Public Return on Public Spending: H2020 needs strong public interest conditions and incentives

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The Societal Challenges pillar of Horizon 2020 (H2020) plays an important role in reinforcing Europeans citizens' confidence in the European Union (EU). Through investing in innovation that directly improves people's lives, such as health, the EU uses its combined resources to provide real, added-value benefits to its citizens.

Health is considered our most basic and essential asset. Article 168 of the Treaty on the Functioning of the European Union (TFEU) states that a high level of human health protection should be ensured in the definition and implementation of all Union policies and activities. However, major inequalities still exist in healthcare capabilities and children´s well-being within EU member states.

Astronomical prices of new drugs for cancer and hepatitis C in Europe have attracted considerable media and public attention, which has brought the debate on access to medicines in the political spotlight of the EU and its Member States. Though the challenge of access to medicines has long been a concern for low- and middle-income countries, **high prices now also threaten equitable access to treatment in the world's wealthiest countries, including Europe**. Public health experts highlight the **need to improve access to high quality, timely and accurate diagnosis, care, treatment** and long term follow up strategies across Europe.[i]

Health also contributes to the economic prosperity of the EU. Without a healthy European society, the EU cannot ensure smart, sustainable and inclusive growth and it will not meet the targets set out in Europe 2020 - the EU's ten-year growth strategy.

Presently, the public interest in H2020 investments is not sufficiently protected. Many leading experts and governments – including EU Member States - have highlighted the need to improve the way public biomedical research and development (R&D) funding is managed. This is crucial to respond more efficiently to the urgent need for affordable new health technologies that meet priority public health needs. Knowledge generated by EU-taxpayer financed research should maximise the general public benefit and not predominantly lead to returns for large private actors (see Box 1).

BOX 1 - Experts, scientists and governments call for more public leadership in biomedical R&D funding

D-G Research Commissioner Moedas called for more open, transparent research as one of his key priorities in his June 2015 Speech 'Open Innovation, Open Science, Open to the World'. In the **Council Conclusions on pharmaceuticals of June 2016, EU Member States** demanded increased data sharing and further exploration of equitable licensing of publicly funded health R&D to ensure a better return on public investment.[ii] **Science Europe** also pointed to the importance of open science, stating that "all research and innovation builds on the capacity of scientists, research institutions, businesses and citizens to openly access, share, and use scientific information".[iii] In a vision paper on the future of H2020 the **Commission's Scientific Panel for Health (SPH)** states that 'better access to research data can multiply the benefit of investment'.[iv] The **Scientific advisory group on health under Horizon 2020** identifies the need for equitable access to results, the use of truly innovative open-innovation and R&D models and real-time sharing of data between all stakeholders as key changes they would like to see in the H2020 funding framework.[v]

Similar demands to put more stringent conditions on public funding to ensure increased data sharing and affordable access to future medicines have featured in leading international reports. The **UN High Level Panel on Access to Medicines (UNHLP)** has recently urged governments to mandate strong, enforceable policies on data sharing and data

access as a condition to public grants, use open models of innovation and a public health approach to managing resulting intellectual property (IP). It also asks governments to mandate manufacturers and distributors of health technologies to be fully transparent on R&D costs, including any public funding received in this process.[vi] These calls are repeated in the recent **Lancet Commission report on Essential Medicines**. This expert committee asks governments to develop and implement comprehensive national action plans to guarantee equitable access to new essential medicines, including open knowledge innovation and fair licensing practices. It also demands governments to take international public leadership for priority setting for essential R&D, with due regard for the public health needs of low- and middle- income countries.[vii]

In this contribution **we highlight the key principles that should drive the next funding framework programme to enhance the quality and efficiency of Horizon 2020 biomedical R&D spending**. Firm and binding requirements need to be put in place by the European Commission (Commission) from basic research onwards to ensure that publicly funded biomedical R&D targets prioritise public health needs and results in health technologies that are suitable, affordable and available for target populations, including those in resource-poor settings.

