Newton's laws, Einstein's theory or just plain science?

Time is running out fast. It may not seem that way – after all, we started with just over 1000 days between the publication of the Delegated Regulation governing the details of the safety features, and there are still about 600 days to go. However, advice issued by both the European Medicines Verification Organisation (EMVO) and the blueprint providers indicate that in any national system at least 6 months of testing with all users connected to the system are recommended, which means that for any country behind schedule, there are approximately 400 days – just over a year – left to get all systems on line for a testing phase.

Once again, the progress report issued by EMVO makes for sombre reading – only seven countries have signed a contract with the service provider and almost two-thirds of countries are behind schedule – which means that the blueprint providers will be faced with a number of national systems requiring commissioning, and the hub of the same systems coming on line *en masse*, close to the deadline, instead of in an ideally gradual manner. The irony – if not outright concern – is that the countries that are ahead of schedule or mainstream, for the most part, are countries with lower percentage losses in sales due to intellectual property infringement, according to the figures of the EU Intellectual Property Office, whilst at least half of the cohort of countries who are behind schedule rank in the top third of countries suffering from these losses, and which, therefore, seem to be most at risk – at least in relative terms in the European territory – of the presence of counterfeit medicines products in their pharmaceutical supply chain.

Clearly, an impetus is needed – if nothing else to address lacunae in knowledge about how the entire system will operate once it is fully operational. It would probably be amiss to believe that, in Newtonian fashion, greater efforts will lead to a proportionately greater speed towards the objective. There are so many consequences arising from the regulation, many related to professional practice as well as technical implementation, that progress appears to be Einsteinian in nature – the progressive increase in the size of the challenge makes every extra amount of energy put into achieving the objective appear less effective at actually moving faster towards the goal.

Yet, just as scientists continue to pour their efforts into overcoming the limitations of Einstein's theory, so must the world of pharma continue to reach for the ultimate aim of protecting all patients from counterfeit medicines. Relative amounts of counterfeit medicines in the EU compared to extra-European markets are of little comfort as long as the patient in every box is at risk. Moreover, just as scientists believe that the universal nature of their work is the key to their eventual success, so must the world of pharma remove all barriers to the universal participation of any pharmaceutical association – trade or professional – in this project. It is only through the active participation of all such associations that the project can hope to achieve the level of success that the investment of finance, time and effort demands.

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