



## Opportunities for medical research charities to engage with Europe

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JULY 2011

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**Notice**

This report is intended to provide a broad introduction to the European Union for medical research charities and to raise and discuss some related questions. It should also be noted that this report was written in July 2011 and may not now be fully up to date. As a result, please be aware that AMRC cannot take responsibility for any actions taken with reference to the report. This report is not a substitute for specific legal advice.

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## Abbreviations

AMRC	Association of Medical Research Charities
BIS	Department of Business, Innovation and Skills
CAF	Charities Aid Foundation
CIP	Competitiveness and Innovation Funding Programme
COMP	Committee for Orphan Medicinal Products
CORDIS	Community Research and Development Information Service
DAFNE	Donors' and Foundations Network Europe
DG	Directorates-General
DH	Department of Health
EF	European Foundation
EFC	European Foundation Centre
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
ERDF	European Regional Development Fund
ERA	European Research Area
ERC	European Research Council
ERNOP	European Research Network on Philanthropy
ESF	European Social Fund
ESRC	Economic and Social Research Council
EU	European Union
EURODIS	European Organisation for Rare Diseases
EUROPABIO	European Association for Bio-industries
EUROPLAN	European Project for Rare Diseases National Plans Development
FP7	Framework Programme 7
GDP	Gross domestic product
GNI	Gross national income
IAPO	International Alliance of Patients' Organisations
ICT	Information and communication technology
IMI	Innovative Medicines Initiative
KICs	Knowledge and Innovation Communities
KWF	Dutch Cancer Society
MEP	Member of the European Parliament
MRCG	Medical Research Charities Group
NCVO	National Council for Voluntary Organisation
NGO	Non-governmental organisation
OECD	Organisation for Economic Co-operation and Development
PAWG	Public Affairs Working Group
R&D	Research and development
SME	Small and medium sized enterprise
STI	Science, technology and industry
UK	United Kingdom
UKRO	UK Research Office
US	United States
VAT	Value Added Tax

### Executive summary

Charities are significant funders of medical and health research in the UK – in 2011 AMRC members invested over £1 billion in research<sup>1</sup>, which equates to approximately one third of all public funding. This considerable charitable investment is relatively unique within Europe. Perhaps for that reason, the medical research charity sector does not have a strong pan-European voice in Brussels. This report aims to raise awareness of EU policy, initiatives and institutions so that AMRC and its members may engage more effectively at a European level.

EU activity impacts the UK medical research community. UK law must comply with EU Directives that govern the conduct of research, including clinical trials and research using animals. Further influence comes from Europe-wide strategic research priorities, which guide where EU research funding is invested.

The Europe 2020 strategy puts research and innovation at the heart of Europe's economic growth plan for 2010 to 2020. Medical research can play a key role in this. The medical research sector needs a strong voice to ensure emerging EU policy does not threaten health research and opportunities to promote medical research are exploited.

Despite acknowledging the potential of the charitable sector in promoting research and development in 2005, EU policy does not make the most of this valuable resource. There are however opportunities to change this, and given the size of the medical research charities sector in the UK, there may be potential for the UK to play a key role in championing the sector in Brussels.

Better engagement with the EU and other European organisations by AMRC and its members will also bring added value by opening up funding streams and developing international partnerships.

This report presents an overview of European policy initiatives relevant to UK medical research charities. It explores the research charity landscape in selected EU member states and examines a case study of a successful Europe-wide research coordination strategy for rare disorders.

The report makes the following recommendations to inform the discussion between AMRC, its members and other stakeholders, about how medical research charities can engage more effectively at a European level.

- 1. Gauging AMRC members' appetite for European engagement:** a number of AMRC members are already engaged with EU policy matters, and there may be scope for further research with member organisations to gauge their level of engagement in Europe; whether they have responded to policy consultations, whether they work internationally or have partners and contacts in other Member States, and whether there is an appetite for further information or engagement with EU affairs. The findings

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<sup>1</sup> AMRC research expenditure database, 2010-2011

<sup>2</sup> AMRC research expenditure database, 2010-2011

of this further research could be used to inform the level of priority that AMRC should give to European work.

2. **Encouraging AMRC members to engage in Europe:** while some of the larger members are already engaged in Europe, AMRC could add value to its services by informing all member organisations of relevant EU policy developments. This could be achieved at minimal cost, for example by AMRC signing up to European Commission email alerts and including one European topic (e.g. policy consultations, new research findings, funding rounds) in member briefings, perhaps on a monthly basis. An alternative approach would be to include a European policy page on the AMRC website, though this would require regular updating and maintenance.
3. **Developing links with AMRC's sister organisations:** Ireland and the Netherlands already have umbrella organisations for the medical research charities sector (MRCG and Gezondheidsfondsen). Further engagement with these organisations on European policy would provide opportunities to share ideas and good practice, with the possibility of moving towards co-ordinating positions on EU policy matters; this kind of cross-border co-ordination would possibly carry more weight with the Commission than hearing from national medical research charity organisations individually.
4. **Making contact with European organisations:** whereas it might initially be difficult for AMRC to justify the €1,000 annual cost of associate membership of the European Foundations Centre, the European Network on Philanthropy and Research Funding might offer a more focused route of entry. Attendance at the annual conference would offer opportunities for networking with European partners.
5. **Lobbying in Europe:** Part of AMRC's success in the UK lies in its access to policymakers and legislators in support of members' objectives. AMRC currently does not have the capacity to replicate this work at European level, though PAWG acts as a forum for co-ordinating positions between key AMRC members. Clearly, AMRC does not have the resources or the political capital to create an equivalent organisation at a pan-European level. However, consultative networks for feeding civil society views into the European Commission are well established in Brussels, and AMRC could investigate plugging into one of these networks, either through an existing organisation such as the European Foundations Centre, or through seeking membership of a consultative body such as the European Health Policy Forum.

Similarly, establishing contact with UK Members of the European Parliament (MEPs) with an interest in the medical research, the charities sector and health, research and innovation policies could prove useful in terms of raising their awareness of AMRC's work and cultivating potential champions for the medical research charities sector in the European Parliament. This could be prioritised in terms of identifying MEPs who have spoken in health debates, asked parliamentary questions on medical research or have a scientific or medical background before their election as an MEP. However, this kind of lobbying and awareness-raising would have significant cost implications for AMRC in terms of the policy work required and possible attendance at meetings and conferences in Brussels and elsewhere.

6. **Using academic research:** academic research can help demonstrate the added value of philanthropy to policy objectives and, with particular regard to AMRC's agenda, how philanthropy can assist medical research. Academic research networks on

philanthropy include ERNOP in Amsterdam/Utrecht and UK contacts at City University: it would be worth making contact with these academics as a means of keeping up with existing research literature and influencing future research programmes on philanthropy.

- 7. Drawing on others' expertise and experience:** before committing to a particular approach, AMRC could look at how others have gone about engaging with Europe, what has been successful and what pitfalls are to be avoided. NCVO, CAF and other charities could prove helpful and making contact with the DH and BIS international policy directorates as well as the UK national contact points for Framework Programme 7 could also provide useful pointers.

### Introduction

The Association of Medical Research Charities (AMRC) is the membership organisation of the leading medical and health research charities in the UK. Working with our member charities and partners, we aim to support the sector's effectiveness and advance medical research by developing best practice, providing information and guidance, improving public dialogue about research and science, and influencing government.

Formally established in 1987, AMRC now has 123 member charities, which together invested over £1 billion in medical research in 2010-11<sup>2</sup> aimed at tackling diseases such as heart disease, cancer and diabetes, as well as rarer conditions like cystic fibrosis and motor neurone disease.

This report is the product of a three-month research internship funded by the Economic and Social Research Council (ESRC). The aim of this report is to raise awareness of policy developments at EU level which are likely to be of interest to AMRC and its members. The report provides information on research and innovation policies, funding programmes, health initiatives and developments in other EU Member States, as a means of starting a discussion on the extent to which involvement in EU policy could contribute to AMRC objectives.

The first section of the report offers an overview of policy initiatives at European level which are relevant to AMRC and its membership. The report then looks at the small body of research on giving and philanthropy in Europe before presenting short case studies on selected EU member states, chosen to reflect the diversity of the EU's 27 Member States. The fourth section of the report presents a case study of rare diseases as a policy area where there has been significant activity at the European level, before concluding with some sources of further information and recommendations for AMRC.

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<sup>2</sup> AMRC research expenditure database, 2010-2011

# EU infrastructure and policy developments

## 1. EU infrastructure and policy developments

### Key messages

- AMRC's policy agenda chimes with a number of EU policy priorities. These include; encouraging research and innovation, the competitiveness and wellbeing agendas, engaging with civil society, policy networking, patient involvement and cross-border issues in healthcare (e.g. rare diseases)
- The EU has acknowledged the contribution of the charity and foundations sectors to research activity. However, progress so far at EU level has been limited to declaratory statements about the role of the sector
- The particularly well-developed medical research charity sector in the UK means that the UK could play a prominent role in developing networks and taking forward the interests of the sector at EU level
- There are opportunities for the medical research charity sector to contribute to policy and to access EU funding opportunities

This first section of the report focuses on the institutions, policies and programmes which are relevant to research and the charities sector, and considers current policy developments at EU level. The European Commission's 2005 report on philanthropy and research is taken as a useful starting point for considering the potential impact of EU policy on the medical charities sector and is followed by an overview of policy initiatives including the 2011 Commission Green Paper on research and innovation, and the current call for health research proposals under Framework Programme 7.

This exploratory research into EU policies and their potential impact on the medical research charities sector highlights a great deal of fragmentation and heterogeneity in the size and shape of the sector in the 27 Member States of the EU. The UK can be seen as a leader in having a well-established, diverse medical charities sector, and although the foundations and charities sector is growing in a number of Member States, the medical research charity landscape elsewhere in Europe does not match the size or diversity of medical research charities in the UK.

This fragmentation or lack of uniformity across Europe can be seen in part as accounting for the relative lack of policy action on the medical research charities sector. Whereas research and innovation have long been highlighted as policy priorities for the EU and its Member States, this has tended to overlook the role of philanthropy and the charities sector. However, since the mid 2000s, there has been a growing recognition on the part of the European Commission of the potential role of the foundations and charities sectors in funding research. So far, the outcome of this has been little more than declaratory statements, recognising the need for the EU to raise its game in promoting philanthropic support for research. But research and innovation policies are assuming greater prominence at EU level, reflecting concern that R&D spending in Europe continues to lag behind the US and Japan, while the pace of competition from developing countries and emerging economies is increasing. This suggests that there are opportunities to promote the role of the research and development in the context of competitiveness, and in the case of medical research, health and wellbeing

## EU infrastructure and policy developments

policies. Given the size of the medical research sector in the UK and the high reputation of UK research institutes (as reflected in the allocation of funds under existing research programmes), there is scope for the UK to play a significant role in this process.

