25 November 2019

DGII Open Doors Meeting

How the European Directorate for the Quality of Medicines & HealthCare (EDQM), Council of Europe, contributes to the missions of DGII.

Distinguished speakers, delegates and colleagues,

Ladies and Gentlemen,

Trust.

Trust (as my colleagues have already mentioned), is a necessary precondition for democratic rule; a decline in trust is thought to fundamentally challenge the quality of representative democracy.

Lack of trust can develop into cynicism, which turns to discontent and fear.

One of the Directorate General of Democracy's (DGII) principal missions is to 'reinforce democratic institutions and citizens trust in them'.

This is where the European Directorate for the Quality of Medicines & HealthCare (EDQM) has an important role to play under the aegis of the Council of Europe, whose role is to protect human rights, democracy and the rule of law.

Health is a social human right. It is indispensable for the exercise of all other human rights, for prosperity and for democratic stability of people in Europe. Enjoying good

health is often something we take for granted, until our health becomes fragile or diminished, and only then do we become acutely aware of the vital role medicines and health care play in our lives to maintain health and wellbeing.

One of the missions of the EDQM is to contribute to the basic human right of access to good quality medicines and healthcare.

Fifty-five years ago, eight countries committed themselves to signing the new Convention on the Elaboration of a European Pharmacopoeia. These pioneering countries chose to unite and harmonise their national laws in pursuit of common specifications for medicinal substances in the greater interest of the peoples of Europe and of public health. The Convention provided a unique legal framework to progressively work towards the elaboration of a harmonised Pharmacopoeia.

Ever since, national pharmacopoeias have collaborated and pooled resources to build together a European Pharmacopoeia, now in its Tenth Edition and consisting of more than 2400 monographs that invoke almost 3000 reference standards. In the first Edition of the European Pharmacopoeia published in 1969, 77 monographs were described and no reference standards!

In line with the increase in monographs, the portfolio of reference standards continues to expand year-on-year and European Pharmacopoeia reference standards are now used in more than 120 countries with demand growing especially in non-European countries. These reference standards are essential for carrying out the tests and assays described in the corresponding monographs of the European Pharmacopoeia.

In order to market products in Europe, pharmaceutical companies must demonstrate that all the ingredients used can be suitably controlled by the quality requirements set out in the European Pharmacopoeia. The EDQM's Certificates of Suitability attest that

this is the case, and are complemented by a programme of inspections to check conformity and compliance with Good Manufacturing Practice.

After medicines are authorised and released onto the European market, a network of around 70 official control laboratories in over 40 countries, coordinated by the EDQM, continues to ensure their quality via a series of market surveillance programmes. The work of these laboratories is essential in preventing substandard medicinal products from reaching patients and compromising the efficacy of their treatment and their health.

This network of laboratories also play an important role in the fight against counterfeit or falsified medicines. The laboratories are responsible for controlling and testing the quality of human and veterinary medicines, before and after they enter distribution chains.

The Medicrime Convention, to which the EDQM contributes, is without a doubt a strong response to growing concerns and fears of it citizens.

It is a powerful instrument – a penal convention that criminalizes the act of counterfeiting medical products. The Convention not only provides Competent Authorities with appropriate tools for preventing such crimes, but also instils public confidence in medicines, in health care systems, in health professionals, the suppliers and sellers of genuine medicines, the pharmaceutical industry and the Regulatory Authorities.

To date, this convention has been ratified by 16 countries and signed by another 16. It is open to signature and ratification by any country in the world.

The EDQM also contributes directly to ensuring the best possible quality and safety in the transfusion of blood and blood components such as plasma and platelets, and the transplantation of organs, human tissues and cells. Protecting both the donors and

recipients matters a great deal to us, and the EDQM promotes the principle of the non-commercialisation of substances of human origin.

Since 2007, the EDQM also publishes recommendations that aim to improve the quality and safety of the ingredients used in cosmetic products, including tattoos, and the quality and safety of materials that come into contact with food.

I am sure you will agree, that these are all very concrete missions, which serve to reassure European citizens and restore their trust and faith in our institution. When they make a purchase in a pharmacy, when they are vaccinated, if they receive a blood transfusion or organ transplant, they can rest assured that the EDQM has played a vital role to ensure that the treatments are safe and effective.

This trust in our institution and the public healthcare system is symbolised by the EDQM's new secondary site, based in Ars Laquenexy (Metz area), France, which was inaugurated on 15 November. The new building will house the contingency stocks of reference standards for medicines and their ingredients, and so allows the EDQM to ensure a seamless and continuous supply of the reference standards in all circumstances.

This new building is a symbol for everything I have just mentioned. It is a great symbol for our organisation, it underlines our ability to thrive in an uncertain world, and ensure the basic human right of access to good quality medicines and healthcare.

It is a powerful testament to the dynamism of the Council of Europe and the trust European citizens can place in our organisation.

Thank you