From Lab to Commons

Shifting to a public interest biomedical system

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Commons Network

Commons Network is a civil society organisation that works with activists, thinkers, pioneers and policy makers to tell stories, build networks and propose policies to support commoners and defend the commons throughout Europe. CN works in favor of more social and ecological societies and focuses on the democratic stewardship of knowledge and the knowledge commons. Access to medicines has been an important part of CN's work since its founding, with a focus on European policy regarding trade, public funding, and incentives for biomedical innovation.

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Acronyms

AMR	Antimicrobial resistance
DNDI	Drugs for Neglected Diseases Initiative
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EOSC	European Open Science Cloud
EU	European Union
GDP	Gross domestic product.
GSPoA	Global Strategy and Plan of Action on Public Health, Innovation and IP
H2020	Horizon R&D programme European Commission
H1N1	Influenza A virus subtype H1N1
HLEG	High Level Expert Group
HTA	Health Technology Assessment
IMI	Innovative Medicine Initiative
IP	Intellectual Property
IPR	Intellectual Property Rights
MPP	Medicines Patent Pool
OA	Open Access
OECD	Organisation for Economic Cooperation and Development
PDP	Product Development Partnership
R&D	Research and Development
SME	Small and Mid-sized Enterprise
SPC	Supplementary Protection Certificates
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
WHA	World Health Assembly
WHO	World Health Organization
WTO	World Trade Organisation
UK	United Kingdom
UN	United Nations
UNDP	United Nations Development Prorgamme
US	United States

Boxes & Graphics

Content

1. Introduction

From the 15th-20th century tens of thousands of powerful individuals, aided by state institutions, enclosed and privatized commonly-held land managed by local communities around the world. This process displaced hundreds of millions of small-scale farmers who, to a great degree, lost their autonomous means of sustenance and were forcibly cast into urban labour markets. This enclosure of life-supporting common land was a vast revolution of the rich against the poor.[1]

In the late 20th century and early 21st century a similar enclosure movement has taken place, aided by international intellectual property laws and treaties, regulatory capture and international trade agreements. This time, the action has transformed the public good of scientific medical knowledge and related health-related technologies into highly protected, privatized and expensive products. Although our current biomedical system has produced important lifesaving and quality-of-life treatments, today billions of people around the world are unable to afford and access these medicines, resulting in over 10 million preventable deaths each year.[2] These outcomes are perpetuated by an unacceptable policy paradigm for biomedical research.

At the same time, across a range of sectors, from wikipedia to renewable energy cooperatives, from open access academic publishing to urban agriculture, from local land trusts to self-managed cultural hubs, from car-pooling to patent pooling, we see people responding with new cooperative attitudes and social structures that promote the common social-environmental good. This means regenerating value for the community rather than enclosing the commons for individual profit and replenishing knowledge and resources rather than extracting utility for competitive advantage.

This paper reviews the main debates around how biomedical innovation is managed in the context of European Union (EU) policy. We build on previous work by Commons Network authors in 2017[I] and 2012[II] which explored EU policy opportunities and suggested a new structural environment promoting the knowledge commons for public benefit.

I. The EU and the Commons: A Commons Approach to European Knowledge Policy, 2015 (Commons Network).
II. Time for the EU to lead on Innovation: EU Policy opportunities in biomedical innovation and the promotion of public knowledge goods, 2012 (HAI, TACD).

In 2018, we go further, showing how a commons approach in biomedical research & development (R&D) can help pull us out of the current crisis of over-diagnosis, over-prescription, low innovation, secrecy and sky-rocketing costs for both patients and health systems. While not exhaustive in our analysis of the many factors affecting biomedical innovation and public health, we propose entry points in the form of policies with the power to transition society away from the current proprietary, centralised and extractive model. In a second step, we put forward a vision for future initiatives in line with commons principles, where the EU should be investing for long-term benefit.

Instead of proposing small tweaks the commons vision challenges the idea of handling medicines principally as a commodity or product, and proposes structural changes in order to approach health as a common good, managed in a democratic, public and equitable manner. There is a growing social willingness to address today's encroachment on the right to health in the biomedical sector, but where would we begin transforming a complex system which today has increasingly been commercialized and commodified? How can we turn the tables and start to 'commonify' what the majority of EU citizens have always considered a common good?

EU institutions should ally themselves with citizens calling for meaningful change so that we can together address taboos around intellectual property and health-care commodification. We must question the root causes, not just the symptoms, of today's biomedical innovation model. By looking at problems through the lens of the commons, EU institutions can ensure the stewardship of health by ushering in a more democratic, affordable and sustainable biomedical system.

Box 1 : What Does the Commons Mean Today?

A commons approach means equitably, sustainably and democratically sharing essential resources, regenerating what is common instead of extracting and enclosing for private use. It means creating abundance with immaterial knowledge goods while wisely governing scarce natural resources.

It means opening up access to resources with clear rules to avoid depletion and free-riding.

It strives to nurture local community culture, economy and environment while working toward inclusive bottom-up, horizontal participative processes and livelihoods that are neither dominated by the market nor the state.

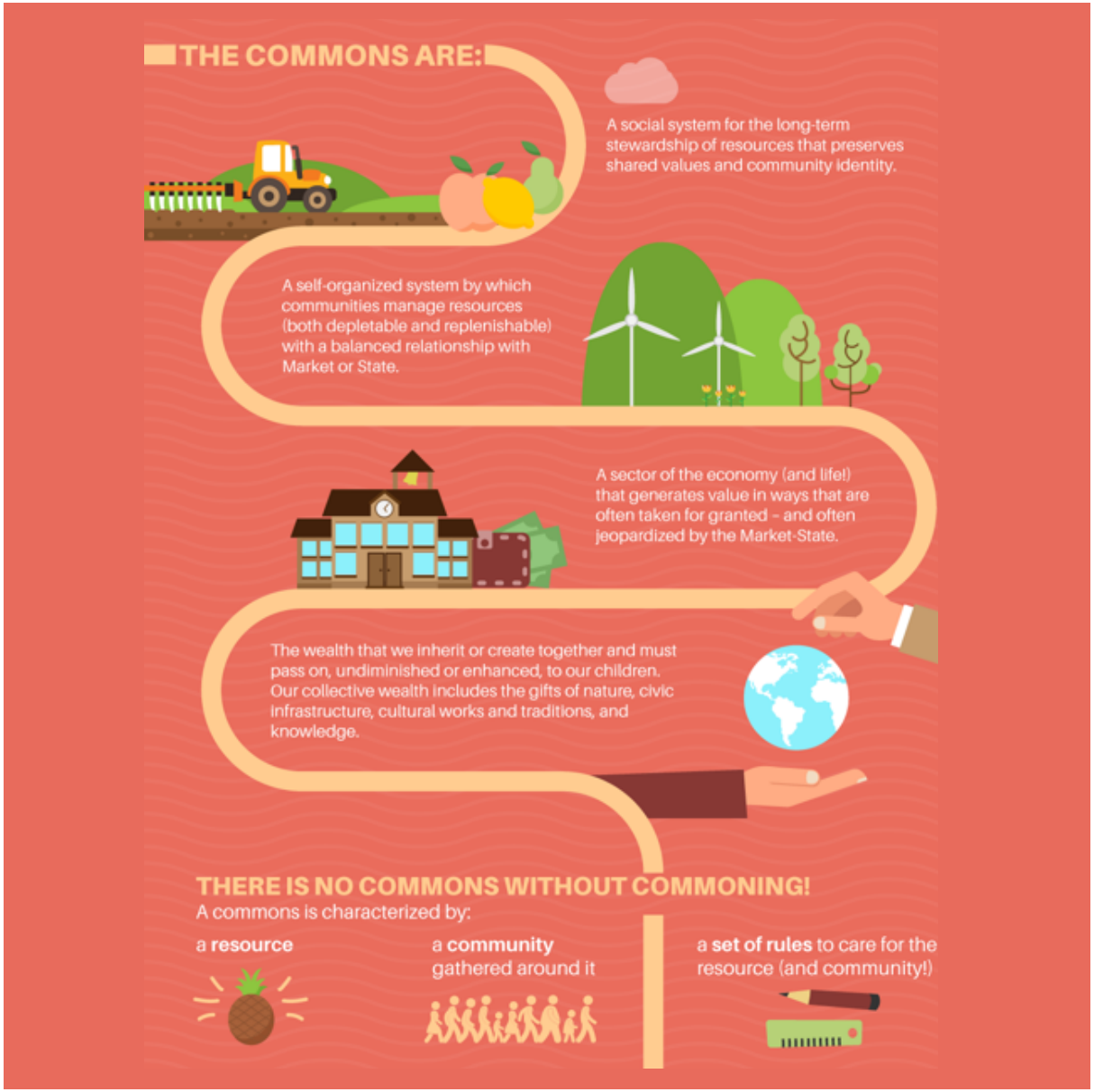
It means considering the common good both socially and ecologically beyond borders, classes or species. It is about universally inclusive collective rights that prioritize our connection with the natural world, combined with a profound respect for gender, ethnicity and individual diversity.

It is not an ideology nor does it pretend to be an all-encompassing narrative.

Gradual change in defence of the commons can adopt pragmatic hybrid forms that attempt to overcome some of our contemporary dualisms like public and private, society and nature, reason and emotion, expert and non-expert.

Graphic I:
What are the Commons?

A commons approach means equitably, sustainably and democratically sharing essential resources, regenerating what is common
instead of extracting and enclosing for private use. It means creating abundance with immaterial knowledge goods while wisely governing scarce natural resources.



Text: *Michel Bauwens, David Bollier, Silke Helfrich, Vasilis Kostakis Stacco Troncoso, Ann Marie Ultratel.*
Designer: *Elena Martinez. CC-BY-SA*

2. Medicines: product or common good?

The current model of biomedical innovation has produced key medicines for several disease areas and has led to some important health benefits. Yet pharmaceutical R&D has not been able to sustain the levels of therapeutically useful productivity and efficiency reached in the second half of the 20th century. Despite advances in the understanding of the biological basis of disease, the current model consistently fails to provide the required therapeutic solutions in crucial medical areas such as Alzheimer's disease or novel antibiotics.

The present model based on patent protection relies on high prices and thrives financially on knowledge enclosure through Intellectual Property (IP) protection accelerated by commercial secrecy.[III] Private actors are not only claiming private ownership rights in fundamental types of medical knowledge, genes and other life forms, but also in scholarly work, mathematical algorithms and images of public buildings. The private enclosure of biomedical research data and results is enormously wasteful and harmful. It is estimated that over 170 billion euros of research funding are wasted each year because outcomes cannot be used.[3] The excessive expansion of intellectual property rights (IPR) has been called a 'second enclosure movement'.[4]

> *"Knowledge is a non- or anti-rival good which gains in use value the more it is shared. Through legal repression or technological sabotage, naturally shareable goods are made artificially scarce so that extra profits can be generated. This is particularly grievous for life-saving or planet-regenerating technological knowledge."*[5] ***Michel Bauwens***

There are great structural tensions between the narrow logic of the market and the open democratic governance needed in order to efficiently treat health as a public good. However the profit-driven system has permeated deeply into institutions, social narratives and scientific methods. The consequences for EU health systems and for citizens are increasingly visible and costly.

