UNITED KINGDOM

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For the most part, English law approaches liability for damage resulting from pharmaceutical products in the same way as it does liability for damage caused by any other product. With some minor exceptions, which will be discussed below,[1] no special rules of civil liability exist in this area, although that is not to say, of course, that significant legal issues are not posed by the pharmaceutical context. The purpose of this article is to sketch the central features of the relevant English law and to consider how they apply to claims in respect of damage caused by pharmaceutical products. The space available permits only a very compact treatment. Readers who are interested in a more comprehensive account of the material principles of English law are referred to the extensive literature in this field.[2]

At the outset it may be helpful to make some overarching remarks about claims in the United Kingdom for damage caused by pharmaceutical products. Such claims have a dismal track record. One leading commentator in the field makes the striking observation that 'not one claim has resulted in damages being awarded by a court against a pharmaceutical company'.[3] There are several reasons for this situation. One is that litigation in the United Kingdom is notoriously expensive, especially where, as in the pharmaceutical context, extensive expert evidence is likely to be required.[4] The cost of litigation passed the point of being extortionate some time ago. The greater the cost of litigation, the less likely it is claims, including meritorious ones, will be brought. A second reason is that English judges are loath to find that failings in the design of objects, as opposed to failings in their operation, attracts liability. This obviously has major implications for the pharmaceutical context. A third reason is that legislation that holds producers responsible for damage caused by defective products, despite providing for strict liability, has done relatively little to extend the net of responsibility. These are all themes to which reference will be made, below.

1. Liability Systems

1.1. What systems of product liability are available? Is liability fault-based, or strict, or both?

English law provides for three civil liability regimes that are relevant to the pharmaceutical context. These systems operate concurrently with each other in the sense that if the claimant can establish a right to relief in one of them he or she will be entitled to a remedy irrespective of whether or not a remedy is available in the others. Where more one system yields a remedy, the claimant is entitled to opt for the most generous one. However, it is, of course, impermissible for a claimant to accumulate recovery obtained in various causes of action. Consistently with a fundamental principle of the law of remedies, a claimant is only entitled to be compensated once, in full, in respect of loss caused by any given wrong.

The first system of liability is provided for by the cause of action in negligence. This cause of action has three elements: (i) the existence of a duty of care owed by the defendant to the

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[1] See 1.2.

[2] An excellent recent account is offered in R Goldberg, *Medicinal Product Liability and Regulation* (Hart Publishing, Oxford, 2013). A more theoretical but now dated account is given in J Stapleton, *Product Liability* (Butterworths, London, 1994).

[3] Goldberg (n 2) 8.

[4] A good illustration of the scale of the expert evidence that may be involved is *XYZ v Schering Health Care Ltd* [2002] EWHC 1420 (QB); (2003) 70 BMLR 88.

claimant; (ii) a breach of that duty of care; and (iii) damage caused by that breach. All three ingredients must be present in order for liability to arise. The duty of care element is unlikely to be in issue in claims against manufacturers of pharmaceutical products. That is because the relationship of manufacturer/consumer is a category that is recognised as giving rise to a duty of care.[5] Other persons in the supply chain, such as distributors, similarly owe a duty of care.[6] In order for there to be a breach of duty, it must be shown that the defendant acted negligently, that is to say, fell below the standard of care that would have been achieved by a reasonable person in the same position. Ascertaining the amount of care that the reasonable person would have exercised requires consideration of the magnitude of the risk and the probability that it would occur on the one hand and the cost and inconvenience of taking precautions to eliminate or reduce the risk on the other. The third element – damage caused by the breach – generally requires proof that but for the breach of duty the loss would not have been suffered. In claims in negligence against manufacturers in respect of harm caused by pharmaceutical products, the breach and causation elements will often be formidable hurdles. It is notorious that the courts are reluctant to find a breach of duty on account of the way in which products are designed,[7] and where the fault is said to lie in a failure adequately to warn of risks, the burden of showing that the claimant would have acted differently had a proper warning been given will often be weighty.[8]

