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Continence products and medical devices: issues that pelvic health physiotherapists need to consider

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Abstract
This paper was inspired by Professor Mandy Fader's talk about continence products and medical devices, which was presented at the 2017 POGP Annual Conference. The author relays Professor Fader's informative advice on male continence products and the nature of medical product regulation, and also considers the role of medical devices and continence products in pelvic floor rehabilitation. The rules governing the manufacturing, labelling and advertising of medical devices are outlined, and the relevant Chartered Society of Physiotherapy quality assurance standards are reviewed. The author goes on to explore the definition of a medical device, the process of CE marking and regulation, and the rules regarding advertising a device in the UK. The responsibilities of physiotherapists who promote, market and advertise services and products to patients and the media are also discussed.

Keywords: continence products, continuing professional development, equipment, medical devices, quality assurance standards.

Introduction

Professor Mandy Fader has spoken before at a POGP Annual Conference, and we were delighted to welcome her back to last year's event, which was held in her local vicinity. Professor Fader, who has a background in nursing, works with the University of Southampton's Continence Technology and Skin Health group. She leads a team of focusing on research into continence products and medical devices, and the effects of incontinence on skin health.

Male containment products

Professor Fader updated delegates on the continuing difficulties faced by men, particularly their access to suitable and effective containment products. She recommended encouraging men to use a mixture of solutions (e.g. pads, pants and sheaths), depending on their needs with regard to activities varying from sleeping to playing golf.

She also gave a warning about the potential for negative outcomes. Men participating in qualitative research studies have reported feelings of guilt about their incontinence. They felt personally responsible for their condition because they believed that they should have tried harder when performing the exercises that they had been prescribed.

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Continence Product Advisor website

Professor Fader's team have worked with the International Continence Society and the International Consultation on Incontinence to develop an impartial online resource called Continence Product Advisor (www.continenceproductadvisor.org). This not-for-profit website is funded by educational grants. It is written and reviewed by continence healthcare professionals and users of continence products. Where possible, the content is based on evidence (or expert opinion, if evidence is lacking), and references to sources are supplied. The information provided is mostly generic, focusing on product designs and types without reference to branded products, except when this is essential.

Like the website, the majority of the team's research focuses on containment products, such as pads, sheaths and catheters, but it also includes medical devices, such as urethral and anal inserts, penile clamps, and some clothing.

The conundrum of medical product regulation

The other section of Professor Fader's presentation opened our eyes to the issue of the design and development of medical products and devices in comparison to the path required for pharmaceuticals. She highlighted that non-pharmacological products are not required to be tested on patients, and very few currently available products have associated published clinical evaluations. The benefits of this less-regulated situation are that it reduces the cost of innovations, lowers the barrier to market entry and allows a wide variety of products to be made available to the public at relatively low costs. However, the low level of regulatory requirements raises health and safety issues, can lead to basic product irrelevance (she showed us a wonderful picture of the most amazingly complex female garment), and permits the marketing of ineffective products. Professor Fader touched briefly on legislations such as the *Conformité Européene* (CE, meaning "European Conformity") mark system for medical devices, and the role of the Medicines and Healthcare Products Regulatory Agency (MHRA), an executive agency sponsored by the Department of Health, in the regulation of clinical trials.

Pelvic floor rehabilitation devices

Despite the titles of their research group and website, Professor Fader's team do not, at present, study many of the products and devices that will be familiar to POGP physiotherapists who work with clients with incontinence (e.g. urethral supports, neuromuscular stimulation units and biofeedback devices). Similarly, a Cochrane Review entitled "Mechanical devices for urinary incontinence in women" by Lipp *et al.* (2014) presented the following definition:

> "Mechanical devices are made of plastic or other materials. They are placed within the urethra or vagina in order to stop or control the leakage of urine." (Lipp *et al.* 2014, p. 2)

Nevertheless, the range of devices that are being marketed as enhancing or simulating pelvic floor muscle exercises (PFMEs) increases each year, as does public interest in these tools. POGP responds to media queries about many topics, and there has been a marked increase in interest in medical devices from journalists and the public in the past year. In particular, there has been curiosity about products marketed as being able to "improve" or treat incontinence, such as stimulation, biofeedback and tracker machines (Gornall & Jourdan 2017).