There have also been attempts at building a more coherent voice for philanthropy and the foundations sector in Europe, for example, the European Foundation Centre (EFC) and, Donors' and Foundations Network Europe (DAFNE). But the work of these organisations goes beyond medical research to cover a wide range of social, cultural and educational objectives alongside research. This wide reach means that medical research charities are not a major focus for their activities.

Nonetheless, this is not a year-zero exercise: the UK government, universities, research institutions, and some AMRC members are already engaged in this policy agenda at EU level. This report aims to take stock of recent developments at EU level, consider trends in European policy, highlight examples of good practice and key players and potential allies in other Member States, and think about priorities for the future. In light of this exploratory nature, this document is aimed at providing a policy context for AMRC and its members as they contemplate how best to engage with Europe.

### 1.1 Early stages: the Giving more for research in Europe report. 2005.

Although not restricted to medical research, the Giving more for research in Europe report (European Commission/European Foundation Centre, 2005) offers a useful starting point for a review of EU activity in this area. Despite a relatively long history of EU research policy and funding, there has been little explicit acknowledgement of the role of the charity sector. In 2005, the European Commission report on the role of foundations and the non-profit sector was the first policy document at EU level to identify the potential of philanthropy in supporting research and development.

The Giving more for research in Europe report makes the case for a strong third sector in a social, economic and political context where the state is no longer seen as having a monopoly on legitimacy or resources. The report envisages clear added value for the foundation and non-profit sectors in terms of delivering funding for blue-skies research, advancing research in orphan areas and early-stage applied activities not sufficiently developed to attract industry funding. The 2005 report also highlights scope for foundations to support wider EU research priorities, including cross-border, interdisciplinary and smaller projects as well as enhancing researcher mobility. Particular strengths of the non-profit sector were seen in terms of providing the flexibility to respond to the needs of the research community, and to trigger research spending from larger funders. The sector's perceived independence from government and industry also implies the credibility to engage public support for research.

However, the European Commission report recognises that the potential contribution of the sector across Europe is limited by barriers to individual and corporate giving. These barriers include a set of highly diverse and complex national policies governing regulatory regimes, legal status, and tax treatment of charitable organisations and donations. At the same time, the role of foundations to contribute to research was limited by the low level of funding allocated by the sector to research and development, as opposed to other activities such as directly funding development and social programmes. Despite the clear potential of the third sector, industry and government were seen as the key players in terms of funding research in the EU. Although data was sparse, the European Commission report suggests that support for

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research from foundations tended to be concentrated in particular research areas, most notably biomedicine, with universities the main recipients of foundation funding.

The 2005 report sets out a number of recommendations aimed at creating incentives and removing obstacles to the funding of research by the foundation and charities sector. These range from measures to encourage giving and philanthropy to encouraging the creation of new foundations, including cross-border organisations. A number of the Commission's recommendations focus on the legal, fiscal and regulatory frameworks under which foundations operate as well as measures to improve the effectiveness of the sector and to encourage partnerships and international collaboration. The report notes a low level of awareness of the role played by research foundations, coupled with a lack of relevant data on the sector across the EU.

### Key policy recommendations from *Giving more for research in Europe, 2005*:

- Improving visibility and information about research foundations: through publicity campaigns highlighting the role of scientific research and emphasising the need for giving, as well as creating a European Forum of Research Foundations to promote co-operation;
- Implementing better fiscal and regulatory regimes: with tax breaks to facilitate charitable donations from individuals and corporations
- Improving mechanisms for leveraging funds for research: through systems of match funding at national and EU levels, encouraging philanthropic venture capital and the creation of umbrella foundations to overcome fragmentation and achieve critical mass
- Promoting more effective funding arrangements through better governance, improving networking and co-operation by the sector, including a more proactive stance on the part of universities in attracting funding for research
- Fostering a more conducive EU-wide environment for the sector, facilitating cross-border co-operation and giving and considering the options for a new legal provision, a European Foundation (EF) Statute, to facilitate cross-border work

### Following up on the 2005 report

The report urged a clear political commitment to raise the profile of giving to research at EU and national levels, and envisaged a review of the report within a year to take forward the recommendations and a follow-up conference hosted by the Commission and European Foundation Centre to discuss the findings of the report and consider potential projects. The creation of a European Forum of Research Foundations was also proposed as a means of monitoring progress, with the aim of implementing the main recommendations by 2010 (see Section 2 of this report for further details on these organisations).

As the next section of this report shows, there has been little concrete follow-up to the 2005 European Commission report on the role of giving and philanthropy in support of research. The role of the charities sector in delivering funding and supporting innovation in research has not been developed at EU level. In light of the increasing prominence of research and innovation and health policy, this would appear to be a missed opportunity.

### 1.2 Key European Union policies, programmes and institutions to support research and innovation

At first sight, the array of EU institutions, initiatives and programmes on health, research and innovation appears complex. This section of the report aims to highlight the key institutions, agencies and programmes, as well as setting out some of the broad themes of research and health policies, including follow-up to the 2011 European Commission Green Paper on research and innovation funding.

#### The European Commission

The European Commission is the EU's executive body, and has responsibility for proposing and enforcing legislation, as well as implementation of policy and allocating EU funds. In terms of institutional architecture within the Commission, the work of three Directorates-Generals (DGs) is relevant to medical research policy and funding. These are DG Health and Consumers, with responsibility for policy on public health, food safety, consumer affairs, animal and plant welfare; DG Regional Policy, which funds economic development programmes; and DG Research and Innovation, which has responsibility for EU research and innovation policies. The legal basis for the Commission's activities in this area can be found under Article 179 of the Treaty on the European Union, with respect to, "promoting all the research activities deemed necessary by virtue of the other chapters of the Treaty." (Foreign and Commonwealth Office, 2008)

#### DG Health and Consumers

Achieving a 'high level of health protection' for all European citizens was enshrined as an objective of the European Union in the Maastricht Treaty, 1992. DG Health and Consumers is responsible for policy on public health, food safety, consumer affairs, and animal and plant welfare. The DG's vision is of, "working for healthier, safer, more confident citizens."<sup>3</sup> The DG brings forward legislative proposals, for example, in July 2011, DG Health and Consumers published new legislation against falsified medicines, due to come into force in January 2013, and carries out a range of publicity and information campaigns, such as the annual European Week Against Cancer. In addition to its public health responsibilities, DG Health and Consumers has oversight of the following bodies:

**European Medicines Agency (EMA)** is a London-based agency responsible for the scientific evaluation of medicines and European marketing approval of medicines for use in the EU.<sup>4</sup> The Agency also monitors the safety of medicines through a pharmacovigilance network and provides scientific and other advice assistance on the development of new medicines, working within a network of over 4,500 'European experts' who serve as members of the Agency's scientific committees, working parties or scientific assessment teams.

**The Innovative Medicines Initiative (IMI)** is a public-private partnership between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The IMI was created with the aim of improving drug development in Europe through research programmes and building networks of industrial and academic experts. Research projects are selected for IMI funding through open calls for proposals. The fourth call for

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<sup>3</sup> [http://ec.europa.eu/dgs/health\\_consumer/about\\_us/our\\_vision\\_en.htm](http://ec.europa.eu/dgs/health_consumer/about_us/our_vision_en.htm)

<sup>4</sup> [http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home\\_Page.jsp&murl=&mid=](http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&murl=&mid=)

funding is due in July 2011 and will cover the three topic areas of: EU medical information system; chemistry, manufacturing and control; and technology and understanding molecular disease.<sup>5</sup>

**The EU Health Policy Forum** acts as a consultative body bringing together umbrella organisations representing NGOs, health professionals, trade unions, health service providers and economic organisations. The aim of the policy forum is to ensure that the European Commission's health policy is transparent and responsive to public concerns.<sup>6</sup> Membership of the Health Policy Forum includes EUROPABIO, the European Association for Bio-industries, and the International Alliance of Patients' Organisations (IAPO), though an annual conference, the EU Open Health Forum is open to wider stakeholders. For example, the 2010 conference highlighted investment in healthcare innovations as a means of contributing towards the research, knowledge and employment agendas as well as supporting the primary objective of improving healthcare (European Commission, 2010).

### DG Research and Innovation

DG Research and Innovation aims to develop and implement EU research and innovation policy with a view to improving EU competitiveness, economic growth and job creation.

The European Research Area<sup>7</sup> (ERA), the umbrella term for activities, programmes and policies in support of knowledge and technologies in the EU, is overseen by DG Research and Innovation. The ERA aims to establish Europe-wide space for research by developing linkages between researchers, institutions and businesses to collaborate and compete across borders. A number of these programmes and organisations are long-established, for example, framework programmes providing funding for research, and bodies such as the European Space Agency. More recent initiatives include the European Research Council, the European Institute for Innovation and Technology, the Innovation Union Flagship Initiative and the Europe 2020 strategy.

### The European Research Council

The European Research Council<sup>8</sup> (ERC) acts as a funding body to support high quality research. ERC grants are awarded through open competition to scientifically excellent projects headed by early-career and established researchers, whether from within or outside the EU. The ERC also carries out peer review and analysis of research performance in the EU as a means of encouraging universities and research institutions to maintain and raise standards.

### European Institute of Innovation and Technology

Based in Budapest, the European Institute of Innovation and Technology<sup>9</sup> aims to bring together the higher education, research and business sectors to stimulate innovation. The objectives of the Institute are to encourage economic growth and competitiveness by

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<sup>5</sup> <http://www.imi.europa.eu/sites/default/files/uploads/documents/4th%20Call/IMI4thCallforproposalsdraft29June2011.pdf>

<sup>6</sup> [http://ec.europa.eu/dgs/health\\_consumer/about\\_us/our\\_vision\\_en.htm](http://ec.europa.eu/dgs/health_consumer/about_us/our_vision_en.htm)

<sup>7</sup> [http://ec.europa.eu/research/era/index\\_en.htm](http://ec.europa.eu/research/era/index_en.htm)

<sup>8</sup> <http://erc.europa.eu/index.cfm>

<sup>9</sup> <http://eit.europa.eu/>

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encouraging world-class innovation. This involves harnessing the capacities of these key sectors from the EU and beyond through the creation of highly integrated Knowledge and Innovation Communities (KICs). The KICs are involved in training of entrepreneurs in higher education, as well as promoting new business creation, including small and medium sized enterprises (SMEs).

