Office for Product Safety & Standards

UK Product Safety Review

A response by the Association of Personal Injury Lawyers

October 2023

Introduction

APIL welcomes the opportunity to respond to the Office for Product Safety & Standards (OPSS) consultation on the long-awaited review of product safety legislation. The purpose of the regulator and the product safety regulations is to ensure products are safe for consumers. However, we are disappointed that the consultation paper's focus is on reducing business burden and encouraging innovation rather than ensuring safety, protecting consumers effectively or enabling redress. This should not be the OPSS' aim and it is not their function as a regulator to support innovation over product safety. The proposals seem more geared towards freeing industry from regulation rather than protecting consumer rights.

APIL is of the view that the questions or the themes in the questions are a repetition of what was queried in previous consultations or the 2021 Call for Evidence. Further, APIL believes that the focus of the consultation is unnecessarily narrow. It is ineffective to separate the focus of the review and exclude the regulation of food, chemicals, medical and healthcare products, construction products and vehicles. If the OPSS plans to change product safety regulations in the UK, all products should be considered within the scope of this review.

There is no acknowledgement in the paper that making changes to product safety regulations and/or diverging from EU standards, will cause trade friction and/or cost money. The OPSS does not highlight any potential adverse consequences to trade of diverging from EU standards, an important consideration in the review being undertaken. Deriving from the regulations under the single market will create problems for UK manufacturers and consumers. On one hand, most manufacturers will comply with the EU standards so that their products are commercialised in the single market and might not want to produce according to only UK standards given that it is a far smaller market. On the other hand, having a different regimen from the EU will create a burden for both businesses and consumers both in the UK and the EU and might mean that certain products are no longer available in the UK, or cannot be sold in the EU or become more expensive.

APIL is disappointed that collective redress is not considered in the consultation paper. We believe that there should be a procedural change in relation to group actions, and the "opt-out" procedure that applies to competition law group actions should apply to product liability claims to allow consumers to seek fair redress. In addition, we believe that more consideration should be given to Schedule 4 of the Environment Act 2021. This sets out producer responsibility obligations to prevent a product or material from becoming waste or reducing the amount of a product or material that becomes waste. It is common for products to enter the market only to become defunct after a short period of time. We believe that the Environment Act 2021 should be taken into account in the structure of any new consumer regulations.

APIL strongly believes that the Law Commission should carry out a holistic review of the Consumer Protection Act 1987 (CPA). We have listed our concerns with the Act in question 23 below.

2. Do you agree that we should examine options for a framework where regulatory requirements are more closely linked to the risks of the product in question? Yes / No / Don't know

APIL agrees with the proposal of a framework where regulatory requirements are more closely linked to the risks of the product. Using a risk-based approach, the Government should play a role and identify higher-risk products. There must be rigorous oversight and proof that products are safe, and that the framework does not result in ease of regulation for manufacturers.

We believe that when building flexibility into the regulatory framework, safety should always come first and is the paramount consideration that the OPSS should take into account. A risk-based approach to regulation could give flexibility and ensure that stricter regulations are imposed on products which have a greater risk of harm to consumers. Sufficient funding is therefore required to underpin the process and ensure that scientific and technical bodies are available to assess the products.

We believe that the issue of UKCA/CE marks highlights the need for a risk-based approach, with more rigorous oversight to ensure that products are safe. There is a significant issue with the UKCA/CE marks being mistaken for a quality assurance mark when in fact it is a form of self-assessment by the manufacturer to confirm that the product complies with the manufacturing specification. The UKCA/CE marks represent a manufacturer perceiving the product to comply with safety regulations, not that the product *actually* complies with safety regulations. It is only in devices of higher risk classification that a designated Notified Body must assess a device prior to the application of the mark. There are certain regulations to comply with to ensure that the product meets the required standard to have the UKCA/CE mark. A product may comply with the requirements of a UKCA/CE mark but may be unsafe for consumers to use. The value of a CE mark is also often misconstrued by the judiciary.

The courts have taken the approach that if a product is the subject of regulatory approval, then that is a very significant factor in favour of saying that the product is safe and not defective. We take issue with this presumption for the reasons explained above, but at the very least, there should be an alternative presumption that if the product is taken off the market on safety grounds, this is sufficient to demonstrate a presumption that it is defective.

