Interview with Sheila Kelly, Chief Executive, Proprietary Association of Great Britain (PAGB)

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Thank you for having us today! You have been chief executive of the Association since 1990 and obviously observed the evolution of the OTC market from close by. From your experience, can you please explain our readers how you have seen the OTC market evolving here in the UK?

From a business perspective, the UK market, as many other developed markets, has gone through a huge period of consolidation. As the trade association for all the major OTC manufacturers PAGB had 70 members twenty years ago. Today, this number has decreased to little over 40 members, caused by the fact that companies have been taking each other over. These mergers and acquisitions are often driven by a drive to create synergies and cut costs, but when you look at the number of products on the market, this has remained relatively unchanged. We have well over one thousand branded OTC products that are very actively marketed. The typical reason behind a takeover is the brand equity these products have, because the fastest way to build a brand is to simply take it over.

From a clinical perspective, the big driver in the market is the fact that medicines are moving from prescription control. While headaches for example used to be treated with Aspirin or Paracetamol, people can now choose Ibuprofen or Diclofenac or Ketoprofen. Many other ingredients that were prescription-only have moved OTC for conditions that everyone knows how to handle themselves. This offers the convenience of not having to go to the doctor to find something that is effective. For me, the more interesting aspect is the number of new indications that come with these products.

This began with Hydrocortisone for Eczema for example, for which Eumovate can now be bought. An infected eye can now be treated with Chloramphenicol. We have OTC medicines like Canesten for vaginal thrush, Alli for weight loss, Flomax for benign prostatic hyperplasia (BPH), and products for conditions like irritable bowel syndrome so there are far more things that people can treat for themselves.

This seems to reflect the views of Prime Minister Cameron aiming to encourage self-care within the UK…

This actually began in 2000 with Tony Blair. At that time, I attended many meetings where it was questioned how medical treatment could be provided when He said it was absolutely right for people to take care of themselves, portraying a solid support for the OTC market. Current Prime Minister Cameron aligns with the idea of self care with his view that people need to take responsibility for their health.

The financial crisis did of course help to look into ways of taking costs out of the system and have patients absorbing these costs themselves. Doctors in the UK are generally in favour of more self care. A recent survey showed that 90% of them believed that people should be caring for their own illnesses, and showed an intention to do more in the future to encourage that. Our doctors are paid whether or not they see a patient, which is very different from other countries where the doctor needs patients to pay a visit in order to be paid. In the UK, the system works with a per capita basis which means a doctor receives an annual fee to provide healthcare cover. This system relies on the fact that a very large number of people will never go to the doctor at all, which is balanced out by a section of older people that take up a large chunk of his or her resources. This does mean that when a doctor sees someone with a headache, he or she will have every interest in saying there is not much to worry about and encourage the patient to treat this themselves

Looking at the number of GP consultations, survey results have shown that 18% of those still represent minor ailments…

And this is even a very conservative estimate. Even in this office, when everyone knows that we are in the business of self care and self medication, people seem to think they should go to a doctor when they feel something is wrong. People seem to have lost the ability to look after themselves.

What do you think remains to be done to decrease this 18% and change the patient culture?

PAGB did research a number of years ago to find this out. First, a study was conducted with IMS to find out what proportion of illnesses are minor illnesses. This showed the 18% figure. Since doctors were complaining about the fact that they were treating patients who could easily treat themselves, the question was raised on why the doctors are not taking any action in this regards.

So the quantitative part of the study was followed by a big piece of qualitative work with doctors, pharmacists, patients and consumers. In that feedback process doctors argued they were already engaged in encouraging their patients to look after themselves. Asking the patients, they would say they would be prepared to do something themselves, but the doctor would not tell them to do so and rather write a prescription. 90% of the time they would go in, they would receive a prescription for a minor ailment rather than advice on how to look after themselves.

The reality is that the average consultation time is around 8 to 10 minutes. The doctors simply do not have the time to educate the patients for such issues. It is much easier and faster to write a prescription. Asking the doctors why they would not send more people to the pharmacist, it was clear that they are more comfortable with speaking to patients and telling them they could do more for themselves, but they are less comfortable saying the patients should see the pharmacist rather than the doctor. This is seen as passing the responsibility to another health professional.