### Europe 2020 Flagship Initiative: Innovation Union

The Europe 2020 strategy follows on from the Lisbon strategy, which initially set a 2010 deadline for the EU to become the most competitive and dynamic knowledge-based economy in the world and set a 3% target for R&D expenditure. Despite the adoption of National Reform Programmes in 2005 to enable Member States to achieve this and other Lisbon objectives, the targets were not achieved by 2010. Innovation Union (European Commission, 2010a) is a flagship initiative of the Europe 2020 strategy that seeks to place innovation at the heart of the EU's strategy for economic growth and dealing with societal challenges.

### The 3% objective for R&D investment in EU Member States: a moving target?

In March 2000, the European Union adopted the Lisbon strategy, setting the target date of 2010 for becoming the most competitive and dynamic knowledge-based economy in the world. As part of the Lisbon strategy, the European Council agreed an objective of raising overall domestic R&D investment to 3% of Gross Domestic Product (GDP) by 2010. This target acknowledges the gap between European spending on R&D and spending by key competitors including the US, Japan, China and India. According to a study cited by the Commission (Zagamé, 2010), achieving this target could create 3.7 million jobs, including a million researcher jobs, and increase annual GDP by up to €795 billion by 2025.

Latest data from the Commission (2009 figures) show that average spending on research and development across the 27 EU Member States was just 2.01% of GDP (EUROSTAT, 2011). The only countries to have hit the 3% target by 2009 were Finland (3.96%), Sweden (3.62%) and Denmark (3.02%). The UK was well short of the target in 2009 at 1.87%, on a par with the Netherlands (1.84%) but behind large Member States including Germany (2.82%) and France (2.21%). Newer EU Member States tended to lag behind on R&D spending, with Cyprus and Latvia bringing up the rear at 0.46% of GDP. Slovenia was an exception amongst the new Member States, spending 1.86% of GDP on research and development. (EUROSTAT, 2011)

A new deadline of 2020 has been set for the 3% target as part of the Europe 2020 strategy, the successor to the Lisbon agenda.

The failure to hit these research and innovation targets can be seen as a result of a 'one size fits all' policy approach which did not take sufficient account of differential levels of economic development and, equally importantly, research and innovation capacity, across the EU. The lack of sanctions available to the Commission to enforce this target can be seen as another factor in this disappointing outcome (Craig and De Búrca, 2011: 619-20). This appears to be a fair assessment of the shortcomings of the Commission's approach in this area, and it is not clear how much the Commission has learnt from the failure of the 2010 target, as the Lisbon strategy objectives have been incorporated into a new competitiveness and innovation strategy, called Europe 2020, with a revised target date of 2020.

Although the 3% target was an undoubtedly eye-catching initiative, it was clearly aspirational rather than achievable for most Member States. Latest data from the Commission show that achieving this target by 2010 has proven to be beyond the reach of the vast majority of

Member States, and in many cases would have meant more than doubling national funding for research and innovation. In the medium term, the impact of economic recession and ongoing constraints on public spending are likely to undermine efforts to raise R&D spending further, particularly as research and innovation tend to assume low political priority for governments. The Organisation for Economic Co-operation and Development (OECD) Science, Technology and Innovation Outlook 2010 (OECD, 2010) indicates that countries have responded to these pressures in different ways. The OECD report that members have already announced cuts in their annual budgets research and development and tertiary education. However, others, including Austria, Germany, South Korea and the United States have increased investment in the science base, strengthening public research and human resources in order to improve future innovation and growth prospects.

### 1.3 Funding opportunities

With a budget of €53.3 billion for research and technological development, Framework Programme 7 (FP7) is the EU's main research funding programme. Health-related research is one of the priority areas for FP7, with activities grouped under three broad headings:

- Biotechnology, generic tools and medical technologies for human health: priorities include high-throughput research, detection, diagnosis and monitoring, prediction of suitable, safe and effective therapies, and innovative therapeutic approaches
- Translating research for human health: integration of biological data and processes, research on major diseases, infectious diseases, brain-related diseases, human development and ageing
- Optimising the delivery of healthcare to European citizens: translation of clinical outcomes into clinical practice, quality of healthcare systems and enhanced health promotion and disease prevention

The objective of health research under FP7 is to improve the health of European citizens and boost the competitiveness of health-related industries and businesses, as well as address global health issues. The Health theme is a major theme of the Cooperation programme and the EU has earmarked a total of €6.1 billion for funding this theme for the FP7 period (2007-2013).<sup>10</sup>

#### July 2011 call for FP7 health research projects

Details of health-related projects funded by FP7 are available at the Commission's Community Research and Development Information Service (CORDIS) database.<sup>11</sup> CORDIS also has information about calls for FP7 funding. The final version of the FP health research work programme for 2012 is due to be published in July 2011<sup>12</sup>, through two calls for proposals with an estimated total budget of €650 million. Proposals will be evaluated through a peer review system during late 2011 and early 2012. The European Commission is also recruiting experts to join its panel of peer reviewers for health-related research project proposals.

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<sup>10</sup> [http://cordis.europa.eu/home\\_en.html](http://cordis.europa.eu/home_en.html)

<sup>11</sup> <http://cordis.europa.eu/fp7/health/>

<sup>12</sup> A working draft of the paper is available at: [http://ec.europa.eu/research/health/pdf/fp7-health-2012-orientation-paper\\_en.pdf](http://ec.europa.eu/research/health/pdf/fp7-health-2012-orientation-paper_en.pdf)

### Competitiveness and Innovation Framework Programme

Although FP7 is the main health research programme at EU level, funding for health-related research is also available under the Competitiveness and Innovation Funding Programme<sup>13</sup> (CIP), which aims to use its €3.6 billion budget to encourage industrial competitiveness, focusing on SMEs. In terms of SME policy, the Commission has highlighted the need to develop research-focused and innovative SMEs. One of the three strands of the programme is an ICT policy support programme, which includes funding for ICT-based initiatives in health, ageing and social inclusion.

### DG Regional Policy: EU Cohesion Fund, Structural Funds and regional policy

Within the European Commission, DG Regional Policy co-ordinates a range of programmes targeted at Member State and regional levels. The Commission estimates that for 2007-2013, around €60 billion was spent on research and innovation across Europe's regions (European Commission, 2011). The Cohesion Fund, accounting for nearly a quarter of EU structural funds, acknowledges economic disparities across the EU and is aimed at Member States whose gross national income (GNI) per inhabitant is less than 90% of the EU average. The Fund aims to reduce disparities in the level of development between Member States and regions economic and social development. The Structural Funds cover a number of policy themes, and funding for research, innovation and enterprise for the current period (2007-2013) is over € 86 billion. The allocation of funds in a given Member State or region varies according to its level of development.

The focus of regional policy in the EU has shifted away from the UK following the southern enlargement of the 1980s (the accession of Spain, Portugal and Greece) and the eastern enlargement of the 2000s (Central and Eastern European states, plus Malta and Cyprus). Furthermore, access to the Cohesion Fund is currently restricted to Member States with lower levels of economic development.<sup>14</sup> However, other regional funding packages, such as the European Regional Development Fund (ERDF) and the European Social Fund (ESF) remain available to part or all of the UK. For the period of the current EU budget (2007-2013), the European Union also funds a number of cross-border economic programmes, aimed at economic fostering funds a number of cross-border programmes, aimed at fostering economic development and co-operation between Member States. The relevant programmes for UK regions are as follows:

**Northern Periphery:** Highlands and Islands of Scotland, Northern Ireland, plus Republic of Ireland, Iceland, Greenland, Norway, Sweden and Finland.

**North-West Europe:** all UK, plus Republic of Ireland, France, Switzerland, Belgium, Luxembourg, the Netherlands and Germany.

**North Sea:** Eastern England, Eastern Scotland, Orkney and Shetland, plus Belgium, the Netherlands, Denmark, Germany, Norway and Sweden.

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<sup>13</sup> <http://ec.europa.eu/cip>

<sup>14</sup> For 2007-2013 the Cohesion Fund is restricted to Bulgaria, Cyprus, the Czech Republic, Estonia, Greece, Hungary, Latvia, Lithuania, Malta, Poland, Portugal, Romania, Slovakia, Slovenia and Spain (Spain receives phase-out funding only).

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**Atlantic Area:** Western England, Wales, Western Scotland, Northern Ireland, plus Republic of Ireland, France, Spain, Portugal.

### Checklist for innovation and research funding

The criteria for the various EU funding programmes that may be available to the medical research community are detailed and complex. The Commission's checklist for EU innovation and research funding is a useful starting point for establishing eligibility for EU programmes and funding streams.

This allows organisations seeking research and innovation funding to establish quickly their potential eligibility for a range of programmes, based on their proposed activity, timeframe, type of support sought, international partners and geographical location.

The checklist is available at: [http://cordis.europa.eu/eu-funding-guide/checklist01\\_en.html](http://cordis.europa.eu/eu-funding-guide/checklist01_en.html)

### 1.4 Current developments in EU research policy

#### European Commission Green Paper, 2011

In February 2011, the Commission published a Green Paper on research and innovation funding, *From Challenges to Opportunities: Towards a Common Strategic Framework for EU Research and Innovation Funding* (European Commission, 2011a). The Green Paper acknowledges long-held criticisms of existing research and innovation programmes at EU level, including the complex, bureaucratic and time-consuming nature of bidding processes. Acknowledging the complexity of the current funding regime, the Green Paper proposes bringing together EU instruments for research and innovation within a common strategic framework as a successor to FP7.

These proposals are set out in a policy context of a pressing need to promote economic growth and employment, as well as calls for a better alignment of research and innovation policies with competitiveness and economic development policies. The potential of research to contribute to European responses to environmental challenges, such as climate change, and demographic challenges, such as an ageing European population, are also acknowledged in the Green Paper.

Economic challenges set out in the Green Paper include continuing constraints on public budgets and the need to maximise the impact of public funding for research and innovation: activities which are organised mainly at national level. Historical underinvestment in research and innovation is also identified as a problem, as well as the need for greater linkages between research and innovation. The Green Paper makes clear the potential for greater efficiencies and co-ordination of programmes to reduce duplication and fragmentation. Finally, in terms of the division of labour between the Commission and Member States, the Green Paper acknowledges that most public funding for research and innovation comes from Member States, but suggests that greater efficiencies can be achieved through initiatives to pool resources.

The framing of the consultation questions in the Green Paper reveals the Commission's own thinking in terms of greater pooling of Member State resources and encouraging joint programme initiatives between Member States. In light of the limits placed on EU finances and continued pressure from some Member States, including the UK, for budgetary restraint at EU level, it is likely that EU Member States will continue to play a key role in financing research

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activities. At the same time, there are significant resources available at EU level for research through FP7, the Competitiveness and Innovation Framework and regional development programmes. Evaluation of existing programmes has highlighted the need for greater coherence and transparency in EU research and innovation initiatives; for example, the need for clearer objectives and streamlined funding processes, paring down bureaucracy and encouraging transparency. Taking account of the cross-border nature of EU research activities, the Green Paper also makes clear an aspiration to broaden participation in EU programmes; in particular stimulating industry and SME involvement, and encouraging participation of female researchers and researchers from newer Member States and developing countries. In terms of economic and societal impact, the Commission anticipates benefits in terms of better uptake of research and innovation and more effective use of results by companies, investors and policymakers, as well as greater involvement of users at all stages of the research process.