7. Do you agree with the proposal to establish a derogation process to help ensure supply of critical products in emergencies?

8. Are there other circumstances, in addition to those set out in this proposal, where a derogation process would be helpful?

APIL believes that if a derogation process is to be established, it should be rigorous and ensure that the compliance and enforcement measures are strict enough to ensure only safe products are placed on the market. There should be regular reports on any adverse events or incidents if derogation is granted to a product. We believe that the pandemic has highlighted that the Government needs more scrutiny in the context of an emergency and that in such occasions, the UK should align regulation with the European Union.

We are concerned that the Medicines and Healthcare Products Regulatory Agency (MHRA) derogation process is used as a case study in the consultation paper. The MHRA derogation process described caused 81 deaths and 455 serious injuries in the UK from blood clots

caused by the AstraZeneca vaccine. The example provided is a catastrophic failure of regulation because of the UK's exceptionalism and failure to align with EU countries.

Our members have provided us with the case study below, which shows the catastrophic results of the MHRA's failure to act.

Case study – Delayed response from MHRA

This case study shows that the MHRA/ Joint Committee on Vaccination and Immunisation (JCVI) failed to appropriately address adverse drug reactions (ADRs) concerning blood clots arising following AstraZeneca vaccination during the pandemic.

On 10 March 2021, the Austrian national competent authority suspended the use of a batch of Vaxzevria (previously COVID-19 Vaccine AstraZeneca) (batch number ABV5300) after a person was diagnosed with multiple thrombosis (formation of blood clots within blood vessels) and died 10 days after vaccination, and another was hospitalised with pulmonary embolism (blockage in arteries in the lungs) after being vaccinated.

There was no indication that vaccination has caused these conditions, which were not listed as side effects of this vaccine at the time. Nevertheless, several EU countries have also subsequently suspended this batch as a precautionary measure, even without a causal link to the vaccine, while a full investigation was ongoing. The European Medicines Agency's (EMA) safety committee Pharmacovigilance Risk Assessment Committee (PRAC) started a review of this issue.

The UK MHRA did not change its advice and adopted a wholesale risk/ benefit analysis with no consideration of age. Only on 8 April 2021, the JCVI introduced the first age parameter for the AstraZeneca vaccine (under 30-year-olds not to receive AZ), and the second on 7 May 2021 (under 39-year-olds not to receive AZ). This meant that whilst the AZ vaccine was suspended elsewhere in the EU, the UK continued to use AZ across all age groups until April 2021.

This has resulted in 81 deaths in the UK from blood clots secondary to the AZ vaccine and 445 serious blood clot-related injuries. Had the MHRA acted in line with the rest of the EU these figures would have been significantly reduced, as per elsewhere in the EU.

The MHRA was standing alone for the first time post-Brexit – outside of the EU and removed from the EMA. Its delayed response to the AZ blood clot issue, which was out of step with the rest of the EU, led to excess deaths and injuries.

9. Are there any other mitigations we need to consider as we look to introduce voluntary e-labelling to devices with screens or designed for use with screens?

10. Are there other labelling requirements to which you consider that voluntary elabelling could be expanded in future (to further types of statutory labelling requirements/additional product areas and/or to permit the use of QR codes)?

11. What additional mitigations, if any, do you think could be needed if voluntary elabelling is expanded in future?

APIL welcomes the mitigations proposed in the consultation paper, in particular, that any information required by product safety legislation which is not a UKCA marking or manufacturer's details, for example, a warning of a choking hazard for a toy, would still need

to be provided physically with the product as an indelible marking or on paper, as required, even where the device has an e-label accessible on the device.

We believe that digital exclusion should be considered when looking to implement e-labelling and the use of QR codes, given that some consumers will not be able to use QR codes. We recognise the advantages of e-labelling and QR codes in relation to the environment and ease of update. To capitalise on these advantages, we believe that there should be a publicly accessible online log that would register the updates and changes made to the product labelling.

Further, there should also be an opt-in alert or communication to all current users/consumers that there was an update of the labelling or warnings about the product. This would create a reciprocal obligation between manufacturers and consumers. On one hand, the manufacturer would be required to log any changes to the product and explain why made. On the other hand, consumers would receive alerts and be kept up to date on the risks of the product.