The Role of Patents & Monopolies

The rationale behind patent protection is that it will stimulate competition and reward innovation, while the point of the expiry date is to allow subsequently affordable products and re-stimulate innovation. Other IP protections for medicines are data exclusivity, supplementary patent certificates (SPCs) and additional market exclusivity. Yet it is a popular myth that patents drive innovation and social progress. The recent inflation of patents actually harms innovation as it often blocks the ability of science

*III. Knowledge enclosure is particularly grievous as it anti-democratically redefines the forum where decisions are made such that, today, virtually all conflicts are settled by state bureaucracies and/or experts controlled to a great extent by powerful lobbies driven by narrow financial interests.

to advance in an open, exploratory manner and hinders competition by focusing on legal protection.[6] Furthermore, poorer countries of the global South are radically hindered from adapting the latest scientific developments to their needs.[7] The original objective of patents to serve universal public needs is no longer being met today and, furthermore, it is clear that the way IP rights are being used today they are doing more harm than good.[8]

Box 2 : A Brief History of Patents

Patents were originally instituted by governments to be limited in scope and time in order to serve public needs; the aim was to "encourage creative intellectual endeavour in the public interest."[9] ***The patent system is currently the dominant incentive framework for the development of new medicines, but this was not always the case.***

The contemporary era of patentability began with the Convention of the Union of Paris in 1883 following the Vienna Conference of 1873. The Patent Cooperation Treaty was signed in Washington DC on June 19, 1970. Most countries in Europe apart from the United Kingdom (UK) just granted patents on process and have only introduced product patents since about 1970 (France 1960), (Germany 1967), (Switzerland 1977), while Italy had no patents on pharmaceuticals at all until 1978.[10] ***Spain only introduced patents on products in 1986 as it was getting ready to join the EU and only implemented the usage by 1992.***[11]

The Agreement on Trade-Related Aspects of IPR (TRIPS) signed in 1995 under the World Trade Organisation (WTO) negotiations globalised the European and United States (US) standards to the rest of the world. Before TRIPS, many developing countries did not grant pharmaceutical product patents, and/or they limited patent terms. Many developing countries opposed TRIPS as contrary to their interest and to the public good.[12]

When put in practice in the biomedical sector, patents often reward even minor variations in a product rather than pushing for high-impact innovation or real clinical advances. Since the end goal is a patent-protected monopoly ensuring the possibility of high prices, patenting encourages copy-cat research, the development of late-stage treatments rather than early-stage prevention or cures and biases in favour of research whose end-products are met with lucrative markets.[13]

Most expensive blockbuster medicines nowadays are biologic medicines, and their part of pharmaceutical sales is growing steadily (27% in Europe in 2014).[14] Biologics are expensive and prices far exceed the most costly classic small molecule medicines-on average 20 times more.[15] Yet for biologics not only IP protection but also the regulatory regime as regards biosimilars/biogenerics is proving to be a pervasive barrier to competition. Regulatory barriers, in what could be seen as a case of regulatory capture, make it difficult to introduce biosimilars swiftly and at cheaper costs.[16] Biosimilar market entry still generally results in significant cost savings, as they are on average 30% lower in price.[17]

To a great extent, in contrast with claims of the industry, most large pharmaceutical companies are not 'innovative research-based' industries. Instead, their speculative financial operations often constitute a type of 'rentier capitalism'.[18] The portion of profits of large EU and US companies that derive from rents on artificially created scarcities such as patents, copyrights and trademark has skyrocketed from 17% in 1999 to 31% in 2016 with the pharmaceutical sector one of the leaders in rent-seeking.[19]

Devilish Choices

> *"Giving a drug company a monopoly where it charges what it can is like negotiating firefighters' pay when they show up at your burning house."* [20] ***Dean Baker***

Contrary to popular myth, the pricing of medicines does not tend to reflect either an increased therapeutic value of the products or research and development costs.[21] Instead, in many cases, the price corresponds to the maximum price the market can bear, irrespective of the consequences on human health nor the financial impact on public health systems.

Millions of Europeans, especially in Eastern Europe, lack access due to rationing of expensive products or because they must pay out of the pocket for much-needed medicines.[22] There exists a moral chasm between high medicine prices and the cost of making them, as one pharmaceutical CEO admits: "the cost of manufacturing a drug is infinitesimal compared to what it gets priced at."[23] Skyrocketing prices in the EU increasingly threaten the affordability of medicines, even depriving patients of new lifesaving treatments, for example for cancer, and create massive financial stress on public health systems such that appropriate treatments must be rationed. Governments are forced to make devilish choices on which patients should be treated when just a few expensive treatments need to be rationed.[24]

Governments face the same dilemma with Hepatitis C. Chronic Hepatitis C affects around 130-180 million people globally and half a million people die from it each year; a chronic infection can also develop into liver cirrhosis or liver cancer. In Europe over 15 million persons are estimated to be infected.[25] Due to the high price of the three-month treatment (ranging from 500 EUR in India to around 20,000 EUR in Spain to over 40,000 EUR in Germany) the majority of patients are not receiving the best treatments for curing the disease.[26]

In many European countries the drug price predicament is mounting pressure on policy-makers, as health journalist Peter O'Donell points out: "they are having to fund ever-growing demands for ever-more expensive treatments from an ever-older population, all at a time of persistent austerity. And in parallel to the wider problems of health systems, the complexities that bedevil the mechanisms for pricing medicines are so numerous that they have, so far, baffled all attempts at breakthrough solutions — rendering any talk of (EU) cooperation and collaboration almost meaningless."[27]

Too Much and Too Little

Capital-driven pharmaceutical markets primarily create and respond to market 'consumer demand' not public-health needs. By enclosing resources, both material and immaterial, and through massive marketing, the pharmaceutical industry and its institutional supporters betray the general public interest by creating artificial knowledge scarcity and at the same time unlimited consumer demands for new medical products.

Just as overeating is a major public health problem alongside malnutrition and hunger, 'drug obesity' grows alongside 'drug famine'. Market-driven pharmaceutical companies actively promote a problematic 'drug obesity' fed by overmedication, over-diagnosis, superfluous 'me-too' products and the false belief that there is a 'pill for every ill'. Public health researchers Ray Moynihan, Jenny Doust, and David Henry concluded: “medicine’s much hailed ability to help the sick is fast being challenged by its propensity to harm the healthy. A burgeoning scientific literature is fuelling public concerns that too many people are being overdosed, over-treated, and over-diagnosed”.[28] One stark example is the case of oxycodone and Purdue Pharma, known for its aggressive promotion of OxyContin in the late 1990s which created its own rapidly expanding market; the approach is credited as one major source of today's opioid epidemic in the US.[29]

At the same time, the less affluent of the world suffer from 'drug famine'. The symptoms are unaffordable essential treatments as well the lack of medicines and diagnostics for patients who do not provide lucrative returns. According to the United Nations (UN) between 2 and 5.5 billion persons, or three-quarters of the world´s population, have very limited or no access to essential medicines.[30] This is not only due to high prices but the fact that only 1% of global R&D expenditures are devoted to diseases prevalent in the Global South. Diseases relevant to high-income countries are investigated in clinical trials 7-8 times more often than are diseases whose burden lies mainly in low-income and middle-income countries.[31]

Return on Investment

While the EU and its 28 Member States are major public funders of biomedical research it is not clear how this public funding provides returns for better health, more useful medical products or the increased health-related knowledge. When asked specifically about the public return of EU public investments in medical research and development, the European Commission was very clear about the main objectives of EU funding: "return on investment from such EU-funded health research consists in creating jobs and economic growth, maintaining leadership of EU health research and innovation, supporting academic research institutions and SMEs*IV , and increasing competitiveness of industry with the pharmaceutical industry being one of the EU's key industries."[32]

The social contract of the second half of the 20th century between the citizens of many Western countries, their governments and economic actors allowed for massive public investments in scientific research in favour of the public good where there was a relative balance between private and public interests. Many breakthroughs in biomedical science come from publicly-funded laboratories at universities, research institutes and government laboratories. Approximately 80% of all funds for basic research for medicines and 30-40 % of all global health R&D is publicly funded.[33]

Yet in the last few decades this equilibrium has been broken in favour of the interests of powerful economic minorities, particularly in the biomedical sector (by means of subsidies, grants and tax-breaks), with a stress on profitability and private return on investment. Public investment often gets privatised during the testing and development phase; taxpayers can end up paying pay twice, first to fund the research, and then again when the new drugs come onto the market at profit-driven prices. [34] Health knowledge, especially if created with public funding, should be a public good and not be sold off for commercial aims. However, this is exactly what is happening with publicly financed research results done by public universities.[35]

**IV. Small and mid-sized enterprises.*

Conflicts of Interest

Conflicts of interest permeate the entire process of drug development, approval and marketing. They appear in medical schools and health sector professional trainings, in ubiquitous marketing campaigns targeting doctors and patients and in the pharmaceutical industry regulatory capture of political institutions and agencies.[36] For example, the European Medicines Agency (EMA) receives 89% of its funding as fees collected from the pharmaceutical industry. Also some EMA officials are the product of 'revolving doors', having worked for the industry before working for the agency[37]. Concern over possible conflicts of interests and bad administration has prompted investigations by the European Ombudsman,[38] as well as many complaints by civil society and scientific organizations such as the Cochrane Collaboration.[39]

Industry-sponsored clinical trials are also characterised by non-transparency and limited public access to results which form the basis of the medicine approvals by the EMA and other European medicines agencies. Manipulation of study designs, methodological biases and selective publication permeate industry-funded clinical studies. A new EU regulation will oblige greater transparency and access to clinical studies (though not the raw data) for evaluation by independent scientists. However, this new rule does not apply to existing medicines nor to some commercially “sensitive” data. A 2018 European Court of Justice ruling establishes that wide access to clinical trial data is in the public interest and cannot be protected as a rule by commercial confidentiality interests.[40] Here it should be noted that independent, democratically governed scientific bodies are needed to set research priorities and downgrade the value of evidence produced under conflict of interest biases.

3. Managing Perverse Incentives

Member states and the EU have several policies in place that aim to manage the current incentives structures, and ensure certain level of affordability, safety and rational use, for example reference pricing, joint procurement and HTAs. However, strong narratives from the pharmaceutical sector further entrench the current system in euphemistic or misleading language. Despite big promises, the solutions put forward often maintain, or even worsen, the status quo of high prices, lack of clear therapeutic value and increasing regulatory loopholes.

Box 3 - Pharmish: Narrative spins

There is a wide vocabulary of terms, slogans and euphemisms first introduced in the US by pharmaceutical companies, and used widely today in discussions around biomedical innovation, which further entrench and protect the status quo. Unmet medical needs, real-life data, early dialogue, personalized medicine, orphan drugs, value-based pricing, speedy market entry, returns on investment, adaptive licensing, real-world evidence, and more uncertainty in exchange for more access, are just a few of the slogans and terms that have been promoted by commercial interests in favour of further enclosure of the health commons.

'Timely access to market of innovative medicines' *This means shortening and simplifying the 'regulatory barriers' (authorization, safety and efficacy testing, clinical trial requirements).*

'Innovation' *This is used to mean any new medicine on the market regardless of its therapeutic added value compared to existing medicines (to which they are rarely compared) and regardless of price. Whatever is protected by IPR, the more patents filed, means more innovation. The longer the monopoly periods of 'data exclusivity' and 'supplementary patent certificates', the more positive 'innovation environment'.*

Real-world evidence' *This means data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than randomized clinical trials in 3 or 4 phases of increasing size and complexity. This is a key element of the EMA´s 'adaptive pathways' proposal. In practice this means weakening the standards for review and approval of supplemental new drug applications and de-facto lower the bar for the type of evidence needed to meet post-approval requirements.*[41]

'Public-private partnerships' *or* ***'joint undertakings'*** *This means that the pharmaceutical industry leads, the European Commission follow and public funds become privatised. The Innovative Medicines Initiative (IMI) is one example of joint EU-Pharma initiatives (1.5 billion EU funds matched by the pharmaceutical industry's opaque in-kind contributions) and is often criticized for its lack of transparency and accountability and the absence of public control over research results and IPR."* [42]

'Pricing transparency' *This usually means no public transparency of medicine prices paid by governments but increasing the number of hoops governments must jump through to justify not buying high priced medicines but generic products instead.*

'Differentiated prices' *This means keeping prices from going down, less price transparency and restricting EU internal market to prevent 'parallel trade'. It means basing pricing on GDP*[*V] *to let the wealthier countries pay more for expensive medicines than poorer ones. However, pharmaceutical companies freely establish the first prices on the market meaning that prices for the poorest EU countries still can be 50-100 times above the cost of production and still unaffordable for the public health system and for patients.*

*V.Gross domestic product.