The contents of the stands in the exhibition hall at the POGP 2017 Annual Conference were a clear indicator of the growth in the medical devices market: the majority of exhibitors showcased therapeutic devices rather than containment products. Conference could not cover its costs without the support of these commercial companies. For many physiotherapists, the opportunity to view, handle and discuss a range of products without cutting into valuable patient treatment time to arrange individual sales representative visits is invaluable. The buzz of conversation in the hall was a testimony to the animated discussions between therapists, manufacturers, designers and distributors.

Many of these items are also sold directly to the public through advertisements in magazines, newspaper articles, social media marketing campaigns, and increasingly, editorial pieces (Hashempour 2017). It was ground-breaking that, in September 2017, ITV dedicated an entire episode of a populist consumer-interest programme, *Save Money: Good Health* (Series 2, Episode 3), presented by Sian Williams and Dr Ranj Singh, to the topic of over-the-counter incontinence products (unfortunately, this episode is no longer available to view). The programme's researchers received input from POGP on the value of PFMEs.

An increase in the number of products being sold directly to the public is an inevitability, especially if National Health Service (NHS) funding for non-acute care continues to be reduced, and patients are encouraged to take control of their own health and well-being. Rehabilitation devices can range in price from £12 for the simplest non-electrical biofeedback tool to £250 for a body-worn stimulation apparatus. As with all consumer products, patients concerned about their health will be willing to spend money at a variety of price points.

Most devices do not require or even suggest assessment or instruction by a physiotherapist before the commencement of self-management. There is often an implication in the marketing of these products that a customer with pelvic floor dysfunction can achieve complete success with a do-it-yourself option. There can also be an inference that these devices are alternatives rather than adjuncts to PFMEs.

There has been some collective doubt about whether POGP should speak publicly about continence devices, prompting the present author's

desire to explore this topic further for the benefit of members. This article seeks to investigate the regulations surrounding the manufacture, labelling, advertising and promotion of pelvic floor rehabilitation devices, and explore how a greater understanding and interest in these products could satisfy our physiotherapy governance requirements as well as improve patient care.

Chartered Society of Physiotherapy quality assurance standards related to medical products and devices

The products and devices found within a physiotherapy department will range from elbow crutches, ice machines, acupuncture needles, nebulizers and gym equipment to ultrasound and biofeedback machines. Departments or private practices may lend out wobble boards, seat cushions, maternity belts, and electrical stimulation, biofeedback and transcutaneous electrical nerve stimulation devices. Physiotherapists give advice on the safe and effective use of products and devices to enhance exercise rehabilitation, assist with posture and relieve pain.

In 2012, the Chartered Society of Physiotherapy (CSP) published quality assurance (QA) standards for physiotherapy service delivery (CSP 2013) that replaced the original core and service standards that were developed in 2000 and updated in 2005:

> "The QA Standards provide an integrated and person-centred approach to practice and service delivery which reflects the complexity of service delivery and physiotherapy practice. They are intended to support members in meeting their legal, ethical and regulatory requirements." (CSP 2013, p. 3)

Section 2.5 of the QA standards highlights the responsibility of the physiotherapist for the safety of medical devices offered for patient use (see Box 1).

Furthermore, Section 10 of the QA Standards recognizes that "CSP members are increasingly involved in promoting products to those who will use or *purchase them*" (CSP 2013, p. 29, present author's emphasis), and sets out standards for promoting, marketing and advertising physiotherapy services and products (see Box 2). Not only do these QA standards confirm that giving advice about products and services is a holistic part of what it means to be a physiotherapist, but this section also suggests that we would be appropriate people for clients to seek advice from, and even to decide which retail outlets to use. Although standard 10.1.2 states that, "The promotion of products is based on evidence" (CSP 2013, p. 29), the reader's attention is drawn to 10.4.1b, which acknowledges that, when necessary, it is also valid to refer to the "member's own experience of the effectiveness of the product" (CSP 2013, p. 29).

Regulation of medicines

Despite these clear criteria, a brief review of questions put to interactiveCSP concerning product recommendation and the sale of items within a department, and also personal correspondence, suggest that physiotherapists may feel doubtful of their position when recommending products, particularly in the public domain (http://www.csp.org.uk/icsp/topics/physiotherapy-products-sale). It is not surprising that some of our colleagues may be confused about their scope of practice when providing advice about medical products. Generally, physiotherapists have been more familiar with the very strict rules governing the invention, testing and advertising of pharmacological products. All medicines must undergo extensive clinical trials, and hence, the slow and expensive path to the marketplace. The advice that can be given to our clients about pharmaceuticals without further training is limited. There is a long training and examination procedure to follow to become a supplementary or independent prescriber.