### UK Government response to Commission Green Paper

The UK Government response to the Green Paper (Department for Business, Innovation and Skills, 2011) supports the allocation of an increased proportion of the EU budget for research and innovation, though with the familiar UK caveats that the overall EU budget should be reduced and that EU activities should focus on adding value to and complementing the work of Member States.

In line with domestic priorities for research funding, the UK supports a focus on funding research and innovation programmes which demonstrate excellence and EU added-value and take account of the needs of business, education and wider society, with a particular emphasis on impact, evaluation, dissemination and knowledge transfer.

Alongside the natural sciences, the UK calls for a stronger emphasis and greater funding for research in the social sciences, arts and humanities. This aspect is also relevant to the medical research charities community in terms of reaching a better understanding of attitudes to research, giving and innovative treatments and therapies. At the same time, the UK approach stresses the need to focus on a small number of well-defined societal challenges, such as an ageing population, as well as continuing to develop key technologies including ICT, nanotechnology, biotechnology, alongside due consideration of overarching issues such as metrology, e-infrastructures and supercomputing.

In terms of making research initiatives more efficient and accessible, the UK also favours a streamlining of EU programmes to support shorter time-to-grant periods and lighter-touch auditing and reporting, paring down bureaucracy and gearing audit activities to their principle objective of protecting public funds.

### The European Commission response to the consultation

The Commission produced an analysis of responses to the Green Paper in June 2011 (European Commission, 2011b). Over 2,000 responses were received, about half of which were from higher education or research organisations. In terms of responses from Member States, Germany generated most responses (272), followed by the UK (248), then Spain (169), Italy (146) and France (145). Given the broad subject matter of the Green Paper and the wide range of opinions expressed, the Commission's response is selective and focuses on the top policy lines.

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The Commission highlights strong support for bringing research and innovation closer together, maximising impact and simplifying funding mechanisms. In its summary document, the Commission takes note of Research Councils UK's proposal for a mapping exercise to identify overlap and reduce, merge or adapt existing funding streams. The Commission also acknowledges the need for greater flexibility in its calls for project proposals, as well as greater targeting to specific groups such as SMEs, though this entails managing major projects, where there is real European added value, alongside smaller projects that will be accessible to SMEs. In terms of achieving an appropriate balance for EU research and innovation policy, the Commission acknowledges the need for close to market activities such as applied research and large scale trials, whilst at the same time providing support for high risk and unconventional projects.

Inevitably, the Commission's response to the consultation appears to try and cater to the needs of different audiences. These include Member States such as the UK with a strong track-record in securing research funding, alongside newer Member States who would like to secure a greater share of funding for themselves. Similarly, there is acknowledgement of the need for the EU to maintain and develop centres of global excellence, whilst at the same time nurturing the role of SMEs and new players in research and innovation. In the context of ongoing funding constraints, there is perhaps a risk that the impact of EU research and innovation policies will be diluted by an attempt to pay at least lip service to numerous objectives and stakeholders, spreading resources too thinly for them to have the impact that the Commission and Member States acknowledge is an important priority for the European Union. Given the failure to meet the Lisbon target on research and innovation funding by 2010, delivery of the agenda set out in the Green Paper is likely to be a challenge for the Commission and Member States.

There is no mention of the role of the charities sector in either the Commission Green Paper on research, or the UK Government response. Although the Green Paper and the Commission's response to the consultation both refer to the need to lever additional sources of funding, they do not consider the role of philanthropy in this process and how it could be developed. This suggests that the conclusions of the 2005 report on the benefits of philanthropy have not had a lasting effect on EU policy, and highlights the need for greater efforts to keep the research role of the charities sector on the Commission's radar. The 2005 report offers an excellent precedent and should be used as a lever to engage the Commission more fully in taking account of the needs of the sector and its actual and to contribute to major EU policy objectives.

### 2014 and beyond

On 29th June 2011, the Commission announced its budget proposals for 2014-2020 (European Commission, 2011c). This includes a commitment to "invest in Europe's brains by increasing the amounts allocated to education, training, research and innovation." For 2014-2020, the Commission proposes allocating €80 billion to Horizon 2020, the newly-named common framework for research and innovation that was proposed in the 2011 Green Paper. This framework brings together existing funding streams and rehearses the familiar objectives of closing the innovation gap between the EU and key competitors, promoting excellence in the science base, tackling societal challenges and boosting competitiveness. The Commission's ambitions for Horizon 2020 include eliminating fragmentation and ensuring better coherence, including linkages to sectoral policy priorities such as health, food security and the bio-economy, energy and climate change. Once again, these are ambitious objectives, and a key part of their delivery is likely to depend on effective scrutiny of the

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Commission's proposals for implementation. Member States with a strong track record in research and innovation should be well placed to take a lead in this process.

### Keeping up to date with EU developments on research and innovation

European Commission health research portal: for information on health research in the EU. Available at: [http://ec.europa.eu/research/health/index\\_en.html](http://ec.europa.eu/research/health/index_en.html)

European RTD Insight: a monthly update from the British Council and the UK Research Office in Brussels on EU research policy and programmes. Available at: <http://www.ukro.ac.uk/insight/index.htm>

### 1.5 Recommendations: EU Policies and programmes on research and innovation

This initial survey of EU policy developments suggests that some initial groundwork has been done in terms of initial awareness-raising of the role of the charities sector within the wider context of EU research and innovation policies. However, there has been little follow-up on the Commission's 2005 report, suggesting that further work is required to raise the profile of charitable organisations and their work in promoting and funding research. With the Commission focusing on research and innovation policies to deliver economic and social gains, there are likely to be opportunities to highlight the role of the sector when the Commission brings forward firmer policy proposals to build on the 2011 Green Paper on research and innovation funding. In the short term, AMRC could consider the following:

**Gauging AMRC members' appetite for European engagement:** a number of AMRC members are already engaged with EU policy matters, and there may be scope for further research with member organisations to gauge their level of engagement in Europe; whether they have responded to policy consultations, whether they work internationally or have partners and contacts in other Member States, and whether there is an appetite for further information or engagement with EU affairs. The findings of this further research could be used to justify further consideration of the resource implications for AMRC that would arise from devoting staff time to EU policy work.

**Encouraging AMRC members to engage in Europe:** this could be taken forward by raising member organisations' awareness of EU legislation and funding opportunities. In order to reduce the risk of information overload, this could be achieved by greater use of existing channels, such as the Member Briefing and AMRC blogs to raise awareness.

#### Connecting with European organisations

Part AMRC's role in the UK lies in lobbying policymakers and legislators in support of members' objectives, and the PAWG policy group offers a valuable forum for co-ordinating positions between key AMRC members for these purposes. Clearly, AMRC does not have the resources or the political capital to create an equivalent organisation at European level. However, consultative networks for feeding civil society views into the European Commission are well established in Brussels, and AMRC could investigate plugging into one of these networks, either through an existing organisation such as the European Foundations Centre, or through seeking membership of a consultative body such as the European Health Policy Forum. However, this would have significant cost implications for AMRC in terms of the policy work required to contribute to policy consultations and attend meetings and conferences in Brussels and elsewhere.

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AMRC could also consider developing partnerships with Medical Research Charities Group (MRCG) in Ireland and Gezondheidsfondsen in the Netherlands, both of which act umbrella organisations for the medical research charities sector. Further engagement with these organisations on European policy would provide opportunities to establish commonalities and potentially to coordinate cross-border input to medical research policy at EU level. This kind of cross-border working is likely to be more eye-catching to the Commission than these organisations working individually.

**European Foundations Centre (EFC):** whilst it might initially be difficult to justify the €1,000 annual cost of associate membership of the EFC, it may be worth making initial contact with the EFC to explore potential common ground

**UK Research Office (UKRO), Brussels:** Jointly funded by UK Research Councils, UKRO offers information and advice on EU funding for research. The annual subscription fee for universities and charities is £3,013, excluding VAT, though the monthly RTD Insight is available free of charge online.

### 2. The charities and foundations sector in Europe

#### Key messages

- There is a growing body of international comparative research on giving, though international comparisons are hampered by issues of definition and research methodology;
- In terms of the EU, recent research indicates a strong culture of giving in the Netherlands, the UK and Ireland;
- However, civil society appears to be growing in size and importance across all EU Member States.

Having established a context for research and innovation policy and funding at EU level, this section of the report looks at efforts to gauge cultures of giving internationally. This is a challenging exercise, as definitions and traditions of giving vary from country to country. However, this analysis may be helpful not only in accounting for the diversity of giving across the EU, but also to assist AMRC in identifying potential commonalities with other Member States and prioritising future networking.

Back in 2005, the Giving in Europe report defines a foundation as:

*“any non-profit private entity serving public goals that is independent of government and industry, with its own governing board and source of income, whether or not it raises income exclusively from an endowment or from fundraising from the public. A foundation uses its resources for the support of public benefit purposes (scientific, health, educational, cultural, social or other) by supporting other organisations or individuals, or by operating its own programmes.”* (European Commission, 2005: 7)

#### 2.1 The European Forum on Philanthropy and Research Funding

This wide definition reflects the diversity of the sector across the EU. In terms of promoting understanding of the sector, the European Forum on Philanthropy and Research Funding was created in 2007 as part of the follow-up to the Giving in Europe report. The forum is a platform for research stakeholders, funders and operators to discuss practical issues and problems around philanthropic and foundation support for research, as well as raising awareness of the role of foundations in promoting European research. The forum has held annual conferences, focusing on the themes of partnership in research (2008), philanthropy (2009, in London) and nurturing talent (2010). Its objectives for 2001-13 are:

- to provide opportunities for peer-learning and networking for philanthropic funders of research and other research stakeholders
- to facilitate transnational co-operation between philanthropic funders of research
- to document the contribution of the European philanthropic sector to research
- to raise the profile of the contribution of philanthropy to research amongst European-level research associations and decision-makers
- to create a sustainable network of independent research Foundations in Europe

### 2.2 The European Foundation Centre (EFC)

The European Forum on Philanthropy and Research Funding is managed by the European Foundation Centre (EFC), a Brussels-based international association of foundations and corporate funders, which work to enhance the legal and fiscal environment for foundations, provide information and strengthen the sector's infrastructure. Gauging the size of the sector in Europe is difficult, as member states classify the third sector in different ways, and some do not keep a central register of voluntary organisations. However, the Giving in Europe report, 2005, cites a mapping exercise by the European Foundation Centre (EFC) Research Task Force in 2003/2004, which estimated that in 2001 there were some 62,000 foundations operating in the EU15 Member States.

