefits and ethical and social issues relating to nanomedicine to facilitate understanding and dialogue.

Communications know-how needs to be fostered among nanomedicine stakeholders, otherwise the development, introduction and application of innovative nanomedical treatments will be significantly delayed or hindered.

Good communication needs adequate financing – this should be built into all nanomedicine funding.

Defining Nanomedicine and Communication

There is much uncertainty in defining the term 'nanomedicine', not least because this relatively new field is transdisciplinary, blurring established boundaries and combining previously unconnected fields. When considering this report's recommendations this uncertainty must be taken into account, as public engagement and deliberation can only be effective if there is agreement on a common foundation on which to build dialogue.

For the purpose of this report 'communication' also needs to be defined. The goal of any nanomedicine communication strategy must be to initiate public debate, deliberating on both personal and social consequences of innovations and acknowledging that a simple discussion of risks and benefits should only be a starting point for dealing with the complex concerns of a technology-dependent society. Furthermore, the communication requirements of individual members of the public can greatly differ, so it is vital for any successful communication strategy to take the range of understandings and expectations into account.

The Importance of Communicating About Nanomedicine

Communicating about nanomedicine is increasingly important because of its significant potential to raise societal and ethical questions concerning risks and benefits; and have an emotional and material impact (arising from benefits and uncertainties) due to the large number of people affected.

However, there is still a considerable lack of public awareness about nanomedicine. At the same time, social, ethical and legal questions are being raised concerning safety, environmental and long-term effects. The best way to answer the demands of an inquiring public is to develop and implement a strategic approach for active public debate.

Any communication strategy needs to take into account the significant changes in communication methods; for example, the internet and new media are replacing doctors as the primary source of medical information. Communication practices must therefore be continuously innovative in order to reach as wide and varied an audience as possible.

Providing Reliable Information About Nanomedicine

In order to enable patients to make informed decisions, the public needs access to reliable and credible sources of information and fora to debate and discuss questions about needs, risks and benefits as well as ethical and social issues related to nanomedicine.

Recommendation 1
The European Commission should establish a platform to provide credible and accessible sources of balanced information on the methods, benefits and risks of nanomedicine, focusing on the communication needs of patients and the medical community.

Establishing such a platform would make it easier for the public to understand fundamental nanomedical issues, and would also support the communication tasks of stakeholders such as doctors, patient groups and health insurers.

Providing Know-How for Communication About Nanomedicine

The majority of current nanomedical research and development is conducted by small or medium-sized enterprises (SMEs) which often do not have the know-how, staff time and financial resources required for initiating and implementing successful communication strategies. This can significantly delay or hinder the development, introduction and application of innovative nanomedical treatments, to the detriment of nanomedicine's medical and economic impact in Europe.

The communication aspects of the related fields of food and environment must be carefully differentiated, or negative tendencies concerning these fields may have detrimental effects on nanomedicine.

Recommendation 2
The European Commission should develop communication guidelines for the various nanomedicine stakeholders and provide good practice examples. Particular care should be taken to differentiate between the communication aspects of the related fields of food, environment and nanomedicine.

Ensuring sufficient resources for communication is important because inefficient or inadequate communication about nanomedicine can lead, on a small scale, to the rejection of an individual treatment method. On a larger scale, a number of such cases of rejection could lead to distrust and fear of the entire field. The question is how to finance communication in a field which is struggling to define itself and which has long development times and therefore long investment return times, meaning that profits are currently negligible.

Recommendation 3
The European Commission, national governments, industry and independent grant organisations should allocate a significant percentage of financial resources in the field of nanomedicine to public communication. The goal of this financial allocation should be to encourage public engagement, foster dialogue and move beyond the simple discussion of risks versus benefits.