Key principles to enhance quality & efficiency of H2020 health spending

1. **More public investments in biomedical R&D**
   - The EU should reverse the budget cuts to H2020 caused by the introduction of the European Fund for Strategic Investment.
   - The EU should increase its investment in biomedical R&D under H2020 and subsequent R&D funding programmes.

2. **Biomedical R&D priority setting determined by public health needs**
   - The EU should keep its Societal Challenge pillar as one of the key cornerstones of its research policies and funding.
   - The EU should adapt priority setting procedures under H2020 and its joint undertakings IMI2 and EDCTP2 to ensure balanced stakeholder involvement and greater transparency in the decision making processes.
   - The EU should increase consistency and cooperation between H2020 and other national and European initiatives in the field of biomedical R&D.

3. **Mandate open access publishing and open data**
   - **Open access publishing**: The EU should prepare a strategy paper for a large-scale transition to open access publishing that addresses current bottlenecks in effective implementation. It should set clear limits on EU research funding compensation for publishers and an EU-wide objective to achieve open access scientific publishing within 5 years for all EU funded research (today it is less than 20%).
   - **Open data**:
     - The EU should limit and further specify the grounds for derogations of open data requirements allowed under the H2020 open data pilot.
     - The EU's open data repository 'Open Aire' should be expanded and reinforced with increased resources to facilitate access and sharing of data from EU financed projects.
     - The EU should consider 'open source dividends' to incentivise through funding reward funding recipients who openly share data, inventions and materials.

4. **Ensure public return on public investment & safeguard equitable access to publicly funded health technologies**

- The EU should make a political commitment to ensure that any taxpayer funding going to biomedical R&D should result in a public health return on investment, in terms of the affordability of end products and access to research results.
- Parties receiving EU biomedical R&D funding need to agree on the affordability of any health technology to be developed as a guiding principle throughout the research and development process.
- EU-funded biomedical R&D projects should include terms and conditions in the governing agreements that require the affordability and availability of products for EU Member States and in LMICs – including equitable licensing.

5. Explore alternative incentive mechanisms for more efficient, high-quality R&D

- The EU should do more to explore the use of milestone prizes and market entry rewards in the field of biomedical R&D. There are several concrete proposals that can be further tested and implemented.
- The EU should ensure the inclusion of conditions requiring affordable access of the end product, access to research data and pro-public health management of IP (e.g. through public ownership of IP) upon reward of the prize to fully de-link the cost of R&D from product pricing.
- Substantially increase the budget for prizes under H2020 to enable larger prizes in the area of biomedical innovation, as well as the development of new diagnostics.

6. Increase transparency of research consortium agreements

- The EU should make research consortium agreements under H2020, including those of its joint undertakings, available through publication. This should include the public (EU) and private shares (in-cash and in-kind) of the contribution to the research consortium.
- Where such publication is not practicable, governance may be accomplished by committees with balanced stakeholder representation (including academia, industry and patient, civil society and consumer groups).

Background note

1. More public Investment in biomedical R&D

Biomedical innovation largely takes place within an incentive framework that prioritises R&D spending not according to public health needs, but according to the expected return on investment. As a result, diseases that primarily affect the poor[viii] and where there is little financial incentive to develop and test new treatments (e.g. new antibiotics or repurposing existing drugs) are largely ignored. Moreover, there has been a striking lack of truly valuable medicines being brought to the market over the last decade.[ix] When market forces alone do not lead to the development of appropriate new health technologies, there is a need for firm public conditions, public sector stewardship and increased investment in biomedical R&D. EU public spending on biomedical R&D is one of the key drivers for better health and patient care, from innovation and implementation to the discovery of original findings. In this context, the EU has a major role to play.

The EU should therefore **reverse the budget cuts to H2020** caused by the introduction of the European Fund for Strategic Investment and **increase its investment in biomedical R&D under H2020 and subsequent R&D funding programmes.** Particular focus should be given to public health

needs that are not presently served by the pharmaceutical market.

2. Improve public health needs-driven priority setting

The Commission Communication on the EU Role in Global Health (2010) highlights that research priorities should focus on those interventions with the 'biggest impact on public health'. For this purpose, the Commission commissioned the WHO Report on Priority Medicines for Europe and the World (2013), which identifies existing pharmaceutical gaps and medicines development needs, to be used as a resource in planning the Horizon 2020 research programme.