Value-based, Personalisation and Orphanisation

The industry has to a large extent embraced the narrative of 'value-based pricing' or 'prices by health outcome'. This means justifying high prices for new medicines protected by patent monopolies on the basis of opportunity cost linked to alternative medicines. A 2017 World Health Organization (WHO) report on 'fair pricing' has also been very critical of this strategy on pricing, stating: "with regard to pricing drivers and strategies, a 'value-based' pricing model is not viable in many countries because it does not take into account affordability and total cost. Used in isolation, it also has the potential to exclude other valuable price-negotiation tools such as tendering and price-volume agreements." [43]

'Personalized medicine' is a development financed by EU research programmes promoted by the pharmaceutical industry which are usually treatments based on costly genomic alterations, e.g. for certain cancers or rare diseases.[44] Top cancer researchers have raised serious doubts citing the lack of hard evidence to validate the claims of these new treatments.[45] More worrisome still is the business model shifting from a few 'blockbuster' medicine products to 'niche busters'. A myriad of new products are produced for the specific ailments of narrow populations; they are allowed to follow much smaller, less expensive clinical trial obligations to prove the efficacy and safety of the medicines and they often enjoy early market entry advantages, lower regulatory barriers and longer market exclusivity. Once these very high-end products are in the market, the patient populations are often subsequently broadened or there is an off-label use for other illnesses.

The EU is now following the path taken by the US where nearly half of new medical products approved are such 'orphan drugs', while 75% of all novel cancer drugs.[46] Nineteen out of twenty of the best-selling drugs in the world today are orphan drugs.[47] In the EU 'orphan' or 'rare disease' indications are the basis of over 25% of new medicines approved by the EMA and it is estimated that by 2025 over 22 billion euros will be spent on these products by EU member state public health systems.[48] Many such new oncology drugs have high prices but uncertain value according to independent studies.[49] One systematic review states that, of 68 new oncology drugs approved by the EMA, 58% had shown no evidence of greater survival or quality of life for patients.[50] An overview of official French health technology assessment reports on new medicines for cancer reveals the majority of new cancer drugs brought to market have limited therapeutic value but high prices. [51]

Trading Away Health: Exporting Harmful Practice

> *"Trade agreements that extend patent monopolies and delay the availability of lower-priced generics put new and innovative health technologies out of reach for those who need them most."* [52] ***The Director General of the WHO, Dr Tedros Adhanom Ghebreyesus, March 2018 .***

The IPR policies pursued by the EU have been those of granting ever longer market exclusivities and stronger enforcement mechanisms, expanding the already substantial rights of pharmaceutical companies.[53] Concerns about the effects of expanded patent protection on generic competition and innovation have been widely recognised, including by the European Commission itself.[54] However the EU actively exports these IPR norms by means of its trade policy with countries around the world.[55] The latest example is the ongoing EU-Mercosur negotiations in early 2018.[56]

It is morally questionable to export such practices abroad while at the same time recognising their possible harmful consequences to health systems and innovation at home. Ultimately, it also undermines Member States' efforts to protect and promote the health of it citizens through IP reforms since a trade agreement locks in these norms in the EU as well, making it much harder to implement changes. [57]

Health Technology Assessments (HTAs): Worth the Price?

In February 2018, the European Commission proposed legislation to harmonize and regulate HTAs. This will define to a great degree how biomedical innovation is evaluated in the EU.[58] Many EU Member States have HTA bodies that carry out studies in order to recommend a decision on whether the medicine should be reimbursed or purchased by the state. The HTAs review clinical trial and other data to decide if the new products have an added therapeutic value as well as calibrating the efficacy and safety of the medicine, performing a cost-benefit analysis and comparing the new product to the performance of the best existing products.

For many HTAs it is nearly impossible to evaluate a new medicine without sufficient patient-level information (often not accessible) beyond summaries of clinical trial studies. The role of HTAs lies at the centre of the EU´s pharmaceutical debate and the European Commission has held a consultation on greater EU harmonisation and centralized control of the HTAs.

However there is a conflict in the EU between strong national HTAs and proposals of lowering standards for new medicine authorizations such as 'adaptive licensing'. Moreover, there is even concern in some EU Member States that centralized EU competence or EMA control over the evaluation of the therapeutic value and safety of new medicines could worsen the present situation by limiting independent evaluation by HTAs with diverse methodologies and restricting access to relevant data.

Reference Pricing

Once an EU Member State decides to reimburse or purchase a new product it chooses a 'basket' of a few countries, usually of similar wealth and purchasing power, as 'external price references'. They establish pricing criteria for negotiations with the pharmaceutical industry that include discounts and rebates 'a la carte' according to volume, capacity to pay and political pressure.

In countries where there is no centralised public procurement there can also be 'internal reference prices' by regions or even by large hospitals. In this process there is a great deal of secrecy about the real prices that are paid as opposed to the official listed prices. Many countries must even sign non-disclosure commitments against revealing the prices actually paid.[59] This 'one-way transparency' strengthens the hand of pharmaceutical companies in negotiations as they are usually the only actors aware of actual prices paid by different EU countries.

Joint Procurement - Voluntary Cooperation

Seeing the potential price reductions of bulk purchasing, in 2014, the EU Commission set up a 'Joint Procurement Agreement on Medical

Countermeasures', an agreement to allow EU Member States to purchase medicines and medical equipment in response to communicable disease epidemics, such as the H1N1*VI epidemic of 2010. Currently, 24 Member States have signed the agreement. Although limited to medicines for communicable diseases, this framework sets a precedent for wider collaboration among countries. Indeed, the EU Health Commissioner has openly encouraged Member States to jointly purchase expensive medicines, going beyond the remit of the 2014 agreement.[60]

A voluntary inter-governmental collaboration initiative between the Netherlands, Belgium, Luxembourg and Austria, more commonly known as 'Beneluxa', appears to be an ambitious attempt to change the balance of power in medicine price negotiations (specially orphan drugs), however its outcomes are unclear thus far.[61] In mid 2017, six southern European countries, Portugal, Spain, Italy, Malta, Greece and Cypress, signed the Valleta Declaration (a number of other EU Eastern-European and Balkan countries signed the declaration by early 2018)[62] which commits themselves to to collaborate to bring down high drug prices, to share information about price negotiations and to consider joint procurement. Bulgaria and Romania, two EU Member States with severe access to medicine problems, have also announced closer bilateral cooperation concerning high drug prices.[63]

While EU-wide medicine purchases are not to be expected, smaller groups of joint procurement of countries with similar income levels could drive prices down somewhat and may even have the support of some industry. As one pharmaceutical industry publication has stated: “the trend of small joint-procurement agreements across the region, however, will allow drug prices to reflect the economic development of each small group. This presents opportunities for drugmakers to sell considerably higher volumes without sacrificing their profit margins.”[64]

Competition Policy

Competition policy is key for keeping monopolies in check from preventing competition from generic medical products. In 2009, the European Commission carried out the Pharmaceutical Sector Inquiry which showed hundreds of patent settlements between originator and generic pharmaceutical companies to prevent or delay competition from generic medicines. These 'pay to delay' operations continue to be monitored by the anti-trust department of the European Commission but no important fines have been applied.[65]

*VI. Influenza A virus subtype H1N1.

4. The Political Context

The lack of affordable medicines and useful innovation in certain disease areas is now an issue on the radar of policy makers who see the need and possibility of change. What may not yet be fully recognised yet is extent of fundamental change required to ensure public return for citizens and to protect public interest against corporate dominance.

European Values

The EU has been built on the free movement of goods, services, labour and capital and framed around equal rights for all citizens before European law, recognising common values of democracy, human rights and solidarity.

Yet today, a massive degree of health inequality exists among EU citizens and between EU Member States[66] and the large "health gap" between wealthier EU regions and poorer ones shows no signs of narrowing.[67] One of the reasons for this chasm is the policy paradigm for biomedical research and production that Member states and EU policy makers continue to embrace.

Applying strict and expansive IPR to new medical treatments – with few legal provisions for meeting public needs despite massive public funding for such research – strengthen barriers to health care treatments for EU citizens, including life-saving medical treatments for patients suffering from cancer, HIV/AIDS and Hepatitis C. A recent study by the European Society of Medical Oncology concluded: "the cost and affordability of anticancer treatments with recent market approval is the major factor contributing to inequity of access to anticancer medications."[68] As long as the free flow of goods inside the EU is accompanied by strong uniform patent monopolies, millions of people with low wages in EU states limited by insufficient public health budgets, will suffer from the high medicine prices set in richer EU countries.

Where is the 'useful Europe' that is often invoked by top EU officials in defence of the European Project? For example, very popular EU legislation was adapted to eliminate abusively high roaming rates for calls and data between EU states. But in case of high priced medicines, there is a contradiction between some of the EU´s single market rules which are focused on a 'fair playing field' for competition, growth and jobs and the commitment to universal access to affordable health treatments.

Shifting Sands in Europe

The modus operandi of EU medicines policy has long been to strengthen patent protection (even with high prices) to seek results for health innovation, competition, growth and jobs. Today this seemingly immovable cornerstone of EU policy has begun to be questioned by EU Member State representatives. EU governments have started to recognize that there are significant flaws in the current biomedical model.

The 2016 Council conclusions under the Dutch Presidency "recognize that new medicinal products may also pose new challenges to individuals patients and public health systems, in particular regarding the assessment of their added value, the consequences for pricing and reimbursement, the financial sustainability of health systems, their post-market surveillance and patient access and affordability."[69] With this the 28 European Health Ministers signed the most strongly worded Council Conclusions to date. They broke a series of taboos and addressed for the first time possible dysfunctions at the core of the biomedical model: the overprotection, misuse and abuse of IP incentives for medical innovation.