Data from an EFC survey of seven EU Member States<sup>15</sup> (European Foundation Centre, 2008) show that health was the most popular area of expenditure for foundations, followed by social services, international development, arts and culture, education and then science. The survey also looked at the geographical scope of foundations work in a subset of countries (Estonia, France, Germany and Italy) and found that around two-thirds of the foundations surveyed were focused entirely on their local area, with most of the remainder working at national level. The findings suggest that very few foundations in these countries were working internationally. The EFC report defines the public-benefit foundation sector in the EU, defined in the following terms:

*“Public-benefit foundations are asset-based and purpose-driven. They have no members or shareholders and are separately-constituted non-profit bodies. Foundations focus on areas ranging from the environment, social services, health and education to science, research, arts and culture. They each have an established and reliable income source, which allows them to plan and carry out work over a longer term than many other institutions such as governments and companies.”* (European Foundation Centre, 2008: 3).

Based on this definition, the EFC survey estimated that there were 273,000 organisations termed ‘foundations’ in 24 of the 27 EU Member States.<sup>16</sup> Data for thirteen Member States<sup>17</sup>, based on EFC surveys in 2005 and 2008, estimated that the top fifty foundations alone in these countries held assets totalling €88 billion, concentrated in the Italy (39%), the United Kingdom<sup>18</sup> (34%), Germany (16%), Spain (4%), Sweden (4%), France (2%) and Finland (1%). There had been a dramatic increase in the number of trusts and foundations in most countries surveyed, with numbers in Germany and Italy more than doubling since the mid-1990s. The increase in the size of the sector is attributed to fiscal and legislative changes, particularly in Central European countries, where civil society has been reformed extensively since the end of the communist era.

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<sup>15</sup> Belgium, Finland, France, Hungary, Netherlands, Sweden and the United Kingdom.

<sup>16</sup> The survey covered all EU Member States except Lithuania, Malta and Romania.

<sup>17</sup> Belgium, Estonia, Finland, France, Germany, Hungary, Italy, Luxembourg, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.

<sup>18</sup> The top 500 trusts only.

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### 2.3 Cultures of giving in Europe: the World Giving Index, 2010

The World Giving Index 2010 (Charities Aid Foundation, 2010) claims to be the first of its kind in terms of tracking giving and patterns of philanthropy and volunteering at a global level. Survey data from 153 countries on three indicators: charitable donations, volunteering and helping strangers, have been aggregated into a World Giving Index.

Australia and New Zealand come out as the most giving nations globally, based on the survey criteria of volunteering, making charitable donations and helping strangers. Within the European Union, the incidence of people giving money to charity ranges from 4% in Lithuania (the lowest global ranking) to 83% in Malta (the highest globally).

#### World giving index top 10

Top ten countries in World Giving Index, 2010: aggregate percentages of the three philanthropic activities covered by the survey: giving money, giving time and helping a stranger.

1. **Australia**
2. **New Zealand**
3. **Canada**
4. **Ireland**
5. **Switzerland**
6. **USA**
7. **Netherlands**
8. **United Kingdom**
9. **Sri Lanka**
10. **Austria**

The report acknowledges the complex cultural, historical and social factors which determine traditions of giving in different countries, with some countries in the index reporting high levels of giving money, with others performing more strongly in terms of volunteering or helping strangers.

There is a wide variety between EU Member States in patterns of giving, with Western and Southern Europe ranking highly in the index, with on average over half the population reporting giving money. Central and Eastern Europe were in the lower half of the index, with less than 20% of those surveyed in Latvia, Estonia, Bulgaria, Romania and Lithuania reporting giving money. This may reflect in part the level of economic development in these countries, which scored higher for volunteering and helping strangers than on monetary donations. These other indicators, however, do suggest a culture of philanthropy, which may transform into financial giving when levels of economic development rise.

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### EU top 10 for charitable donations

In terms of the single criterion of giving money to charitable organisations, EU Member States are ranked as follows:

1.	Malta	83%
2.	Netherlands	77%
3.	United Kingdom	73%
4.	Ireland	72%
5.	Austria	69%
6.	Denmark	67%
7.	Italy	62%
8.	Luxembourg	58%
9.	Sweden	52%
10.	Germany	49%

The survey also provides a wellbeing index, based on how respondents to the survey rated their own happiness on a scale of 1-10. The results of this measure suggested that the key lever for giving is not GDP or economic wealth, but rather happiness. However, there were not always positive correlations: the UK had a low wellbeing index, but was still a leader in terms of giving, whilst France was much lower down the list with a giving rate of 31% but a higher wellbeing index than the UK. Similarly, Finland and Sweden had very high wellbeing indexes but were below the UK in terms of giving money.

As with all research, the methodology may offer clues to particular findings. For example, the World Giving Index survey, respondents are recruited exclusively from urban areas, thereby excluding the rural population. In some countries, the survey was conducted by telephone, which could have the effect of selecting out poorer respondents, and in all countries, the survey questions were limited to activity over the past month, a factor which could give rise to peaks and troughs in giving as a result of religious festivals or other seasonal factors, such as telethons. In any case, these headline figures suggest a complex relationship between economic prosperity, individual attitudes and social expectations around philanthropy, altruism and giving.

### 2.4 Research literature on philanthropy in the European Union

The World Giving Index is a welcome addition to the literature on giving, as data across the EU tend to be patchy and a number of Member States do not carry out national surveys on philanthropy. Existing literature is often highly specialised and focuses on particular sectors or aspects of giving. In their review of literature on philanthropy, Bekkers and Wiepking offer a very wide definition of charitable giving as, “the donation of money to an organisation that benefits others beyond one’s own family.” (Bekkers and Wiepking, 2007, p.2). Completion of tertiary education and membership of a religious organisation are often highlighted in research

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studies as positive factors in individual propensity to give to charitable sources, though studies contradict each other on the precise nature of these effects. Equally, findings on gender differences in giving are mixed, with most studies identifying no reliable differences between males and females in patterns of giving.

According to the literature review, a key mechanism that motivates individuals to give are awareness of a need for support for a cause, whether through public campaigns, media coverage, personal experience or the experience of a family member or friend. Solicitation, or actively seeking donations, was another key factor, although this needed to be well targeted and timed to reduce the risk of 'donor fatigue,' or alienation of potential donors as a result of repeated requests. These themes are taken up in the UK Government White Paper on giving (Cabinet Office, 2011). Cash and time costs were also seen as an important factor for donors, in terms of making donating easy, removing obstacles for potential donors and maximising the impact of donations through gift aid schemes. The research literature also shows that donors may be responsive to benefits attached to donations, for example invitations to events, though providing gifts such as pens with requests for donations appeared to have mixed results.

Individuals may also perceive their donations as contributions to services that they may use at a later date. For example, a 2005 study in Ireland (Amárach Foundation, 2005) found that support for health related charities rose steeply with age, whereas there was a contrary effect for children's charities, which received fewer donations from older people. In terms of giving to medical research charities, Burgoyne, Young and Walker (2005) suggest that donations to medical research charities may be seen by donors as a means of securing their own future health needs. At the same time, altruism and pro-social values, for example, a desire to make the world a better place, could also provide strong motivation to donors. Efficacy is another important element, with donors responsive to evidence that their donations would have an impact on the charity concerned. Reputation is a further factor identified in research literature, with donating to charitable causes seen as a pro-social activity which enhances the social standing of the donor, an effect that can perhaps account for the popularity of ribbon campaigns and other initiatives related to the visibility of giving, practices described by West (2004) as 'conspicuous compassion'.

Giving to charity may also provide psychological benefits, contributing to a positive self-image and delivering beneficial emotional effects; a 'warm glow' or 'joy of giving' (Andreoni, 1989). Cross-national comparators have been hampered by a lack of comparative data. Whereas individual research studies have been carried out on philanthropy in EU Member States, the lack of consistency in the time periods covered by research, their methodologies and focus mean that it is difficult to draw useful comparisons. A survey of twelve EU Member States by the European Research Network on Philanthropy (Wiepking, 2009) highlights a lack of systematic data on philanthropy across the EU but points to piecemeal efforts by some member states, for example France, Spain and Italy, to encourage philanthropy through tax breaks. The report suggests that encouraging philanthropy may be more difficult in countries such as France and Sweden, where cultural models of a strong, interventionist state funded by taxation tend to restrict the potential role of civil society. However, with public finances constrained across the EU in the wake of the financial crisis (European Commission, 2009), the role of civil society organisations in providing public services is likely to become more prominent.

### Why do surveys on giving vary so much in their findings?

Estimates of charitable giving can vary widely, according to who is included, the reference period, and the definition of charitable giving (NCVO/CAF, 2010). Surveys generally ask about who gives and how much they give, though results will depend on whether the survey focuses on donors, intermediaries (e.g. tax authorities) or recipients. Other factors that may affect survey data include the reference period; whether the survey includes donations made during the previous week, month or year, as well as how charitable giving is defined, and which donations are included. A small change in definitions can lead to a big change in results; for example surveys restricted to very recent giving can give different results according to the time of year they are carried out, with spikes in giving likely to occur around telethons, religious festivals or particular campaigns.

## 2.5 Recommendations: cultures of giving in Europe

**Using evidence of cultures of giving as a basis for international partnerships:** Existing reports on philanthropy reveal wide disparities between EU Member States in terms of patterns of giving and volunteering. These insights could help AMRC prioritise initial partnerships with organisations within Member States that share particular traits such as high levels of giving to charity.

**Keeping abreast of literature on research:** there is a small but growing body of research literature on charitable giving in the EU and beyond. AMRC members will already be aware of the research evidence on philanthropy and charitable giving. This literature is particularly useful in terms of highlighting existing patterns of giving and pointing towards future trends. AMRC could consider engaging more closely with academics in the field as a means of gaining additional insights into the factors that motivate giving to medical research charities in particular. ERNOP (European Research Network on Philanthropy), at Amsterdam/Utrecht<sup>19</sup>, and the Centre for Civil Society Studies at Johns Hopkins University in the US<sup>20</sup> are useful starting points for international perspectives, whereas the ESRC Centre for Charitable Giving and Philanthropy, based at City University, London<sup>21</sup>, would offer access to UK expertise.

This kind of engagement with academia could also help AMRC influence the design of future academic research studies on giving, with potential for a greater focus on medical research charities as a key constituency of the charities sector.