Second, an individual who suffers damage as a result of using a pharmaceutical product may be entitled to relief in a claim for breach of contract. A severe limitation on the usefulness of this mode of redress is that the action lies, subject to exceptions, only against the person who sold the product. The details as to when, precisely, liability will arise are complex and cannot be explored in any detail here. It will suffice for present purposes simply to observe that, pursuant to implied warranties provided for by legislation concerning contracts for the sale of goods, the seller will be strictly liable (i.e., without proof of fault) to the purchaser if the product was not of 'satisfactory quality'[9] or not fit for the purpose for which the purchaser indicated to the seller that he or she wanted the product.[10]

The third liability regime derives from the Consumer Protection Act 1987 ('the 1987 Act'), which gives effect to Council Directive 85/374/EEC concerning liability for defective products.[11] Although both the 1987 Act and the Directive were principally a reaction to the thalidomide tragedy that occurred in the 1960s, neither is specifically concerned with medicinal products. The 1987 Act, which for the most part applies to the whole of the United Kingdom,[12] imposes liability in respect of damage caused by 'defective products'. Liability is imposed on 'producers', persons who hold themselves out as the product's producer by adding their label to a product made by someone else, and importers of 'defective products'. Hence, liability may descend under the 1987 Act on persons who are not necessarily responsible for the defect in issue.

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[5] *Donoghue v Stevenson* (1932) AC 562 (HL).

[6] See A Dugdale et al (eds), *Clerk & Lindsell on Torts* (22nd ed, Sweet & Maxwell, London, 2017), para 11-12.

[7] The issue is illuminatingly discussed in P Cane, *Atiyah's Accidents, Compensation and the Law* (8th ed, CUP, Cambridge 2013), 46–50, 102.

[8] 'Since warnings are often disregarded in practice, this is likely to be a heavy burden which will make it difficult for many claimants to succeed on a "failure to warn" basis': Dugdale (n 6) para 11-33 (footnote omitted).

[9] '[G]oods are of satisfactory quality if they meet the standard that a reasonable person would regard as satisfactory, taking account of any description of the goods, the price (if relevant) and all the other relevant circumstances': Sale of Goods Act 1979, s 14(2A). See also Consumer Rights Act 2015, s 9(2).

[10] Sale of Goods Act 1979, s 14; Consumer Rights Act 2015, s 9.

[11] The European origins of the 1987 Act are explored in CJS Hodges, 'Product Liability in Europe: Evaluating the Case for Reform' [2000] *Bus L Int'l* 171.

[12] Section 49.

The 1987 Act does not provide a comprehensive definition of a 'product'. Instead, it provides that the term 'product' means 'goods … and … includes a product which is comprised in another product, whether by virtue of being a component part or raw material or otherwise'.[13] The term 'goods' is in turn defined to include 'substances'.[14] In *A v National Blood Authority*,[15] it was conceded that contaminated blood was a 'product'. Pursuant to section 3 of the 1987 Act 'there is a defect in a product … if the safety of the product is not such as persons generally are entitled to expect'.[16] All of the relevant circumstances are taken into account in determining whether this requirement is satisfied,[17] and the burden of establishing defectiveness rests on the claimant.[18] This (circular) test for defectiveness is broadly similar to that used in connection with the breach element of the tort of negligence. For example, and in outline, a product will not be regarded as being defective on account of its design unless the risks that it poses are greater than the benefits that it is expected to bring, which is essentially the same analysis that is employed in determining how much care a defendant to a claim in negligence was required to take. Much the same can be said about allegations that a product is defective because of the absence, or inadequacy, of risk warnings.