12. Do you agree with the proposal to clarify cooperation duties for new business models, particularly 'online marketplaces'?

APIL agrees that online market places should have duties to cooperate with enforcement authorities to provide information and take appropriate actions if products are unsafe or non-compliant. However, we argue that the Government should go further and impose joint and several liability on online market places so that consumers have a statutory right when they purchase a product through an internet platform from a third party. Many online purchases involve a complex supply chain and the third party may not be traceable or may no longer be solvent.

Most UK consumers assume their statutory rights in such platforms are broadly equivalent to making a purchase on the High Street. However, Amazon's terms and conditions include a jurisdiction clause providing that the contract is made according to foreign law. Amazon themselves do not guarantee that the product is of satisfactory quality, fit for purpose, reasonably durable or has any of the statutory consumer rights. Customers are not adequately warned of this in the purchasing process.

In addition, regardless of where the product came from, it should be subject to the law in the jurisdiction in which it was purchased by the consumer. If the product was purchased by a consumer in England and the product was produced by a third party in China, the product safety issue should be dealt with under English law. We strongly believe that the Government should change legislation to make online market places, such as Amazon, a producer rather than a supplier under the CPA. This should also be implemented into the Sale of Goods Act 1979 and Consumer Rights Act 2015 (CRA) to ensure that such platforms also owe a statutory duty of satisfactory quality.

14. Do you agree with the proposal to introduce due care requirements in relation to unsafe product listings?

We believe that introducing due care requirements for online market places in relation to unsafe product listings is not enough to protect consumers. There is a risk that online marketplaces assessing if they are meeting due care requirements could present a false picture that products are safe. In reality, due care requirements cannot ensure consumers

are protected given that this would only require online market places to collect information about products and sellers. We are concerned that the information collected by online market places could only be used to fight a product liability claim.

As mentioned above, APIL believes that the most effective way to regulate online market places is by imposing joint and several liability on market places so that consumers have a statutory right when they purchase a product through a platform from a third party.

17. Do you agree with the proposal to enhance the leadership and coordination role of OPSS?

19. Do you agree with the proposal to have a single point of contact for product safety recalls?

The current system of enforcement devolving trading standards to local authorities is not effective in today's society. We do not think that enhancing the leadership and coordination role of the OPSS would address this issue. A single point of contact for product safety recalls should also include the regulation of food, chemicals, medical and healthcare products, construction products and vehicles, which are excluded from the scope of this consultation. A more holistic and joined-up approach should be taken.

APIL believes that the Government should set up a central enforcement agency that would better deal with product safety issues. It would deal with product safety issues nationally rather than locally, and thus be more effective. A single point of contact would only make sense once there is a centralised, simplified and more powerful regulation, and would reduce the present duplication of functions in local authorities and the additional costs and inefficiencies this brings.

A national enforcement system requires sufficient resources, funding and expertise to collect data, identify risks, undertake thorough investigations, raise awareness of risks and intervene where necessary to protect consumers from defective or unsafe products. We also believe that the Patient Safety Commissioner should play a role in ensuring that consumer safety is the central focus behind regulation and enforcement.

18. Do you agree with the proposal to create a new legal data gateway?

APIL agrees with this proposal. We believe that having an effective mechanism where data is collected is essential to ensure consumer protection. The reporting and sharing of data with operators in the product safety system should be mandatory. It is crucial that the OPSS or any alternative national enforcement authority thoroughly investigates defective and unsafe products identified by the data collected and enforces corrective action or recalls where necessary.

We also recommend that a system such as the yellow card scheme should be implemented for all products. The yellow card scheme is a not compulsory UK system which collects and monitors information on suspected safety concerns or incidents in relation to medicines and medical devices. A system similar to the yellow card scheme for all products should be mandatory to ensure that manufacturers are reporting data on incidents. This can ensure that issues with unsafe and defective products are collected so that risks can be identified, and thorough investigations can take place.

20. Do you agree with the proposal to consolidate and align existing enforcement legislation? Yes / No / Don't know

APIL agrees with this proposal.