The Council commissioned a study to be carried out for "an evidence-based analysis of the impact of pharmaceutical incentives and rewards, including the Supplementary Protection Certificates (SPC), data exclusivity and market exclusivity on innovation, availability and accessibility of medicinal products in the EU."[70] As the European Public Health Alliance has stated, the terms of reference for the study echo an "unprecedented critique of the additional forms of patent protection and the abuse of the incentives in the case of drugs created specifically to tackle rare diseases (orphan drugs)."[71]

Issuing a hard-hitting critique of drug pricing, an expert panel report on medical innovation, which published Future Scenarios for Drug Pricing in the EU under the auspices of the health ministers of the Netherlands and Belgium, concluded that "an inescapable conclusion is that drug development and pricing will have to go through a significant transition to respond to the 21st century public health challenges. ……Conventional ways of dealing with IP rights will have to be revised for medicines, which, after all, are not consumer goods but products with a public goods character."[72] (see box in section ***Transitional and Transformative Initiatives***)

In 2017 the European Parliament approved the Cabezón Report on "Access to Medicines" which reviewed key aspects affecting the affordability and efficacy of medicines in the EU. The report recognises that "the high level of public funds used for R&D is not reflected in the pricing owing to the lack of traceability of the public funds in the patenting and licensing conditions, impeding a fair public return on public investment."[73] The European Parliament report makes a clear call for more transparency in the cost of R&D, questions the widespread use of fast-tracking of marketing authorisations. It also criticizes 'value-based pricing' as potentially undermining an 'optimal distribution of social welfare', as well as questioning the added therapeutic value of many new products citing that the "data supporting the assessment of the added value of innovative medicines is often scarce and not sufficiently convincing to support solid decision-making on pricing." Furthermore it calls for exploring de-linkage mechanisms for neglected research areas.[74]

The Global Receptivity to New R&D Models

> *"We must not tolerate systems that put the protection of intellectual property ahead of the protection of health. Patients must always come before patents."*[75] ***The Director General of the WHO, Dr Tedros Adhanom Ghebreyesus, March 2018 .***

The mood has been also changing on an international level around global health governance. In 2016, recommendations of the UN Secretary-General´s High-Level Panel on Access to Medicines[76] were published. They demonstrate the scientific, financial and moral shortcomings of the current pharmaceutical R&D model and highlight the need for a radical overhaul in favour of affordability, new financing mechanisms and open-source science. Also in 2016 the Organisation for Economic Cooperation and Development (OECD) issued a strong statement on "the proliferation of high-cost medicines and rising drug prices that are increasing pressures on public health spending and calling into question the pharmaceutical industry's pricing strategies".[77]

Debates about the need for alternative incentives for innovation in health products at the WHO have been ongoing for over 15 years but have newly gained momentum. Proposals building on the 2008, WHO Global Strategy and Plan of Action on Public Health, Innovation and IP (GSPoA), have led to concrete recommendations for financing and coordinating new incentives for R&D to meet global health needs. A high-level expert group has emphasized the importance of 'delinking' the costs of R&D from the price of the end product as well as 'open knowledge innovation', and recommended that governments begin negotiations for a multilateral global health R&D convention.[78]

The 2018 Executive Board meeting of the WHA has pushed further. The lack of access to medicines and need-driven innovation has traditionally has been a priority for 'developing countries' and NGOs. This is the first WHO Executive Board meeting where several developed countries (especially European countries) raised the challenges with lack of access and high medicine prices and asked WHO DG to priority this issue. Some of the stronger statements on this came from EU Member States, like Portugal and Netherlands.[79] The Executive Board of the WHO approved a five-year work plan in favour of affordable access to medicines that supported the UN High-Level Expert Panel recommendations with the discomfort of the US and the EU and the enthusiasm of most of the rest of the world.

Acknowledgment of the need for new norms and global agreement on principles on R&D funding is also slowing advancing. The 2016 UN political declaration on AMR was significant because all UN Member States agreed on the need for new incentives and funding strategies to stimulate the development and production of new antibiotics that de-linked from price and sales volume to ensure investment, affordability and rational use."[80]

5. The Commons Vision for Biomedical Science

In contrast to health commodification and its resulting tragedies, the commons framework recognizes health as a common good to be managed in a deeply democratic and equitable way. The commons refers to shared resources, the communities that manage them and the specific rules, practices and traditions that those communities devise. The concept is anchored in an ethical perspective favouring indirect reciprocity as well as social and ecological sustainability. In this framework, well-being and social wealth are not defined by narrow economic performance indicators, but are guided by more comprehensive set of criteria including moral legitimacy, social cohesion, level of participation, equity and social justice.[81]

The current approach to medical science in Europe has created an emphasis on mechanistic interventions with, such as pharmaceuticals and medical devices that often do not fully reflect the complexity of the living world and human experience.[82] For instance, depression is often

depicted as caused by the deficit of a single neurotransmitter, serotonin, and hence could be simply fixed by fixing this system (with SSRIs). Such a gross oversimplification is not only an insult to the patients it also hinders the development of more comprehensive treatments. This scientific, social and moral complexity should be recognised more broadly."[83] Although these technologies can play a very important role in health, over-reliance has come at the expense of ignoring the great influence of our social contexts, our physical environment and our lifestyle decisions. Furthermore, these other causal factors should also not be studied in isolation. As complexity science taught us, we cannot understand the whole by the causality of the parts, we need a comprehensive framework that aims at understanding the full complexity of health systems. This has broad implications ranging from the education of medical students to policy choices on what type of intervention to support.

Beyond Individual Rights

The commons perspective provides a rich framework for defending social, environmental, democratic and societal objectives that go beyond individual rights. With a focus on community and sustainable social ecosystems, it provides an alternative to a pure human rights perspective based on the limitless needs of the individual in a market-oriented worldview disconnected from the realistic needs of the community. Sometimes there is a moral and practical conflict between the sum of individual demands and the sustainability of the collectivity. This does not mean abandoning the human rights perspective but extending it with a collective sustainability perspective. In practice we can combine both with a 'bifocal' vision.

There are two distinct ideas of justice that partially overlap complementarily. The first is the individual rights or human rights perspective, as embraced by many public health advocates. This perspective concerns the moral duties owed to any individual person as a member of humanity to procure access to health-care and treatment. The other sense of justice refers to the provision of common goods crucial for the attainment of health and refers to the collective responsibility for, and the collective governance of, health.[84] As such the commons perspective gives special emphasis to the creation and institutionalization of global health-related common goods*VII (which in turn are one

*VII. Common goods are goods that benefit all people in society and are fundamental to their every day lives. Health, education and public infrastructure, for example, have long been considered common goods that public bodies oversee, manage or protect. Public goods- in economic terms- are goods that are both non-excludable and non-rivalrous in that individuals cannot be effectively excluded from use and where use by one individual does not reduce availability to others. Some use the term "global public good" for public goods which is non-rival and non-excludable throughout the whole world, as opposed to a public good which exists in just one national area. Knowledge has been held to be an example of a global public good, but also as a commons, the knowledge commons.(Wikipedia)

of the best strategies for securing the human right to health).

In other words, the commons perspective goes beyond the human rights approach by adding another layer for considerations of sustainability, social burden and social sufficiency to individual rights demands.

The Tragedy of the Anti-commons

The original narrative of the 'tragedy of the commons' expressed by Garret Hardin[85] tells the story of how insatiable, self-interested individuals cause ruin and scarcity by unlimited exploitation of physical resources. Hardin in fact did not describe a commons but a free-for-all, open access context with no clear rules nor monitoring to defend the common good. The solution often given to the overuse of an unregulated commons is private ownership but as we see in today´s world too much concentrated private ownership can also result in harmful overuse and/or unfair underuse of a resource. specially immaterial ones.[86] The biomedical model today is not failing society because it is a commons which has become overused; it is the opposite: a model with artificial scarcity of immaterial knowledge goods, unbridled enclosure and social exclusion due to a market structured to favour corporate interests. Today we see instead the 'tragedy of the anti-commons'.[87]

The logic of the homo economicus lies at the heart of IP policies and the neoliberal paradigm. This fictional abstract individual of standard economics forever maximizes his personal material gain through rational calculation[75]. People are actually motivated by reciprocity, social cooperation and recognition, as least as much as material gain.[88] The IP system assumes ‘free riding’ by competitors or that producers will unfairly steal from prior work and undermine any incentives to create and invent and therefor enclosure is necessary for innovation. On the contrary, research accelerates through sharing and collaboration, as already recognised by a scientific method which has always required an ethos of open, rational, broad-based exchange and debate.[89] Furthermore, it could be said that it is precisely the pharma industry that 'free rides' massive public financing of R&D, tax-credits, enormous taxpayer purchases of their often over-priced products, monopoly IPR privileges conceded by the state and extraordinary cross-party political support for their business model in legislations and international trade agreements.

Yochai Benkler observes how the enclosure of knowledge is now being confronted by emerging social commons- oriented practices propelled by digital technologies: ".. Social trends in the past few years, however, are pushing in the opposite direction. These are precisely the trends of networked information economy, of non-market production, of an increased ethic of sharing, and an increased ambition to participate in communities of practice that produce vast quantities of information, knowledge, and culture for free use, sharing, and follow-on creation by others. The political and judicial pressures to form an institutional ecology that is decidedly tilted in favor of proprietary business models are running head-on into the emerging social practices."[90]

Biomedical Knowledge as a Commons

Nested in the broader ethical perspective of stewarding health as a commons is the management of biomedical knowledge as a commons. In this sense knowledge commons refer to the 'institutionalized community governance of the sharing and, in some cases, creation, of information, science, knowledge, data, and other types of intellectual and cultural resources'.[91] Knowledge commons are of a different nature than natural resource commons, in part because knowledge is immaterial and one person's use does not subtract from others possibility to use them. Importantly, a knowledge resource is a public good and it often makes sense to share it outside of a particular limited commons. Fortunately knowledge can be governed as a commons but still have an open character (such as open licenses on medicines patents).Once knowledge is considered as a joint responsibility, policy alternatives appear which facilitate equitable access and which result in abundant and regenerative knowledge. Knowledge commons could facilitate open global research and local production adapted to local contexts-needs. The mode of production, both of knowledge, scientific process and physical products, would be generative rather than extractive, avoiding the great waste, duplication and opacity of our present model.

From Open to Commons

There is an important distinction to be made between unregulated openness and the commons. In general, systems such as open access publishing, open data, open source software, represent a significant improvement over closed proprietary systems. However 'openness' varies

in practice and, while introducing some essential change, it may or may not automatically favour the broader common good. For instance 'open innovation' may not guarantee wide access to the products of shared knowledge. The principles of openness might be applied solely to early research and pre-competitive processes, leaving companies free to privatize the value and knowledge that is created later, as is the case for much research captured from universities by the pharmaceutical sector. The virtues of 'openness' can be even more problematic because sharing data online may end up violating privacy and commodifying digital identities.[92]

Yet purely understanding a knowledge commons as a temporary means of managing knowledge for efficiency reasons is also problematic. Placing health knowledge in a commons means introducing a set of democratically-established rules, boundaries and limits to assure equitable and sustainable sharing of health-related resources. These constraints are meant to thwart 'free-riders' (such as those who take but don´t contribute) and extractive privatization. Commons governance should be understood as a type of stewardship - the term 'stewardship' in this sense represents the responsible and careful management of entrusted resources.

Stewardship goes a step further than openness by addressing governance to sustain resources over time and ensure their protection. It implies participatory management of knowledge in vetting its accuracy, assuring its accessibility, hosting public dialogue about it, and ensuring its financial support. It does not mean just sharing data, knowledge and facts without regard for their social use, access and preservation. Stewardship involves creating structures, channels and organisational pathways to enable participation in re-interpreting, re-creating and inserting knowledge into socially and ecologically meaningful contexts.

Box 4: Ostrom Guiding Principles

Building from the seminal work of Elinor Ostrom, a set of principles emerge which can also guide the selection and choice of biomedical initiatives which have the potential to deliver a health commons for the public good.

Ostrom's Commons Principles [93]	***Biomedical Knowledge Commons Principles***
1. Define clear group boundaries.	1. Define the community of people sharing the commons, e.g. researchers, contributors, users, public, private and civic actors.
2. Adapt rules of use to the type of commons and its user.	2. Adapt rules as every knowledge commons is different, e.g. a patent pool does not require the same rules / repository infrastructure as a data commons
3. Ensure that those affected by the rules can participate in modifying the rules.	3. Ensure participation, even outside the immediate community; it means a bottom-up, open, democratic debate between experts and non-experts.*VIII
4. Make sure the rule-making rights of community members are respected by outside authorities.	4. Ensure authorities / the state / laws regulalte and protect the commons in a capacitating and partner role.
5. Abuse by individuals or "free-riding" needs to be curbed in a gradual way.	5. Avoid abuse and free riding, such as the enclosure & privatisation of knowledge, e.g. restrict enclosure of publicly-financed research or the patenting of life forms in the natural commons.
6. Use graduated sanctions for rule violators.	6. Use sanctions, e.g. enforce the protection of knowledge commons such as for the non-sharing of existing or new clinical trial data.
7. Provide accessible, low-cost means for dispute resolution.	7. Implement fair, transparent dispute resolution mechanisms.
8. Build responsibility for governing the common resource in nested tiers from the lowest level up to the entire interconnected system.	8. Responsibility for governance is subsidiary throughout the system, noting the bottom-up institutional context. [94]

**VIII. In recognition of the complexity in genetic, chemical or biological processes and their crucial interrelationship with the social realm, the commons perspective strives to overcome modern society-nature, culture-bio-physical world dualisms. One consequence is opening up the processes of biomedical science to a wide democratic debate between different kinds of experts and non-experts.*

Comprehensive Healthcare and Scientific complexity

There is no pill for every ill and technological interventions are not always the solution. Yet currently our societies routinely take medical scientific approaches to issues or problems that should actually be addressed through social, environmental, and economic means. This technological solutionism approach often serves markets more than public health needs. Contrary to "scientism" the commons perspective helps re-contextualize scientific inquiry within a clear social and moral framework.