The Advertising Standards Authority (ASA) is the self-regulatory organization of the British advertising industry. It upholds strict rules for medicines, including: not addressing children; not suggesting that a product's effects are guaranteed or absolutely safe with no side-effects; and not using health professionals or celebrities to endorse a medicine. Prescription-only medicines are prohibited from being advertised to the public, and can only be promoted in places restricted to viewing by medical professionals (e.g. in a medical journal) (CAP 2010).

However, the situation for both medical and non-medical devices and products is far less regulated, and more difficult to understand.

What is a medical device and what is not?

Thousands of products and devices are mass-produced every year. When manufacturers create goods that they wish to trade on the single market in the European Economic Area (EEA), they have a responsibility to label the product, packaging and accompanying literature with a

Box 1. Section 2.5 of the Chartered Society of Physiotherapy quality assurance standards for physiotherapy service delivery [adapted from CSP (2013, pp. 11–12)]: (MHRA) Medicines and Healthcare Products Regulatory Agency

2.5. All medical devices are safe and fit for purpose, ensuring service user, carer and physiotherapy team safety

Criteria

2.5.1. There is a process in place for:
- (a) registration to receive by e-mail patient safety and MRHA alerts;
- (b) cascading information on Patient Safety Alert notices;
- (c) acting upon Patient Safety Alerts and other communications that relate to the safe provision of physiotherapy; and
- (d) ensuring that action is taken on new guidance about medical device safety, and on Patient Safety Alert notices issued on treatments/interventions that affect practice.

2.5.2. There are policies in place that include:
- (a) the use of medical devices according to manufacturer's instructions;
- (b) regular servicing of medical devices, whereby servicing is undertaken and action taken when indicated;
- (c) visual and physical safety checks of medical devices prior to use or issue to service users;
- (d) the identification, reporting and recording of action taken regarding faults of medical devices;
- (e) cleaning of medical devices according to manufacturer's instructions, and policies for control and prevention of infection;
- (f) removal of faulty medical devices;
- (g) evaluation of new medical devices in the context of a clinical trial to meet the requirements of research governance;
- (h) safe equipment for the care of bariatric service users [to include visible maximum weight of furniture (e.g. treatment couches, waiting-room chairs, department toilets and upstairs flooring)]; and
- (i) weighing and recording of the weight of service users where indicated.

2.5.3. There are polices in place that ensure:
- (a) training is provided in issuing and maintaining medical devices;
- (b) a training record is kept;
- (c) a record is kept of medical devices and/or products loaned to service users;
- (d) a record is kept of medical devices and/or products purchased by the service user; and
- (e) where medical devices and/or products are loaned or sold to service users, instructions on the safe use are provided.

CE mark. Not everything requires CE marking, but it is mandatory for anything covered by the scope of one or more of the New Approach Directives. These products include electrical equipment, toys, medical devices, and more recently, some smartphone applications (apps) and software. CE marking is not required for chemicals, pharmaceuticals, cosmetics and foodstuffs, which are regulated differently.

Also called the "European passport", a CE mark is a declaration that a product complies with essential standards, particularly those of safety, so that it can be sold in the Single Market, i.e. the 28 member states of the European Union, as well as Norway, Iceland and Lichtenstein. The objective is to simplify the movement of goods into and within the EEA (see Box 3):

> "CE marking does not mean that a product was made in the EEA, but states that the product is assessed before being placed on the market. It means the product satisfies the legislative requirements to be sold there. It means that the manufacturer has checked that the product complies with all relevant essential requirements, for example health and safety requirements." (DBIES 2012)

There are five different classes of CE marks, and corresponding legal requirements for testing and regulation. This reflects the escalating potential for risk to the consumer. Manufacturers are responsible for the classification, but essentially, they are guided by a series of factors:

Box 2. Sections 10.2, 10.3 and 10.4 of the Chartered Society of Physiotherapy quality assurance standards for physiotherapy service delivery [adapted from CSP (2013), p. 29, numbering corrected]

10.2. Information provided on products accurately reflects those offered
Criteria
10.2.1. Information accurately reflects the products offered and supports the decision-making process.
10.2.2. The promotion of products is based on evidence.
10.2.3. The use of benchmarking and comparative statements is based on fact.