21. Do you agree with the proposal to introduce improvement notices, civil monetary penalties, and enforcement undertakings? Yes / No / Don't know

APIL agrees with this proposal.

22. Do you agree with the proposal to explore changing inspection powers?

There should be transparency regardless of where the product is being produced. Officers must be allowed to carry out inspections even if the business is home-based. We would agree with changing inspection powers so that officers are only able to access the parts of the property where a business is operating from, as suggested in the consultation paper.

23. To inform consideration of whether the civil product liability regime remains fit for purpose, can you provide any examples where the current product liability regime:

APIL has recently sent a detailed briefing to the OPSS highlighting issues with the current product liability regime and the Consumer Protection Act 1987 (CPA). We ask that the briefing is considered as a response to this question.

We have highlighted the main issues below.

a) is unclear because of technological developments (e.g., lack of clarity about who is responsible for safety of an AI/smart product or when software is updated); or

While the CPA is equipped to deal with new technologies (the state-of-the-art defence can deal with changing technology in a flexible way), the Act fails to establish a high enough bar for safety. It is extremely challenging for a consumer to face a well-resourced manufacturer in a product liability claim due to the unleveled playing field. There should be consideration of how to better protect consumers in light of new technologies, particularly AI.

The increasing use of software and emerging technologies in consumer products make claims even more complex and challenging for consumers to pursue. We are concerned that people who are injured in the UK will be forced to bring complicated, costly international claims against, for example, foreign-based software developers, and will be left with no route to redress in the UK courts.

Vehicle technology: Automated vehicles and Remote driving – strict liability

The Automated and Electric Vehicles Act 2018 introduced strict liability for autonomous vehicles. Unfortunately, the provisions of the Act are still not effective because the Secretary of State has not yet listed any vehicle capable of being driven autonomously. Thus, no vehicles currently have the benefit of strict liability under the Act. The legislation is not currently operating as Parliament intended yet there are vehicles already on UK roads which are driving autonomously where software is dynamically and adaptively controlling the vehicle's steering and speed.

In the event of a collision, the issue will inevitably be whether the software was a defective product within the meaning of CPA. We recommend that the liability provisions in the Automated and Electric Vehicles Act 2018 should now be extended to all software-controlled vehicles and remote driving, or that similar new legislation is enacted so that vehicles capable of automated or remote driving are under a strict liability regimen.

We believe that any other way of pursuing a claim involving an automated or remotely driven vehicle would be extremely unfair to the injured party and might make it virtually impossible for innocent but injured persons to obtain redress.

3D products

There is a need for the definition of manufacturer to be reviewed considering the way technology is changing. If a consumer 3D prints a product and hires it out or sells it, they should become a producer by definition and thus be liable for any harm. We suspect that these types of cases will become more frequent in years to come. For online sales of such products, platforms such as Amazon should make consumers aware of their responsibilities regarding this.

APIL believes online platforms should be jointly and severally liable for harm caused by unsafe and defective products sold through their platform including those which may be homemade. This would put the onus on platforms to ensure products they sell are safe.

b) doesn't enable consumers to seek fair redress; or

Collective redress: An "opt-out" approach to group actions

APIL is disappointed that this consultation does not consider collective redress. We believe that there should also be a procedural change in relation to group actions, and the "opt-out" procedure that applies to competition law group actions should apply to product liability claims to allow consumers to seek fair redress.

Currently, in order for a group action to be brought for a product liability claim, all claimants must proactively opt in to that action. It is difficult to bring claims for product liability on an individual basis because they tend not to be high value and it is difficult to obtain funding to do so. However, if the competition law model were to be adopted, whereby a single claimant can represent a defined class of claimants, and if the claim succeeds, everyone who fits within that defined class is entitled to compensation even if they were not previously involved with the claim, this would improve access to justice hugely.

An opt-out approach would ensure that funding would be available to run these cases and would ensure that compensation is provided to a wider group of people who have been injured by defective products. It would also help to prevent the UK from being left behind in terms of product safety and access to justice for those injured by defective products. Throughout the EU, the Representative Actions Directive applies, aiming to ensure that consumers can pursue their collective interests. Several jurisdictions have interpreted the directive to establish opt-out mechanisms for product liability group actions, including the Netherlands and Portugal. While other jurisdictions have not yet gone this far, there are still improvements in bringing group actions throughout the EU as a result of the Directive.