Liability under the 1987 Act is notionally strict.[19] It is unnecessary to establish fault, although it remains essential to establish causation and to find a responsible defendant. Nevertheless, the strict liability system created by the 1987 Act is long way from what may be regarded as a pure strict liability system.[20] A constellation of defences[21] ensures that fault on the part of the defendant remains relevant to liability. Furthermore, as has just been observed, the test for defectiveness effectively allows questions of fault to intrude. These features of the 1987 Act expose it to the criticism that it does far too little to overcome a fundamental defect in the tort system, namely, that it makes no sense that the tort system is concerned with questions of fault in circumstances where the actual wrongdoers never pay and damages awards are instead met by insurers or governments. Conversely, to the extent that the 1987 Act gives favourable treatment to persons who are injured by defective products, it can be queried whether giving such persons preference is rational given that it is generally a matter of luck whether a person happens to injured by a defective product as opposed to in some other way.[22]

1.2. Does the state operate any schemes of compensation for particular products?

Two relevant schemes exist.[23] The first is the compensation system that was established in the wake of the blood contamination scandal involving the National Health Service. It provides for relatively modest payments to be made to persons who contracted HIV and hepatitis C from infected blood prior to 1991. The other scheme benefits persons who

[13] Section 1(1).
[14] Section 45(1).
[15] [2001] 3 All ER 289 (QBD), [2] (Burton J).
[16] This means the amount of safety that the public can legitimately expect rather than what the public actually expects: *A v National Blood Authority* [2001] 3 All ER 289 (QBD), [31(vi)] (Burton J).
[17] Section 3(2).
[18] *A v National Blood Authority* [2001] 3 All ER 289 (QBD), [31(iii)] (Burton J).
[19] 'The criteria, therefore, for liability is defectiveness, not fault': *Worsley v Tambrands Ltd* [2000] PIQR P95 (Ebsworth J).
[20] See further J Stapleton, 'Products Liability Reform – Real or Illusory?' (1986) 6 *OJLS* 392.
[21] See 3.1.
[22] Both of these themes are powerfully developed in Cane (n 7) 101–103.
[23] They are discussed in more detail in ibid, 105–108.

suffered disability as a result of vaccinations.[24] This compensation system was established by the Vaccine Damage Payments Act 1979 on the recommendation of the Pearson Royal Commission.[25] In order to recover compensation, significant disablement resulting from a prescribed vaccination must be established. If an entitlement is shown, a one-off payment of £120,000 will be made. Participation in these schemes does not prevent redress from being obtained via an action in the tort of negligence, for breach of contract or under the 1987 Act.

1.3. Who bears responsibility for the fault/defect?

In the case of a claim in the tort of negligence in respect of damage caused by a pharmaceutical product, the defendant is likely to be the manufacturer of the product concerned. In relation to an action for breach of contract, it is the seller of the product to the claimant purchaser who will most probably be the target on account of the general requirement that a claim for breach of contract will lie only where the parties are both parties to the contract in issue. In proceedings under the 1987 Act, producers, persons who hold themselves out as the product's producer by adding their label to a product made by someone else, and importers, are exposed to liability.[26]

1.4. In what circumstances is there an obligation to recall products, and in what way may a claim for failure to recall be brought?

Producers are obliged to notify an enforcement authority in respect of products that do not meet the requirement of 'safety'.[27] Recall notices can be issued by the enforcement authorities in respect of dangerous products,[28] although various less onerous notices may be issued, too. A failure to recall a product can result in enforcement action being taken but it will not necessarily give rise to any entitlement to a private law remedy. A claim may arise in the tort of negligence for failing to monitor for defects, warn of those defects, and recall products but only if the failure to do so was unreasonable.[29] Conversely, no post-sale or supply obligations arise in contract under of the implied warranties or pursuant to the 1987 Act.

1.5. Do criminal sanctions apply to the supply of defective products?

Supplying defective products potentially constitutes a wide range of offences. A detailed analysis in this regard is impossible in this article. It is sufficient to note that placing unsafe products on the market is an offence under the General Product Safety Regulations 2005.