10.3 Products sold or supplied to service users are necessary in delivering effective care
Criteria
10.3.1. Medical devices and products sold or supplied are appropriate to the presenting condition to support the achievement of expected treatment outcomes.
10.3.2. The costs, to the service user (or service), of supplying medical devices are considered.
10.3.3. Where possible, service users are offered information on sourcing products, and a choice in the goods recommended and the retail outlets for these goods.

10.4. The endorsement of a product or service, by a member, is based on sound clinical reasoning, evidence, and consideration of cost and quality
Criteria
10.4.1. When exploring the endorsement of a product, members consider:
(a) the appropriateness of the product or service in respect of presenting conditions;
(b) the member's own experience of the effectiveness of the product or service;
(c) the evidence presented by the manufacturer with regard to the stated purpose and benefit of the medical device; and
(d) a reasonable assessment of the quality and cost of the service or product.

Box 3. The Council of the European Communities definition of a medical device (CEC 1993, pp. 3–4)

"[M]edical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

– diagnosis, prevention, monitoring, treatment or alleviation of disease,
– diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
– investigation, replacement or modification of the anatomy or of a physiological process,
– control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means

"Depending on its Intended Purpose, a medical device may be classified as Class I [with extra requirements for sterile devices (class Is) and devices with a measuring function (Im)], Class IIa, IIb and III, with Class III covering the highest risk products. The higher the classification the greater the level of assessment required." (WTC 2009)

The classification of a medical device is determined by several factors (WTC 2009):

- how long it is intended to be in continuous use (e.g. some invasive devices are Class I as long as the use is transient, i.e. < 60 min);
- whether or not it is invasive, as opposed to intimate, or surgically invasive;
- whether it is implantable or active; and
- whether or not it contains a substance that is considered to be a medicinal substance in its own right, and has an action ancillary to that of the device itself.

Patient and clinical data are not required for Class I products to gain a CE mark. Laboratory evidence of safety is required, but there is no obligation for the data to suggest that a product

actually works, nor for Class I products to be tested on people or patients. Only some Class I products and devices, i.e. those claiming to be sterile (Class Is) or that have a measuring function (Class Im), and those that are Class II or above are also assessed by the manufacturing company's country's notified body. In the UK, this is the MHRA. However, regardless of its usually lower-class rating, a medical device must also have MHRA approval for it to be in a clinical trial.

Intention for use

Ultimately, the classification of a medical or non-medical device, and then, within the former group, the class of an individual medical gadget itself, is not decided on the particular technical characteristics of the device, but on its intended purpose. Hence, as Professor Fader explained in her presentation, a manufacturer may successfully avoid a higher classification by clearly defining on the labelling the intended purpose, so that the device falls into a lower class.

It is acknowledged by the MHRA that many products are "borderline", and need special assessment to determine whether these are even medical devices. This agency publishes flow charts that help to determine the positioning of a product (MHRA 2017). Even many apps and pieces of stand-alone software are classified as medical devices. These gather data from a person or a diagnostic device (e.g. diet, heartbeat or blood glucose levels), and then analyse and interpret the data to make a diagnosis, prescribe a medicine or recommend a treatment.

Patient safety

Many of the appliances that are used within a rehabilitation setting will be in the lower classes of devices, and as such, tend to present lower risks to the patient. However, beyond the specific classification, physiotherapists who recognize the CE mark take a basic step towards clinical safety. They know that it is the responsibility of the manufacturer to ensure that basic safety checks and balances are in place, and that products are fit for purpose. Furthermore, the CE mark assures clinicians that there is a centralized system for reporting any adverse effects associated with devices and products. The MHRA promotes patient safety as a priority:

> "We continue to encourage people to report any safety or performance issues involving medical devices, including apps, to MHRA via our Yellow Card Scheme online [yellowcard.mhra.gov.uk]." (MHRA 2016)

The Medical Device Alerts (MDAs) web page is the primary means of communicating safety information to medical device users working in health and social care (MHRA 2018). Standard 2.5.1 of the CSP QA standards requires physiotherapists to register for alerts, and have a system in place to cascade information (Box 1).

