

United we stand

Varied regulatory methods in different countries are hampering medicines uptake



As we face the most challenging economic downturn for decades, every route must be explored in the quest to wring the maximum value from the money in healthcare budgets. All aspects of healthcare expenditure must come under scrutiny, including the ever more complicated arena of the health technology assessment (HTA).

The National Institute for Health and Clinical Excellence (NICE) in the UK increasingly influences the provision of health services across Europe. This is resulting in burgeoning regulatory processes in most European countries that severely restrict clinical development, add cost pressure to health services and the pharmaceutical industry and slow the rate at which effective medicines reach patients.

Whole system change to health services is needed before the escalating and repetitive costs of appraisal and regulation become unsustainable. As the pace of this change is likely to be slow, in the short term, the pharmaceutical

industry will need to adapt rapidly and radically in order to eke out profits in ever decreasing markets.

NICE has just celebrated its tenth birthday. It costs the UK taxpayer £80m each year, which represents an eightfold increase since its inception. There have been numerous articles and many debates around the fairness of NICE HTAs, particularly in the light of the influence NICE has across Europe.

Inconsistencies

All European countries have variable access to medicines as a result of the spectrum of differences in their regulatory systems. The mutual recognition procedure (MRP) system - where one EU member state is expected to recognise the marketing authorisation (MA) approved by another, unless there are serious patient safety issues - does not work consistently. It fails because countries often demand different studies or requirements before granting a MA, even though MRPs

should be standard throughout Europe.

Some countries are trying to protect local manufacturing and therefore impose additional demands for registration on products manufactured in India, for example, even though there is no regulatory demand for this. Companies have to pay regulatory authorities a lot of money for scientific advice. However, the advice they receive is not binding. There are many instances where scientific advice from a regulatory authority has not been adhered to and products have had to be withdrawn from the regulatory process because demands have changed. If regulatory scientific meetings are to be chargeable, the subsequent advice should be enforced and not subject to any change of view or left open to interpretation.

Examples of how the variability in regulatory processes can prevent medicines reaching patients are plentiful across Europe. A product can be approved in one country where the safety data have been

gathered for a long time, yet other countries do not always recognise the file. This means that the product has to undergo a new and costly development programme, which prohibits it reaching other markets.

A product approved for 20 years in France was recently refused authorisation by another member state that would not recognise the data used by Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). As a result, the product was not launched in the neighbouring market and clinicians there were forced to follow therapy guidelines and used an unlicensed product in critical care. This demonstrates that the system does not function. Clearly, either the product licensed in the French market for 20 years should be recognised in other member states, or it should be withdrawn in France. Member states should behave as one market and recognise the data from other authorities.

The CEO of a French pharmaceutical company told me recently how, despite national guidance through AFSSAPS, his medicine was being "blocked" in certain geographical areas by new organisations set up at regional level to conduct therapeutic appraisals, thus repeating the work done at government level. This meant an increase in the time taken for the treatment to reach patients.

"This trend will continue and more regional drug groups will be established"

The same repetitive processes are happening in Italy, where small bodies are forming to create their own guidance, despite having a national appraisal and regulatory system in place. It is likely that this trend will continue and more regional drug review groups will be established in other EU countries.

This emerging picture is familiar; a myriad of regional review bodies has appeared in the UK over the last five years, at great cost to the taxpayer. Why are processes being repeated at a regional level, and what will these regional bodies unearth that NICE has missed?

Working with the UK healthcare system has become costly and problematic for the majority of

pharmaceutical companies. Recently, several drugs have not been launched in Scotland or Wales, because of the prohibitive cost required to conduct the HTA demanded in those countries. Consequently, sales representatives there have been made redundant.

At a Primary Care Organisation (PCO) level, further problems exist, as appraisal processes are repeated by various prescribing committees performing their own evaluations. Each of these PCOs interprets information differently and no two organisations seem to be able to agree on how clinical trial evidence and prescribing data should be evaluated and interpreted.

The perception is that the pharmaceutical industry is against HTAs. It is not. What the industry cannot understand is why the national process, handled by NICE and designed to create equity, is being repeated, and therefore diluted, at a regional and local level at immense financial cost to the health service and immeasurable clinical cost to patients.

This flawed, duplicated and wasteful appraisal system also adds costs to the pharmaceutical industry. In the UK, once a drug has received MA from the Medicines and Healthcare products Regulatory Agency (MHRA), it can take a further four to five years to reach patients because of the numerous assessment hurdles that now exist. For every week that a major drug is kept from market, the cost to the company is in the region of £5m. Pharmaceutical companies cannot support this for long and disinvestment is the likely outcome. This, combined with the financial crisis in the health service, means patient care will suffer.

I read and study guidance and formularies all the time. I have noticed that, as a result of regional review bodies, the access to everyday medicines has become harder for the patient to obtain. I witnessed this first-hand recently when trying to help a member of my family with diabetes. They could not get the diabetic agent they needed where they lived, but could where I lived because the formulary was different. The distance between our homes is just 50 miles!

During the economic downturn it is unlikely that the health service in any European country will alter course in the near future, in terms of new medicine assessment and appraisal. In the UK, every PCO is eager to save money wherever possible and

believes quick wins can still be found in prescribing efficiencies. Until the UK's National Health Service accepts that its management system is broken and needs to change, the pharmaceutical industry must adapt and adapt quickly.

Traditional sales forces, marketing campaigns, sandwich lunches and marketing literature handouts are finished. I recently had dinner with some friends. The father is a sales representative in a pharmaceutical company, and his 15-year-old daughter wanted work experience ideas. I suggested she could shadow a medical representative for a day. Her answer: "No way, all Dad does is dish out sandwiches!"

"This adds to the debate about the skills we need ... with a different customer"

This adds to the debate about the skills and competencies we now need as an industry with a different customer. Many companies make the claim that they have moved or are moving to key account management. Simply changing the badge on your existing salesforce after a three-day training package is not enough. A complete cultural change in the business is needed to make it succeed. This will mean redundancies for those who cannot adapt or change.

From a marketing perspective, marketers will have to embrace regional style marketing while linking into a national campaign - something I have not yet seen done properly yet.

The future lies with the industry and health services working together in robust, holistic, patient-centred projects that will stop the inertia and wasted resources. Only when the health services and industry agree to combine the efficiencies of such radical change will improved access to medicines and better outcomes for patients be realised. Until someone within the health service shouts "the Emperor is wearing no clothes", like the child in the fairytale who stated what everyone knew but was too afraid to say, it will be left to the pharmaceutical industry to lead the way.

The Author

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