In this issue Soller and colleagues present a detailed synthesis of information from applications to the FDA for non-prescription status. Pharmaceutical companies will doubtless find this paper of great value for predicting the focus of FDA concerns to be addressed in advisory committee meetings, particularly for first-in-class switches. However it is striking that there has not been a New Drug Advisory Committee meeting on a switch proposal since 2007. The reasons for this are unclear. It is possible, for example, that many applications are withdrawn before progressing to an advisory committee meeting and therefore do not become public. Whatever the underlying cause, the reality is that bringing a new class of medicines to non-prescription status is in danger of becoming a rare event in the US.

In Europe, new non-prescription status most often means that medicines are sold only in pharmacies. The involvement of a Healthcare Professional in the selection of a medicine for self medication arguably changes the risk/benefit equation in favor of allowing a broader range of medicines to be sold in this way. Perhaps reflecting this, there are several classes of medicines long available without a prescription in one or more European Union (EU) countries that are not available in the US. However, even within the EU, the Directive governing the legal status of medicines has been employed more enthusiastically to reclassify medicines in some member states (notably the UK) than others, and discrepancies of legal status across European borders abound.

To add further complexity, Europe is now entering an era in which many medicines approved for prescription use by the centralized procedure are reaching the stage of their lifecycle where non-prescription status might be considered. The regulations dictate that these drugs should be reclassified by the centralized procedure. But there is understandable skepticism about the ability of European regulators to achieve agreement on legal status routinely across 27 member states all with different attitudes and history in relation to switch. The experience to date suggests that relatively uncontroversial switches may indeed be possible by this route. It remains to be seen whether more contentious switches, such as some of those approved by the UK in the last 10 years, could ever be introduced across the whole of the EU.

If the future for new category switches looks more uncertain now than it has for some years, the need for new self-care options has arguably never been greater. Governments globally face unprecedented constraints on all aspects of their expenditure and healthcare costs are a prominent and growing burden. In turn, the rise in these costs is driven in part by demographic and societal changes that are inescapable, at least in the medium term. Encouraging self-care and having the individual take responsibility for, and bear the cost of, some interventions aimed at preventing ill health or treating suitable conditions seems an obvious response. In the prevailing
economic climate, shifting some of the burden of healthcare costs to individuals who choose to afford it, is perhaps less politically contentious than it might once have been.

Self-care and self-medication need to be both recognized as an important part of healthcare delivery and actively encouraged by governments. The environment for self-care and self-medication also needs to change so that such practices are seen as a starting point for healthcare rather than as substitutes for professional-led services.

It is not hard to agree that more self-care is a ‘good thing’. But when self-care includes self-medication, views become more polarised. The motivations that governments might have to save money and that companies certainly have to make a profit, inevitably raise suspicions that new switches are more about money than public health. However self medication can play a major role in public health, not only in treating minor ailments (where the freeing up of healthcare professional time may be an under-appreciated societal benefit) but potentially also in the prevention of serious disease. For these benefits to accrue, applications to reclassify medicines to non-prescription status need to be encouraged. It is in everyone’s interest that regulators and companies work in partnership to deliver the next generation of effective and well tolerated self medication drugs.

More successful applications for non prescription status would be a promising starting point, but not enough by itself. The health care landscape needs to change to put self-care and, when appropriate, self-medication at the centre of delivering wellness. For this to happen, HCPs may need to be encouraged, and probably incentivized, to support the principle of putting self-care first.

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REFERENCES