However, in H2020 Societal Challenge 1 - Health, Demographic Change and Wellbeing - no reference is made to 'unmet public health needs' as a driver for public investment. Nor does this Challenge mention tackling market failures or call for publicly funded medical tools to be affordable, suitable, and accessible.

In practice, priority setting in public-private partnerships funded through H2020, and joint undertakings under H2020, are often determined by private stakeholders and not by the public interest. This is mainly due to a lack of pluralistic stakeholder participation and a weak political leadership. For example, the Innovative Medicines Initiative 2 (IMI2), Europe's largest public-private initiative under H2020, had the original purpose of developing treatments and essential medicines, particularly in areas where there is an **unmet medical need**. However, research priority setting under IMI2 currently remains largely industry-driven.

The current priority setting process under H2020 - and IMI2 in particular – needs to be changed if we want to achieve the greatest impact on public health of Horizon 2020 public R&D spending. **Priority setting for biomedical R&D spending should be adapted to ensure a balanced, pluralistic stakeholder involvement and strong public leadership in priority setting.** In addition there is a need to increase consistency and cooperation with other national and European initiatives in the field of biomedical R&D, which so far have been limited.

3. Mandate open science with a greater societal impact

The sharing and of data and knowledge from the scientific process accelerates and improves outcomes. Non-disclosure of essential R&D health data means additional delays, bottlenecks and wasteful and – in the case of clinical trials – unethical repetition in the development of life-saving medicines. Broad sharing of data resulting publicly funded projects is therefore essential to reinforce collaborative and cumulative processes to increase scientific knowledge. Better access to research data can multiply the benefit of EU investment under H2020 and subsequent funding programmes.

The Commission has enthusiastically embraced open science and open innovation in its public statements, saying that: *'the on-going transitions in the way research is performed, researchers collaborate, knowledge is shared, and science is organised. In the short term, Open Science is expected to lead to more transparency, research integrity, openness, inclusiveness and networked collaboration.''*[x]

Open science also allows for transparency and greater participation, allowing for innovative solutions and the engagement between science and society (Science with Society).[xi]

Having made important steps in mandating open access publishing and open data in H2020, it is now time to rigorously implement these open science & open innovation principles, especially in the priority area of health.

Open Access Publishing

Although open access publishing is a mandatory obligation under H2020 Rules of Participation, the practice of Open Access still only accounts for 14% of new scientific articles published in the EU. The increase in open access publishing in the EU has been only 1% each year. This is not satisfactory in a context in which scientific publishers have a rate of return on investment of between 30 and 40% and while scientific and academic libraries often cannot afford subscriptions costs.[xii]

Therefore, the Commission should **prepare a strategy paper for large-scale transition to open access publishing** with an economically viable plan for creating the best conditions for this transition with concrete measurable goals for both EU financed research and general scientific research in the EU. This should address current bottlenecks in effective implementation with clear limits on EU research funding compensation for publishers.

Open Data

In H2020, the Commission has launched a **flexible pilot for open access to research data (ORD pilot).** The pilot **aims to improve and maximise access to and re-use of research data generated by H2020 projects**.[xiii] Given the importance of data sharing, exemptions to open data requirements should be extremely limited. However, under this pilot, participants can opt-out of research data sharing at any stage - before or after the signature of the grant agreement. Reasons have to be provided, but the list of admissible grounds for opting out is very broadly formulated: including for intellectual property rights (IP) concerns, privacy/data protection concerns, national security concerns, if it would run against the main objective of the project or for other legitimate reasons.[xiv]

Health has been added to the scope of this pilot project only in 2016 – it is therefore too early to evaluate how often this opt out mechanism has been exercised in practice in this area. However, given the clear need for increased data sharing to facilitate follow-on biomedical research, we are concerned about the wide scope and lack of specific guidelines for opting out under the current pilot.