The other problem doctors are experiencing is to define what can be considered as a minor illness. There is always this fear however remote, that a headache might indicate a brain tumour for example. The mixed messages around such symptoms may therefore be of concern to some patients.

Some chronic patients might also get used to taking certain medicines containing codeine for example. Can this make people dependent on certain medicines?

This is a separate issue. A medicine can only be OTC if it has a low potential for addiction and dependency. While codeine does have an addiction potential, a comprehensive review of the ingredient by PAGB has recently shown that it is mostly about education and telling people to read the labels properly. It is a very good painkiller for toothache, period pains, arthritic conditions, etc. so on balance it is still valuable as OTC. But it can only be bought in pharmacies and pharmacists are much more careful about selling these medicines nowadays. Furthermore, the pack sizes are very small too. When we switch something to OTC, it is not a case of everything goes. It will be a match of pack size with the duration of use and the instructions on the label which should say how long to use it for. This all contributes to safety.

It seems that you do not seem too concerned about the abuse of OTC medicines, but what makes you think the British consumer is in safe hands?

They are in their own hands! Doctors do not make things safe. The vast majority of people in the UK are in fact very cautious about medicines. Many people are also very worried about addiction and think that when you take medicines when you do not really need them, they will not work when you do need them. All the information for safe use is on the label and if there was a serious problem of abuse the products would not be available for self medication.

How would you rate the quality of OTC advertising in the UK?

Every piece of advertising seen in the UK market is checked by PAGB. Except for Germany, in most other countries pre checking of OTC advertising is done by the Health Authority. PAGB was created by the industry in 1919 for this purpose. We still check everything from TV through print to digital media and as a result there have never been any complaints about OTC advertising in Britain.

Do you still see room for improvement then?

The advertising is very good but I believe that there is room for more creativity. Agencies will say that the regulations restrict them but in my experience the clients take a more conservative stance that leads to less creative OTC advertising. To be fair, what the client is trying to do is to match what the customers want and perhaps people in this country prefer the more conservative approach.

Effective advertising is especially important in view of the competition from the pharmacies' and supermarkets' own label medicines which are now perceived as brands. How can the branded OTC manufacturers defend their market share?

PAGB's members are constantly bringing out line extensions so just like in any other market, innovation remains key. Switch from prescription control is important but so is formulation development. In the analgesic market for example you see many new formats, faster acting products, easier to swallow products and different flavours. Similar to any other consumer product markets, companies have to keep up with the customers. I am not sure whether other markets are as innovative as the UK, but here there are many opportunities for further line extensions. That keeps the brands new and offers advantages over own label.

Is there any significant innovation of this kind you would like to highlight?

If you look at the switch categories, there is Alli, Flomax, and so on. There are now also products for Chlamydia, which allow the patient to diagnose and treat the disease themselves. This is particularly important for sexually active young people that are not too keen on spending their time at a clinic. This allows them to discreetly deal with the disease themselves. Similarly with Alli, people using Weightwatchers, trying diet foods, etc. are not going to go to a doctor. Making these products OTC allows these people to try something different. The Flomax product is for BPH problems, for which some do not even realize there are treatments. This again is where innovation comes in.

You are also on the board of the European Proprietary Medicines Manufacturers' Association (AESGP). How do you rate the attractiveness of Britain's OTC market for international players?

The UK players would all like to be more active within Europe and take their brands to these markets. The problem is that all these markets are isolated into national pockets because of the regulatory system. For a prescription drug, it is sufficient to register once at the EMA, which is valid across Europe. With OTCs you still need to go from country to country, although clusters of countries are being formed now. At its worst, a dossier is going to be looked at 27 times. Given the differences in the markets from very developed to new markets in Eastern-Europe, the outcome is always quite unpredictable.

The culture in a regulatory body relates to who the people in that agency are accountable to. If a market authorization needs to be issued in France for example, it will need to be assessed there. When something goes wrong in that market, it is not a valid answer to state that the product was assessed in the UK.

How can this problem be solved then?

The question really is when and how we can obtain real mutual recognition. While we thought we were heading that way 15 years ago, the big mistake we made was allowing each country to have a look at the dossier, which naturally lead to different outcomes. People bring to these decisions their own cultural approach to medication and self-medication, as well as their own ideas on how doctors and pharmacists and people behave. There needs to be found a solution across Europe for this. We cannot have that the vibrant and thriving UK market ends up moving at the pace of the slowest.