2. Causation

2.1. Who has the burden of proving fault/defect and damage?

The claimant carries the onus of proving all of the elements of the cause of action on which he or she relies. Thus, all of the elements of the tort of negligence must be established by the claimant in order to recover compensation in respect of that wrong, and the same goes in relation to proceedings for breach of contract. In relation to claim under the 1987 Act, it is

[24] For further discussion, see R Goldberg, 'Vaccine Damage and Causation: Social and Legal Implications' (1996) 3 *Journal of Social Security Law* 100.
[25] *The Royal Commission on Civil Liability and Compensation for Personal Injury* (Cmnd 7054–1) (1978).
[26] Section 2(2).
[27] General Product Safety Regulations 2005, cl 9(1).
[28] Ibid, cl 15.
[29] See, eg, *E Hobbs (Farms) Ltd v Baxenden (Chemical Co) Ltd* [1992] 1 Lloyd's Rep 54 (QBD).

irrelevant whether the defendant was at fault. However, the claimant must prove that the product in issue was defective and that his or her damage was caused wholly or partly by that defect. In respect of all three liability regimes, proof to the usual civil law standard – the balance of probabilities – is required.

2.2. What test is applied for proof of causation?

In English law, questions of causation are decided according to 'informed commonsense'[30] and, generally, the 'but for' test, pursuant to which it is asked whether the damage would have been suffered 'but for' the conduct of the defendant concerned. If the answer to that question is 'no', causation will be established. In relation to claims that are based on a failure to warn, the question is whether this particular claimant (as opposed to a reasonable claimant) would have acted differently had the postulated warning been given. Where it cannot be established that no statistically significant connection exists between a product and a particular adverse effect, such that it is not possible to say confidently whether an observed difference between two samples of person is attributable to chance, causation will not be established.[31] Some support exists in favour of the proposition that causation can be proved pursuant to the 'doubling of risk' theory. In *XYZ v Schering Health Care Ltd* claims were brought under the 1987 Act by women who asserted that they had suffered injury as a result of using the defendant pharmaceutical companies' oral contraceptives. The judge said:[32]

> 'If factor X increases the risk of condition Y by more than 2 when compared with factor Z it can then be said, of a group of say 100 with both exposure to factor X and the condition, that as a matter of probability more than 50 would not have suffered Y without being exposed to X. If medical science cannot identify the members of the group who would and who would not have suffered Y, it can nevertheless be said of each member that she was more likely than not to have avoided Y had she not been exposed to X'.

2.3. Does any form of market-share liability apply?

English law is fundamentally opposed to any form of market share liability. It rigidly insists that the particular defendant sued must be shown to have caused the damage concerned before he or she will be held liable in respect of it.

2.4. Does a failure to warn give rise to liability and, if so, in what circumstances? What information, advice and warnings are taken into account? Is there any principle of 'learned intermediary'?

A failure to warn in respect of a risk can give rise to liability in negligence but the hurdle of establishing that the failure was causally relevant will often be a high one. A failure to warn is unlikely to be relevant to a claim based on breach of the contractual warranties. The absence of a warning is specifically said to be relevant to the issue of whether a product is defective for the purposes of the 1987 Act.[33]

The learned intermediary doctrine is usually regarded as being a qualification or exception to the general rule that the duty of care owed by manufacturers requires them to take

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[30] *Kuwait Airways Corpn v Iraqi Airways Co (Nos 4 and 5)* [2002] UKHL 19, [2002] 2 AC 883, [71] (Lord Nicholls of Birkenhead).
[31] *Vadera v Shaw* (1998) 45 BLMR 162 (CA), 174 (Henry LJ).
[32] [2002] EWHC 1420, [2002] 70 BMLR 88 (QB), [21] (Mackay J).
[33] Section 3(2)(a).

