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How Europe is dealing with the innovation in medicine?

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Abstract

The term innovation is often associated to health nowadays. Innovation in health means on one hand, new drugs, and innovative treatments, such as those against hepatitis C virus recently introduced on the market, and, on the other hand, procedures, tools such as personalized medicine or solutions for electronic health (eHealth) or new forms of collaboration for health. The need for health services is growing and the resources of any kind are decreasing or remain constant. The accelerated progress of medical diagnosis of diseases and technological advance is a concern for both the EU countries, which have the main competence in the field and the European Commission, at the transnational level. Nowadays, only exchange of information, best practices and experiences based on national models of the EU countries are allowed, but in the future, the situation may change. We note that EU countries tried to make some progress in the field of pharmaceutical collaboration. The EU Council Presidency aims to facility voluntary cooperation between EU countries in pricing and reimbursement of medicines. In this context, the agencies of medicines from EU countries do not discuss the mechanisms to regulate prices of medicines which are sensitive and political issues, but rather some technical issues, such as more flexible ways for trading of innovative medicines on the market, relations between authorizations on market and Health Technology Assessment, incentives in the EU pharmaceutical legislation, or how to identify alternative models for sustainability of the budgets for medicines. This a clear signal that both EU Member States move in this direction, pressed by the heavy burden of the high cost of new drugs and advanced therapies that will not be continuously supported by public system health insurance, and they seek to identify viable alternatives, including through the mechanism of co-payment and private insurance.

Keywords: *Europe, Innovation, Medicine*

Innovation in health means, on one hand, new treatments (e.g.: drugs against hepatitis C virus or orphan drugs for rare diseases) and on the other hand, procedures, tools such as e-health solutions (e.g.: ePrescrition or Patient summary in cross-border care), personalized medicine or new forms of collaboration for health.

The term innovation is often associated to health area, especially with health needs, but also with market opportunities. In the actual fast-changing times, many societal challenges appear, as seen in the figure 1, and the European Union (EU) is proposing changing in the policy and possible strategies.

