# Executive Summary

Health technologies and medicines are today more advanced and sophisticated than ever before. Highly targeted and even personalised therapies (particularly biologic drugs) are revolutionising the treatment of many life-threatening and chronic illnesses such as diabetes, cardiovascular conditions, cancer and autoimmune diseases. This greater utilisation of pharmaceuticals (and longer periods of use) means that more patients in North America and the EU are, in one way or another, dependent on medicines and medical treatments. Indeed, by most estimates the global use of prescription drugs is set to increase rapidly, with more patients taking more medicines for longer periods of time. In the US, for instance, prescription drug spending is set to almost double by 2017. While the health benefits of this are undeniable, the cost and the therapeutic and safety implications raised by this rise in demand, choice and utilisation are quite serious. One important issue this raises is the practice of switching patients between different medicines or medical therapies and/or using different therapies interchangeably. The introduction of biosimilar drugs – and whether or not regulators should treat these in the same way as they do chemically-based generic drugs – further complicates matters for prescribers and patients alike.

This paper outlines how therapeutic switching and interchange has gained traction in many countries and is becoming a key tactic for local and national healthcare bodies in implementing more cost-effective prescription policies. In the five surveyed countries – the US, Canada, the UK, Spain and Sweden – switching and substitution policies are being actively used to limit rises in pharmaceutical expenditure and to streamline prescription practices. The way in which switching policies are being implemented varies a great deal between the surveyed countries and depends largely on the design of their respective healthcare systems. For example, the fragmentary nature of the American healthcare system means that a variety of healthcare actors, ranging from the central government and state governments to private health insurers, all, in one form or another, shape the formulation and implementation of therapeutic interchange policies. In the UK the decentralised nature of healthcare delivery (largely in the hands of local Primary Care Trusts) and the lack of clear national guidelines has resulted in a virtual postcode lottery in how switching takes place.

Whether switching takes place as part of a formal protocol or based on the discretion of a patient's physician, it has many benefits and risks. It may help identify more effective and sometimes more cost-effective treatments, improving the quality of life for patients dealing with chronic conditions. But therapeutic switching may also result in undue medical risks and jeopardise the independence and preference of patients if it is not done cautiously and with the appropriate information. This is especially the case for risky patients and those that are already stabilised on a treatment regime.

In addition to switching for chemical-based medicines this paper also examines how biological drugs and, in particular, biosimilars have figured within switching and substitution policies. By and large, this paper has found that, in the surveyed countries, regulators and health policymakers have taken a much more active role with regard to formulating switching policies for biologics and biosimilars than they have with chemical-based drugs. While this finding does not mean that all surveyed countries have embraced the same policies, it suggests that policymakers have real concerns over the switching and substitution policies for biologics and biosimilars. Indeed, many experts highlight the immunogenic potential of biologic agents, saying that this factor makes finding the most appropriate therapy a risky process. Once the best treatment is identified, switching to another biologic – whether a biologic or biosimilar – carries an unjustified risk, and thus involves a decision that must be taken carefully and based on as much information as possible. For this reason, many healthcare authorities recommend or mandate that the decision to switch a biologic must be taken by the patient's physician and many EU countries actively prohibit the automatic substitution of a biologic drug with a biosimilar.

Based on these findings, the following recommendations are intended to give policymakers an overview of how to design and implement effective and safe switching policies:

- **Patients should be made aware of any switch to their medication.** When a switch is to take place, both the advantages and disadvantages of this switch should be explained clearly. This is especially true for balanced patients, those with chronic illnesses and co-morbidities, and where the switch involves a biologic or biosimilar drug. In such cases where the patient and/or physician disagree with the proposed switch, scope must be left for the patient to either appeal the decision or be allowed to make a co-payment and keep his or her original prescription.
- **The benefits and risks of therapeutic switching need to be better understood at all levels of medical practice.** This should help eliminate the wide variations in how switching is understood and implemented on the ground. For example, in the UK individual PCTs largely set switching policies themselves. This can create a postcode lottery for patients as to which medicines and treatments they can access. Information should also be improved for patients.
- **Healthcare practitioners and policymakers understand the significant risks involved with switching biologic medicines.** They must be made aware that biologics and biosimilars are a fundamentally different set of medicines from chemical-based drugs. Biosimilars are not the same as generic drugs and should be treated differently. Regulations, guidelines and educational information should be clear regarding this difference. Policymakers at all levels of health care should take caution in listing biologics as therapeutically equivalent or therapeutically interchangeable.

- **A distinction should be made between those patients who are on medication for shorter periods of time and whose medical condition requires less invasive treatment versus balanced patients whose conditions are long-term (including chronic) and require prescriptions on a daily basis over long period of time (even for life).** For the latter group establishing an effective, safe and comfortable prescription regime – i.e. achieving the objective of "balancing" the patient - is a time-consuming and arduous task. In these cases switching should only take place with the full knowledge and consent of the prescribing physician in consultation with the affected patient.

Taking these recommendations as general principles, countries and regions can form positive policies on the selection of medicines, which will help balance future medical innovation, financial pressures and patient safety and choice.