Furthermore, the commons vision of scientific enquiry reflects the general ideas of complexity theory. Unlike reductionism to a single cause or linear thinking (that does provide some degree predictability), complexity science theory is characterized by non-linearity, transdisciplinarity, and the dynamic and sometimes unpredictable interaction of bio-physical, social, lifestyle and genetic factors.[95] The pharmaceutical industry benefits from the outdated Newtonian notion of the body as a "mechanical clock" (today with genetic and biological terminology) in which there is a high degree of linearity and direct cause-effect with a sometimes overly specialized focus on one organ or a part of an organ or one health indicator.[96]

Additionally, as Thomas Kuhn has pointed out, science responds to agreements and provisional consensus on paradigms in dispute. Here the changes in alliances and support for certain paradigms which are socially conditioned change in different sciences providing epistemic validity to different scientific theories. Hence, it is also this social process and not a value-less immaculate method that often drives science.[97] If scientists define their method as "objectively neutral" in values and social objectives and if different kinds of knowledge and narrow methodological approaches are kept in separate hyper-specialized isolated silos(often conditioned by commercial interests), it is quite possible that many of the results to not reflect well the complex reality of the living bodies they study.[98] This again underlines the need to open up the objectives and processes of medical sciences to a wide debate among multidisciplinary experts and non-experts, policy-makers and citizens.[99]

**IX. From complexity theory and post-normal scientific perspectives scientific decisions often face a four-fold challenge: "'facts are uncertain, values are in dispute, the stakes are high and the decisions are urgent". From the commons perspective sometimes we need to extend accepted "facts" beyond the supposed objectivity of traditional research. This "extended peer community" of new non-expert participants, without a direct vested interest in the process, would not be treated as passive learners at the feet of experts; instead, they will share the work of quality assurance of the scientific inputs to the process, and would sometimes help arrive at the resolution of complex issues through open debate and dialogue. http://www.ejolt.org/2013/02/post-normal-science/*

The State and Private Actors vis-a-vis the Commons

The commons perspective envisions a 'partner state' that helps forge public-civic collaborations, including risk facilitation, to generate a biomedical health commons.[100] A 'partner state' would mean a radical shift for the present context in which most states act in a tight alliance with the interests and commercial goals of large pharmaceutical industries, often their 'national champions'. It would also mean substituting many 'public-private' partnerships (that often result in the privatization of public knowledge) with 'public-civic' partnerships based on broad expert and non-expert participation, full transparency, pro-commons licensing and universal health needs.

If a biomedical good is publicly owned this can be an important but insufficient factor for the health commons. A state-owned good, immaterial or material, can be a part of the health commons if it is democratically governed in favour of universal health needs with wide civic participation, knowledge sharing and transparency.

A private company could also contribute to a biomedical commons, as a service provider or if it prioritizes the common objectives above rent-seeking, ensures the defence of universal public health needs, uses patents in a limited and fair way and commits to regenerative knowledge management.

6. Transitional & Transformative Initiatives

There is a growing willingness to address today's encroachment on the right to health in the biomedical sector, but how to begin transforming such a complex system with entrenched narratives and interests? There are many initiatives and suggestions already helping to transition away's from today's biomedical crisis where the EU should invest further and encourage improvement, being wary that some do not go far enough to ensure the health commons and may even be counterproductive if the transition is not accompanied by an insistence on affordable access to resulting treatments.

They include open knowledge and collaborative innovation, using incentive systems where IP does not establish a barrier to access/use, while innovators are still rewarded and focusing R&D on added therapeutic benefit. Such initiatives seek to protect knowledge as a public good, for example through socially responsible licensing of public research results (with strict rules for sharing and transparency and against speculative technology transfer), robust open data policies, a science commons infrastructure of repositories, and trade policies that open up instead of enclose biomedical knowledge and technology transfer for the global South.

In contrast with these transitional initiatives which, while positive, work within the current paradigm to invoke change, the commons approach envisions a new paradigm. This includes a 'partner state' that helps forge public-civic collaboration and that aims at ensuring structural conditions for stewardship of a biomedical health commons.

Some follow the lead of other sectors experimenting with open source and decentralised production, e.g. blockchain technology, 3-D printing and peer to peer co-operatives. Such civil society stewardship promises structural change, however initiatives would need to be scaled up significantly and adapted to ensure equitable access at the end of the process. Finally, they all build on the crucial progress of transitional initiatives. e.g. open knowledge and de-linkage.

Box 5: Future Scenarios for Drug Pricing in the EU[101]

In the Future Scenarios for Drug Pricing in the EU, published under the auspices of the health ministers of the Netherlands and Belgium, proposals range from minor changes to a major overhaul of the prevailing biomedical innovation model. EU governments and institutions should explore back these ideas with resources, pilot programmes and viability studies. Scenario 3 and 4 would move us away from status quo while 1 & 2 are suggestions for progressive initiatives in parallel with the present model of biomedical innovation.

Scenario 1 – Needs-oriented Public-Private Partnerships

Public actors and drug developers are tackling public health priorities in vigorous and pragmatic partnerships. The public actor identifies indications representing high public health needs; specifies criteria for the performance levels of drugs to be developed for those indications; and indicates his willingness to pay. Through procurements with enforceable contractual commitments, the public actor enters into a partnership with drug developers to find solutions for these needs. Developers are prepared to enter into the partnership and to give price concessions for a pre-negotiated fixed agreement on price and volume, and speedier access to market, which reduces their development risk. This drug development and pricing model is close to existing governmental procurement practices in research intensive areas such as public transport, defence and space exploration.

Scenario 2 – Parallel Drug Development Track

EU Member States set up a parallel, not-for-profit drug development track that exists alongside, but independent of, the pharmaceutical and biotechnological industry. The aim of the parallel track is to develop cheaper drugs without compromising safety and effectiveness. After having made up an inventory of the public health gaps and priorities in healthcare, EU Member State authorities ask leading public research institutes which discoveries, assets, tools and capabilities they possess in order to develop solutions addressing (some of) the needs that were identified.

Starting from the match between demand and available expertise, coalitions are built between these (not-for-profit) research institutes, payers, authorities and patient organisations. All these partners make the commitment to participate in an open and transparent way in clinical research projects. IPR are acquired early on in the development process by the partners of the consortium, and ownership is shared. Alternatively, the parallel research infrastructure can completely de-prioritise ownership, i.e. inventions and developments in the parallel track are not protected and are in the public domain.

Scenario 3 – Pay for Patents

A consortium of European countries has joined forces and has established a 'Public Fund for Affordable Drugs'. Each of the participating countries deposits a fixed annual percentage of what they currently spend on drugs into the Fund. Private payers (including insurance companies) can also join. The Fund continuously screens the research market for 'interesting' drugs that are being developed in phase II or in phase III for indications with clear health priorities. The Fund buys off the patents from developers, conducts or commissions the last phases of research in public research institutes, or subcontracts to private partners (but then with strict public oversight), and guides the submission process for market authorisation. Because the drug is then put on the market at a relatively low price, this generates substantial savings for the public payer.

Once the system is functioning 'at cruising speed', these savings can (partly) serve to replenish the Fund. The 'Pay for Patents' model de-links research and development from manufacturing and sales. The prices decrease because the partners in the Fund consider medicines as public goods, which should not be financed through monopoly prices. Hence, once the patent is owned by the public sector, after a successful development and authorisation trajectory, the rights to produce, distribute and sell the drug can be licensed to manufacturers and distributors that provide the best deal in terms of quality, safety, and accessibility for the lowest cost. As a rule, various private partners compete with each other, with the result that 'new drugs enter the market at generic prices'.

Scenario 4 – Public Good from A to Z

Drug development is essentially a public enterprise, and has been radically reoriented from serving private profits towards serving the public interest and the needs of patients. In a drug development system that is essentially a public enterprise, private drug companies still have a role, albeit with a completely different business model. They mainly manufacture drugs and deliver services to the public provider on a competitive basis. With drugs and other health technologies essentially public goods, there is no role for patents or monopolistic prices.

Patients and public health providers, not corporations, choose which unmet needs research should address. Public authorities regularly publish lists of research priorities, based on objectively established and patient-informed unmet medical needs. Governments organise and fund that research

through a variety of mechanisms, including requests for proposals based on well-defined targets that any research team, public or private, can compete for milestone compensation, and active management of the innovation process.

By paying directly for R&D and active management of the drug development pipeline, nations and healthcare systems pay much less than the patent-protected prices of the past. Ultimately, drug prices are set on the basis of the real costs of manufacturing, quality control and distribution, which are decoupled from R and D costs.

Shifting Incentives to needs-driven innovation: delinkage

There is a need to shift to approaches to innovation that are health-needs driven rather then market-driven. A paramount concept to achieve this transition is the principle of delinkage. The concept of delinkage refers to the separation of the incentives for financing research and development from the price and volume of the sales of the developed product.

Delinkage describes the idea that temporary monopolies and the associated high drug prices should not be used to fund pharmaceutical research and development, as well as a set of policy proposals that would replace monopolies and high prices with alternative incentives based upon cash rewards, and expanded funding for research, drug development, and clinical trials through a combination of grants, contracts, tax credits, and other subsidies. Delinkage would transform the business model of the pharmaceutical industry in order to expand access, improve outcomes, and reduce costs."[102]

Here it is not the expectation of a profitable market then drives investment but the expectation of a substantial health impact that is rewarded. Generic competition would be possible right from the start as there would be no market exclusivity for the medical technology. There are a

range of ways in which de-linkage can be achieved through both push and pull funding.[103] Some would claim that only private companies are able to finance risk for new drug development, and that therefore delinkage is unviable, however this is incoherent with the already significant public funding invested in biomedical research.

Progressive delinkage will allow governments to implement reforms over time that sequentially and progressively move prices closer and closer to affordable generic prices, and reform incentives so they no longer rely upon high prices. Incentive mechanisms that currently rely on the granting of product monopolies and high prices (patents, test data monopolies, orphan drug exclusivity, etc.), would be progressively replaced with new incentives including, most importantly, cash innovation inducement prizes or prize funds.[104]

Prizes, or market-entry rewards, can act as a mechanism for de-linkage and a path to affordability, by rewarding the development of products with cash. They can be designed to reward mid-term milestone results or only be paid upon market entry, or both.[105]

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, H2020 has delivered one prize entitled ‘better use of antibiotics’ of one million Euros 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 with public control of the IPR.

Open source dividends are another incentive geared towards the sharing of knowledge, yet specifically in the research phase. They seek to reward scientists and researchers who openly share data, inventions, materials and knowledge considered significant and useful to other researchers in the area.[106] 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.

Sharing Knowledge

Thanks to digital technologies the past two decades have seen unprecedented new forms of collaboration in the creation and sharing of knowledge. Progressively, a variety of actors, including governments and researchers, are seeing the benefits of moving away from closed proprietary models to open inclusive ones. The sharing of useful knowledge brings significant economic, social and civic benefits, allowing for access to knowledge goods and broad participation.