1. Societal challenges nowadays

Fig.1: Key societal challenges for health in the EU for the incoming period

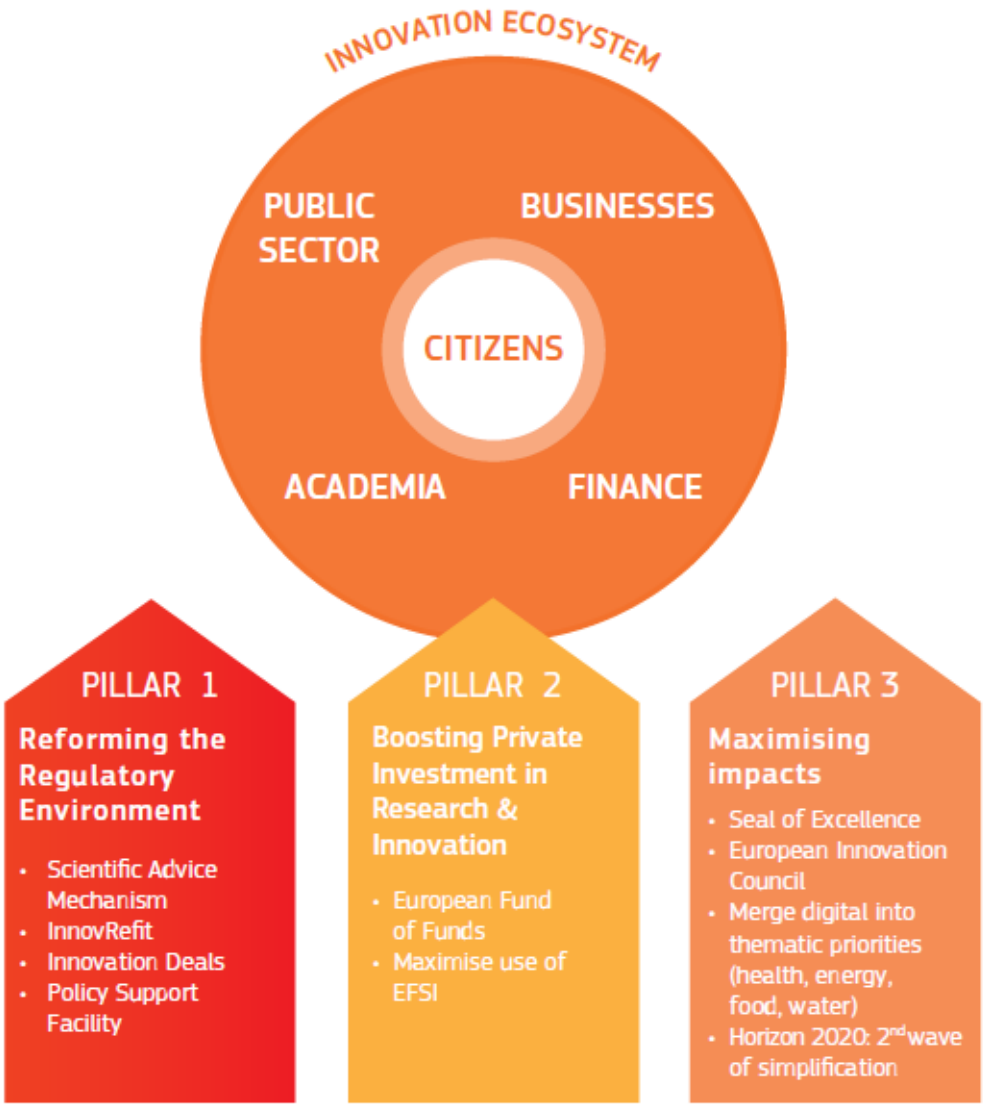
2. Concept of Open Innovation

At the European level, there is a Commissioner for Research, Science and Innovation and a Commissioner for Health and Food Safety, who are dealing with innovation in health among others themes. (2) The General Directorate Santé has the third Health Programme 2014-2020, which includes 25 common actions for the EU (e.g.: rare diseases, antibiotic resistance, transplant etc.). This programme is focussing on health technology assessment, e-health and European Reference Networks. The General Directorate for Research is dealing with research in the medical area which is dealted within the research programme Horizon 2020.

The concept of Open Innovation is characterized by: combining the power of ideas and knowledge from different actors (whether private, public or civil society/third sector) to co-create new products and find solutions to societal needs; creating shared economic and social value, including a citizen and user-centric approach; and capitalizing on the implications of trends such as digitalization, mass participation and collaboration.

The Commission aims to ensure that the appropriate framework conditions for innovation are in place through the three pillars of its Open Innovation policy. These are: Reforming the Regulatory Environment, Boosting Private Investment and Maximising Impacts (fig. 2) (2). First, Europe needs to create the right regulatory environment that removes obstacles to innovation and keep up with rapidly changing technologies. The second pillar is comparing the levels of investment in the EU and the US, which shows that the European Innovation ecosystem is lacking adequate private financial instruments (with far less venture capital in Europe, and venture capital funds do not have the scale or scope to grow companies). Under the third pillar, the Commission will strive to get the most out of EU-level support for innovation by developing new actions to get more innovation impact out of Horizon 2020, including through better synergies with the Structural Funds (2).

Fig. 2: The European Commission three pillars of action (2)



EFSI = European Structural and Investment Funds

3. Mechanisms created by the EU

- The **Structural Funds** provide funds for research in the pharmaceutical field. Several funds have regions that feature strong academic biomedical faculties, generics industry or a manufacturing capacity which could be better linked and strengthened.
- Regarding the new medicines, the current EU legal framework does not preclude single MS from releasing marketing authorisations valid at national level, but it creates several routes for manufacturers to secure an EU-wide marketing authorisation. The most

important of these is the "**centralised authorisation procedure**", which allows for a single marketing authorisation of a new medicinal product that is valid in all EU countries and Iceland, Liechtenstein and Norway (3). The **European Medicines Agency** (EMA), created in 2004, manages this centralised procedure for new medicines (4). The **health technology assessment (HTA)**, which encompasses a systematic evaluation of criteria used to evaluate a new medicine or drug in order to enter the market. HTA is conducted by interdisciplinary groups using analytical frameworks drawing on a variety of methods, with the main purpose of informing technology related policymaking in health care (5,6). Almost all EU Member States have put in place agencies responsible for conducting HTA of new medicinal products. These agencies may provide input into the assessments conducted during the marketing authorisation, but more often their input feeds into the pricing and reimbursement process. This varies from one Member State to another. Even if centrally approved, the market access and uptake of a new medicinal product will vary substantially across Member States.