Advertising of medical services and devices

The ASA guidelines state that medical claims may only be made for medical devices that are CE marked to show that these have been approved under the relevant EU legislation:

> "Under the advertising rules, a medicinal claim is defined as a claim which suggests a product can be used to make a medical diagnosis, or can be used to treat or prevent disease, injury, ailments or adverse conditions of the mind or body, in humans." (ASA 2018a)

Furthermore, the ASA clarifies:

> "It is important to note, a CE mark does not automatically mean advertisers can make claims about the efficacy of a product without holding additional evidence which supports the claim and can be provided on request.
>
> "Other rules that are important when advertising a medical device include ensuring the ad does not encourage consumers to use a product to excess, or discourage them from essential treatment for conditions for which medical supervision should be sought. Advertisers also must be careful not to confuse consumers by using unfamiliar scientific words for common conditions." (ASA 2018a)

Physiotherapists may benefit from familiarizing themselves with the separate ASA guidelines for health conditions (ASA 2018b). Although product advertisers and clinicians themselves may wish to list the ailments that they believe their products or therapies can treat, the advertising rules restrict the types of claims anyone other than qualified health professionals can make, and there are specific guidelines for osteopaths and physiotherapists. It is of interest that, at present, "incontinence" and/or pelvic floor dysfunction are not detailed in the list of medical

conditions that physiotherapists (or osteopaths) can claim to treat (CAP 2016a).

The ASA rules classify ailments into two groups: those that can be acceptably referred to in advertisements targeted at the general public; and those that cannot because these are considered to be too serious to be diagnosed or treated without relevant medical supervision. Any claims made must be backed up by robust evidence. Examples of ailments that may be referred to in advertisements, if the advertiser can prove the efficacy of the product or therapy, include: arthritic pain, trouble sleeping, smoking cessation and minor sports injuries. Examples of ailments that cannot usually be referred to in advertisements include: arthritis, depression, diabetes, infertility and impotence. The ASA advises that claims that a product can "cure", "restore", "prevent", "avoid", "fight" or "heal" should be avoided. It is important to note that ASA non-broadcast rules apply to all forms of social media, including websites, blogs and vlogs, as well as platforms such as Facebook and Twitter (CAP 2016b).

The present author does not have the space to detail the ASA regulations, but readers are referred to the organization's website (www.asa.org.uk) for a comprehensive explanation of their role, extensive guidelines and an archive of previous complaints. If you feel that an advert or marketing campaign is inappropriate, there are clear guidelines on the process to follow, first to challenge the marketeer directly, and then, if unsuccessful, to submit a complaint for investigation. The CSP itself has complained in the past, but encourages individuals to pursue issues independently (CSP 2012).

How can physiotherapists' knowledge of products and devices help improve patient care? Practical examples

Registering a product with a CE mark and as a medical device is just a first step in supporting its clinical use. As they do in other areas of practice, physiotherapists draw on available evidence to give patients the information that they need to make an informed choice. However, since most products and devices are not required to undergo traditional clinical trials to provide evidence of their effectiveness, physiotherapists will benefit by working in partnership with manufacturers and distributors to seek further information about the differences between products and their distinguishing features, which may be of benefit to patients.

The EZ Magic pelvic wand (IC Relief, LLC, Tampa, FL, USA), a therapeutic aid for internal massage, is registered with the MHRA as a Class I device, in accordance with Annex IV, Rule 5 (i.e. an invasive, transient, non-sterile, non-surgical device). This means that the manufacturer is liable for it being fit of purpose. Furthermore, the company is also responsible for making information available about contraindications, indications for use, warnings and precautions, cleaning, care, and the contact details of suppliers. Although similar devices can be purchased from medical distributors and on the Internet, other manufacturers have opted for a lower classification by describing the wand's intended purpose as for leisure or pleasure. It is understood that there are plans to register some of the other aids for CE marks, and possibly, seek MHRA approval for use in a clinical trial in the future. However, at present, neither the consumer nor the therapist can be as confident about the safety standards or production values of these devices. The ASA rules suggest that such products should not be recommended for use in the treatment of medical conditions until these are classified accordingly.

Lubricants are Class I devices (i.e. invasive and transient). Advising physiotherapists can use their understanding of product function and classification to guide patients towards the product most suited to their needs. For example, when discussing lubricants for short-term use as an aid to sexual intimacy, physiotherapists can determine the value placed by a patient on: a standard formulation, such as the widely available K-Y Jelly (Reckitt Benckiser Group plc, Slough, UK); generic, own-brand lubricants; or more expensive but higher-quality formulations such as the YES range (The Yes Yes Company Ltd, Greatham, Hampshire, UK) or Sylk Natural Intimate Moisturiser (Sylk, Kingston upon Thames, UK). A lubricant should also be pH-matched to the natural environment of the vagina or rectum, as required, and YES-brand organic lubricants have different formulations for vaginal or anal use. Similarly, the following examples illustrate the kinds of information that can easily be communicated to patients by physiotherapists: oil-based lubricants are unsuitable for use with condoms; oil and water products can be mixed; and there is a risk that alternatives such as kitchen oils can become contaminated or rancid.

