European & National Medicines Regulatory Systems:
challenges for an equitable, timely and suitable access to innovation

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European Economic and Social Committee - Room VMA1
rue Van Maerlant 2, 1040 Brussels

Final remarks

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Key messages and recommendations:

Health literacy: one of the priorities is authoritative, independent information able to transmit trust and awareness and to provide people with the tools they need to orient themselves in the flow of often partial, unreliable and distorted information, disseminated especially in the web on issues related to health and healthcare.

HTA: Join efforts to reach the goal identified by the Commission: strengthening cooperation between the EU Member States to leverage economies of scale and pool resources for the systematic implementation and harmonisation of HTA, whose approaches differ widely from State to State and even within individual States (as in Italy).

Special fund for innovative medicines: to push the Ministry of Health at national level to create or increase a special fund for innovative medicines, in addition to the healthcare fund, intended for all therapeutic areas affected by the gradual introduction in the market of increasingly effective innovative drugs. However, transparency about the management of this fund should be guaranteed.

Risk of moral hazard for the industry and patients' right to information: this point can be summarised by the words of the past Director General of the Italian Medicines Agency, who said that, "Clearly, manufacturers must have their profit, but at what price? An efficient pharmaceutical market needs not only innovative medicines but also informed patients and consumers, so as to understand the dynamics of negotiation procedures".

New authorisation models & new drug policies in a changing world
A more united European Union involves also a new approach and new policies on medical products. European regulatory agencies have recently confirmed the need for coordination between agencies, aimed at a more effective and consistent negotiation of the price with the manufacturer.
The cornerstone could be represented by a change at European level, inviting Member States to make their drug pricing and reimbursement procedures as consistent as possible and experiencing, through the European Medicines Agency (EMA), with new marketing authorisation methods.

Next steps

The outcomes of the 11th European Patients' Rights Day will be implemented through several follow-up activities:

- Initiatives will be promoted in the different Member States, in partnership with local civic and patient associations attending today, in order to sensitize the National Authorities about patient involvement in their internal processes.

- Training courses addressed to the leaders of European civic and patient associations on themes such as European and national Regulatory Systems; Health Technology Assessment; access to generic medicines; etc., to encourage an active exchange of reflections and experiences.

- Concrete policy suggestions will be shared thanks to the commitment of the MEPs Interest Group "European Patients' Rights & Cross-Border Healthcare". The first follow-up event has been held on June 28th at the European Parliament. During the meeting a concrete European proposal to ensure timely and equitable access to innovative therapies for diseases with unmet needs has been presented to relevant stakeholders. For further information, please click here.

- A new subject to add in the framework of sustainability of health systems and access to medicines: the therapeutic adherence to pharmacological and non-pharmacological medical plans.

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