Product Liability newsletter

April 2021

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Introduction

Welcome to the latest edition of our product liability bulletin, looking at key news articles and cases affecting the industry. In this edition we look at: OPSS guidance following Brexit, Group Action against Vauxhall, new button battery safety campaign & much more. We hope you enjoy this edition.

OPSS guidance and call for evidence following Brexit

Following the UK's exit from the European Union in January 2020 and the end of the transition period on 31 December 2020, the Office for Product Safety and Standards (OPSS) has sought to clarify the resultant changes by way of publication ('the Guidance') found here. The Guidance sets out the current law for the market of Great Britain (England, Scotland and Wales). Separate guidance is available for Northern Ireland.

From 1 January 2021, the European Union (Withdrawal) Act 2018 took effect to retain any EU-based legislation in UK law. This operates in tandem with the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 which rectify any shortfalls or misapplications caused by the UK's withdrawal. The combined effect of the two pieces of legislation is that, subject to legislation concerning specific industries, the law effectively continues to apply as before and the safety and technical requirements have not changed. Similarly, products placed on the European Economic Area (EEA) or UK markets before 1 January 2021 can continue to circulate in the UK.

The UK has also published a list of references to designated standards: these set out the standards needed to demonstrate a product's conformity to the GB essential requirements (which, as above, are substantively the same as the EU's essential requirements) and mirror the EU's harmonised standards to ensure there is consistency across the markets.

Whilst predominantly the same, there are some subtle changes to the product safety framework. The Guidance also addresses what will change. Several changes have already taken effect:

- The new UK Conformity Assessment marking ('UKCA') has been introduced and should be used on products for placement on the GB market as soon as possible and by 31 December 2021 at the very latest in most cases (although with some differing timeframes, such as for medical devices, as detailed on the gov.uk website). We previously considered the UKCA marking regime in more detail here.
- From 1 January 2021, UK Notified Bodies automatically became UK approved bodies meaning they can carry out conformity assessment for products on the GB market and thereafter successful products can be UKCA marked. UKCA marking is not recognised by the EU for the purposes of CE marking and placing on the EEA market, but is recognised for the Northern Irish market (in which case, products should be marked CE and UKNI).
- From 1 January 2021, some UK businesses that bring products into GB from an EEA state who were previously "distributors" became "importers" and acquired new legal duties.
- From 1 January 2021, mandated authorised representatives for the GB market can no longer be based outside the UK (and Northern Ireland).

The Guidance also sets out upcoming changes:

- Products meeting EU requirements, such as those that have been lawfully CE marked and/or tested by an EU recognised conformity assessment body, can continue to be placed on the GB market until 31 December 2021. Thereafter, the products will need to be UKCA marked and approved by an approved body.
- Similarly, products tested by UK Notified Bodies before 31 December 2020 but not yet on the market, can also continue to be placed on the GB market until 31 December 2021.

Whilst the law continues to operate very similarly, the Guidance makes clear that businesses should be aware of the present and upcoming changes in order to ensure compliance.

In addition to the Guidance, the OPSS has also published its intent to review the product safety regulatory framework in place with a view to ensuring the framework is fit for the future. On 11 March 2021, the OPSS published a call for evidence as part of its UK Product Safety Review.

The call for evidence seeks the views of any interested party on a series of 25 questions, available here, with responses due to by 3 June 2021. The questions can be broadly broken down into 5 categories: product design, manufacture and placing on the market (1-8); new models of supply (9-13); new products and product lifestyles (14-16); enforcement considerations (17-22); and diversity and inclusivity (23-25).

The questions asked raise some topical and interesting areas of consideration; for example, regarding the effect of 3D printing and integral software updates. Publication of the results will be eagerly awaited.

Group action against Vauxhall for cheating emissions tests

Following accusations of cheating emissions tests and recalls of vehicles in or around 2016, Vauxhall finds itself in the news again.

Campaign group Vauxhall Pay Up, which was launched on 18 January 2021, claims that Vauxhall installed software which enabled the cheating of emissions tests in 600,000 of their vehicles. It is understood that this applies to Vauxhall vehicles purchased or leased between 2009 and 2019.

The software is referred to as a "defeat device" and purportedly detects test environments, whereby it tells the engine to reduce pollutants in order to pass the test. Vauxhall Pay Up allege that the vehicles were, in actual fact, unable to meet international emissions standards and should never have been allowed on the road.