However, vaginal moisturizers are Class IIa products because these are intended to be present in the body for longer than 60 min, and to be classified as such, undergo greater laboratory

testing. To relieve vaginal dryness, an iso-osmotic formulation is needed to hydrate the area over a longer period of time without pushing or pulling water into or out of vaginal tissues. For example, physiotherapists can suggest YES VM (vaginal moisturizer), which has been designed for this purpose and is regulated as such.

Biofeedback devices that involve pressure or electromyographic technologies have been commonly used by physiotherapists to enhance PFMEs for over 20 years. Being electrical products, these have to be CE marked and registered as medical devices. With advances in technology, these products have become smaller: many hand-held units are now available; the internal probes are more cosmetically appealing; and a wider range of shapes and materials are for sale. The newer technologies do not fit so neatly into previously understood categories. For example, the Elvie PFME trainer (Chiaro Technology Ltd, London, UK) combines an internal probe with a smart phone app, and measures force and motion simultaneously with a force sensor and accelerometer (Coggins *et al.* 2017). The Elvie is classified as a Class I device (i.e. invasive, intermittent use). If a manufacturer believes that a current generic device code does not appropriately describe a product, then a short description can be employed. This is why Chiaro Technology uses the phrase "pelvic trainer for personal use" in its marketing of the Elvie.

Many devices designed to treat incontinence have been registered, but it cannot be assumed that these all do the same job because of sharing a similar bureaucratic classification. Physiotherapists should look beyond this to the available evidence (including clinical trials and pilot studies), understand the technology involved, and assess the usability and performance of the item.

Myra Robson, a POGP member and the designer of the Squeezy PFME app (Propagator Ltd, London, UK) explained the processes involved in regulating this product to the present author in personal correspondence. Squeezy did not need to be classified as a medical device because it neither changes anything, nor has a direct impact or "therapeutic" effect on the user's pelvic floor. Its intended purpose is to serve as a reminder and exercise support: the app only advises users on what to do; it is the PFMEs that they then perform that have a therapeutic effect. Propagator Ltd, the developer and manufacturer, employs a safety engineer to cover the medical software, while Myra herself acts as the appointed clinical safety officer:

> "We have huge documents called safety cases and hazard logs that list all possible side effects of the software and our plans to minimize them. The product manager [. . .], myself and the engineer sign them all off after many checks and discussions, and we review them on a regular basis. It has been fascinating to see what goes on behind the scenes." (M. Robson, personal correspondence)

Another clinical example for readers to consider is the practice of using ordinary sanitary tampons as urethral splints. Many clients report that this approach is an effective way of reducing stress urinary incontinence while running. However, a tampon is not intended to be used for therapeutic treatment, and therefore, it is not classified as a medical device and has not undergone the same regulatory process as one. If patients disclose that they use tampons for this purpose, physiotherapists can use their clinical knowledge and understanding of regulations to guide them towards a more suitable alternative. If an appropriate pessary is used, then the onus – and liability – lies with the manufacturer to ensure that the material is fit for purpose and can be cleaned, and that its shape reduces the risk of any complications. The company must also provide instructions, contraindications and warnings to enable patients to make informed choices and use the product correctly. Again, as with other devices, any faults or issues can be reported through the Yellow Card Scheme.

While many devices that physiotherapists use fall outside the remit of what is classified as a medical device, readers should remember that these may still be important instruments in practice, or form an essential part of patient rehabilitation; for example, an icepack for cryotherapy or a vibrator to encourage someone to explore a return to enjoying intimacy. These are the "borderlines" that physiotherapists are used to treading when utilizing their skills to manage patients holistically from acute injury back to enjoying full sporting activities or wholly engaged relationships. The MHRA recognizes borderlines, and similarly, we can let common sense prevail.