Open Science

"Open Science is the practice of science in such a way that others can collaborate and contribute, where research data, lab notes and other research processes are freely available, under terms that enable reuse, redistribution and reproduction of the research and its underlying data and methods."[107]

Open science allows for transparency and greater participation, resulting in more innovative solutions through the engagement between science and society.[108] Open science includes the shift from the standard practices of publishing research results in scientific publications towards sharing and using all available knowledge at an earlier stage in the research process. The European Commission has enthusiastically embraced open science and open innovation in its public statements. They state, for example: "open science represents a new approach to the scientific process based on cooperative work and new ways of diffusing knowledge by using digital technologies and new collaborative tools. In the short term, Open Science is expected to lead to more transparency, research integrity, openness, inclusiveness and networked collaboration".[109] Yet they fall short in their actions. For a coherent policy of science and innovation to be truly 'open' would also mean lowering the high walls of commercial confidentiality and patent monopolies that weaken the social return of public investments in biomedical R&D.

Open Science can contribute to more efficient and productive science and innovation, as well as greater quality and integrity of the research process.[110t] To promote open science legal barriers of data exclusivity and commercial confidentiality, creating competition rather than collaboration among scientists, need to be removed. The non-disclosure of essential R&D health data means additional delays, bottlenecks and waste; in the case of clinical trials, there is a risk of unethical repetition in the development of life-saving medicines.

Beyond the measurement of research productivity by certain journal publications or the number of patents filed, success metrics should include openness and social objectives of the medicine discovery system, judged in last instance, by the efficacy, safety and affordability of new medical treatments.

Open Access Publishing

Open Access (OA) "refers to online research outputs that are free of all restrictions on access (e.g. tolls) and free of many restrictions on use (e.g. certain copyright and license restrictions). Open Access can be applied to all forms of published research output, including peer-reviewed and non peer-reviewed academic journal articles, conference papers, theses, book chapters and monographs."[111]

Even though research is largely funded with public money, results remain behind barriers and privatised, instead of being public goods. Open access publishing models make knowledge available online to the public for free. OA publishing is a mandatory obligation under H2020 Rules of Participation, yet in 2016 the practice still only accounted for 14% of new scientific articles published in the EU, with annual rate of increase of only 1%.This does not present a transformative shift of an entrenched publishing model. Moreover, academic publishers have been charging high publication fees from researchers who wish to publish under immediate open access conditions(without a one year embargo period). 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, there is need for faster progress.[112]

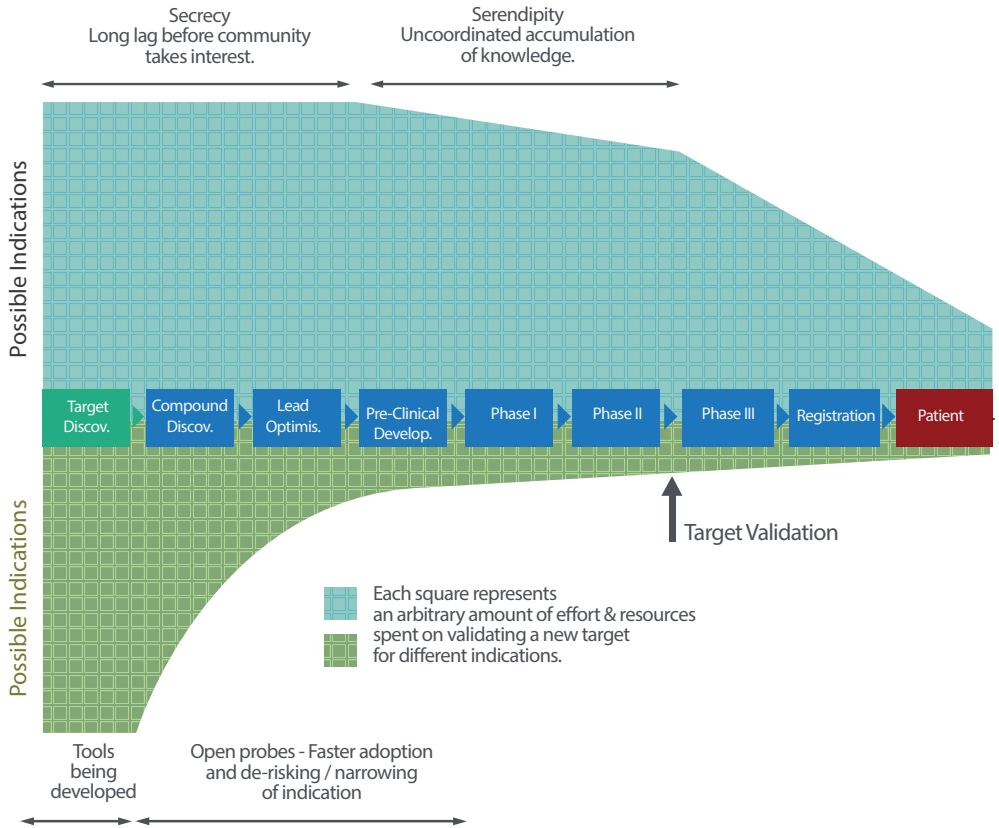
Open Data

'Open data is the idea that some data should be freely available to everyone to use and republish as they wish, without restrictions from copyright, patents or other mechanisms of control.' [113]

In the Horizon 2020 programme (H2020), the Commission launched a flexible pilot for open access to research data (ORD pilot). The pilot aims to improve and maximize access to and re-use of research data generated by H2020 projects.[114] The Pilot balances openness with 'protection of scientific information, commercialisation and IP rights, privacy concerns and security and data management questions'. Given the clear benefits and 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.[115] A European Commission overview completed in 2016 found 68% of the funded projects in the core areas participated in the ORD policy.[116]

Graphic II: Open Science

Open science accelerates identification of the best drug indications, in the correct population.



Closed Model

-Knowledge accumulation is linear, repetitive and slow.
-Longer to de-risk.
-Limited access to global academia.
-Small non-pooled funds.

Open Model

-Open access & freedom to operate ensure much quicker adoption.
-Knowledge accumulation is exponential, less repetitive and fast.
-Longer to de-risk.
-Unlimited access to global academia.
-Larger pooled funds.

The closed (upper half) model is compared to the open (lower half) model; the availability of open access chemical tools for novel proteins and the resulting freedom to operate enable a global community of researchers to explore different indications and diseases in parallel and quickly share their results through publications. The breadth and depth of the studies in the open model lower the risks of failure in subsequent stages in a typical drug discovery programme, allowing the scientists to focus on the most promising indications, whilst reducing the level of effort (open squares), wastage, and duplication engendered by the secrecy that characterises the closed models. Each square represents an arbitrary amount of effort and resources spent on validating a new target for different indications. Source: Lee, W.H. (2015). Open access target validation is a more efficient way to accelerate drug discovery. PLoS Biol, 13(6): e1002164.

Socially Responsible Licensing

Socially responsible licensing which is also referred to as equitable licensing, refers to all kinds of contract clauses and licensing forms that secure the possibility for inventors and technology suppliers to share their IP, most notably for low and middle income countries outside the EU but also for EU Member States. A basic principle is the use of licensing provisions that foster generic competition or other mechanisms to ensure low end prices of the product.[117]

The rationale behind socially responsible licensing is to generate the highest possible social benefit out of publicly funded research. The concept is appropriate in the case of public research institutions licensing results to private companies, but also in the case of private companies which are receiving public funding for their R&D. A legal framework is still needed that ensures licensing and exploitation of publicly funded research results fulfil broad social objectives. An open pro-public-civic management of results – including IP - needs to be included as an end goal early in the development process, making it a condition for receiving grants, for example.

Licensing conditions include pricing caps according to public health needs and full transparency mandates on trial data, know-how, prices and technology transfer, aim to ensure (a) accessibility and affordability of biomedical products (b) that publicly funded research remains free for use for further (clinical) research, professional education and training, validation of test results, etc. A public funder could retain the right to intervene in the partial or total exploitation of results if affordable access to the product is not ensured. The licensee would be obliged to use different tools for improving access to the products, such as transparent technology transfer, and access and training program [See Annex for more information].

Managing Knowledge as a Commons

The initiatives mentioned in this section incorporate a knowledge commons approach to the management of biomedical knowledge and medical technology. Hence these apply to institutionalised community governance of knowledge and/or data.[118]

Data Commons

The data commons is a robust area of practical innovation that is increasingly being used by scientists across the globe. Data commons for biomedical R&D are a shared virtual space where scientists can work with the digital objects of biomedical research such as data and analytical tools. Data commons as a model of organisation allow for the storing, accessing and sharing biomedical data and associated tools. This approach can help accelerate new biomedical discoveries by providing a cloud- based platform to perform novel scientific research including hypothesis generation, discovery, and validation.[119]

The treatment of data as a common-pool resource means the aim of data policies is maximum re-use, re-formulation and re-interpretation of the data. This contrasts from our present dominant models that seek to sell or trade data re-use resulting in wide scale privacy invasions.
A commons approach to data means a given community can manage data sharing and re-use by deciding on a series of equitable principles, institutions and protocols that create a high level of trust and high protection of personal data.[120] Simply opening up data without stewarding does not lead to socially useful results, it is therefore key to introduce a commons-based governance. A blueprint for data-sharing in New Zealand has detailed some the needed steps to promote consensual protocols that break down the segmented silos of data and establish rules to govern personal data or to share biological information.[121]

There are initiatives linked to the generation of large-scale biomedical data which are creating unprecedented opportunities. Crowdsourcing the analysis of complex and massive data has emerged as a framework for robust methodologies. A decentralized biomedical research ecosystem working in basic and translational science applies the concepts of network science, open science and participant-centred science together.

Box 6 - European Open Science Cloud (EOSC): Developing as a Commons?

In 2015, the European Commission announced the creation of an open repository cloud of scientific data for millions of European researchers and academics. The EOSC initiative basically intends to create a large knowledge commons with European infrastructure, to "enable trusted access to services, systems and the re-use of shared scientific data across disciplinary, social and geographical borders."[122] The Commission High Level Expert Group (HLEG) on the European Open Science Cloud describes: ''...we consider the EOSC as the European contribution to a global scientific commons. When we use this term we refer to the concept of a common public good that allows data publication, stewardship and re-use. We emphasize that public as well as private service providers can participate in this commons." [123]

While showing great promise, the European Cloud initiative, as laid out in the 2015 Communication, raises concerns about the way the open science agenda is developing. No clear distinction seems to be made between Big Data and Science data, while the cloud service seems to be placed in function of business, innovation and growth. Unlike in the HLEG report, little is stated about the common good, or even the progress of curiosity-driven sciences. This blurring of boundaries and concepts raises concerns about data sovereignty, the use of public data and the EU's approach to science.

For the EOSC to operate in a way that is inclusive and community based, it is important the right infrastructure is built, interoperability standards are developed and public interest oriented data governance is in place. The Commission should avoid any superficial 'open-washing' and ensure the end result - that the open science cloud leads ultimately to the delivery of public goods including medical technologies products that are affordable & accessible

Box 7: Sage Bionetworks

Sage Bionetworks is a non-profit research organization based in Seattle, US that seeks to develop predictors of disease and accelerate health research through the creation of open systems, incentives, and standards. Building and managing a knowledge commons is at the basis of their vision. It creates strategies and platforms that empower researchers to share and interpret data on a colossal scale, crowdsource tests for new hypotheses, and contribute to knowledge through community challenges.