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<sup>19</sup> <http://www.ernop.eu/>

<sup>20</sup> <http://www.ccss.jhu.edu/>

<sup>21</sup> <http://www.cass.city.ac.uk/research-and-faculty/centres/cgap/>

### 3. Country case-studies on research and the charities sector

Having outlined key aspects of EU policy on research and summarised research literature on cultures of giving, this section of the report presents an overview of research spending and innovation in EU Member States, drawing on the European Commission's Innovation Scoreboard; an annual exercise which ranks countries in terms of their research and innovation performance. This overview and comparison of EU performance with key competitor countries is followed by brief snapshots of selected EU Member states focusing on policy statements and spending on research, the charities sector and culture of giving. Further sources of information are also given.

France, Hungary, the Netherlands and Spain were chosen for snapshots on the basis that their responses to the OECD Science, Technology and Industry Outlook (OECD, 2010) highlighted medical research as a priority for science, technology and industry (STI) policy. Germany was included as a leading large EU Member State, based on its ranking in the Innovation Scoreboard, 2010.

#### 3.1 Assessing Member States' performance on research funding

Countries at the top of the ranking for the composite innovation indicator share a number of strengths in their national research and innovation systems. These include strong performance in business R&D expenditure, good linkages between the science base and businesses, and effective commercialisation of technological knowledge.

#### The Innovation Scoreboard, 2010

As part of the Innovation Union initiative, the Commission has assembled twenty-five indicators into a scoreboard, ranking Member States in terms of the performance of their research and innovation systems. Member States are placed into four categories (European Commission, 2011c):

**Innovation Leaders:** Denmark, Finland, Germany; the strongest performing Member States, all of which show a performance well above of the EU27;

**Innovation Followers:** Austria, Belgium, Cyprus, Estonia, France, Ireland, Luxembourg, Netherlands, Slovenia and the United Kingdom; with a performance close to the EU 27 average. The UK is the strongest performer in this group;

**Moderate Innovators:** Czech Republic, Greece, Hungary, Italy, Malta, Poland, Portugal, Slovakia and Spain all perform below the EU average;

**Modest innovators:** Bulgaria, Latvia, Lithuania, Macedonia and Romania bring up the rear, with innovation performance well below the EU27.

### 3.2 International comparisons

The OECD 2010 Scoreboard shows that the US and Japan are maintaining their lead over the EU27 and whereas the EU27 is holding its lead over India and Russia, it has been losing part of its lead over Brazil and China.

A good part of the performance gap in favour of the US can be explained by higher scores in license and patent revenues from abroad, public-private co-publications, participation in tertiary education and business R&D spending. Trends show that the US performance is improving faster as regards doctorate degrees, license and patent revenues and international co-publications. However, the EU outperforms the US in indicators such as knowledge-intensive services exports and its performance is growing faster in public R&D spending.

The following sections of this report offers short case studies of selected EU Member States, looking at their overall innovation performance, highlighting key policy documents, their cultures of giving, and sources of further information.

### 3.3 France

France is an innovation follower, ranking 11th in the EU Innovation Union Scoreboard, 2010, and spending 2.21% of GDP on research and development in 2009 (EUROSTAT, 2011).

France's relative strengths are in human resources, financial support and outputs. Weaknesses are in terms of private sector investment, networks and entrepreneurship as well as intellectual assets and innovators (European Commission, 2011d)

#### Culture of giving & the charities and foundations sector

France ranked 18th out of the EU27 in the World Giving Index, 2010. The number of organisations in the non-profit sector is estimated to be 700,000. The sector relies on government funding for social services, with remaining funding coming from service or membership fees and from private contributions. Whereas corporate foundations have tended to focus on the arts and culture, they are increasingly becoming involved in health and social service provision (European Foundation Centre, 2008).

#### Key strategy documents

##### National Research and Innovation Strategy, 2010.

Healthcare, nutrition and biotechnology are grouped into one of four priority areas for a strategy which aims to place research and innovation at the heart of French society. The report acknowledges a growing social and economic need for health and medical research and envisages a focus on characterising living matter, developing large-scale cohort studies and tackling key public health challenges including neurodegenerative disease as well as emerging and re-emerging infectious diseases. The report emphasises translational research as a means of delivering the potential of medical research, and prioritises better nutrition and securing individual autonomy through treatments, therapies and medical technologies.

##### Biomedical and Health Research Framework Document, 2009.

This document reports on the work of a Ministerial committee, set up in 2008 to address concerns about the weakness of the research sector in France. The report reflects high-level political concern about the erosion of France's international position in research and innovation. The report highlights challenges for France's research system in terms of

## country case-studies on research and the charities sector

organisational fragmentation and bureaucracy, historically low levels of research funding and difficulties in recruitment and retention of researchers. Only 5% of doctorates awarded in 2004 were in the biomedical and health sciences and France's share of international publications fell from 5.6% to 4.4% from 1995 to 2005.

The report envisages reforming organisational and funding structures, making research careers more attractive, and prioritising clinical research, health security, inequalities and longitudinal cohort studies. Apart from direct state funding, the main source of public funding for biomedical and health research comes from clinical research credits provided by health insurance funds, administered by the Ministry of Health and allocated to university hospitals. In support of excellence, the allocation of these credits has been reformed to channel resources towards the best performing university hospitals.

The framework document concludes that investment in biomedical and health research is an imperative for the future in terms of maintaining France's global position and acknowledging unprecedented demographic and public health challenges.

### Sources of further information

National Research and Innovation Strategy, 2010: Available at:

[http://media.enseignementsup-recherche.gouv.fr/file/S.N.R./28/7/SNRI\\_rapport\\_general\\_GBdef\\_158287.pdf](http://media.enseignementsup-recherche.gouv.fr/file/S.N.R./28/7/SNRI_rapport_general_GBdef_158287.pdf)

Biomedical and Health Research Framework Document, Ministry of Health: Available at:

<http://www.sante.gouv.fr/IMG/pdf/DOCORR.pdf> (French only)

Ministry of Higher Education and Research: <http://www.enseignementsup-recherche.gouv.fr/pid24528/ministere.html> (French only)

National Institute of Health and Medical Research (INSERM): <http://www.enseignementsup-recherche.gouv.fr/pid24528/ministere.html>

Institut Pasteur (public health research foundation): <http://www.enseignementsup-recherche.gouv.fr/pid24528/ministere.html>

### 3.3 Germany

Germany is an innovation leader, ranking 4th in the EU Innovation Union Scoreboard, 2010, and spending 2.82% of GDP on research and development in 2009 (EUROSTAT, 2011). Germany's relative strengths are in intellectual assets, innovators and research and innovation outputs (European Commission, 2011d).

In terms of overall expenditure, Germany has the largest research system in the EU, with annual spending on research and development estimated in 2007 at €61.5 billion and over 500,000 staff employed in the sector. An aim of the Federal Government's health research policy is that "everyone should be able to profit from the results of research," with research geared towards new and better diagnostic procedures and therapies, new approaches to prevention, less invasive treatment and shorter hospital stays. The Ministry is providing €5.5 billion for health research between 2011 and 2014 (Federal Ministry of Education and Research, 2011).

### Culture of giving & the charities and foundations sector

Germany ranked 10th out of the EU27 in the World Giving Index, 2010. Germany has a large and highly-developed non-profit sector, with social services and health dominating the sector, acting as a fall-back for state services, and receiving government funding for their activities. It is estimated that over 1.12 million people are employed in the non-profit sector in Germany and corporate citizenship is well developed, especially in the former West Germany. The tax regime offers incentives for private philanthropy and corporate citizenship (European Foundation Centre, 2008).

### Key strategy documents

#### Health Research Framework Programme, 2010

Adopted in December 2010, the Framework Programme refocuses the Federal Government's health research policy towards the themes of tackling common diseases, individualised medicine and rare diseases, prevention and nutrition research, innovation in the health system and basic life science research. A further priority for the Federal Government lies in promoting international co-operation in research.

### Sources of further information

Health Research Framework Programme, 2010:

[http://www.bmbf.de/pub/health\\_research\\_framework\\_programme.pdf](http://www.bmbf.de/pub/health_research_framework_programme.pdf)

Research in Germany: Land of Ideas: <http://www.research-in-germany.de/52/home.html>

Max Planck Society: comprises 80 institutes and research units in the natural, social and life sciences, mainly in the field of basic research: <http://www.mpg.de/en>

Helmholtz Association: Germany's largest scientific research organisation, made up of seventeen research centres: <http://www.helmholtz.de/en/research/health/>

Leibniz Association: comprises 87 research institutions in the natural sciences, life sciences, social sciences and humanities: <http://www.leibniz-gemeinschaft.de/?nid=ubu&nidap=&print=0>

## 3.4 Hungary

Hungary is a moderate innovator, ranking 22nd in the EU Innovation Union Scoreboard, 2010, and spending 1.15% of GDP on research and development in 2009 (EUROSTAT, 2011).

Hungary's relative strengths are in outputs but it also has numerous identified weaknesses: including a relative lack of openness and excellence, poor finance and support mechanisms, alongside insufficient investment, linkages, innovators and entrepreneurship. A more encouraging indicator for Hungary has been a high growth for sales of new products (European Commission, 2011d). In comparison with other Member States, research has been heavily financed by government. Business provides a relatively low share of funding and research tends to be dominated by large, foreign-owned companies in a handful of sectors, for example the chemical industry. The SME sector, on the other hand, is weaker, and lacks resources and managerial skills. There are low graduation rates in science and engineering and exploitation of R&D results is poor, reflecting weak systems for co-operation between academia and industry (ERAWATCH, 2009).

### **Culture of giving & the charities and foundations sector**

Hungary ranked 22nd out of the EU27 in the World Giving Index, 2010. The lack of a culture of giving in Hungary appears to be confirmed by Wiepking (2009), who ranks Hungary as the lowest givers in the European Union. However, earlier research suggests greater generosity, with a 2004 random sample survey on giving finding that two-thirds of the population aged 14 years or above had donated to a non-profit organisation. However, donations were largely restricted to churches and religious organisations, although health and social care were increasing their share of all donations (Czike and Kuti, 2009).

### **Key strategy documents**

#### **Science, Technology and Innovation Policy Strategy (2007-13)**

This document was approved in March 2007 as the first ever comprehensive STI policy strategy for Hungary. The main aims of the strategy are to enhance competitiveness and make knowledge and innovation driving engines of the Hungarian economy. The policy strategy sets out breakthrough opportunities for the Hungarian R&D sector. Key technology areas include life sciences and biotechnology with the stated policy aim of translating science and technology opportunities into economic success in knowledge-based industries including pharmaceuticals, chemicals and innovative services. Six “development poles” have been created, including Debrecen for the pharmaceutical industry and agricultural innovation; Miskolc for nanotechnology, the chemical industry, mechatronics and renewable, alternative energies and Szeged for health and environmental industries well as agricultural biotechnology.