We encourage the Commission to **take measures to further limit and specify the grounds for derogations of open-data requirements** allowed in the rules for participation and dissemination in H2020, so they can be consistently applied in all programs. This is needed to guarantee legal and procedural certainty for all participants, and ensure an equitable and fair treatment of participants regarding open access to the results generated within all projects, including of its joint undertakings (such as IMI2). Moreover, **the EU's open data repository "Open Aire" should be expanded and reinforced** with increased resources to facilitate access and sharing of data from EU-financed projects.

The Commission should further consider 'open source dividends' to incentivize the greatest degree of openness and social responsibility with data, results and, even technology transfer and IP in sensitive areas such as biomedical research. Such an 'open source dividend' would reward scientists and researchers who openly share data, inventions, materials and knowledge considered significant and useful to other researchers in the area.[xv] This could be funded with a percentage of additional

grant financing and should be available in areas of societal benefit, including public health, security or the environment.

4. Ensure public return on public investment & safeguard equitable access to publicly funded health technologies

The introduction of new, expensive medicines comes at a huge cost to health systems and their percentage of total pharmaceutical expenditure has been rising.[xvi] EU Member States are currently struggling to afford new medicines with excessive price tags, such as for cancer and hepatitis C.[xvii] Prices are set in a way that bears no relation to the cost of R&D or production, but rather according to the maximum of what we will pay to care for our sick, while the real costs of R&D remain unknown.[xviii]

Strong EU public leadership in this area is crucial. About 80 percent of all funds for basic research for medicines[xix] and 30 to 40 percent of all global R&D for health[xx] is publicly funded. However, despite this large share of public contribution, none of the relevant Work Programmes of H2020 – including IMI2 and the European & Developing Countries Clinical Trials Partnership 2 (EDCTP2) - contain provisions to ensure affordable access or suitability of the final medical product. Binding provisions on how to ensure patients' access to medical tools and access to research data should be in place for all R&D consortiums that receive funding from the EU.

Ensuring equitable access and facilitating patient-driven innovation needs to be considered by the EU from the very start of the R&D process and in each research agreement. This pro-public health management of results – including IP - needs to be included as an end goal early in the development process, by making this a condition for receiving R&D grants in the first phases of R&D (basic research, etc.). It is all the more important that private companies that receive public grants need to remain engaged until the later stage of the development process. In that case they would not be bound by the IP management rules and the EU is left without leverage to require affordable access. These conditions are so crucial that we cannot afford to have faith in voluntary cooperation down the line and therefore this needs to be a binding commitment throughout the development process.

Many of the concrete strategies and decisions will need to be taken on a case by case basis, since the solutions will be different depending on the product, the disease and the market. However, there are principles and goals that are of general applicability and that can help guide EU reform of H2020 the Rules of Participation in this area. As a start, the EU needs to **ensure that parties receiving funding agree on the affordability of any health technology to be developed as a guiding principle** throughout the research and development process. In the case where the EU provides contributions at a later stage (or any stage) of the R&D process, it should establish clear access criteria for what it will fund and how the resulting technologies will be made available to patients.

IP management has the potential to enable or restrict access to public funding-derived health technologies. Given the EU's fundamental role in research as well as their responsibility to prioritize public interests in H2020, it must actively promote, and not restrict, access to health products. Therefore:

- Parties receiving EU biomedical R&D funding need to agree on affordability of any health technology to be developed as a guiding principle throughout the research and development process

- EU-funded biomedical R&D projects should include terms and conditions in the governing agreements that require affordability and availability of products for EU Member States and in LMICs – including equitable licensing (see Box 2).

The EU needs to be clear that R&D funding proposals under H2020 and subsequent funding programmes need to include a robust access strategy focusing on making the final product accessible. If proposals contain restrictive provisions that undermine access, these proposals should not be eligible for public funding.

An important strategy is 'equitable licensing' of IP for R&D that has received EU funding. The rationale behind this type of licensing is to generate the highest possible social benefit out of publicly funded research. A basic principle is the use of licensing provisions that foster generic competition or include other robust mechanisms to ensure low end prices of the product. The public funder keeps the right to intervene if societies' access to the product is not ensured. The licensee is obliged to use different tools for improving access to the products, such as, technology transfer, and access and training programs.[xxi] (See Box 2).

