Memoirs of a European pharmacist

by Fernand Sauer, former Executive Director of the European Medicines Agency (1)

I have devoted my whole career to building a Europe that would protect the health of its citizens on a daily basis.

But what does Europe have to offer in terms of health protection? How does it meet your needs? I hope to be able to answer these questions, at least in part, by sharing with you some of the highlight of my commitment to healthcare in Europe.

I first encountered the Council of Europe in the 60s, when I was a pharmacy student in Strasbourg. The old pharmacy school, then located on the rue de l'Argonne, had a display window showing souvenirs of the great Louis Pasteur who had taught at the school a century before. There was a "Council of Europe" plaque on the door of a room on the same floor which I, pharmacy student that I was, found intriguing. What possible link could there be between the pharmaceutical sciences and Europe's leading human rights organisation?

Later on in my career, when I was working as a representative of the French Ministry of Health, I got some of the answers from a group of pharmaceutical experts from the Council of Europe.

At the start of the 60s, the Council of Europe had been asked to take over a number of pharmaceutical standardisation tasks from the Western European Union (WEU), for civil protection purposes, during the Cold War.

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The origins of today's medicinal product and healthcare framework in Europe

A number of humanitarian disasters, including World War II and the devastating floods that swept across northern Europe in January 1953, triggered great outpourings of solidarity aimed at providing victims with medicines, vaccines and blood. Unfortunately, these efforts did not have the expected life-saving impact simply because the units, dosages, quality requirements and instructions on the product packaging differed from one country to another.

Before international harmonisation, there could be more than 19 different quality standards for the ingredients that go into our medicines existing side-by-side in Europe. These standards were compiled in compendia or "national pharmacopoeias" whose basic role was to ensure the safety and quality of the medicines available on the market. The texts included in pharmacopoeias describe purity requirements for products. One of the functions of these requirements is to make sure that any impurities arising during the manufacturing process are maintained at levels that are not harmful to health.

Similarly, the lack of a common legal framework for the registration of medicinal products meant that patients were often denied rapid access to new medicines.

These were obstacles which had to be overcome in order to protect public health in Europe and ensure that all its citizens had equal access to good quality medicines.

Why a European Pharmacopoeia within the Council of Europe?

The idea of a European Pharmacopoeia was first put forward in 1964 when the eight founder members, all also members of the Council of Europe, agreed to sign the new *Convention on the Elaboration of a European Pharmacopoeia*, demonstrating their ambition to give Europe a single reference work for public health protection in their respective countries.

It was impossible to envisage this joint pharmacopoeia without the participation of Switzerland and the United Kingdom, both of which were major players in the medicines industry.

The European Economic Community (EEC, the forerunner of today's European Union) and the Council of Europe corresponded during the drafting of the Convention: on the basis of their exchanges, the EEC decided not to publish its own pharmacopoeia but to adopt that created under the aegis of the Council of Europe instead.

The Council of Europe was therefore given free rein to create a continent-wide pharmacopoeia. The main objective of this initiative was to facilitate the international exchange of crucial medicines in the event of a disaster or urgent need. An initial list of 120 medicines was therefore established.

The European framework for healthcare and medicines was gradually taking shape, in both Strasbourg and Brussels. The initial partnerships between the Council of Europe and the European Union have been strengthened over the course of some fifty years of close

cooperation. These achievements should also be seen as the work of a few outstanding individuals, convinced Europeans who have worked tirelessly to overcome the obstacles that prevented Europe's citizens from gaining access to quality medicines and healthcare.

Amongst the figures whose path I have had the immense privilege of crossing and who have actively contributed to developing these efficient and fruitful partnerships, I would like to mention Léon Robert (Luxembourg) who chaired the very first meeting of the European Pharmacopoeia Commission in 1964. He played a major role in shaping the European regulatory landscape, not just here in Strasbourg at the Council of Europe, but also in Brussels, through his work for the EEC. As the first chair of the EEC's Committee for Proprietary Medicinal Products, he was one of the pioneers of what was to become a long history of collaboration between the two organisations, and was instrumental in developing an intelligent legislative framework for healthcare in Europe which made the best possible use of available expertise and financial resources.

Throughout my career, I have also strived to nurture these partnerships and drive progress in the European medicinal products and healthcare sector.

Developing the European medicinal product and healthcare landscape

My commitment to Europe continued in 1985 when, as Director for Public Health at the European Commission, I proposed a set of 13 pharmaceutical measures in a White Paper on the completion of the single market. Several of these measures were related to activities that were the province of the Council of Europe, i.e. the pharmacopoeia, vaccines, blood products and access to medicinal products and their supply.

The rapprochement between the two institutions then accelerated when the European Community decided to join the European Pharmacopoeia. This was a major step forward whose importance must not be underestimated: to date, the European Union has ratified very few Council of Europe conventions.

As I had been an observer to the European Pharmacopoeia Commission since 1983, I was entrusted with leading the long and difficult negotiations to have the Convention revised, which meant obtaining the agreement of the non-EEC countries involved and, of course, enlisting the support of our own members.

In June 1994, I had the immense honour of ratifying the Act of Accession of the European Union to the *Convention on the Elaboration of a European Pharmacopoeia*, with Daniel Tarschys, the Secretary General of the Council of Europe at the time.

