NEW EU PHARMACEUTICAL STRATEGY: *HIDDEN TREASURES* AND PROPOSED IMPROVEMENTS

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15 September 2020

The successful development of a New EU Pharmaceutical Strategy should be based on the identification of *Hidden Treasures* that deserve to be defended and strengthened. In this respect, the following EU-wide structural advantages present themselves:

1. Most EU citizens are on average very healthy, in particular in Southern Europe, and their life expectancy is the highest in the world.
2. The universal health care systems the Member States have built over the years provide the best possible infrastructure for state-of-the-art treatment and drug development and distribution.
3. Drug prices in the EU are structurally lower than in the United States, but untapped opportunities remain to be seized. Germany and France should give up their resistance against EU purchasing programs.
4. The EU is well placed to introduce cooperative models in drug development to capture scientific breakthroughs, to lower costs and to reduce the "time to patient", in contrast to the currently prevalent extraordinary wasteful competition model.
5. The EMA plays a very constructive role regarding drug development by large and small companies. Its decentralised structure, immune from political pressure, mobilises the best scientists in the approval process.

Building on those *Hidden Treasures*, we put the **EU Pharmaceutical Strategy in a broader context,** pointing at the need for the EU to work closely with the Member States and propose new policy initiatives.

Reducing demand for medicines:

1- We are convinced that investing in comprehensive prevention, including regular consultative services from cradle to adulthood and reintroduction of sport in school's curricula, could dramatically reduce the demand for (expensive) health care and medicines. Healthcare insurers should be allowed to change their business model, building on their experiments in financing prevention programmes.

2- As approximately 50% of all treatments are not evidence-based, there is ample scope to evaluate the effectiveness of medicines and to cull those that do not contribute to recovery. We further support prevention of over-treatment, which is a product of so-called defensive medicine to prevent patients' complaints and to cope with increased rules-based supervision.

3- Poor therapy compliance by an estimated 30% to 40% of all patients and by 70% of the many patients with chronic diseases leads to considerable waste in the health system. As the WHO has observed, potential gains in therapy compliance outweigh the benefits of the development of new medicines.

4 While improving healthcare, there is every reason to curtail the sales of alternative medicines, not to speak of outright quackery by scrutinising health claims and by withstanding pressures for reimbursement.

5 Demand for medicines may be further reduced through better diagnostics. Whereas the benefits of large screening programs are debatable, monitoring of patients in risk groups will lead to early and less expensive treatments. The exploding metabolic syndrome and Central Nervous System diseases need to be brought under control.

Cost reductions and supply increases:

1. Negotiations with Big Pharma to control the prices of their medicines are frustrating and do not yield enough results. A new and more assertive approach would focus on three fronts as new rationales to demand discounts: (1) marketing costs representing up to 25% of revenues are spent to stimulate the sales of supposedly superior medicines; (2) the failures of too many, very costly phase III studies, and the *de facto* cross-subsidies by medicines that reach the

market; (3) value destruction as a result of industry consolidation, the costs of failure of most mergers and acquisitions run into the tens of billions.

2. The EMA should redesign its procedures to grant "orphan disease" status to medicines, in order to prevent abuse of the monopoly position the successful applicant enjoys.
3. The withdrawal of useful generic drugs from the market by Big Pharma that no longer meet their profitability targets provides opportunities for reintroduction by European SMEs. Simplifying and shortening the regulatory process will help.
4. Based on forever deepening scientific insights, there is considerable potential in re-purposing old or even discarded medicines as development costs are low and "time to patient" limited. This represents another opportunity for SMEs.
5. New forms of cooperation should be encouraged. There is substantial potential in cooperation between research hospitals and the key opinion leaders they employ and SMEs. Much value can be created before large investments are required. Honest brokers can bring large companies, SMEs and government institutions together on a project-by-project basis. Co-operation can be stimulated among the applicants for EU grants.