Commons Network

From Lab to Commons

Shifting to a public interest biomedical system

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Shifting to a public interest biomedical system

Although our current biomedical system has produced important lifesaving and quality-of-life treatments, today billions of people around the world and their health systems cannot afford these medicines, resulting in over 10 million preventable deaths each year. These outcomes are perpetuated by an unacceptable policy paradigm for biomedical research.

Many Europeans, now lack access due to rationing of expensive products or because they must pay out of the pocket for much-needed medicines. 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. Governments are often forced to make devilish choices on which patients should be treated when expensive treatments need to be rationed.

EU Biomedical policy needs a paradigm shift to be more productive, affordable, accessible and democratic. 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 which resonates deeply with core European values. It also puts forward a practical approach to managing knowledge with multiple benefits. Commons Network (CN) proposes taking ambitious steps to place cooperation, sharing and universal access to affordable and effective medicines a the top of our political priorities.

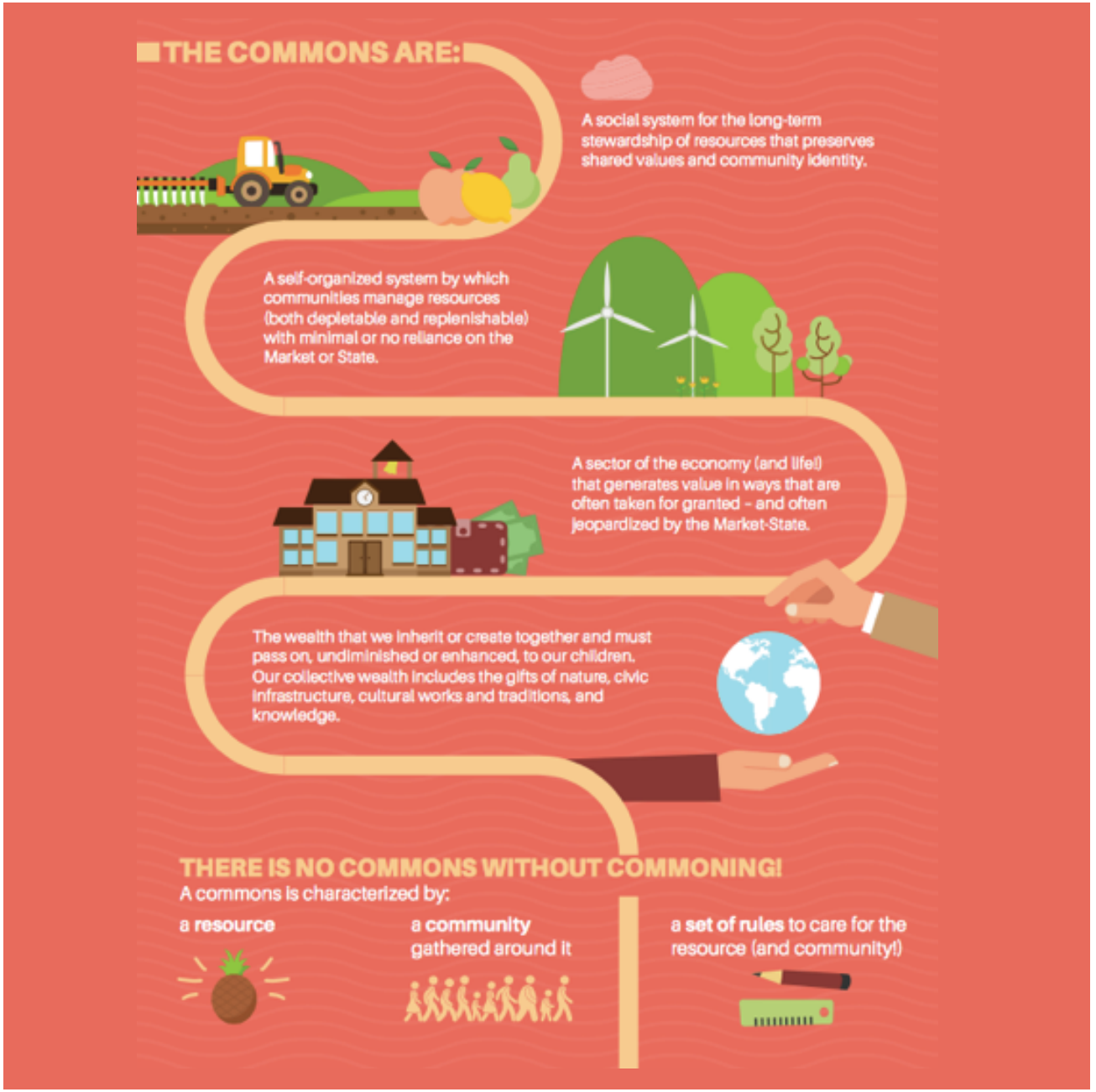
Commons vision

The commons refers to shared resources, the communities that manage them and the specific rules, practices and traditions devised by those communities.. 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.