Do you also see this as one of the reasons why there are changes going on in the distribution channels across Europe?

The driver in other countries is the politicians. They want to see competition in the market and they want to see prices coming down. People here were very interested in the possibility of opening pharmacy chains in other countries. This case went to the European Court of Justice last year, which was about whether or not the rule could be implemented that every pharmacy had to be owned by a pharmacist. The court ruled that member states could impose this restriction. This ownership issue is a clear limit to pharmacy chains.

In the meantime, it is a very buoyant time to be in the UK with reforms of the healthcare system, government budget reviews, a shift from the Pharmaceutical Price Regulation Scheme (PPRS) to Value-Based Pricing (VBP) and so on. How do you see these changes affecting the OTC market?

2014 will be the big moment for the PPRS, which is unlikely to affect the OTC market where the price is decided by the retailer. While this is not an issue to us, the time between now and 2014 will be an important period. With the changes in the NHS, doctors will have GBP 80 billion to spend. At the moment, we keep telling the doctors to encourage self-care but now that the Primary Care Trusts (PCTs) will disappear, doctors will have more responsibility for their clinical decisions as well as their consequences. When they now write a prescription for a very expensive treatment, they will need to make sure they have the funds in their consortium to pay for that. This is a big change. This is expected to make the doctors more aware and take more active measures to help people manage their minor ailments. In the end, these changes present an opportunity to align good clinical practice with good economic behaviour. This will bring people away from the doctors and encourage self-care.

Between now and 2014, PAGB will therefore be working together with the doctor’s organizations. While we already have the support of many eminent doctors, it is especially important to gain the support of the grassroots doctors too. One initiative we are engaged in is a training programme with the Royal College of General Practitioners for example. Right from the time when someone becomes a General Practitioner, self-care will be imposed as part of the culture.

The financial crisis has also given everyone the opportunity to look back and wonder “is this really what we should be doing?”. Equally, when people are spending their own money they will pay more attention to the price of a generic over a branded product. This will be a driver for companies to innovate their brands and keep them fresh. One consequence is for example the increase in online advertising that has been occurring. We will see advertisers trying to keep up with the changes in media and in the way people behave.

Is there any topic you feel we have not covered?

Everyone thinks the changes come as a big opportunity for pharmacists, but I do not think they necessarily see it that way at the moment, since most of their income still comes from the NHS. The pharmacy part of the NHS budget is getting squeezed and as more people are getting older and more prescriptions are being written, this budget is being stretched. Therefore, pharmacists have to make quite a bit of their money from buying the drugs as cheaply as possible. Even if they succeed in making money from procuring, the government can take some of it back.

They have been developing a more clinical role providing additional services, such as medicines use reviews, smoking cessation clinics, and so on. At the moment, the PCTs control this money. In the new world of GP commissioning, pharmacists will now apply to GP commissioners, while these in turn are told to consider any willing provider. This means that anyone can start competing with pharmacists for these services. This competition will be challenging for the pharmacists but I am sure the larger chains will be well placed to provide those services.

Another budget has been set up for local councils to do health improvements and promotions, although it is not clear yet how this will work. It is possible that this will allow some of the smaller local pharmacists to implement initiatives on a local basis. The more entrepreneurial pharmacists will take the opportunity to provide these services, They will all have to look at the whole of their business and maximise the OTC business potential.

What has been the most rewarding aspect of being in charge of the Association for 20 years?

I am very proud of PAGB. We are a very good association that is often considered as a benchmark for other associations. One of the things we have been very active in over the past few years has been better regulation. I believe that we are now overwhelmed by regulation that was in fact designed for prescription drugs rather than OTC. Developing OTC products is already a lengthy process, adding to that the necessary promotional efforts and so on, it has become more rewarding for pharmaceutical companies to spend their money elsewhere.

For the last four or five years, we have started to wind the clock back to get rid of some of the worst of regulation, but we still have a long way to go. In an ideal world, you will be able to put an OTC product on the market with a minimum of regulatory pre-clearance and a lot of post-marketing checking to make sure it is safe.. It is therefore essential to lose this regulatory burden on the OTC market and that is still my greatest challenge.

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