Response to the Office for Product Safety & Standards:

UK Product Safety Review – Call for Evidence

Introduction to FOCIS

The FOCIS members act for seriously injured Claimants with complex personal injury and clinical negligence claims including group actions.

The objectives of FOCIS are to:

1. Promote high standards of representation of Claimant personal injury and medical negligence clients.

2. Share knowledge and information among members of the forum.

3. Further better understanding in the wider community of issues which arise for those who suffer serious injury.

4. Use member expertise to promote improvements to the process and to informed debate.

5. Develop fellowship amongst the members.

See further www.focis.org.uk

Membership of FOCIS is intended to be at the most senior level of the profession, currently standing at 25 members. The only formal requirement for membership of FOCIS is that members should have achieved a pre-eminence in their personal injury field. Eight of the past presidents of APIL are members or Emeritus members of FOCIS. Firms represented by FOCIS members include:

Anthony Gold	Hugh James
Atherton Godfrey	JMW
Ashtons Legal	Irwin Mitchell
Balfour + Manson	Leigh Day
Bolt Burdon Kemp	Moore Barlow
Dean Wilson	Osbornes
Digby Brown	Potter Rees Dolan
Fieldfisher	Serious Law
Fletchers	Slater and Gordon
Freeths	Stewarts
Hodge Jones & Allen	Thompsons NI

FOCIS members act for seriously injured Claimants with complex personal injuries and clinical negligence claims. In line with the remit of our organisation we restrict our responses relating to our members experiences, and to practices and procedures relating to complex injuries claims only. We leave it to others to respond to the impact relating to other classes of case.

Office for Product Safety & Standards: UK Product Safety Review – Call for Evidence

FOCIS welcomes the opportunity to respond to the Office for Product Safety & Standards' call for evidence relating to the review of product safety in the United Kingdom. The UK now has an opportunity to address the gaps within the consumer protection framework and to enhance the protection afforded to victims of unsafe products.

We have limited our response to questions within the consultation that are within the remit of our organisation. In several instances, we have adopted the submissions of Hugh James, a FOCIS member firm, having had sight of their own response to this call for evidence when preparing our own.

Product Design, Manufacture and Placing on the Market

Question 1: How easy is it to understand the current framework of public safety regulation? What areas, if any, could be simplified or made easier to follow?

We observe that the Consumer Protection Act (CPA) 1987 (**"the Act"**) seeks to provide remedies to the victim of a defective product, whereas the General Product Safety Regulations (GPSR) 2005 (**"the Regulations"**) seek to avoid injury in the first instance by placing a duty on distributors and producers intended to prevent them from putting unsafe products on the market. The pre-emptive nature of the Regulations, which give rise to a number of offences, intertwined with the CPA 1987, leaves a product safety framework that is so complex and fragmented that it can cause difficulties, even for specialist lawyers. We agree with Hugh James' submission that the existing legislation and regulations must be simplified, whilst remaining comprehensive and effective. This would lead to greater understanding by consumers, who must be aware of their protection and enforcement rights. The Government should not ignore any changes that are made to the Product Liability Directive by virtue of having left the EU. That is an instrument that currently underpins the CPA 1987. A level of harmony between the regimes will likely be beneficial and we should look to implement any amendments which may benefit our framework moving forward. We also note and support the ongoing importance of a 'unanimity of standards' post-Brexit given increasing internet and cross-jurisdictional supply. Come what may the Government ought to ensure that protection of UK consumers continues to at least match those of EU consumers.

Question 2: In what areas, if any, should product safety regulation be strengthened or improved?

The prioritisation of consumer protection within the regime together with the way in which a defective product is defined within the CPA 1987, represent two key areas which ought to be addressed by the Office for Product Safety & Standards (OPSS).

At the outset, it was the intention of the European Commission for consumer protection to be the central tenet of its framework. Where a product caused injury, there should not have been a need for the consumer to prove fault on the part of the supplier, rather they ought only need to demonstrate that the product did not reach the appropriate safety standards which they were generally entitled to expect and that they were a victim of that product. The courts of England and Wales have recently interpreted the drafting of the Act in ways that move away from that position; despite the original intention to impose strict liability for damage caused by products. Consequently, it now seems that consumers in the UK who are injured by defective products need to prove fault by the manufacturer or supplier. That a weighty evidential burden, that puts many injured consumers off from even attempting to pursue claims and increases the duration, cost and complexity for the brave few who do go down that long road. It also leaves UK consumers with lesser protections than those applicable in most EU member states. We would echo the sentiment of Hugh James in this respect and emphasise the need for the OPSS to ensure that our own safety standards and relevant legislation are clear and robust.

