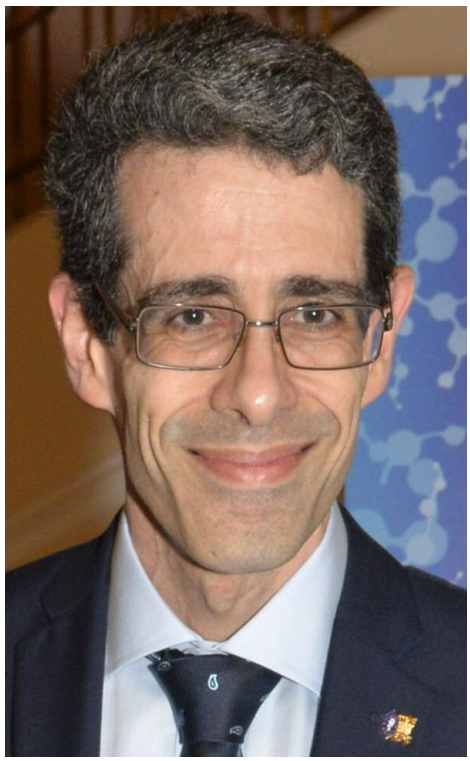
To speed or two speed: is that the question?



It is that time of the year when EIPG is busy preparing for its General Assembly – an eagerly awaited annual event that brings together our delegates from member organisations all over Europe. Last year, the Assembly in Paris was a significant one for us, as we celebrated the 50th anniversary of EIPG. We looked back on the notable changes that have taken place in the history of medicines and medicines regulation in Europe in that time span. However, the time for reminiscing is over, and, notwithstanding fond memories, it is to the future that we must now cast our attention.

This passing year has seen another significant European event – that of the 60th anniversary of the Treaty of Rome. It is, however, concerning that the anniversary of the birth of the Community comes at a time when the very ideal that engendered this reality is constantly being questioned. From the revival of the notion of a two-speed Europe to, more worryingly, the oft-repeated claim that healthcare, particularly where the accessibility to medicines is concerned, is not uniformly available to all European citizens. Yes, size matters. It matters in terms of market size and economies of scale, and it matters in terms of the resources that different countries – indeed sometimes different regions within the same country – possess in order to bring the latest life-saving medicines to patients in a timely manner at an affordable cost, be it directly to a single patient or to society in general when called upon to finance these costs to some greater or lesser extent through fiscal measures.

It is this very concern that has prompted, on either side of the Atlantic, measures, or at least the thought of them, that can achieve the objective of speeding not only the drug discovery, but also the regulatory process through which the risk–benefit balance of medicines are evaluated before becoming available to patients. The concept of speeding the process, however, has drawn divided opinions on the subject, and whilst the idea, in general, is one worthy of consideration, concerns have also been expressed by both the pharmaceutical industry and some regulatory authorities at the potential ramifications of unduly accelerated pathways. Quality, cost and speed – the saying goes that you can have any two, but not all three, and, therefore, we should be careful of policies that advocate rushing into a path where angels would fear to tread.

Yet, not to try is not an option either. We are on the edge of exciting discoveries in medicine that are set to become a reality in healthcare even in our lifetimes. Technology is, however, potentially getting ahead of our ability to surmount challenging social hurdles, and achievements in medicine risk finding us ill-prepared. We still grapple with the problem of finding solutions to differences in accessibility to cures, when such cures are, for the larger part, aimed at curing the individual, and have yet to face the reality when the provision of a cure means that not only the individual, but also his or her progeny, will consequently have been given access to a state of health free of an illness.

Therefore, *festina lente* – make haste slowly.
I look forward to meeting our member associations and guest organisations soon in Malta, so that together we can face these challenges and move forwards together, without having to accept that to speed, or two speed, are the only options available to the pharmaceutical world.

Professor Claude Farrugia
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