- Pricing and reimbursement measures, which are adopted at national level, have significant impact for a new medicinal product to become available to patients and rest a national competence(under the Treaty of Functioning of the EU). The EU Council Presidency aims to facility voluntary cooperation between EU countries in pricing and reimbursement of medicines (8). In this context, the agencies of medicines across EU countries do not discuss the mechanisms to regulate prices of medicines which are sensitive and political issues. The EU Member States are pressed by the heavy burden of the high cost of new drugs and advanced therapies that will not be continuously supported by public system health insurance, and they seek to identify viable alternatives, including through the mechanism of co-payment and private insurance.

- The Cross Border Healthcare Directive further improved the conditions of information exchange between all the Member States by creating the framework for e-health, "voluntary networks connecting national authorities and bodies responsible for health technology assessment"(9), which were called the **Health Technology Assessment Network** and **European Reference Networks.** Joint Action on HTA is coordinated by **EUnetHTA,** another network between the EU member states, the accession countries and regional agencies and not-for-profit organisations. Its purpose is to develop guidelines for effective joint working models for HTA collaboration, as well as transparent governance tools; to prevent duplication of work between national agencies; and to promote sharing and exchange of HTA information (10).

4. Examples of innovation in health in Europe:

The **European Orphan Medicinal Products** Regulation incentivised investments by pharmaceutical companies in order to provide adequate support for relatively few patients suffering from rare diseases who require sometimes expensive care. This has led to a big increase in funding for research in orphan drugs, which resulted in almost 100 orphan medicines approved in Europe since 2000 (12).

The ongoing public health problem of tuberculosis in Europe demonstrates the weaknesses of the current innovation model. There have been no new diagnostic tools or medications for this disease for forty years and new global public private partnerships (PPP) such as the **Tuberculosis Vaccines Initiative** have been developed to fill this urgent gap (12).

Antibiotic resistance is another major problem of the health systems. In the past 45 years only five new antibiotics have been brought to the market and no new classes of antibiotics have been developed since 1987. The EU is engaged in combating Antibiotic resistance through enhanced surveillance by the European Centre for Disease Prevention and Control and funding for research through EU framework programmes (e.g.: The Joint Programming Initiative on Antimicrobial Resistance)(12). But greater efforts are needed to develop new and alternative models. The Horizon Prize for better use of antibiotics has been proposed to encourage research teams around the world to compete in drug discovery. New forms of PPPs are also being proposed to stimulate funding for drug discovery and greater collaboration within the industry. At European level, the **Innovative Medicines Initiative (**IMI), itself a ground-breaking process between the EU, member states and the pharmaceutical industry association named EFPIA, features a programme to develop new antibiotics (13). IMI created a PPP in 2013 called **The European Lead Factory** to find valuable candidates for the development of novel treatment options. To achieve this goal, the EU Lead Factory provides a unique library of more than 300,000 compounds selected from the collections of seven major European pharma companies (the first **European Compound Library**) and the opportunity to screen those compounds against potential drug targets to the broader community (the first European Screening Centre) (13).

The new **Medical Devices Regulation** covers a vast array of medical products from plasters to pacemakers and revises outdated laws from the 1990s following health scandals such as the PIP breast implants in 2011. The patient safety took precedence with focus on high-risk devices, and enhanced post-market surveillance and industry innovation (14).

European Innovation Partnership on Active and Healthy Ageing is dealing with the deployment of innovations (several good practices with evidence of benefits) and scaling up of good practices in Active and Healthy Ageing (online repository of innovative practices under development; collection of assessment, decision and implementation tools regarding new policies and innovations)

A continuing open and constructive multi-stakeholders dialogue with member states, with pharmaceutical industry, patient organisations and other stakeholders is necessary to ensure future developments of new medicinal products and the sustainability of the system in the EU.

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