An Action Plan for the strategy was published in August 2007 for the period 2007-2010, listing 93 tasks and setting deadlines and identifying key players and budget lines. As many of these original deadlines were missed, the Action Plan was scaled down in 2009 with fewer action points and extended deadlines.

#### **Economic Development Operational Programme (2007-2013)**

EU structural funds play an important role in priority-setting and financing STI policy, and the Economic Development Operational Programme sets out priorities for the €990 million available for research and development and innovation during the period of the programme. These include promoting demand and marketing for R&D results, developing human resources and infrastructure, establishing a network of bridging organisations, technology parks, incubators and technology transfer offices; enhancing domestic and international co-operation and improving access to financial resources.

### **Sources of further information**

National Innovation Office: the RDI organisation of the Hungarian government:

<http://www.nih.gov.hu/english>

Ministry of National Resources: covers higher education and science:

<http://www.nefmi.gov.hu/english>

Hungarian Research Directory (2005): provides a directory of PhD schools, research institutes and research groups. Includes a chapter on health sciences, including medical sciences, neurosciences and pharmacological sciences: Available under R&D and innovation tab at: <http://www.nih.gov.hu/english/hungarian-current/national-research>

### 3.5 Netherlands

The Netherlands is an innovation follower, ranking 8th in the EU Innovation Union Scoreboard, 2010, and spending 1.84% of GDP on research and development in 2009 (EUROSTAT, 2011).

The Netherlands' achieved the highest EU27 score for open, excellent and attractive research systems, and also scored highly on finance and support and world-class intellectual assets. Relative weaknesses were in investments and innovation (European Commission, 2011d). Other barriers to R&D investment in the Netherlands were low R&D intensity, a lack of on the part of SMEs and the relative unattractiveness of the Netherlands as a destination for foreign researchers and R&D intensive firms. There is a looming shortage of science and technology graduates in the Netherlands and a history of low interaction between universities and SMEs. (ERAWATCH, 2009)

#### Culture of giving & the charities and foundations sector

The Netherlands ranked 2nd out of the EU27 in the World Giving Index, 2010. Limits on public spending have led to increasing interest in private and corporate philanthropy in the Netherlands. Charities received €17 million in 2008 for research and the charities sector is particularly important as a private funder of health research. Key charities in this field are the Dutch Cancer Society (KWF) and The Netherlands Heart Foundation. The Gezondheidsfonden acts as an umbrella organisation for medical research charities in the Netherlands.

Research findings on giving in the Netherlands include a 2008 study of the Netherlands Heart Association, which concluded that personal experience with cardiovascular diseases was associated with a higher likelihood of donating, especially among those with higher levels of empathic concern and social responsibility, and among those who were not in excellent health themselves (Bekkers, 2008).

#### Key strategy documents

##### Freedom and Responsibility: Coalition Agreement, 2010.

The policy programme of the coalition government, elected in June 2010, highlights the importance of major academic and scientific research for the Netherlands. Improving the translation of research results into marketable applications is identified as a priority, in line with the government's objective of promoting research collaboration between the business community, government and universities.

##### Working Together, Living Together, 2007-2011.

In terms of research policy, the previous government's policy programme focused on creating an innovative, competitive and entrepreneurial economy. Priorities include developing young researchers and promoting independent, scientific research. At a strategic level, ICT, genomics and nanotechnology were identified as key areas for research.

#### Sources of further information

Dutch government policy programme: Freedom and Responsibility:

<http://www.kabinetsformatie2010.nl/dsc?c=getobject&s=obj&objectid=127511>

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Gezondheidsfondsen (umbrella organisation for medical research charities):  
[www.gezondheidsfondsen.nl](http://www.gezondheidsfondsen.nl) (website in Dutch only)

Dutch Cancer Society: <http://dcs.kwfkankerbestrijding.nl/about-us/Pages/default.aspx>

### 3.6 Spain

Spain is a moderate innovator, ranking 18th in the EU Innovation Union Scoreboard, 2010, and spending 1.38% of GDP on research and development in 2009 (EUROSTAT, 2011).

Spain has intensified its R&D and innovation-related policies in the past decade, and delivered substantial increases in both private and public expenditure. Although moving in the right direction towards the Lisbon and 2020 targets, there is still a significant gap between Spain and more advanced Member States. Structural problems include a lack of transparency and low quality research outcomes, including poor technology transfer and knowledge circulation (European Commission, 2011d).

Economic integration has led to an awareness of the need to compete on innovation and quality rather than on cost. At the same time, EU cohesion funds have been put to use in support of research and development activities (ERAWATCH, 2009).

#### **Culture of giving & the charities and foundations sector**

Spain ranks 17th out of the EU 27 in the World Giving Index, 2010. It is estimated that there are more than 175,000 associations and 6,000 foundations in Spain, many of which focus on education, culture, health and social services (European Foundations Centre, 2008). Non-profit organisations in Spain receive almost half of their funding from government, though since the 1990s, the corporate sector has widened the scope of its charitable activities to address social exclusion, education and environmental issues.

Medical research in Spain is funded largely by the public sector (Carlos III Health Institute is the major player), with private foundations playing a minor role. Key private sector players are the biotechnology and pharmaceutical industries and Spain does not have a well-developed medical research charities sector (Archontakis, 2009).

#### **Key Strategy Documents**

##### **National Research and Development and Innovation Plan, 2008-11**

The plan includes funding for strategic research in health, biotechnology, energy and climate change, telecommunication and information societies, nanotechnology, new materials and new industrial processes.

##### **Sources of further information**

Ministry of Science and Innovation:

[http://www.micinn.es/portal/site/MICINN/?lang\\_chosen=en](http://www.micinn.es/portal/site/MICINN/?lang_chosen=en)

Carlos III Health Institute: state-sponsored medical research institute:

<http://www.isciii.es/htdocs/en/index.jsp>

### 4. Rare diseases in the European Union

This final substantive section of the report focuses on legislative and policy developments around research on rare diseases at EU level. This is a policy area where there has been tangible progress at EU level, and rare diseases offers a useful basis for exploring potential success factors for cross-border initiatives.

Rare diseases are defined by Aymé and Rodwell as:

*“those of genetic origin... life-threatening or chronically debilitating diseases which are of such low prevalence (less than 5 people affected per 10,000 people in the European Union, as defined by the European Orphan Drug regulation) that special combined efforts are needed to address them so as to prevent significant morbidity, perinatal or early mortality, or a considerable reduction in an individual's quality of life or socio-economic potential.” (Aymé and Rodwell, 2010: 11)*

Aymé and Rodwell estimate that between 5,000 and 8,000 distinct rare diseases exist, affecting between 6% and 8% of the EU population, or between 27 and 36 million people in the European Union. Most of the people included in these statistics suffer from less frequently-occurring diseases affecting one in 100,000 people or less.

The field of rare diseases is an area where there has been significant legislative and policy action at EU level. Given the very low prevalence of these diseases, the widely dispersed population of sufferers and the comparatively high cost-per-patient of developing new treatments and therapies, there is clear scope for co-ordinated action at EU level to add value to the efforts of individual Member States.

#### 4.1 Key EU legislation

Legislation has been implemented in the following areas:

##### **The Orphan Drug Regulation, 1999**

The Regulation aims to promote research and development of new therapies and treatments for rare diseases by providing a system of incentives for the development and marketing of drugs to treat, prevent, or diagnose rare conditions. This includes criteria for the designation of orphan drugs, based on a definition of orphan drugs as products targeting a life-threatening or chronically debilitating condition affecting no more than five in 10,000 persons (about 250,000 persons in the EU).

##### **Regulation of clinical trials**

Clinical trials are defined as, “investigations in humans intended to discover or verify the effects of one or more investigational medicinal products” (Aymé and Rodwell, 2010: 13). The Clinical Trials Directive, 2001, was implemented in 2004 and provides requirements for the conduct of clinical trials in the EU. The Directive provides for a database, EudraCT<sup>22</sup>, listing all ongoing or concluded clinical trials in the EU. The provisions of the Directive were reinforced in 2005 by the “Good Clinical Practice Directive” (Directive 2005/28/EC).

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<sup>22</sup> <http://www.cass.city.ac.uk/research-and-faculty/centres/cgap/>

### Regulation on advanced therapies

This 2007 Regulation aims to promote free movement of advanced therapy products within the EU through a centralised marketing authorisation procedure and the creation of an expert Committee for Advanced Therapies within the European Medicines Agency (EMA) to assess advanced therapy products and follow scientific developments. The Regulation acknowledges the role of SMEs and offers new incentives for firms involved in developing advanced therapies.

### Regulation on medicinal products for paediatric use

This 2006 Regulation ((EC) 1901/2006) aims to foster high-quality research into the development of medicines for children. Its objectives include better information about medicines used by children and, in the longer term, ensuring that most medicines used by children are specifically authorised for such use. The Regulation establishes an expert paediatric committee within the EMA, with the role of assessing the content of paediatric investigation plans. For orphan medicines, the reward for compliance is an additional two years of market exclusivity added to the existing ten-years awarded under the EU's Orphan Drug Regulation. The legislation also provides for an EU inventory of the therapeutic needs of children to focus the research, development and authorisation of medicines, and creates a network of investigators and trial centres to conduct research and development, as well as a public database of paediatric studies.

### Achieving orphan status: the Committee for Orphan Medicinal Products (COMP)

COMP was set up in 2000 within the European Medicines Agency (EMA) and is comprised of health professionals, patient organisations and others, which meets monthly to review applications from persons or companies seeking orphan medicinal product designation and provide expert advice to the Commission.

Of the 910 applications for designation considered by COMP between 2000 and April 2009, 634 were successful (approval rate of almost 70%). Oncology has had the highest rate of approvals (40% of positive opinions), followed by products for the musculoskeletal and nervous system (12%) and cardiovascular and respiratory systems (11%). 64% of positive opinions are for conditions with prevalence lower than three in 10,000 people.

### National Plans for Rare Diseases

Member States have agreed to adopt national action plans for rare diseases by 2013 as part of a wider strategy to ensure patients have access to high quality care, including diagnostics, treatments and, if possible, effective orphan drugs. EUROPLAN (European Project for Rare Diseases National Plans Development) is co-ordinating this process at EU level. So far, Belgium, Bulgaria, Czech Republic, France, Germany, Greece, Luxembourg, Portugal, Romania and Spain have submitted their national plans.

### The European Organisation for Rare Diseases (EURORDIS)

EURORDIS acts as an umbrella organisation for national patient groups and individuals active in the field of rare diseases. EURORDIS aims to build a pan-European community of patient organisations and people living with rare diseases and focuses on empowering patient groups, raising awareness and providing advocacy, improving access to treatment, care and support, promoting research and developing treatments and drugs.