reasonable care to warn consumers about foreseeable risks of injury posed by the product.[34] The doctrine permits a manufacturer to discharge its duty by providing information regarding a product's risks to a 'learned intermediary'. Paradigmatically, it applies where the manufacturer of a drug informs a doctor of the drug's dangers. In English law, the doctrine is implicit in the tort of negligence in that it expresses the basic propositions that: (i) the tort of negligence requires only that a person who owes a duty take reasonable care, (ii) the law does not prescribe how reasonable care is taken; and (iii) if reasonable care is taken, it is irrelevant how it was taken. The doctrine is irrelevant to claims for breach of the contractual warranties, which impose strict liability. It has been suggested that room remains for it in considering whether a product was 'defective' for the purposes of the 1987 Act,[35] although the case law appears not to support this view.[36]

3. Defences and Estoppel

3.1. What defences are available?

Claims in the tort of negligence are subject to the contributory negligence defence, which is discussed below.[37] As a practical matter, no other defences are likely to be available in relation to a claim in negligence or for breach of contract in respect of damage caused by a pharmaceutical product, save for limitation, discussion of which is also reserved for later.[38] Exclusion or limitation of liability clauses or notices are ineffective in relation to claims in negligence for personal injury.[39] By contrast with the limited range of defences that are likely to be available in claims in negligence and for breach of contract in the pharmaceutical liability context, the 1987 Act provides for a complex network of defences. These defences are as follows. First, it is a defence for the defendant to show that the defect concerned was 'attributable to any requirement imposed by or any enactment or with any EU obligation'.[40] Second, it is a defence for the defendant to establish that he or she did not supply the product in issue.[41] Third, and in outline, it is a defence to show that the product was supplied otherwise than in the course of a business and by a person who is not a 'producer' or who is a 'producer' 'by virtue only of things done otherwise with a view to a profit'.[42] Fourth, it is an answer to liability to demonstrate that the defect did not exist when the product was supplied.[43] Fifth, liability will not arise where 'the state of scientific and technical knowledge' at the time of supply was 'not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products while they were under his control'.[44] This 'development risk defence', as it is generally known, is likely to be the most significant by some margin in the case of claims in respect of pharmaceutical products, and it is examined further below.[45] Sixth, it is a defence for a producer of a defective product to show that the product was incorporated within a subsequent product and the defect was 'wholly attributable' to the design of the subsequent product or to compliance 'with instructions given by the producer of

[34] See, eg, Goldberg (n 2) 74.
[35] CJS Hodges, 'Compensating Patients' (2001) 117 *LQR* 528, 532.
[36] *Blood v National Blood Authority* [2001] 3 All ER 289, [55] (Burton J).
[37] See 3.5.
[38] See 5.
[39] Unfair Contract Terms Act 1977, s 2(1); Consumer Rights Act 2015, s 65(1).
[40] Section 4(1)(a).
[41] Section 4(1)(b).
[42] Section 4(1)(c).
[43] Section 4(1)(d).
[44] Section 4(1)(e).
[45] See 3.2.

the subsequent product'.[46] Finally, the contributory negligence defence applies to proceedings under the 1987 Act.[47] It is worth adding a few remarks about defences that are not available to claims under the 1987 Act. The 1987 Act does not provide for a defence on account of the claimant having voluntarily assumed the risk of injury. Exclusion or limitation of liability clauses and notices are wholly ineffective in relation to claims under the 1987 Act.[48]

3.2. Is there a state of the art/development risk defence?

In the case of a claim in negligence, the adequacy of the defendant's conduct falls to be decided according to what the reasonable person in the same position as the defendant would have done at the relevant time. Thus, a defendant will not be held to a higher standard of care on account of subsequent scientific advances.[49] No development risk defence is available in claims brought in respect of a breach of the contractual warranties. Section 4(1)(e) of the 1987 Act provides for a 'development risks defence', and it paradigmatically applies where a producer puts a pharmaceutical product into circulation that has some dangerous side-effect which could not have been discovered at the time.

3.3. Is it a defence for the manufacturer to show that he complied with regulatory and/or statutory requirements relating to the development, manufacture, licensing, marketing and supply of the product?