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.

What are the Commons?

A commons approach means equitably, sustainably and demo-cratically 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.



How the Commons approach can help overcoming our current crisis

How can a commons approach for biomedical research & development (R&D) help us overcome the current crisis of over-diagnosis, over-prescription, low innovation, secrecy and sky-rocketing costs for both patients and health systems? There is a growing 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? We put forward a vision for the future

A vision for the future

Health care is not just technological solutionism

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, political and economic means. This technological interventionism serves mainly markets and not so much health needs. Contrary to “scientism” the commons perspective helps re-contextualize scientific inquiry and medical interventions within a clear social and moral framework.

Beyond Individual Rights

The commons perspective goes beyond the beyond a human rights approach by adding another layer of collective considerations such as sustainability, universal health needs and the limits of sufficiency on top of individual rights demands. This 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 governance of health.

Tragedy of the Anti Commons

Today´s biomedical model 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 the 'tragedy of the anti-commons'.

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".

Knowledge commons are of a different nature then natural resource commons, in part as knowledge is immaterial and one person's use does not subtract from others possibility to use them. A knowledge resource is a public good and it often makes sense to share 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). Knowledge commons could facilitate open global research and local production adapted to local context 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. 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 – in the sense of the responsible and careful management of entrusted resources.

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. A 'partner state' would mean a radical shift from the present context in which most states act in a tight alliance with the interests and commercial goals of large pharmaceutical industries. It would also mean substituting many 'public-private' partnerships with 'public-civic' partnerships based on broad expert and non-expert participation, full transparency, pro-commons licensing and universal health needs.

Transition and transformation

How can we begin transforming such a complex system with entrenched narratives and vested interests? There are many initiatives and suggestions already helping to transition away' from today's biomedical crisis where the EU should invest further and encourage improvement.

They include open knowledge and collaborative innovation, using incentive systems where Intellectual Property (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.

> *"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***

Building on these transitional initiatives which 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 democratic stewardship of a biomedical health commons. Some follow the lead of other sectors experimenting with open source and decentralised production, e.g. blockchain technology, and peer to peer co-operatives. tSuch civil society stewardship promises structural change. Yet, the institutional ecology will have to be adapted and they can all build on the crucial progress of applying transitional initiatives such as open science and de-linkage.

Initiatives & Proposals towards a Commons Based R&D System

Shifting Incentives to needs-driven innovation: de-linkage

There needs to be a shift to alternative incentives for investment in R&D instead of market exclusivity(patent protection) and high prices. De-linkage is a crucial principle to achieve this.

> "Delinkage refers" to the separation of the incentives for financing research and development from the price and volume of the product. It refers to 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.". Under these conditions medicines would reach the market with either generic prices or near marginal cost prices. The IPR would be either under non-exclusive or open licenses or, in any case, governed in the common interest.

Innovation Inducement prizes

Monetary prizes that 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 to be paid upon market entry, or both. In exchange, the knowledge generated would be under a non-exclusive, open licenses or under public control.

Open source dividends

Rewards 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. researchers in the area.133

Tax credits

A company spending on R&D for can qualify for a tax credit in exchange for providing open access to results depending on the health-needs focus of the declared expenditure.

What is delinkage? At Delinkage.org http://delinkage.org/overview/

Sharing Knowledge

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.

Open Access Publishing

Online research publications that are free of all restrictions on access (e.g. pay-walls) and free of many restrictions on use.

Open Data

A company spending on R&D for can qualify for a tax credit in exchange for providing open access to results depending on the health-needs focus of the declared expenditure.

Socially responsible licensing

Refers to all kinds of contract clauses and licensing forms that secure the possibility for inventors and technology suppliers to share their IP. A basic principle is the use of licensing provisions that foster generic competition or other mechanisms. to ensure low end prices of the product.