They seek advances through a fundamental shift in the traditional roles and rewards for individuals and organizations involved in collaboration. The organisation "works to redefine how complex biological data is gathered, shared and used, redefining it through open systems, incentives, and norms. It challenges the traditional roles of individuals and groups, patients and researchers." They have learned that "sharing data without an interested community (of researchers, patients) does not lead to substantial knowledge production."[124]

Patent Pools

Patent pools are classical knowledge commons in the sense of the Ostrom tradition of jointly managing a resource- institutionalised governance of knowledge and or data.[125]

Box 8: The Medicines Patent Pool (MPP)

The MPP is a UN-backed public health organisation working to increase access to HIV, viral Hepatitis C and tuberculosis treatments in low- and middle-income countries. Through its innovative business model, the MPP partners with governments, industry, civil society, international organisations, patient groups and other stakeholders to forecast, prioritise and license needed medicines. The organisation encourages generic manufacture and the development of new formulations through patent pooling.

The MPP manages knowledge as a commons by pooling the IP, creating opportunities to accelerate innovation, share it, build on it, combine it and provide affordable access through generic competition. To date, the MPP has signed agreements with nine patent holders for twelve HIV antiretrovirals, two Hepatitis C direct-acting antivirals, one tuberculosis treatment and one HIV technology platform. Its generic partners have distributed 12.9 million patient-years of WHO-recommended HIV, Hepatitis C and tuberculosis medicines to 131 countries, including 113 countries that were previously unable to benefit from generic competition (January 2012-December 2016). [126]

Public-Civic Partnerships

Public-civic partnership is a broad term referring to many possible ways to increase the stewardship and governance of resources by citizens. This contrasts with the current default of public-private partnerships, where public goods or services often end up being privatised. A shift towards public-civic partnerships has conceptual, policy and practical implications.

Science as a New Bottom-up Social Contract

Some prominent scientists propose a new social contract based on a "scientific process less dependent on a 'top-down' hierarchy that would be able to establish research priorities based on a 'bottom-up' decision-making scenario. Science will only be able to meet the expectations of society by rebuilding ties with the spirit of the common good."[127] As John Iaonnidis envisions from a scientific commons civic engagement perspective: "the ideal goal would be to end up in a society where all citizens are also 'scientists' to some extent–that is, they have a fair, balanced view of how much we know; and, more importantly, how much we don't know."[128]

The EU framework programme for Research has three pillars: one for academic 'excellence', another for industrial leadership (economic competition) and a third for 'societal challenges' such as health, climate, energy, food and transport. While the first two tend to serve the demands of academic and industrial elites (defined by metrics of certain publications and patents), the societal challenges pillar should be a place for robust citizen involvement to define objectives, process and impacts.

Today this is not the case. In practice there is little or no civil society implication in the agenda setting and monitoring of the 'societal challenges' of the present Horizon 2020 Framework Programme for Research. As a recent EU study has concluded: "If the EU research and innovation policy wants to safeguard its legitimacy vis a vis citizens..arenas of knowledge co-creation and innovation need to be designed into which a broad variety of stakeholders are involved."[129]

A few steps in the direction of public-civic partnerships include the EU´s Responsible Research and Innovation programme in the Horizon 2020 funding program, [130] as well as a number of 'science in society' funding schemes that finance R&D partnerships with civil society. Furthermore, some "citizen science" projects supported by the EU are good examples to follow.[131] However, the European Commission leads a European initiative to foster R&D through the IMI, a public-private partnership with the European Federation of Pharmaceutical Industries and Associations (EFPIA). IMI is a largely publicly funded project plagued by concerns about industry dominance, weak public governance, private priorities and a lack of public return on investment.[132]

Product Development Partnerships (PDPs)

Product Development Partnerships (PDPs) are non-profit organisations which develop affordable, innovative biomedical solutions for people affected by poverty-related and neglected diseases. They are public-health-driven and focus on patients' needs, designing products for use in low-and middle-income countries with high disease burdens. Knowledge is shared throughout a collaborative process and various incentive mechanisms are used. Thus PDPs could easily become vectors for the commons, exerting social control over the IP, greater transparency and open data and public control over results.

PDPs work along the product development continuum from early discovery to product implementation, covering specific research gaps in the innovation cycle. They engage with academia, public research institutions, the private sector, government, and civil society organisations, stimulating medical research in developing countries and linking scientists across the global North-South divide. PDPs increasingly deal with what constitutes a significant proportion of the global burden of disease, yet they would need adaptation and expansion to effect systemic change. There are many efficiencies that can be introduced into the way PDPS work, but these again depend on a broader structural change in the way in which knowledge is generated, shared and passed on in the drug discovery process.

Box 9: Drugs for Neglected Diseases Initiative (DNDI)

Amongst PDPs the Drugs for Neglected Diseases Initiative (DNDI) comes closest to managing knowledge as a commons. DNDI is a not-for- profit R&D organisation that produces drugs for neglected populations, and in a manner that accounts for their access as a key component of its drug development process and affordable for the majority of the inhabitants of the Global South. By using "Target Product Profiles" that include affordability and acceptability criteria, and involving affected populations and communities from the outset, DNDi assures that its work benefits inhabitants of the Global South. This patient-needs-driven initiative sets stringent public interest criteria for its work with the pharmaceutical industry, and maintains its independence through a 50/50 split in its funding from public and private/philanthropic sources.

It considers its intellectual property as a public good and delinks final medicine prices from R&D costs. DNDI applies rigorous policies of data sharing, open source research and transparency. It orients its medicine research toward un-met needs of the world´s poorest populations with a present focus on Hepatitis C, Chagas, Sleeping sickness, filarial diseases, leishmaniasis, mycetoma and paediatric HIV/AIDS.[133]

Box 10: EU´s Innovative Medicine Initiative (IMI) as a Commons

Let´s imagine the EU´s IMI as a commons: What would IMI look like if it were managed as a commons?

The main goal of the IMI is now the creation of biomedical public goods to respond to public health needs.

A broad-based and informed democratic debate governs the research priorities of the IMI based on principles of solidarity, independence, transparency and results of public investments leading to public-civic ownership. The legal entity is similar to a cooperative with the principal goal of serving public health needs.

IMI carries out pilot programmes on new forms of biomedical innovation based on de-linkage and the management of knowledge as a commons. In these pilot programmes patent monopolies associated with high drug prices are not used to fund pharmaceutical research and development.

The IMI launches experimental R&D programmes that are replacing commercial scientific bias, monopolies and high prices with alternative incentives based upon innovation inducement prizes (such as expanded H2020 prizes), public funding for research, drug development partnerships, and independent clinical trials through a combination of grants, contracts and institutional agreements. All licenses on results would be non-exclusive with clear rules for openness, affordability, no commercial conflicts of interest and high research standards..

The IMI mandates default open data rules in its consortiums and strong open access policies. The IPR generated by IMI is governed by non-exclusive licensing to favour knowledge sharing, affordable prices and universal access to medical knowledge and technologies.

Only private pharmaceutical companies who accept these conditions can participate with real economic contributions (as opposed to the present in-kind contributions) that in any case should never exceed 30% of the consortium budgets.

Open-source medicines development and biohacking/DIY bio.

There are also some small but very interesting ground-breaking developments in the field of open source drug development, biohacking[134] and synthetic biology regarding the managing knowledge as a commons. These fields include an ethos of sharing, collaboration, openness, and open source working methods.[135]

Open-source is a concept that stems from software development. It involves open data sharing, collaboration, and results sharing, as well as 'the possibility of participation in a project by anyone in real time and a form of shared ownership that ensures the underlying method and data are public domain.[136] Open-source methods in medicine speed up drug discovery and have the ability to make drugs far more affordable. Open source methods widen the pool of researchers applying their expertise to a problem and cut down duplication. Like open-source software, any modifications are in principle also open and not patented. Initiatives include the Open Source Pharma Foundation (OSPF) and the Structural Genomics Consortium.[137] Most open source drug development initiatives engage in pre-clinical research due to high costs, yet the OSPF will soon run clinical trials.[138]

The Do-It-Yourself Biology (DIYbio) community applies open source working methods and is emerging as a movement that fosters open access to resources permitting modern molecular biology, and synthetic biology among others. Since 2010, community labs started opening up and became embodiments of the nascent DIYbio community, a grassroots movement of enthusiasts seeking to popularize and democratize biotechnology.[139]

> *"Synthetic bio seems to be now where the computer industry was in the late 1970s: still nascent, but about to explode. The hacker culture that drove the development of the personal computer, and that continues to drive technical progress, is forming anew among biohackers."* ***Mike Loukedis***[140]

Box 11: Counter Culture Labs - Open Insulin Project (Oakland, CA)

> *"Biology is the technology of the 21st century, and has the potential to affect our lives as much as or more than computers did in the 20th century. Our goal is to demystify and democratize this technology, putting tools into the hands of those who want to learn. We believe in the power of diversity and peer-to-peer education; everybody has something to teach and everybody has something to learn."* ***Countercultural Labs*** [141]

Over 400 million people in the world suffer from diabetes and millions cannot afford the best insulin at affordable prices. More and more Americans cannot afford their insulin and are desperate for something they can afford. The lack of generic alternatives on the market results in exorbitant prices. Around the world, groups of bio-hackers have set up small cooperative labs, often financed by crowdfunding, with the objective of contributing to the biomedical commons. In this case the objective is to make excellent insulin at a cost of 10 Dollars a month.

Counter Culture Labs, a community of scientists, tinkerers, biotech professionals, hackers, and citizen scientists who have banded together to create an open community lab — a hackerspace for DIY biology and citizen science in Oakland California, 30 minutes from Silicon Valley. Here the Open Insulin Project is developing their own non- proprietary process for insulin and is planning to start a coop to treat patients. As a biological medicine the regulatory process is not easy and they intend to navigate it by starting a (patient) coop with decentralised production and patient led decision-making.

Co-founder of the Open Insulin initiative, Anthony DiFranco, a medical researcher, a type 1 diabetic and bio-hacker shared in an interview: [142]
"The establishment views and treats diabetes and diabetes patients as a means of making money, and not as a group of people who need to be cured of an ailment. A significant number of the people who supported us have been people with diabetes who couldn't afford their own insulin....many people are desperate even in the Western world. By making the market competitive for insulin and eliminating these absurd profit margins, we want to contribute to the realignment of incentives in health care." [143]

These developments are happening and policy makers should consider how to best be a partner to them, how to provide guidance, how to optimize these developments for patients and society as a whole. Institutions can offer support through research frameworks and regulatory frameworks. Instead of considering these experiments as problematic activities, public institutions should explore how to adapt the policy framework to accommodate and promote these bottom-up citizen science trends.

Coordinating Common Goods Creation at a Global level

There are several initiatives at the global level that aim to produce medicines as public goods, to ensure they are universally accessible. These initiatives propose using either centralized or decentralized funds, under conditions of de-linkage models and based on open knowledge frameworks.

The international community has been working towards a binding convention on health R&D for over 15 years.

Box 12: Global Agreement on Research & Development.

Through a global R&D convention, countries would agree to a sustainable system of medical innovation with adequate and predictable financing, to deliver products that are focused on the priority health needs. The agreement would for example require Member States to spend at least 0.01% of their GDP on R&D that addresses the special health needs of developing countries, and it would require at least 20% of that funding to be spent through a single pooled funding mechanism. The convention would create norms to ensure that the fruits of innovation and new medical products are accessible and affordable. Such a convention has been discussed for years in WHO negotiations and recommended by its expert committee in 2012.[144]

Box 13: Global Framework for AMR.

WHO Member States have started to negotiate a Global Framework for Development & Stewardship to Combat Antimicrobial Resistance(AMR) given that "the majority of pharmaceutical companies are no longer researching a new antibiotic which is a global concern for human and animal health". The Global Stewardship and Development Framework for Antibiotics is intended to cover the development, control, distribution and appropriate use of different tools to tackle AMR. Focusing on access and stewardship, the framework will thus encompass the whole lifecycle of a product from product development, marketing authorization and regulatory requirements to end-users.[145]

The majority of initiatives currently gaining attention focus on the early phase of biomedical R&D, namely the generation and management of knowledge, science and new ideas. However, we are starting also to see initiatives emerging later in the process which can even better ensure the equitable access of the treatment for patients. The EU should also seek out initiatives which approach clinical trials and manufacturing with the same principles of transparency, self-regulation and community-based quality control.