The full report and annexes can be viewed and downloaded at www.nanomedroundtable.org

NanoMed Round Table Participants

Steering Committee

Chair	
Prof Sir John Beringer	Formerly Pro Vice-Chancellor, University of Bristol, Symbiotic Consultancy Ltd, UK
Coordinator	
Prof Julian Kinderlerer	TU Delft, Netherlands/ University of Cape Town, South Africa/ European Group on Ethics in Science and New Technologies
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Serene K. Chi	TU Delft, Netherlands

WP2 Patients' Needs

Chair	
Alastair Kent	Director, Genetic Interest Group, UK
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Avril Daly	Fighting Blindness, Ireland
Laura Gilbert	Rapporteur
Melissa Hillier	Genetic Interest Group, UK
Dr Mahendra Gonsalkorale	Former member of European Parkinson's Association
Lorraine Le Floch	Independent Patient, European Multiple Sclerosis Platform (EMSP)
Sabine Lobnig	European Patients Forum
Rod Mitchell	Chairman, European Crohn's and Colitis Organization (ECCO)
Liuska Sanna	European Patients Forum

WP3 Ethical and Societal Aspects

Chair	
Prof Alfred Nordmann	Technische Universität Darmstadt, Germany & University of South Carolina, USA
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Dr Donald Bruce	Edinethics Ltd., Edinburgh, Scotland
Dr Karin Christiansen	University of Aarhus, Denmark
Prof José Manuel de Cózar	University of La Laguna, Spain
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Prof Uffe Juul Jensen	University of Aarhus, Denmark
Jan Reinert Karlsen	University of Oslo, Norway
Prof George Khushf	University of South Carolina, USA
Dr Thorsten Kohl	Technische Universität Darmstadt, Germany (Researcher, Rapporteur)
Dr Ineke Malsch	Malsch TechnoValuation, Netherlands
Dr Sabine Müller	Universität Bonn, Germany
Prof João Arriscado Nunes	University of Coimbra, Portugal
Prof Jan Helge Solbakk	University of Oslo, Norway
Prof Mariachiara Tallachini	University of Milano, Italy
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WP4 Economic Impact

Chair	
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Dr Bernhard Buehrlen	Fraunhofer Institute for Systems and Innovation Research, Germany
Dr Giorgio Cassara	Don Gnocchi Foundation, Italy
Dr Paul Garassus	Clinique du Tonkin, France
Dr Laurent Levy	Nanobiotix, France
Dr Christine M'rini	Mérieux Alliance, France
Dr Christine Muzel	Philips Healthcare, Netherlands
Prof Reinhard Rychlik	Institute for Empirical Health Economics, Burscheid, Germany
Dr Jürgen Schnekenburger	University Clinic Münster, Germany
Dr Paul Smit	Philips Healthcare, Netherlands
Dr Klaus-Michael Weltring	Bioanalytik-muenster, Germany

WP5 Regulation

Chair	
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Dr Mike Adcock	Durham University, UK
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Serene K. Chi	Delft University of Technology, The Netherlands
Prof Ken Donaldson	University of Edinburgh, UK
Dr Bärbel Dorbeck-Jung	University of Twente, Netherlands
Joel D'Silva	Leuven University, Belgium
Dr Thomas K. Epprecht	Swiss Re, Switzerland
Dr Steffi Friedrichs	Nanotechnology Industry Association, Belgium
Dr Peter Hatto	CEN/ISO, UK
Dr Juergen Hirschfeld	Bayer, Germany
Dr Peter Kearns	OECD, France
Prof Julian Kinderlerer	Delft University of Technology, The Netherlands/ University of Cape Town, South Africa/ European Group on Ethics in Science and New Technologies
Dr Horst Siebold	Siemens, Germany
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Dr Rob Slobbe	Philips, Netherlands
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Participants continued