Professional practice

If physiotherapists observe the CSP QA standards (CSP 2013), they will meet the requirements of both the CSP Code of Members' Professional Values and Behaviour (CSP 2011), and the Health and Care Professions Council. By following these criteria, they will be able to

promote, assure and demonstrate quality in both clinical practice and service delivery. The QA standards can also be employed by anyone using a physiotherapy service to assess the quality of its provisions and care. An audit tool is available for each section of the QA standards (CSP 2013).

Many esteemed POGP members pioneered the research and development that has led to the pelvic floor rehabilitation devices that are available today. However, these products are no longer the sole domain of physiotherapists, and can be sold directly to the public by a manufacturer or distributor. Meanwhile, engineers, biomechanists, sports scientists and fitness professionals, and not least, self-proclaimed online "health experts", can all claim an interest in the development, use and promotion to the public of such devices.

Physiotherapists should not be afraid to recommend products if they believe that these will aid their patients' recovery, and are ideally skilled to offer unbiased, clinically reasoned opinions. They study biomechanics, electrotherapy, analytical thinking, patient subjective and objective assessment, and clinical reasoning over the course of the 3-year university degree. Physiotherapists are examined on health and safety, choice of treatment, and the use of evidence-based therapy. Postgraduate-trained pelvic health physiotherapists, most especially full POGP members, have the competency to perform hands-on examinations of the pelvic floor complex. They can determine the difference between a hypotonic or hypertonic pelvic floor, or a neurally disconnected movement pattern. Furthermore, they have the time to advise patients about overuse, suitable lubricants and self-care. Some devices are fiddly and tricky for a novice to use effectively, but experienced physiotherapists will be able to help clients to maximize the potential of a device and choose appropriate settings for their needs. Using products and devices within a physiotherapy-guided treatment plan ensures that patients enjoy the benefits of personal accountability, problem solving, motivation and reassurance. This also allows for an appropriate change of approach if the chosen treatment plan does not work.

Physiotherapy is both an art and a science, and we excel at both. We can spot the nuances that tell us which mothers will actually be motivated by a gadget. Such individuals will find that the private time and intense focus that are needed to use a handheld biofeedback device are the best way to improve their pelvic floors. In contrast, we can also tell which women will be overwhelmed by anything more than encouragement to do their exercises while they clean their teeth!

If it is not a requirement that the manufacturers and distributors of medical devices should have tested their designs on patients, then physiotherapists could consider it an important part of their role to ensure that they fully understand the products that they use to enhance patient care. With patient safety also a priority, they should also ensure that these adhere to MHRA regulations.

Similarly, we have some responsibility to inform manufacturers and consumers if we believe that claims of a product's efficacy are inaccurate or irrelevant. There appears to be no other way that these anomalies will come to light. A distributor once remarked to the present author that, "If it didn't work, the patients wouldn't buy it," which is illogical. We are all seduced by big marketing budgets. How many items do we all have at home that we bought by mail order, but could not be bothered returning when these disappointed?

Physiotherapists could consider presenting themselves as "servant leaders" to industry: supporting and working closely with those manufacturers and distributors who are making efforts to add value to patient purchases; being discerning in their choice of product range; and acting as virtual information and educational resources. Distributors are happy to work closely with the physiotherapy community, offering a channel allowing private clinics to hold stock, and for the NHS to recommend reliable retailers. We could offer suggestions about products to trial, and promote design improvements, not only to the products themselves, but also to their instruction booklets (and most likely in the future, videos too).

If industry respects our profession for our candid support and enthusiasm, we could lobby our commercial partners to shout more loudly to their customers about the essential need for a proper vaginal/anal assessment, and guidance from a postgraduate-trained specialist pelvic floor physiotherapist. There could be better support and signposting for customers who are not making the progress that they desire through do-it-yourself methods alone.

Conclusions

Although the classification of products and devices as either medical or non-medical in nature, and the corresponding rules and regulations are complicated, physiotherapists have a professional

obligation to be not only fully informed, but also willing to share their knowledge and experience with their clients.

Devices and technology form a vital part of the future of healthcare, and used correctly, these could even unburden some of the strain on the healthcare system.

The present author advocates that we should take ownership of this area of continence devices. We should strive to remain the leaders in research into and the appropriate clinical use of pelvic floor rehabilitation products. It would be good to see the Continence Product Advisor website add a section dedicated to rehabilitation devices that is researched and curated by pelvic health physiotherapists.

For a member of the public faced with the symptoms of pelvic floor dysfunction, the future does not need to be either a self-help device found online or individual physiotherapy. If industry and professionals continue to work together, we can improve the quality of life of the large number of people who will be faced with bladder or bowel issues during their lifetimes.