The courts currently consider four key factors in determining a defective product:

1) Risk benefit and the 'avoidability' of the defect;

2) Compliance with appropriate standards;

3) Compliance with any regime under which the product was regulated; and

4) Any warnings given about the product.

Wilkes v DePuy International Ltd [2016] and *Gee v DePuy International Ltd* [2018] are now established in product liability law and demonstrate the court's increasing support of the evidence of manufacturers, as opposed to the evidence of the victims of a defective product. It seems clear that the current test under the CPA 1987 is not one of an absolute level of safety, instead it is the level of safety that the general public is "generally entitled to expect" which matters. Such an approach conflicts with the initial (and widely considered correct) application of the Act in the courts, which held avoidability to be irrelevant in establishing defectiveness. On current interpretation, the definition of a defective product weighs in favour of the manufacturer and the result is a considerable dilution of what lawyers representing injured consumers had considered to be the purpose of the Product Liability Directive. Whilst it is necessary to consider the context of companies seeking to innovate and produce technologically advanced and improved products, it should not be lost that the approach set down in *Depuy International Limited* could make it more difficult for consumer victims of defective products to pursue claims against large corporate manufacturers who already have the benefit and weight of finance, science and product expertise behind them.

Question 6: How well is the conformity assessment system working? What are your experiences of it and of self-assessment?

Generally speaking, the conformity assessment is carried out by the manufacturer and, as Hugh James have noted in its response, we agree that self-assessment does not work.

We recognise that there are certain ancillary procedures, such as the involvement of a conformity assessment body and also market surveillance, which serve to ensure the smooth functioning of the internal market and that legislative requirements are met. However, the way in which the safety of products are checked pre and post-market needs to improve. At present, CE marks are granted after a self-assessment process carried out by an auditor, as selected by the manufacturer, whilst manufacturers are increasingly assessing their products in line with design specification as opposed to product safety. We contend that safety standards should be compulsory, and in our view assessed independently. The CE mark does not currently provide absolute assurance of a product's safety, rather it merely confirms a manufacturer's declaration of conformity with all the necessary legal requirements for the product to be sold within the European Economic Area. More ought to be done to guarantee that products which achieve CE compliance undergo rigorous safety checks pre and post-market. This should go some way to prevent unsafe products from entering the market whilst fostering consumer confidence in the safety of products.

Question 8: What role should voluntary standards play in product safety? What are the benefits and drawbacks of linking regulation to voluntary standards?

Voluntary standards play an important role in establishing consensus in consumer product safety practice. Such standards foster market compatibility, serve as a safeguard, simplify product development and can increase the speed in which a product is brought to market. In any related litigation courts will also often hold manufacturers to a "generally accepted" standard relating to product design, as agreed from industry to industry. Whilst voluntary standards carry weight and demonstrate a company's commitment to high quality and safe products, there are issues simply by

virtue of being “voluntary”, notably there exists no obligation to comply. However, safety standards should be compulsory, rather than voluntary, and we contend that all products must satisfy specific minimum requirements before they are brought to market. If voluntary standards are to continue in relation to product safety, they should be understood only as a guidance tool and manufacturers should therefore go above and beyond such standards in order to build improved safety into their products.

New Models of Supply

Question 9: What are the key challenges for regulating product safety in online sales? What has worked well in terms of regulation and where are the opportunities?

The major challenge for the regulation of product safety in the online realm will likely be how liability for the safety of a product will be attributed and designated, given the increasing number of parties involved in a single transaction. Responsibility for the product could lie with sellers, importers, the suppliers, manufacturers, warehouse workers or even an online trading platform. As the online eco-system becomes more complex, it is only going to get more difficult to determine who should be liable for defects following sale. Hugh James also raise the issue of joint and several liability and ascribing liability to third parties who may be located outside of the jurisdiction or who might otherwise be untraceable and we agree that there will likely be problems for the court to overcome. A common example might be where a product is produced abroad, passes safety tests in a different country, and is marketed for sale by a UK seller.

A UK initiative akin to the EU Product Safety Pledge, which aims to increase the safety of products sold online by third-party sellers, would represent a good starting point, but as a voluntary initiative with no powers of enforcement, we would argue that a more robust form of regulating product safety in online sales will be necessary, both where the product is manufactured in the UK or abroad. This is a point that the Government ought to keep in mind when negotiating international trade deals beyond the EU.