Conclusions

EU biomedical policy needs a paradigm shift to be more productive, affordable, accessible and democratic. It is increasingly clear that health-care treatments cannot remain at the mercy of massive marketing, speculative financing and the gross manipulation of the scientific method.

The Commons approach – building upon but going beyond the individual rights perspective and openness – puts forth a vision of collective benefit far more pertinent to European citizens in their current circumstances which resonates deeply with core European values. It also puts forward a practical approach to managing knowledge with multiple benefits.

New technologies are facilitating new forms of knowledge production and medicine development outside of the current dominant model. These new developments are starting to take root and they need to be nurtured and supported by financial and regulatory frameworks. The European Commission and EU Member States should explore, support and guide initiatives which have the potential of transforming our present biomedical innovation model in favour of the common good.

European policy-makers, civil society organizations, health-care professionals and citizens will all be crucial to the process of negotiating a transition from the today's deficient market-driven biomedical model to a model designed to serve universal health needs. Knowledge and innovation should not be the exclusive playing field for investors, industry and their political allies to lock in closed, proprietary and rentier business structures. We propose taking ambitious steps to place cooperation, sharing and universal access to affordable and effective medicine at the top of our political priorities.

9. Recommendations

Supporting the Transition

Investing in New Models

- Commit to the de-linkage of medicine prices from R&D costs; carry out feasibility studies and pilot programmes into needs-driven innovation models.
- Implement Innovation Prizes with conditions on knowledge sharing and non-exclusive licensing of IPR.
- Implement progressive policies to delink r&d investments from the final price of medicines.
- Implement recommendations of the UN High Level Panel on Access to Medicines on affordability, new innovation models and much greater transparency.[146]

Ensure public return on public investment

- Include requirements for all EU grant-funded research results to be managed with maximal openness as a default throughout the R&D process, force compliance with open access and open data policies, and reform IP licenses in the public interest.
- Prevent new copyright legislation that could be barriers to open policies in the scientific sphere.

Democratic governance of knowledge

- Co-develop with civil society new metrics of success for EU public research investments based on public health needs, affordability of health-care treatments, social value and knowledge sharing.
- Implement policies to mandate the transparency of prices, clinical trial data, of R&D expenditures & ensure strict compliance with the 2018 European Court of Justice ruling on access to trial data in the public interest above commercial confidentiality claims. [148]

Forging a Commons

Building new models

- Create a European Patent Pool to ensure affordable access to certain expensive lifesaving medicines.
- Support and contribute to the creation of a global agreement for the financing of biomedical R&D of medicines as public goods.
- Create a EU research & innovation fund for independent public interest R&D and clinical trials to produce affordable treatments without patent monopolies.
- Nurture, guide and support financial and regulatory frameworks emerging social trends propelled by digital technologies in open source medicine and DIYBiology (adjust the institutional ecology).

Public Civic Partnerships

- Public interest data governance & stewardship in the EU Open Cloud Initiative with broad-based accessible repositories of scientific data, research results and academic articles.
- Reform the EU´s Innovative Medicines Initiative as a commons, ensuring public ownership of research results, affordability of final products, transparency of all research data and democratic decision making.

Public governance of knowledge

- Implement a European Patent Pool for a needs-based selection of lifesaving medicines.
- Ensure broad civil society participation in the governance and stewardship of the Ninth Framework Programme for Research and Innovation (FP9) with the creation of a 'Citizens Research Convention' and a 'Civil Society High-Level Group'[147]
- Co-develop with civil society new metrics of success for EU public research investments based on public health needs, affordability of health-care treatments, social value and knowledge sharing.
- Establish EU programmes for democratic and transparent bottom-up debate and decision-making by researchers, patients, health-care professionals and citizens on the objectives, methods and ethics of of biomedical research, the exploitation of results and accessibility of technologies.

Supporting the Transition

Trade Policy, Intellectual Property & Policy Coherence

- Refrain from exporting unbalanced stringent IPR norms to third countries and further racketing up IP norms through trade. Respect IP flexibilities for medicines access in lower and middle income countries.
- Facilitate and support the use of compulsory licenses when a lifesaving medicine is prohibitively priced.

Producing reliable evidence for health-care decisions

- Default regulatory paths should include testing against the best current standard of care in order to evaluate added therapeutic value.
- Health Technology Assessments must guarantee a high level of evidence, transparency without commercial confidentiality, open debate among diverse scientific methodologies, the testing of new products against existing top-level care and which avoids conflicts of interest.[149] All clinical data on health outcomes must be shared with HTA agencies, as well as being available for peer evaluation.

Forging a Commons

Trade Policy; Creating Public Goods.

- Include provisions in trade agreements that mandate knowledge sharing and enable collaborative production.
- Promote and support the development of multilateral treaties or conventions that implement the creation of medicines as public goods.

Producing reliable evidence for health-care decisions

- Implement policies that recognize there is a scientific, social and moral complexity beyond biomedical intervention.
- Ensure the methods and objectives of biomedical r&d are undertaken independently from commercial consideration.
- Ensure independent evaluation of all post-market authorization trials on new products to check clinically meaningful, patient-centred health outcomes and harms, publishing full methods and results

Annex I: Principles, Practices, Outcomes of Biomedical Innovation

Principles		
Privatised Biomedical Innovation	**Transition**	**Biomedical Commons**
Individualised personal gain as incentive	Delinkage of R&D costs from prices with new market incentives.	Biomedical knowledge and technologies are public goods.
Proprietary	Open	Democratic & community-based governance
Extractive	Economic Sustainability	Regenerative
Market driven	Balance of health needs and market realities	Health needs driven
Artificial scarcity through exclusivity and IPR	Using IPR with increased flexibility.	Post-IPR knowledge abundance
Interventionist and product-based	Placing health products under socio-political governance	Systemic complexity of social-environmental determinants of health
Deregulation for health sector growth, jobs and global competition	Regulation for public health goals	Regulation to promote democratic debate and bottom-up governance of science and health.

Practices		
Privatised Biomedical Innovation	**Transition**	**Biomedical Commons**
Industry-led evidence production and testing	Independent, public-led evidence production and testing	Curiosity-driven research with civic dialogue and community-based evidence production and testing
Stronger/longer IPR protection and enforcement	Public health exceptions to IPR and socially responsible licensing	Open licensing and pooling of patents for public health benefit in decentralized public repositories
Market-driven deregulation agenda setting for greater return on investment	Strong public regulation to direct innovation to health needs and added-therapeutic value	Public goods based on added therapeutic value and precautionary principle
High prices and patent monopolies as innovation incentives	Progressive de-linkage, e.g. in the form of innovation inducement prizes,open-source dividends and milestone prizes.	Globalized open R&D and production adapted to local conditions: design globally, produce locally. No privatised medical knowledge
Commercial confidentiality on trial data and trade secrets	Open access and sharing of trial data	Clinical trial data and medical know-how as public goods for humanity
Privatization of public research funding	Public-interest affordability and transparency conditions on public funding	What is in the public domain remains in the public domain: regeneration knowledge commons.
Public research geared towards private sector growth, competition and jobs	Public investments guided by public health returns, transparency and affordability	Public research goals guided by public health needs in open civil dialogue.
Industry financed medical regulatory agencies, health professional training and heavy marketing of products	Limits to conflicts of interest, independent education for health professionals, restrictions on drug marketing	Publicly financed and public-civic led regulatory agencies. No marketing to health-care professionals
Drug orphanisation, deregulation and new norm of early market access.	New incentives for affordability with less focus on market access and more on added health value.	Little or no pharma market

Outcomes		
Privatised Biomedical Innovation	**Transition**	**Biomedical Commons**
Innovation chill from knowledge enclosure and legal uncertainty	Knowledge sharing, transparency and flexible IPR reform accelerates useful innovation	Mandatory medical knowledge repositories fuel socially responsible innovation
Increased patient risk from lack of transparency	Open knowledge makes medical information more available to scientists, doctors and patients	Democratic, broad-based governance of pooled knowledge by experts and non-experts
Unsustainable health budgets from high, market-driven prices and privatisation of publicly-funded research	Lower prices and more generic competition by means of new market incentives and stricter regulation	Medicine prices determined by cost of production, distribution and real R&D costs. Open-source, patent-less drug development
Patients cannot access treatments with artificially high costs alongside overmedication and over-diagnosis	Affordable patient access with new R&D incentives that limit patent monopolies	Public patent buy-outs to regenerate health commons
“Stock-outs” in weak markets. Focus on lucrative upscale markets for chronic diseases: “more is more”	Greater public-civic investments in antibiotics, neglected diseases and rare diseases: “less can be more.”	Innovation according to local needs and environment. Share knowledge globally, produce locally
Overmedication, over-diagnosis and “a pill for every ill”	Rational use and controlled prescriptions through new regulations,	Complex, systemic socio-environmental approach to preventive health to limit overmedication and over-diagnosis.

Annex II. Socially Responsible Licensing[150]

In order for publicly financed research to revert to the public good, a new EU legal framework is needed to assure that licensing and exploitation of publicly funded research results fulfil broad social objectives.

We propose socially responsible licensing conditions to be attached to the rules of participation of the EU Programme for Research and Innovation – 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.

An appropriate set of such socially responsible conditions should include non-exclusive licensing as a default. Non-exclusive licensing would generally allow for 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 owner of an invention (research institute, etc.) or funding authority may retain the right to intervene in case of unmet market or public health needs.

The licensee may further be obliged to use different tools for improving access to the products in middle- and low income countries: the humanitarian use licensing conditions. For example, by implementing the obligations for companies that commercially exploit a product derived from public funded research to implement a differential pricing scheme to ensure affordable access to the health technology in developing countries. Alternatively such licensing conditions can dictate the obligation to allow for open, non-exclusive licenses to enable competition in developing countries that will lower the price of biomedical products. Other elements that can be included are clear obligations to engage in meaningful technology transfer, and including access and training programs. [151]

To sum up, licensing conditions for EU-grants for biomedical research could include the following principles:

1. No unjustified transfer of ownership of (IPR protected) research results from research institutes to private companies, and non-exclusive use of publicly funded research results as the default principle.

2. In case of non-exclusivity, licensees should be prevented from using additional or follow- on IP claims on licensed inventions to constrain or block competitive exploitation of licensed research results.

3. In case of exclusivity, the right to use research results and practice the inventions for research and/or educational and teaching purposes should be retained.

4. In the conditions for EU grants, socially responsible licensing could also mandate certain conditions requiring the affordability and accessibility of products produced with research results financed by EU funds. For example, when an overriding social demand exists, the European Commission and EU Member States should retain the right to exploit the research results on a royalty-free basis or to permit exploitation by third parties in order to confront unmet market needs or to confront clear societal challenges, such as public health.

5. The EU can establish, when appropriate, specific conditions for pricing, open competition and accessibility for the public procurement of the commercial exploitation of EU financed research results in order to fulfil EU policy objectives.

6. The EU should further establish clear humanitarian use licensing conditions to improve access and affordability of biomedical products in middle- and low income countries. For example by making non-exclusive licensing mandatory for exploitation of research results in this region, or, in case of exclusive licenses, by requiring the implementation of meaningful differential pricing or other access schemes resulting in low- or no-cost access.

7. The EU should establish specific conditions to ensure that EU financed research contributes to meaningful health technology transfer to developing countries in fulfilment of EU policy objectives with regards to global health and access to medicines.

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