From 1995, as Executive Director of the newly created European Medicines Agency (EMA) in London I was able to strengthen the ties between the institutions.

Then, in 1996, the Council of Europe created its European Directorate for the Quality of

Medicines & HealthCare (EDQM) with Agnès Artiges at its head. She and I worked together to define the practicalities of cooperation between our organisations, particularly with regard to sharing existing expertise and exchanging representatives of our technical secretariats for all activities of mutual interest.

Today, Susanne Keitel is the Director of the EDQM, a technical directorate with a staff of more than 300 located in Strasbourg's European district, which works hand-in-hand with the EMA, the EU's healthcare agency which has a headcount of 900 and has just left London for Amsterdam. These two organisations rely on input from several hundred external experts appointed by their respective countries and covering matters related to both human and veterinary medicine.

It is interesting to look back over the way the cooperation between the Council of Europe and the European Union has developed and how it has helped shape public health protection in Europe. In the beginning, the Council of Europe focussed on the quality of active substances and other ingredients used in the manufacture of medicines, together with public health concerns such as blood transfusion. In 1964, the Council went on to open the *Convention on the elaboration of a European Pharmacopoeia* for signature and to adopt a set of resolutions on various public health issues.

On the other hand, the EEC initially concentrated on the problem of medicinal product marketing authorisations, issuing a first and binding directive in 1965.

In 1975, the European Pharmacopoeia was integrated into European pharmaceutical legislation. It thus became binding for all EEC member states, even those who had not directly signed the Convention.

More generally, the Council of Europe has played a pioneering role, and has always had a larger membership of European countries, thus anticipating the successive enlargements of the European Union.

Its pharmaceutical expert and public health committees and blood transfusion experts have therefore been able to explore new avenues with the support of member states wishing to contribute to its work.

The European Commission has taken the progress made by the Council of Europe and, sometimes relying on the same experts, has used it to develop standards that have then been made mandatory in the domestic law of EU members by the European Council and the European Parliament.

The EDQM, guardian of the quality of medicines worldwide

Whether they are innovative, high tech or generics, the European Pharmacopoeia is there to watch over the quality of medicines. The 10th Edition contains almost 3000 quality

standards, plus a catalogue of 3000 reference standards (samples of known quality which are used to perform the tests prescribed in the European Pharmacopoeia) for use by manufacturers, health authorities and researchers.

The development of the EDQM and the European Pharmacopoeia has kept pace with that of the EMA and the regulatory framework in the European Union.

Over the years, a number of complementary programs have been set up to provide a firm framework ensuring the quality of biologicals such as vaccines which are complex to manufacture, difficult to analyse and require special quality control measures. Since 1991, the EDQM has run the European "biological standardisation" program through which biological reference standards are established and quality control methods appropriate for this type of complex product are validated. The program is co-financed by the European Union.

At the request of the European Union and again with its support, the EDQM runs the network of official medicines control laboratories (OMCLs) whose mission is to promote mutual recognition of quality controls carried out by participating member states, with a dedicated program for the quality control of new medicines assessed by the EMA.

Furthermore, since 1994 the EDQM has also operated a worldwide quality analysis program for starting materials used in the manufacture of pharmaceuticals. So you see, if you take any sort of medicine, the work carried out by the EDQM directly concerns you!

The EDQM's involvement in general healthcare

Falsified medicines have become a major concern in Europe over the last few years. The EDQM works to reduce the risks related to falsification in conjunction with the European Union which adopted a directive on falsified medicines in 2011.

The EDQM also supports the Council of Europe's MEDICRIME Convention, adopted in 2010, by providing training on good anti-falsified medicines practices for national responsible stakeholders.

As the leading defender of human rights and ethics, the influence of the Council of Europe in promoting the principle of non-remunerated donation of blood and organs within the European Union has been and remains considerable.

Operating under the aegis of the EDQM since 2006, the role of the Committee on Blood Transfusion and the Committee on Organ Transplantation is to provide an ethical framework for the collection of blood and organs and to ensure the quality and safety of substances of human origin. Protection of both donor and recipient is a priority.

Lastly, if you are concerned about the ingredients used in cosmetics or about food contact

materials, you might like to know that the EDQM also has a work program dedicated to reducing and preventing the health risks related to these materials.

The EDQM contributes to the international influence of the Council of Europe

Since the 60s, the pharmaceutical sector has taken on European and now global proportions. For the majority of patients, this globalisation has brought with it many advantages in terms of access to healthcare but it also means higher risks, as a result of the increasing number of starting material and medicinal product manufacturing sites operating worldwide.

In the early years, a few academics and national officials would get together periodically in austere premises. The creation, over 20 years ago, of a modern scientific agency with qualified staff operating from dedicated premises has allowed the EDQM to gradually build on its activity portfolio within the Council of Europe, from the Pharmacopoeia to healthcare and consumer protection.

This broader panel of responsibilities has been underpinned by large-scale digitisation of procedures and publications and by investing in quality management systems, a policy that has been recognised by French and Belgian certification bodies. As part of the Council of Europe, the EDQM is rightfully seen as a key global player in the quality of medicines for human and veterinary use, serving the citizens of Europe and beyond.

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April 2019