H2020 must bring science and innovation closer to citizens. Products, data and findings resulting from such public financing must be converted into accessible public goods. Accessibility, product suitability and affordability should be the key elements on which Horizon 2020 is based.

BOX 2

Equitable licensing

Equitable licensing is promoted in the United States (US) by several leading technology managers of US universities, including UC Berkeley which has implemented the "Socially Responsible IP Management Program".[xxii] Through this programme, UC Berkeley has collaborated with several companies on licensing agreements to ensure affordable pricing in low-income countries for products stemming from university research. Projects with agreements under this programme include, among others, tuberculosis (TB) vaccine research, malaria artemisinin-combination therapies (ACTs) research and research for a possible HIV treatment.

Equitable licensing conditions can be attached to the H2020 Rules of Participation, specifically to grants funding biomedical research. We recognize that specific licensing conditions between research institutes and private parties need to be determined on a case by case basis. However, this does not preclude the Commission from formulating and implementing clear guidelines, and where appropriate mandatory rules, regarding the use and licensing of research results generated under an EU grant. We recommend particularly far-ranging equitable licensing conditions in the field of poverty-related and neglected diseases and new antibiotics, vaccines and diagnostics.

An appropriate set of such conditions should enable non-exclusive licensing as a default. Non-exclusive licensing would help to achieve broader access to health technologies and products, as it allows for more than one company to exploit the innovation, thereby enabling generic competition and as a consequence lowers prices of health technologies and products. If an exclusive licence is negotiated, the EU should retain the right to intervene in case of unmet market or public health needs.

Rules for spin-off companies

In some cases the results of publicly funded research are outsourced to spin-offs/start-up companies that take responsibility for further development. Equitable access to the final product should be considered when negotiating the IP rules, even if it is clear that it might take several years to reach market entry. If the IP is completely transferred to the spin off company, the public originator of the invention should keep a function in the advisory board to ensure involvement during further development.

5. Explore alternative incentive mechanisms for more efficient, high quality R&D

The need to invest in alternative models of innovation

The predominant model for incentivising biomedical innovation relies on market exclusivities, and thus high product prices. Pharmaceutical companies develop drugs based on the likely return that a product will offer through sales. This business model is undergirded by the patent system which effectively establishes monopolies, allowing companies to sell their products without generic competition for a limited time period.

There are, however, several limitations to this model. The first is that it leads to high prices as it locks out competition. Many governments and medical providers face unsustainably high prices for medicines, such as for the hepatitis C drug sofosbuvir that costs up to US$1,000 per pill. It also fails to prioritise according to health needs. The patent monopoly system concentrates investment on products that will sell well and not necessarily on public health priorities. For example, the urgent need for new antibiotics has been widely documented, but governments have been slow to put in place the right incentive mechanisms to encourage development of new antibiotics, and this medical priority remains unanswered by pharmaceutical companies. Further, exclusive IP rights encourage scientists to work in isolation from, and in competition with, one another. Follow-on innovation is also restricted; for example, creating a multidrug regimen or a combination pill cannot easily happen if the relevant patents are owned by competing companies. This siloed approach has blocked the development of new therapies against tuberculosis.

Prizes as a mechanism for de-linkage and a path to affordability

In order to overcome these challenges, policy-makers should actively seek to break the link that today binds biomedical innovation to drug sales and high prices backed by exclusivity rights. Public policies that drive industry to embrace new approaches to R&D, and that do not rely on exclusivity as the method to incentivise innovation, are urgently needed. The concept of de-linkage refers to the separation of the incentives for financing research and development from the price and volume of sales of the developed product (drug, diagnostic or vaccine). As such it provides a pathway to affordable products, by removing the incentive to charge high prices. In order to achieve full de-linkage, the full cost of R&D and adequate incentives need to be provided, and conditionalities need to be attached to funding.

There are a range of ways in which de-linkage can be achieved through both push and pull funding. **Prizes, or market-entry rewards, can act as a mechanism for de-linkage and a path to affordability, by rewarding the development of products up front**. They can be designed to reward mid-term milestone results or only be paid upon market entry, or both.