## Sources of further information

European Medicines Agency:

[http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home\\_Page.jsp&isenabled=true](http://www.ema.europa.eu/ema/index.jsp?curl=/pages/home/Home_Page.jsp&isenabled=true)

National Action Plans on rare diseases:

[http://ec.europa.eu/health/rare\\_diseases/national\\_plans/detailed/index\\_en.htm](http://ec.europa.eu/health/rare_diseases/national_plans/detailed/index_en.htm)

EURORDIS: The European Organisation for Rare Diseases: <http://www.eurordis.org/>

## 4.2 Conclusions: Evaluating rare diseases policy

Rare diseases can be seen as a policy area where there is demonstrable added value arising from co-ordination of activities between Member States. Whereas the number of people affected by a particular rare disease in a given Member State is likely to be small, when numbers are aggregated across the EU, patient numbers are more likely to reach a level where an appropriate sample size for clinical trials becomes achievable (Luisetti et al, 2010) and treatments and therapies become economically viable. Given the small numbers of patients in each Member State, cross-border collaboration also adds value for researchers, in terms of building cohorts for research studies.

The well developed body of legislation on rare diseases and orphan drugs in the EU, including the incentivisation of treatments, is in line with earlier policy developments in the US and Japan (Tambuyzer, 2010). This can be seen as reflecting a degree of political traction in that rare diseases is an area in which the EU can demonstrate added value and benefits for citizens. Heemstra et al (2008) maintain that EU regulation has begun to play an important part in stimulating innovation, in a similar manner to the Orphan Drug Act in the United States. However, their review of orphan drug designations in the EU between April 2000 and December 2007 shows an uneven distribution in the country of origin of designated orphan products. France and Germany accounted for a large proportion of the 300 designations, whereas within the EU-15 (member states before the enlargement of the early 2000s), Luxembourg, Portugal, Ireland did not account for any orphan designation. As this disparity cannot be explained by differences in access to the incentives provided by the EU orphan drug legislation, Heemstra and his colleagues claim this as evidence of a strong relationship between orphan drug development and pharmaceutical innovation performance in individual Member States. They go on to suggest that policies based on stimulating pharmaceutical innovation in EU Member States may provide the key to further progress in this area. In a more recent study, Denis et al (2010) maintain that the number of marketed orphan drugs continues to vary significantly between Member States.

With regard to building support for research and new therapies, the role of patient organisations such as EURORDIS is another important factor (Schieppati, Henter, Daina and Aperia, 2008). Increasing awareness of the difficulties associated with rare diseases has led to greater understanding of the importance of international collaboration and, of course, in terms of promoting EU activity, rare diseases also provide a media-friendly topic, with ample scope for media coverage of the human interest stories related by sufferers and their families, as well as scientific breakthroughs.

### 5. Conclusions and recommendations

This brief report offers an overview of EU policies and programmes on research and innovation, summarises research findings on cultures of giving in Europe, offers snapshots of key EU Member States and considers the factors that have contributed to the relatively high level of policy activity on rare diseases.

It should be clear that the AMRC policy agenda chimes with a number of EU policy objectives, including the Europe 2020 agenda that seeks to place innovation at the heart of EU competitiveness and economic growth. Public health is also of increasing concern at EU level in the context of an ageing population, continuing constraints on healthcare funding and the prevalence of chronic diseases in the EU population. The European Union is highly relevant to AMRC and its member organisations, whether through legislation, funding programmes, or its use of legislative powers on research, innovation and public health. In this context, AMRC should continue to take a balanced approach to engagement in EU research and health policy. Whereas new legislation, for example on clinical trials, can be seen as presenting challenges and potential threats to the medical research sector, other aspects of EU policy, notably funding programmes, offer opportunities to enhance the work of member organisations and to build partnership with colleagues across Europe.

Although research and health policies take high priority at EU and national levels, the potential contribution of the medical research charities sector remains undeveloped at EU level. This is particularly disappointing, given declaratory statements made by the Commission as far back as 2005. Taking a long-term view, continued pressure on public finances, an ageing population and demand for more effective treatments and therapies, mean that medical research is likely to become even more prominent as a policy issue. This tightening of public finances could lead to new understandings of the role of the charities sector in funding and supporting medical research across Europe. Bearing in mind the size of the medical research charities sector, there is scope for the UK to play a leading role in drawing attention to this contribution to research, innovation, economic growth and health outcomes.

At the same time, it is important to be realistic about the scope for a major rethink on research policy at a European level. The Lisbon target of raising research and development spending to 3% of GDP by 2010 will only have been met by three Member States, and trends across the EU suggest that the revised target date of 2020 is still an ambitious one. Transforming declaratory statements into action is likely to remain a long-term objective.

In terms of replicating AMRC's successful lobbying in achieving firm government commitments to medical research in the Health and Social Care Bill, it is clear that different approaches would be required to exert influence in a European Union which will soon comprise thirty Member States. At European level, this would involve plugging into existing consultative mechanisms in Brussels, effective lobbying of MEPs and officials and, crucially, achieving critical mass in building a coalition of support from a range of Member States. Nonetheless, AMRC is not starting completely from scratch in developing its oversight of EU policy developments. The Science and Health Policy Group, for example, already operates as a highly useful forum for discussing policy developments at European level and co-ordinating positions where possible. A small number of AMRC members are, of course, also active at EU level and are already contributing to cross-national policy discussions.

If AMRC decides to pursue a more active agenda at EU level, a logical place to start might be to explore deeper links with comparable organisations in Ireland and the Netherlands. This

## conclusions and recommendations

could be helpful in terms of learning lessons from their experience, as well as keeping each other informed of developments and, potentially, working towards a loose, voluntary kind of co-ordination where circumstances allowed for this. Looking upwards from the national agenda, AMRC could also consider having input into policy consultations at EU level, though this is likely to require significant resources.

There is also potential for AMRC to add value to its members by raising their awareness of policy developments at EU level. In the 2010-11 AMRC members' survey, only one respondent (St Peter's Trust for Kidney, Bladder and Cancer Research) suggested information on European funding as an additional benefit that AMRC could provide. This could suggest that members are either satisfied with their own information gathering on Europe (possibly true for some of AMRC's larger members), or that they may be unaware of European possibilities (possibly the case for some of the smaller members), or that they are not engaged at all in European matters.

This report makes a case for greater attention to EU affairs as a means of enabling AMRC and its members to contribute to and influence policy initiatives at EU level, building strategic links with colleagues and counterparts in other Member States, and facilitating access to EU funding programmes. A simple action would be for AMRC to publicise calls for FP7 funding applications when these are open as an opportunity to lever additional funding for members and demonstrate AMRC's awareness of current developments at EU level. However, it would be important to approach this in a sustainable manner, perhaps by acting as a conduit for information rather than dealing with EU bodies on behalf of member organisations. At the same time, AMRC would need to consider whether this could be achieved without raising members' expectations above what is achievable, given AMRC's current resources.

Obviously, any decisions around engaging in Europe will require resources, commitment and time. AMRC needs to decide at what level it wants to engage in Europe and whether this is possible, desirable or feasible with current resources. AMRC may conclude that no further action is required or possible at this point. But this report will hopefully start a discussion within AMRC about some of the possibilities that the European policy agenda offers for medical research charities.

### Recommendations

- 8. Gauging AMRC members' appetite for European engagement:** a number of AMRC members are already engaged with EU policy matters, and there may be scope for further research with member organisations to gauge their level of engagement in Europe; whether they have responded to policy consultations, whether they work internationally or have partners and contacts in other Member States, and whether there is an appetite for further information or engagement with EU affairs. The findings of this further research could be used to inform the level of priority that AMRC should give to European work.
- 9. Encouraging AMRC members to engage in Europe:** while some of the larger members are already engaged in Europe, AMRC could add value to its services by informing all member organisations of relevant EU policy developments. This could be achieved at minimal cost, for example by AMRC signing up to European Commission email alerts and including one European topic (e.g. policy consultations, new research findings, funding rounds) in member briefings, perhaps on a monthly basis. An

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alternative approach would be to include a European policy page on the AMRC website, though this would require regular updating and maintenance.

**10. Developing links with AMRC's sister organisations:** Ireland and the Netherlands already have umbrella organisations for the medical research charities sector (MRCG and Gezondheidsfondsen). Further engagement with these organisations on European policy would provide opportunities to share ideas and good practice, with the possibility of moving towards co-ordinating positions on EU policy matters; this kind of cross-border co-ordination would possibly carry more weight with the Commission than hearing from national medical research charity organisations individually.

**11. Making contact with European organisations:** whereas it might initially be difficult for AMRC to justify the €1,000 annual cost of associate membership of the European Foundations Centre, the European Network on Philanthropy and Research Funding might offer a more focused route of entry. Attendance at the annual conference would offer opportunities for networking with European partners.

**12. Lobbying in Europe:** Part of AMRC's success in the UK lies in its access to policymakers and legislators in support of members' objectives. AMRC currently does not have the capacity to replicate this work at European level, though PAWG acts as a forum for co-ordinating positions between key AMRC members. Clearly, AMRC does not have the resources or the political capital to create an equivalent organisation at a pan-European level. However, consultative networks for feeding civil society views into the European Commission are well established in Brussels, and AMRC could investigate plugging into one of these networks, either through an existing organisation such as the European Foundations Centre, or through seeking membership of a consultative body such as the European Health Policy Forum.

Similarly, establishing contact with UK Members of the European Parliament (MEPs) with an interest in the medical research, the charities sector and health, research and innovation policies could prove useful in terms of raising their awareness of AMRC's work and cultivating potential champions for the medical research charities sector in the European Parliament. This could be prioritised in terms of identifying MEPs who have spoken in health debates, asked parliamentary questions on medical research or have a scientific or medical background before their election as an MEP. However, this kind of lobbying and awareness-raising would have significant cost implications for AMRC in terms of the policy work required and possible attendance at meetings and conferences in Brussels and elsewhere.

**13. Using academic research:** academic research can help demonstrate the added value of philanthropy to policy objectives and, with particular regard to AMRC's agenda, how philanthropy can assist medical research. Academic research networks on philanthropy include ERNOP in Amsterdam/Utrecht and UK contacts at City University: it would be worth making contact with these academics as a means of keeping up with existing research literature and influencing future research programmes on philanthropy.

## conclusions and recommendations

- 14. Drawing on others' expertise and experience:** before committing to a particular approach, AMRC could look at how others have gone about engaging with Europe, what has been successful and what pitfalls are to be avoided. NCVO, CAF and other charities could prove helpful and making contact with the DH and BIS international policy directorates as well as the UK national contact points for Framework Programme 7 could also provide useful pointers.

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