The Claimants are being represented by Milberg London, who have experience in handling similar claims. The claim will proceed via a Group Litigation Order, the procedural mechanism also being used in the highly publicised Volkswagen litigation concerning their own emissions.

Vauxhall denies the allegations, maintaining that their vehicles meet the applicable regulations.

American automaker Ford is also facing pressure in relation to the safety of their vehicles. Ford will recall 3 million of their vehicles in the US and Canada due to suspected issues with the airbags.

The airbags were manufactured by the now-bankrupt Japanese company Takata, who previously manufactured a similar version of the airbags which caused multiple deaths and injuries to over 400 people. Although the airbags which are subject to the present recall are not the same as the defective airbags, safety regulators consider that the similarities in the airbags create too high of a risk, rejecting any argument to the contrary put forward by Ford.

Automakers GM and Mazda have also been the subjects of rejected appeals by the US National Highway Traffic Safety Administration recently, forcing both companies to recall a large number of vehicles.

The global focus on environmental improvements and reducing the emissions of harmful substances is placing ever increasing pressure on the manufacturers of not only motor vehicles, but all products which may emit harmful substances.

The publicity regarding emissions in the media over the past several years highlight the strict approach which regulators will take with manufacturers where there is concern relating to emissions fraud.

OPSS launches new Button Battery Safety Campaign

There has been growing coverage of concerns over the safety of batteries and the accidental ingestion thereof. Research in the US suggests that more than 3,500 incidents of accidental button battery ingestion are reported to US poison control centres each year and similarly the Queensland Injury Surveillance Unit in Australia also estimates that four children a week are admitted to hospital after swallowing batteries.

So-called button batteries are identified as being one of the most dangerous types of batteries. By their nature, they are small, flat and unfortunately easily ingestible. It is believed that most cases involve children under the age of 6, where the button batteries are often used in toys and can easily be mistaken for sweets. Due to size, the batteries can also be placed into ears and noses.

In addition to risks of choking on the batteries, they can also cause serious internal damage. When combined with water, the electrical current from the batteries produces caustic soda which can then burn through the oesophagus and stomach, cause internal bleeding and in the most serious cases, can result in death.

In an attempt to raise awareness of the risks, the OPSS has launched their new button battery safety campaign. This provides the following guidance:

- Store button batteries securely;
- Know what products use button batteries (and put the products out of children's reach);
- Educate older children about button batteries;
- Discard dead batteries straightaway; and
- Act promptly if you suspect a child has swallowed a button

Further guidance and resources can be found on here.

Hastings v Finsbury Orthopaedics Ltd and *Stryker UK Ltd*: first instance decision upheld on appeal (Scotland)

On 26 January 2021, the Inner House of the Court of Session in Scotland (the House) handed down its decision in the appeal of *Hastings v Finsbury Orthopaedics Ltd and Stryker UK Ltd*. The House has upheld the first instance decision in favour of the defendant manufacturers.

We analysed the first instance decision in the February 2020 edition of our bulletin (found here). The Pursuer (the Claimant, in Scotland) alleged that the metal-on-metal total hip replacements he had been implanted with were defective.

The judgment has implications for insurers in the UK as a whole. As the House noted, the Scottish Court has reached the same conclusion as the English Court in two of the most authoritative English product liability judgments of recent years: *Wilkes v DePuy International Limited* and *Gee* and *others v DePuy International Limited*.

The issues aired on appeal included the quality of the evidence relied upon by the Pursuer, whether the judge at first instance had given adequate weight to the rights of consumers and whether the approach in *Wilkes* and *Gee* should be followed.

In deciding whether the products met the relevant standard of safety under the Consumer Protection Act 1987, the House confirmed that the correct approach was to assess whether the product in question had a worse safety record than other comparable products. Ultimately, the evidence presented by the Pursuer was not robust enough.

The decision serves to highlight that whilst a Claimant or Pursuer may have a prima facie case, this may not be enough if the evidence is weak. This follows similar criticisms of the Claimants' evidence in the case of *Gee*.

Insurers on both sides of the border are likely to welcome this judgment as reflecting the general trend of recent product liability decisions that have been decided in favour of medical device manufacturers.

This case may not be over yet. If *Hastings* is appealed then industry and insurers will await the outcome of a rare Supreme Court examination of product liability issues.

[1] [2021] CSIH 6

[2] [2017] All ER 589; [2018] EWHC 1208 (QB)

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