WP6 Communication

Chair

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Prof Dr Harald Krug	EMPA Materials Science & Technology, Switzerland
Prof Dr Phil Macnaghten	Durham University, UK
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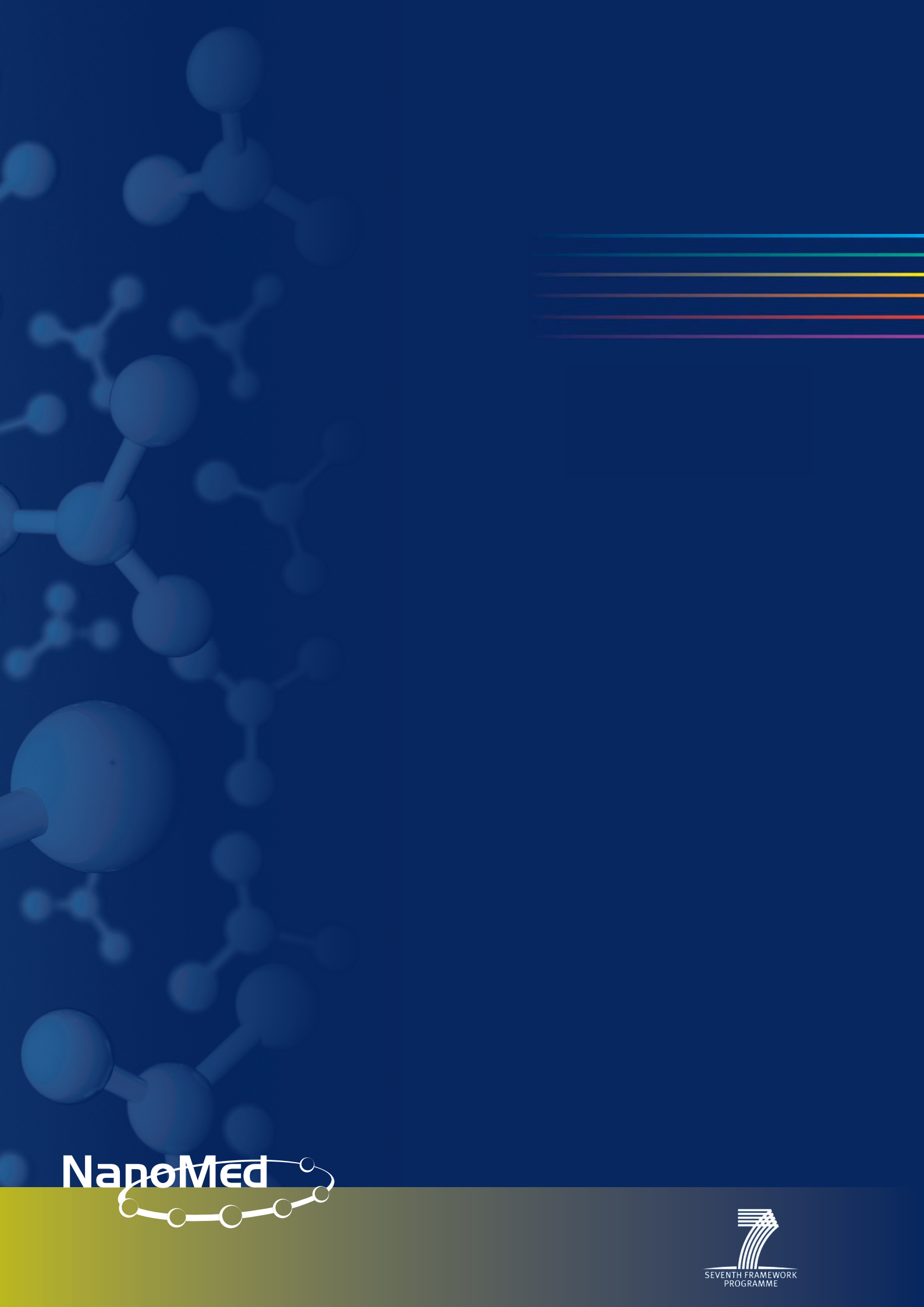
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