The present author encourages readers to have confidence in their skills and be diligent with their adherence to the CSP QA standards. Who would we like the public to turn to for advice about pelvic floor rehabilitation, and the relevant products and devices? If not us, specialist pelvic, obstetric and gynaecological physiotherapists, then who? And if not now, while our patients and the media are interested, when?

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References

Advertising Standards Authority (ASA) (2018a) *Medical Devices*. [WWW document.] URL https://www.asa.org.uk/topic/Medical_devices.html

Advertising Standards Authority (ASA) (2018b) *Health Conditions*. [WWW document.] URL https://www.asa.org.uk/topic/Health_conditions.html

Chartered Society of Physiotherapy (CSP) (2011) *Code of Members' Professional Values and Behaviour*. [WWW document.] URL http://www.csp.org.uk/publications/code-members-professional-values-behaviour

Chartered Society of Physiotherapy (CSP) (2012) *Guidance for CSP Members on Submitting an Advertising Standards Authority (ASA) Complaint*. [WWW document.] URL http://www.csp.org.uk/publications/guidance-csp-members-submitting-advertising-standards-authority-asa-complaint

Chartered Society of Physiotherapy (CSP) (2013) *Quality Assurance Standards for Physiotherapy Service Delivery*. [WWW document.] URL http://www.csp.org.uk/publications/quality-assurance-standards

Coggins J., Cartwright R. & Bergmann J. (2017) Measures of pelvic floor strength by age and parity using the Elvie device. [Abstract.] *Journal of Pelvic, Obstetric and Gynaecological Physiotherapy* **120** (Spring)**,** 72.

Committees of Advertising Practice (CAP) (2010) *Medicines, Medical Devices, Health-Related Products and Beauty Products*. [WWW document.] URL https://www.asa.org.uk/type/non_broadcast/code_section/12.html

Committees of Advertising Practice (CAP) (2016a) *Health: Physiotherapy*. [WWW document.] URL https://www.asa.org.uk/advice-online/health-physiotherapy.html

Committees of Advertising Practice (CAP) (2016b) *Remit: Social Media*. [WWW document.] URL https://www.asa.org.uk/advice-online/remit-social-media.html

Council of the European Communities (CEC), The (1993) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. *Official Journal of the European Communities* **L169** (12 July), 1–43.

Department for Business, Energy and Industrial Strategy (DBEIS) (2012) *CE Marking*. [WWW document.] URL https://www.gov.uk/guidance/ce-marking

Gornall J. & Jourdan T. (2017) *What Every Man Needs to Know About Their Prostate and the Key to Curing Those Painful Urine Infections: How to Beat Health Problems When Your Plumbing Goes Wrong*. [WWW document.] URL http://www.dailymail.co.uk/health/article-4818148/How-beat-health-problems-plumbing-goes-wrong.html

Hashempour P. (2017) *8 Pelvic Floor Exercises That Will Spice up Your Sex Life*. [WWW document.] URL https://www.healthista.com/8-best-pelvic-floor-exercises-that-will-spice-up-your-sex-life/

Lipp A., Shaw C. & Glavind K. (2014) Mechanical devices for urinary incontinence in women. *Cochrane Database of Systematic Reviews*, Issue 12. Art. No.: CD001756. DOI: 10.1002/14651858.CD001756.pub6.

Medicines and Healthcare Products Regulatory Agency (MHRA) (2016) *Is Your App a Medical Device? It's Healthy to Know: Regulator Issues Updated Guidance*. [WWW document.] URL https://www.gov.uk/government/news/is-your-app-a-medical-device-its-healthy-to-know-regulator-issues-updated-guidance

Medicines and Healthcare Products Regulatory Agency (MHRA) (2017) *Medical Device Stand-alone Software Including Apps (Including IVDMDS)*. [WWW document.] URL https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/648465/Software_flow_chart_Ed_1-04.pdf

Medicines and Healthcare Products Regulatory Agency (MHRA) (2018) *Medical Device Alerts – MDA's*. [WWW document.] URL https://www.health-ni.gov.uk/articles/medical-device-alerts-mdas

Wellkang Tech Consulting (WTC) (2009) *Guidelines for Classification of Medical Devices.* [WWW document.] URL http://www.ce-marking.org/Guidelines-for-Classification-of-Medical-Devices.html

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