Question 11: To what extent are product safety issues arising from consumers producing (e.g. 3D printing) and / or hiring out and selling products to each other?

Modern manufacturing techniques, including 3D printing, have enabled products to be built more readily within the homes of consumers and yet consumers are largely unaware of their responsibilities in respect of product safety under the regulations. Ignorance of such obligations under the regulations will likely have a detrimental effect on the quality and safety of products. It is therefore important that more is done to ensure that consumer-produced products undergo the required testing to meet the minimum standard. Online market place providers should be compelled to do more to make consumers selling home-made and second-hand products more aware of their obligations via their website terms and conditions. This might include, for instance, preventing the sale of products which have not gone through the necessary safety checks. It is important that potential purchasers of such products are fully informed as to the origin of the product

New Products and Product Lifecycles

Question 15: How can we build flexibility to the regulatory framework to adjust to changes in product lifecycles and technology, including changes in understanding risk? How do businesses integrate safety considerations with other aspects of product regulations such as environmental considerations?

Whilst it is important that the understanding of risk keeps pace with modern technology, any regulations and legislation should be drafted with a degree of flexibility so as not to stifle this unprecedented period of technological advancement. A producer’s freedom to innovate must

therefore be combined with availability of information to consumers to ensure that adequate safeguarding is in place and simple but effective redress for consumers injured by product defects.

Manufacturers need to innovate to produce new products which are useful, safe and environmentally friendly. All three of these aims are important and they do not inherently contradict each other.

Questions 16: For how long should responsibility for the safety of the product lie with the manufacturer? What responsibilities should apply to software that is integral to the product, second-hand goods or supply of replacement parts?

Manufacturers can escape liability for injuries caused by their products 10 years after the product is put into circulation. As this extinguishes the consumer's right to pursue a claim under the Act, this can be unfair and unjust in the context of certain products where a defect may not become apparent until later in the life of that product. We echo Hugh James' comments as to the applicability to medical and pharmaceutical products and devices which have great potential for latent damage and suggest that the 10 year period should be "at least" doubled.

With the increasing influence of new technologies, where an existing product has had its software updated, it is also significant to clarify whether the "new" product has undergone equal and proportionate testing to ensure that the software update has not compromised the safety of the original product.

Enforcement Considerations

Question 17: How is enforcement of product safety changing in light of new products (e.g. connected devices, 3D printers) and new ways of distributing products (e-commerce, sharing economy). What are the greatest challenges?

Raising awareness of the responsibilities of those smaller at-home producers, increasingly using more accessible manufacturing methods such as 3D printers, represents one of the greatest challenges to product safety. More will also need to be done in circumstances where liability is ascribed to parties outside of the jurisdiction and who might be otherwise untraceable, as this will create more problems for the court to overcome in respect of enforcement. A consumer must have the ability to gain redress from a supplier of a product and receive compensation and so, as part of its review of the current product safety framework, the United Kingdom ought to strengthen market surveillance, including online sales, and intensify compliance controls and promote close cross-border cooperation amongst enforcement authorities.

Question 20: What toolkit of enforcement duties and powers is needed for effective enforcement now and in future? Do enforcement authorities have the right tools they need, including data availability, to do the job?

We echo and agree with Hugh James submissions on this section and defer to enforcement authorities as to whether their tools and funding is sufficient to effectively engage with enforcement actions.

Question 22: When it comes to product liability, do consumers have the right tools and information to take action on their own behalf? Please explain.

As already noted, the legislation and regulations in their current form are too complex for many legal practitioners to fully understand, let alone for them to be understood by the ordinary consumer. Recent judicial decisions have, we submit, misinterpreted the legislation in ways that are inconsistent

with the underlying Product Liability Directive and are in favour of the manufacturer. Outdated use of terminology, such as the way in which a product 'defect' is defined, ought to be simplified in order to assist the judiciary and to be more effective in providing recourse to those injured by unsafe products.

A Diverse and Inclusive Product Safety Framework

Question 23: Does the current framework adequately protect all people in society, including vulnerable groups and those with particular needs? And could it be improved?

No and yes.

Within what is an outdated framework, more must be done to enhance the protection afforded to disadvantaged groups within society, such as the elderly, disabled, vulnerable and also minors. The way in which products are marketed and presented to these groups should be assessed, adapted and improved to allow for, for instance, simplified (and yet still comprehensive) instructions. It should also not be assumed that the whole of the population have access to online resources on consumer safety and related requirements for product safety. The legislation and regulation in this area should be simplified and strengthened, then publicised clearly, perhaps through a simple advertising campaign as to their consumer rights.