Managing Knowledge as a Commons

Data Commons

A shared virtual space where scientists can work with the digital objects of biomedical research such as data and analytical tools.

Patent Pools

Companies license their IP to a pool, creating opportunities to accelerate innovation, share and build on it in order to share technologies for affordable access.

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."

Bottom up Science

Scientific process less dependent on a 'top-down' hierarchy that would be able to establish research priorities based on a 'bottom-up' citizen decision-making scenario.

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.

Imagining the the EU´s Innovative Medicines Initiative 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.

Open Source medicine and Do it Yourself (DYI) Biology

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

Open Source medicine

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.

DIY Biology

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.

> *''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.*

Global commons goods creation

International agreements on the development of medicines and universal access. 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 or based on open knowledge frameworks.

Biomedical R&D Convention

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.

Global Stewardship and Development Framework for AMR

WHO Member States have started to negotiate a Global Framework for Development & Stewardship to Combat Antimicrobial Resistance(AMR)intended to cover the development, control, distribution and appropriate use of different tools to tackle AMR.

New technologies are facilitating new forms of knowledge production and even medicines development outside of the current dominant model. These new developments are starting to take root and they need to be nurtured and supported.

Supporting the Transition	Forging a Commons
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.	**Building new models** Create a European Patent Pool to ensure affordable access to certain expensive lifesaving medicines.
Implement Innovation Prizes with conditions on knowledge sharing and non-exclusive licensing of IPR.	Support and contribute to the creation of a global agreement for the financing of biomedical R&D of medicines as public goods.
Implement progressive policies to delink r&d investments from the final price of medicines.	Create a EU research & innovation fund for independent public interest R&D and clinical trials to produce affordable treatments without patent monopolies.
Implement recommendations of the UN High Level Panel on Access to Medicines on affordability, new innovation models and much greater transparency.	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).
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.	**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.
Prevent new copyright legislation that could be barriers to open policies in the scientific sphere.	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.
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.	**Public governance of knowledge** 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'
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.	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.

Final Report. “Access to Medicines” United Nations. September 14. 2016 See at: http://www.unsgaccessmeds.org/final-report/

http://www.ghadvocates.eu/en/fp9-engaging-citizens/

Research Policies for Peace, People and Planet. “A civil society perspective on the next EU Research Framework Programme (FP9)

URL: http://www.ghadvocates.eu/wp-content/uploads/2017/07/EU-Research-Policies-for-Peace-People-and-Planet.pdf

Supporting the Transition	Forging a Commons
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.	**Trade Policy; Creating Public Goods.** Include provisions in trade agreements that mandate knowledge sharing and enable collaborative production.
Facilitate and support the use of compulsory licenses when a lifesaving medicine is prohibitively priced.	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 Default regulatory paths should include testing against the best current standard of care in order to evaluate added therapeutic value.	**Producing reliable evidence for health-care decisions** Implement policies that recognize there is a scientific, social and moral complexity beyond biomedical intervention.
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. All clinical data on health outcomes must be shared with HTA agencies, as well as being available for peer evaluation.	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

Principles, Practices, Outcomes Of Biomedical Innovation

Privatised Biomedical Innovation	Transition	Biomedical Commons
Principles		
Individualised personal gain as incentive	De-linkage 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		
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. Market-driven deregulation agenda setting for greater return on investment	Public health exceptions to IPR and socially responsible licensing	Open licensing and pooling of patents for public health benefit in decentralized public repositories
High prices and patent monopolies as innovation incentives	Strong public regulation to direct innovation to health needs and added-therapeutic value	Public goods based on added therapeutic value and precautionary principle
Commercial confidentiality on trial data and trade secrets	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
Privatization of public research funding	Open access and sharing of trial data	Clinical trial data and medical know-how as public goods for humanity
Public research geared towards private sector growth, competition and jobs	Public-interest affordability and transparency conditions on public funding	What is in the public domain remains in the public domain: regeneration knowledge commons.
Industry financed medical regulatory agencies, health professional training and heavy marketing of products	Public investments guided by public health returns, transparency and affordability	Public research goals guided by public health needs in open civil dialogue.
Drug orphanisation, deregulation and new norm of early market access.	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
Market-driven incentives	New incentives for affordability with less focus on market access and more on added health value.	Little or no pharma market

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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.

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For full paper see:
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