H2020 prizes for health R&D - not used enough

We note that prizes - called 'challenge' prizes (or 'inducement' prizes) - exist under H2020 and aim at offering a cash reward to whoever can most effectively meet a defined challenge. In the field of public health, Horizon 2020 has delivered *only one single prize* entitled ‘better use of antibiotics’ of €1 million in 2016 to be awarded for ideas on developing and/or bringing-to-market a test to quickly identify whether a patient can be treated safely without antibiotics. At the current funding level, such a prize is more a signal of recognition, than an incentive that seeks to spearhead development in an underserved area.

As part of the conditions mentioned, "*the test needed to be cheap, rapid, easy-to-use for healthcare providers and non- or minimally invasive for patients*". We strongly support the inclusion of low-cost and affordability as part of the eligibility criteria for applicants. However, we urge that the Commission go further and **ensure that affordability is a mandatory condition** of eligibility. Adapting the conditions to prioritize affordability as a mandatory selection criteria would send a strong signal to developers to ensure affordable access is built into the design and planning phases of their work.

Forward looking: Prizes for health R&D under H2020

As prizes aim to create an incentive benefiting all Europeans, the Commission should **make sure that there are conditions attached** concerning socially-responsible IPR governance to the delivery of a large amount of public money through a prize incentive, exclusively coming from the EU budget, i.e. from European tax-payers.

Experts[xxiii] have recommended that the prize rewards need to be set at a level where they are a credible incentive for private investors, and not simply a token of recognition. In addition, a prize should be linked with credible governance institutions; clear rules for the award of prizes and reputable scientific advisory committees.[xxiv] The most important recommendation is, however, that prizes should - as a central purpose – de-link the costs of R&D from product prices to promote affordable access to products. **For real de-linkage to be achieved, the granting of the end prize/market entry reward or milestone prize must be accompanied by obligations** for the developer to license their intellectual property, know-how and data on the product to allow for affordable access. By contrast, the notion of 'partial de-linkage' will marry the granting of the market entry reward to certain conditions, but would still enable the developer to set prices and to recoup at least part of their investment through product sales.

Often the opportunity to ensure de-linkage is overlooked by public funders, including the EU, because the funding for R&D is not linked or coordinated. For example, the EU framework programmes have supported a lot of basic science and early stage research and the EDCTP has provided funding for clinical trials from Phases One through Four. However, unless the EU attaches conditions to this funding, the potential for de-linkage to lower prices and steer needs-driven R&D will not be achieved.

Prizes allow for incentivizing innovation in priority areas, and for ensuring the inclusion of conditions requiring affordable access upon reward of the prize. The EU, however, has only used this incentive mechanism once in the field of health – and without any mandatory access conditions attached. The EU should do more to explore the effective use of milestone and end prizes/market entry rewards in the field of biomedical R&D. There are several concrete proposals that can be further tested and implemented.

BOX 3 – Example prize proposals

The 3P project

As a successful example, the '3P Project' offers a viable and immediately implementable solution to address the shortfalls in tuberculosis (TB) drug development. The first two pillars of the 3P Project – "pull" and "push" funding – address this issue by incentivizing and rewarding participation, especially among small- and medium-sized companies, through breaking down the drug development process into distinct, manageable stages. By introducing the prize (the pull mechanism) early in the pipeline, the 3P Project helps the organisations currently investing in TB drug R&D to see a timely return on their investment in the early costs of drug development, and aims to stimulate a large increase in such investments by essentially creating a market for the prize - and thus a market for the development of pre-clinical drug

compounds, where none had previously existed. The 3P Project's third pillar – IP and data "pooling" – responds to the unique needs of TB treatment. By pooling IP through licensing and ensuring data sharing, the 3P Project allows earlier, faster and more innovative combinations to be trialed. This mechanism of funding effectively delinks R&D financing from the end product price, so drugs can be made available at affordable prices.[xxv]

Cancer Prize Fund proposal
Another proposal is to create an innovation fund for cancer drugs that includes an allocation for innovation inducement prizes to reward new drugs for cancer. This proposal would include the following features:

1. De-monopolize cancer drugs
2. Put 10 percent of EU member state treatment budgets into an innovation fund
3. Provide half into grants for cancer research (push funding)
4. Provide provide 40 percent for end product prizes
5. Provide 3 percent for open source dividends
6. Provide 7 percent for milestone prizes.

