OPENING REMARKS

Good afternoon and welcome to the second appointment of the year in the framework of the Members of European Parliament Interest Group "European Patients' Rights and Cross-border Healthcare". The Interest Group was promoted in 2015 thanks the endorsement of almost 100 associations, with the aim to underline the relevance of patients' rights before the European Institutions and other relevant stakeholders.

First of all, I would like to thank the European and national Institutions, and of course special thanks to the MEP Brando Benifei, for having hosted this initiative.

This meeting is organized by Active Citizenship Network in partnership with SIAR, the Italian Society for Regulatory Activities and intends to be a first follow up of the last European Patients' Rights Day, celebrated last 10th of May here in Brussels. In that occasion, in particular, we discussed new approaches to the existing European and national medicines regulatory systems, for better management of access to innovation.

Starting from a concrete proposal, the meeting today aims to stimulate a reflection on all the possible options to ensure a more rapid and real access to innovative medicines as well as to strengthen the specific knowledge on the topic within patient organizations, for a more effective advocacy towards national regulators, ministries of health, etc.

As stated in the 7th right of the European Charter of Patients' Rights, each individual has the right to receive necessary treatment within a swift and predetermined period of time and this right applies at each phase of the treatment.
Of course, it is in the interests of patients, in cases of unmet medical needs, to obtain fast access to new innovative medicines.

At this time, the process for Marketing Authorization (MA) consists of a set of steps and procedures to ensure the drug safety and the safeguard of citizens' health. The current rules tend to seek a balance between the protection of health and the need to give quick answers to patients who often are in urgent need to treat severe conditions. Unfortunately, this collides with approval and reimbursement times that sometimes are very, if not even too, long.

The EU pharmaceutical legislation already provides regulatory tools for the authorisation of medicinal products in order to meet unmet medical needs and facilitate timely access of patients to innovative treatments under certain circumstances and subject to certain conditions.

Almost all the innovative and important drugs follow the centralized procedure to obtain marketing authorization (necessary time: about one year). After that, the price-setting procedure for reimbursement starts, and it can last more than an additional year. Thus, depending on the institutional framework of each Member State, citizens can then rely on the actual availability of an authorized drug only after a reasonably long period.

In March 2014, the EMA has proposed a first solution to speed up patient access to new medicines, identifying the adaptive pathways. The approach, formerly known as "adaptive licensing", is a process which provides the early authorization of an innovative drug for a targeted subgroup of patients and its subsequent expansion depending on the evidence gathered. This approach speeds up access and strengthens the collaboration between all those involved in the life cycle of the drug, but at the same time, pushes patients to accept a higher level of uncertainty and risk.

Then, in March 2016, EMA has launched the "PRIME" (PRIority MEdicines) program which provides for the acceleration of the drugs regulatory path, supporting companies (including academic startups) and reducing evaluation times (50 days instead of 210). This new procedure will focus on the development of drugs considered priorities, which can offer great advantages over existing treatments or provide an opportunity to patients with no other treatment options.

However, this process relates to the centralized procedure for the marketing authorization by the European Commission but not the procedures for defining pricing and reimbursement, which depends on each Member State. So, their role is crucial.

Considering all of the above, the European Parliament made a motion for a resolution on EU options for improving access to medicines (2016/2057(INI)) sharing the concern expressed in the 2016 Council conclusions on strengthening the balance in the pharmaceutical systems in the EU.

Indeed, in the context of the Maltese semester of presidency of the Council of the European Union, the Council adopted its conclusions - during the meeting in Brussels on 9 June 2017 - encouraging a voluntary cooperation between Member States' health systems. This could result in better outcomes for patients and health care professionals and increase the efficiency of health systems.
Voluntary cooperation can help improve patients' access to treatment, in particular of those patients suffering from rare diseases. It may increase expertise within Member States and access to innovative health technologies, ensuring continuity, sustainable and effective actions and maximising the impact of the cooperation initiatives.
It was agreed that the exchange of information on national pricing and reimbursement policies and the sharing of information on pricing agreements on pharmaceutical products could improve transparency and Member States' leverage in negotiations with industry, and might make medicinal products more accessible.
EU health ministers welcomed the Commission's proposal for a European pillar of social rights. They agreed with the objective of providing timely access to affordable, preventive and curative health care of good quality, provided that Member States' competencies in health policy are respected.

We hope the proposal promoted by SIAR can be seriously taken in consideration. I do expect an open debate with no misconceptions, and hopefully concrete actions to follow up this initiative.

Last but not least, special thanks – muchas gracias – to Joseph Torrent Farnell, for agreeing to chair this conference. I am sure his great experience will be beneficial for the discussion of the topics in the agenda.

Thank you once again, I wish you a useful and interesting conference.

Mariano Votta