Proposal for a feasibility study on *funding for mechanisms of progressive delinkage (Direct funding, subsidies, incentives, international cooperation) on drugs which are able to produce concrete outcomes for affordability, access and public health needs*

Proposal development by **Commons Network** and **Knowledge Ecology International** for a Pilot Project & Preliminary Action scheme

Offsetting impact of shorter exclusivity for drug monopolies on investments in R&D by means of a non patent reward system - a circular approach

Type of research:

- Econometric studies
- Legal study
- Organisational study of European Institutions/EU member states

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Feasibility study
The feasibility study would test the possibilities of introducing a new scheme of financing future medicines which will reduce prices for patients and financially relieve public systems without having negative effects on innovation.

By conducting a feasibility study, EU's policy makers and advocates will have a strong tool on their hands to fulfill better access to medicines for patients while at the same time fostering R&D.

Basic dilemma
Governments now rely up a time limited monopoly to induce investments in biomedical R&D. Companies abuse the monopoly with high prices, and high prices have negative impacts on access. Efforts to reform pricing of biomedical inventions (drugs, vaccines, cell and gene therapies, diagnostics, etc.) are generally opposed on the grounds that lower prices and company profits will decrease investments in R&D and lead to less innovation.

Delinking R&D incentives from prices
This "policy incoherence" was explored by a **UN High Level Commission on access to medicine**, and by **many academic and policy experts**, who collectively have called upon policy makers to explore mechanisms to delink R&D incentives from prices. The main criticism of delinking R&D incentives is that it is such a big change, legislators and policy makers won't do it. Basically, the transition from today to a newer system is daunting, and discourages many from spending time, money and political capital to promote this approach.

Progressive delinkage
One way forward is **progressive delinkage**. Progressive delinkage involves two steps. First, agreeing that delinkage of R&D incentives from prices is desirable, and second, committing to progressively enhancing non-price incentives (such as market entry rewards) and subsidies while lowering drug prices. It hardly matters what instruments are used to lower drug prices, so long as there is a parallel and at least compensatory measure to address R&D funding (including incentives), that is not tied to the price of a drug or other technology.

Proposed feasibility study: ***Offsetting impact of shorter exclusivity for drug monopolies on investments in R&D by means of a non patent reward system - a circular approach***

Study the feasibility of one or more European countries to adopt a policy of reducing the term of exclusivity of new drugs, through measures such as compulsory licensing (or alternatively, introducing more aggressive price controls), after a drug had generated a target cumulative global revenue. Reducing the term of exclusivity would allow for earlier generic competition which implies a drastic price reduction and increased access for patients.

This reduction in the term of the monopoly for a blockbuster product can be implemented through granting compulsory licenses on relevant patents when global revenues for the drug reached a benchmark.

The study would estimate the negative impact of a shorter term of exclusive rights (or more aggressive price controls) on the industry-wide incentive to invest in R&D, and estimate how much money a government would have to spend on one or more of the following four mechanisms to advance biomedical innovation: (1) grants on early stage biomedical research, (2) grants on early stage biomedical research that are required to make research outputs open source, (3) subsidies for clinical trials on drugs to treat diseases where innovation is a priority, and (4) market entry rewards for drugs that provide a significant advancement in medical benefits over existing treatments.