European Medicines Agency
Communications and Networking

London, 9 December 2008
Doc. Ref. EMEA/662143/2008

Welcome address ALMP
Sinisa Tomic

Dear Colleagues,

Allow me to wish you all a heartfelt welcome to the Croatian Cultural Centre at Sušak in Rijeka and the international conference “EU regulatory network – challenges and opportunities for Croatia”. We are also celebrating the fifth anniversary of the Croatian Agency for Medicinal Products and Medical Devices.

The Agency was founded five years ago with the merger of two national institutes by virtue of a law that transformed them into a single competent authority for medicines and medical devices that would more efficiently carry out the tasks within its competence. In this way, the Agency could significantly contribute to protecting the interests of public health.

Since then, the Agency has been entrusted with ensuring that the medicines and medical devices marketed in Croatia meet all the conditions for granting the marketing authorisation in our country. To that effect, the Agency constantly assesses data that influence our knowledge to date and, pursuant to its public authority, makes hundreds of decisions each year that change the properties of medicines and their manner of usage.

The involvement of the Agency in the field of ensuring quality, safety and efficacy of medicines is evident in all cases when it is necessary to weigh the risks and expected benefits for patients. Oftentimes, Agency teams are faced with professional and regulatory challenges that require quick and synchronized action and cooperation among our departments dealing with documentation assessment, surveillance of production, quality control or pharmacovigilance. They also often cooperate with international networks of experts or with international authorities. Our experts represent the guardians of the interests of public health in the field of health care products, and their contribution is key to the Agency's successful operation.

Though five years may not be a long time in the life of an institution, there have been many cases in which the Agency's reaction was quick and allowed it to take control of the situation and avoid a crisis, and it reacted to the needs of the Croatian health care system. This is the primary mission of the Agency that is so necessary for the trust that our citizens want to have in the regulatory system.

Our openness to cooperation with all target groups is best seen in our constant efforts to increase the transparency of the regulatory system and the accessibility of objective and clear information about medicines and medical devices to health care professionals, the pharmaceutical industry and the general public. To this effect, the Agency has launched a new redesigned website.

Furthermore, the Agency works closely with the Ministry of Health and Social Welfare, which is responsible for surveying the work of the Agency and for drafting legislation and regulations. The Agency has made its expert and legal contributions to this process, particularly in the drafting of the new Medicines Act and the new Medical Devices Act, and a number of ordinances that introduced changes to the regulatory system and represent progress in the harmonisation of the Croatian

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 85 01
E-mail: conferences@emea.europa.eu http://www.emea.europa.eu

legislation with the *acquis communautaire*. This legislation has also demanded a transformation and adjustment of the work of the Agency itself.

Moreover, these new laws prescribe a more active role of the Agency concerning the safety of health care products in our country, and in the vision of Croatia as a future member of the integrated European regulatory system, bearing in mind the impacts of globalization on research, development, production and distribution of medicines.

The Agency has adjusted its operations in light of new circumstances in the regulatory environment, while nurturing the fundamental values that are important for the functioning of an institute with public authority, and in particular, for an Agency for Medicinal Products and Medical Devices. This includes an organization based on processes, transparency, adopting a corporate culture and offering equal opportunities for all.

Today, more than ever, the public wants to know what the Agency is doing, and it expects that what Agency is doing benefit patients at large.

In line with this, the Agency for Medicinal Products and Medical Devices is sensitive to the growing demands of the public for the responsibility and relevancy of public institutions. We listen to those we serve: patients and their associations, industry, health care workers, line ministries and the academia. Each of these public groups assesses the Agency depending on the quality of service it receives.

In the context of Croatia's rapprochement to EU membership, it is necessary that our staff is receiving the best professional and regulatory knowledge and skills. To that effect, we are constantly investing in their training and strengthening out cooperation with the European Medicines Agency, the European Commission, and the European Directorate for the Quality of Medicines and the Agencies of EU Member States, in order to implement good European practices.

With its expert and motivated team, the Agency wholeheartedly wishes to preserve the necessary enthusiasm to fully meet the high standards expected of us by the Croatian health care system, and by our patients and all stakeholders in the pharmaceutical sector.