We believe that the UK should align the process with Europe. It should not be harder in the UK to bring a group action for a product liability claim than it is in the EU. Again, we are at risk of the UK falling behind and becoming a jurisdiction where unsafe products are allowed

to be marketed and tested to the general public, due to lax regulation and an inability for injured consumers to pursue justice.

Complexity

The current framework of product safety regulation is complicated to understand. Specialist lawyers find it challenging to comprehend and follow at times, so there is no doubt that individuals and businesses will find it complex. The regulations are written with manufacturers in mind rather than individuals. There are likely to be few circumstances in which a consumer will be navigating the system of regulations themselves so the crucial aspect for consumers is that they understand the system of regulation and redress in relation to product safety.

APIL believes that the regulations should be rewritten to ensure that they are simpler to understand and also make the enforcement of consumer rights easier. We strongly believe that the Law Commission should carry out a holistic review of the CPA and properly address consumer rights and redress.

Long stop

APIL believes that it is unfair and unjust for the CPA to impose a ten-year long-stop limitation date on product liability claims. It unfairly prejudices those under the age of majority as well as protected parties and victims of pharmaceuticals and medical devices where the injury is latent and does not appear or be capable of diagnosis until either shortly before the end of the long stop period or afterwards.

A consumer may have a reduced time to take action because they may not receive the product until a few years after circulation. This is a particular issue where a consumer may have purchased a second-hand product. We believe the longstop is wholly unnecessary - a manufacturer's liability diminishes over time due to the wear and tear of the product. In other areas, there is a discretion to extend the longstop – but this is not the case in product liability cases. Further, instead of being a defence that can be employed, the longstop simply extinguishes the right to pursue a case after ten years. In some cases, a claim can be extinguished before a consumer even became first aware they had suffered an injury due to the product, which is unfair.

The Government should abolish the ten-year long-stop for product liability claims. If there is to be a long stop, the clock should begin to run only from when the consumer receives the product, not an arbitrary date from which the product was “put into circulation”.

Dilution of the CPA following High Court cases and hip replacement cases – what is a “defective product”

The theory behind the Act is that if a product is not produced to the level of safety that persons are generally entitled to expect then that product is defective and if that causes injury then compensation should follow. The first time that this was properly tested in the courts of England and Wales was in what became known as the “Blood Products case”.

Patients who received contaminated blood sued the relevant Government department. Its evidence was that it had done all that it possibly could to avoid the contamination but it nevertheless arose. The court acknowledged these efforts but applying the Act properly, explained that avoidability was irrelevant; and that the product was defective and compensation followed. That case has long been criticised by manufacturers of devices and products, their insurers and the lawyers that represent them.

Regrettably, recent years have seen a shift in judicial interpretation which has considerably diluted the effect of the Act. Some High Court Judges have considered avoidability and it is suggested that if a product is the subject of regulatory approval, then that is a very significant factor in favour of saying that the product is not defective. It is very clear however, the regulatory approval and the granting of a CE mark is not a measure of safety. It merely confirms the product has been manufactured to its stated specification. It is based on assumptions of safety related to previous products, and it does not mean that it has been properly tested or regulated.

Inability to recover from a supplier where the producer is no longer able to satisfy claims

There are also issues experienced when producers are known but no longer able to satisfy claims. In these cases, it is not possible to recover any damages from the supplier. This was highlighted in the PIP Breast Implant Litigation. This demonstrates a need to impose a statutory requirement on manufacturers to maintain sufficient product liability insurance.

Issues with the date of supply

We believe that there should be a simpler approach relating to the date of supply, implantation, receipt, gift etc. The date of supply should reflect when the consumer receives the product.

Issues identifying the producer

There are often delays with CPA cases at present because potential defendants do not identify who the producer/manufacturer of a product is. There is a lack of obligation on defendants, producers or a company within a group of companies one of whom at least is the producer to identify the producer within the definition of the Act, and the date of supply. Delays are felt more keenly in these cases, particularly given the ten-year-long stop. Defendants can employ delaying tactics in order to simply run down the clock until the claim is extinguished.

Any queries relating to this response should, in the first instance, be directed to:

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