More information at: http://delinkage.org/.

6. Increase transparency of research consortium agreements

Effective governance is essential to ensure and monitor that the implementation of Horizon 2020 biomedical R&D spending is driven by priority health needs, spent efficiently, and leads to new health technologies that are available and affordable to those in need.

To ensure transparency and accountability, **research consortium agreements under Horizon 2020 (including those of its joint undertakings: IMI2 and EDCTP2) should be made available through publication.** This should **include the public (EU) and private shares (in-cash and in-kind)** of the contribution to the research consortium. This is crucial because without this transparency any discussion about the sustainability of the R&D process remains impossible. Where such publication is not practicable, governance may be accomplished by committees with balanced stakeholder representation (including academia, industry and patient, civil society and consumer groups).

ENDNOTES

[i] Report (2016) Advice 2016 of the Horizon 2020 Advisory Group for Societal Challenge 1, "Health, Demographic Change and Well-being", p. 48. Available at: https://ec.europa.eu/research/health/pdf/ag_advice_report_2018-2020.pdf (Accessed 11 January 2017).

[ii] Council Conclusions (EC) press release no. 350/16 of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States.

[iii] Scientific Panel for Health (May 2016) A vision on 'Better Research for Better Health", p. 7. Available at: http://ec.europa.eu/programmes/horizon2020/sites/horizon2020/files/SPH_Vision_Paper_27052016.pdf (Accessed 11 Janaury 2017)

[iv] Ibid endnote iii – p.14.

[v] Ibid endnote i -p.37.

[vi] United Nations High Level Panel on Access to Medicines (2016) *Promoting Innovation and Access to Health Technologies.* Available at: http://www.unsgaccessmeds.org/final-report (Accessed 28 September 2016).

[vii] Ref lancet report

[viii] Such as tuberculosis, neglected and poverty-related diseases, rare diseases like Ebola, etc.

[ix] Independent drug bulletin *La Revue Prescrire* has rated new patented medicines that were brought onto the market from 2000-2013 and concluded that only 9% offer a therapeutic advantage as compared to existing products on the market. See:

Revue Prescrire (2011) New drugs and indications in 2010: inadequate assessment; patients at risk. *Revue Prescrire*, 20(115): pp.105–110. Revue Prescrire (2015), 35 (376), pp. 132-148; Revue Prescrire (2005), 25 (258), pp.139-148.

[x] DG Research & Innovation : http://ec.europa.eu/research/index.cfm?pg=dg

[xi] As stated in the EU Parliament Resolution on Horizon 2020 in 2012*: ''Finding the right answers to the challenges Europe is facing requires the involvement of as many diverse actors as possible in the research and innovation process. Traditionally, interaction between science and society has been limited to a one-way, top-down, transfer of knowledge from experts to citizens. Advancing towards an open, effective and democratic knowledge-based society requires a change to a more bidirectional dialogue and active cooperation beyond traditional science education or the current conception of citizens as mere consumers of research findings. This dialogic relationship and active cooperation will undoubtedly allow science and innovation to proceed more responsibly.''* Resolution available at: http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&mode=XML&reference=A7-2012-427&language=EN.

[xii] Schimmer, R. (2016) 'Making moves towards the large-scale transition to Open Access', Max Planck Digital Library, published by SPARC Europe. Available at: http://sparceurope.org/wp-content/uploads/2016/11/Schimmer_231016_Final.pdf.

[xiii] Webpage European Commission 'Open Access and Data Management'. Available at: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-dissemination_en.htm (Accessed 11 January 2017).

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[xv] Love, J., (2014), 'The Value of an Open Source Dividend', Managing Intellectual Property, 16 October [Online]. Available at: http://www.managingip.com/Blog/3390962/The-value-of-an-open-source-dividend.html

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