Reference has already been made to the regulatory compliance defence to liability arising under the 1987 Act.[50] Consistently with general principles of tort law applicable in the United Kingdom, the fact that any defendant complied with regulatory standards or requirements is not necessarily an answer to liability. Equally, non-compliance with regulatory prescriptions will not, without more, demonstrate the existence of negligence.

3.4. Can defendants claim that the fault/defect was due to the actions of a third party?

Where a defect is introduced to a product by a third party after the product has gone into circulation no liability will arise on the part of the producer under the 1987 Act, as discussed above.[51]

3.5. Can defendants allege that the claimant's actions caused or contributed towards the damage?

Claims made in the tort of negligence are subject to the defence of contributory negligence.[52] That defence applies where the claimant failed to take reasonable care for his or her own safety and that failure was causally connected with his or her damage.[53] If these twin

[46] Section 4(1)(f).
[47] See 3.5.
[48] Section 7.
[49] *Roe v Minister* of Health [1954] 2 WLR 915 (CA).
[50] See 3.1.
[51] See 3.1.
[52] For an illustration of a product liability case brought in the tort of negligence in which the defence applied, see, *Devilez v Boots Pure Drug Co Ltd* (1962) 106 Sol Jo 552 (QBD).
[53] For an empirical study of the operation of the defence in English law, see J Goudkamp and D Nolan, 'Contributory Negligence in the Twenty-First Century: An Empirical Study of First Instance Decisions' (2016) 79 *MLR* 575; J Goudkamp and D Nolan, 'Contributory Negligence in the Court of Appeal: An Empirical Study' (2017) 37 *LS* 437

requirements are satisfied, the court will reduce the claimant's damages pursuant to the Law Reform (Contributory Negligence) Act 1945.[54] Section 1 of that statute provides that a 'just and equitable' reduction in the quantum of the claimant's recovery must be made bearing in mind the parties' respective shares of responsibility for the damage. The courts take into account two considerations in this regard.[55] First, the causal potency of the parties' conduct will be considered. Second, account will be taken of the parties' relative blameworthiness. In contrast with the position in relation to the tort of negligence, the contributory negligence defence does not apply where the claimant sues in respect of a breach of a strict contractual duty as opposed to a requirement to take reasonable care.[56] However, the contributory negligence defence is available to a claim under the 1987 Act[57] although it does not appear that there are any cases brought under the 1987 Act in which the defence has been found to apply.

4. Procedure

4.1. In the case of court proceedings is the trial by a judge or a jury?

Virtually all civil litigation in the United Kingdom is conducted before a judge sitting alone. A court can, on an application by a party, order a case to be tried by a jury[58] but only in situations that are irrelevant for present purposes.

4.2. Does the court have power to appoint technical specialists to sit with the judge and assess the evidence presented by the parties (i.e. expert assessors)?

No such facility exists. The judge (civil juries now being effectively extinct in the United Kingdom) is the sole arbiter of all questions of both fact and law. However, both the parties legal representatives and expert witnesses are professionally obliged to assist the court,[59] and it is of course imperative for any party that hopes for success in litigation to ensure that the evidence is presented in such a way that it is readily comprehensible. In particular, the court must be given assistance so that it can understand complex epidemiological data before it can be expected to rely upon that data.[60]

4.3. Is there a specific group or class action procedure for multiple claims?

The Civil Procedure Rules provide for the court to make a group litigation order where there are several claims that 'give rise to common or related issues of fact or law'.[61] Discussion of this procedure must be sought elsewhere.[62]

4.4. Can claims be brought by a representative body on behalf of a number of claimants?

[54] The statute applies in Scotland: s 5. The corresponding provision in Northern Ireland is the Law Reform (Miscellaneous Provisions) Act (NI) 1948, s 2(1). It is couched (in relevant part) in identical terms.
[55] *Stapley v Gypsum Mines Ltd* [1953] AC 663 (HL), 682 (Lord Reid).
[56] *Forsikringsaktieselskapet Vesta v Butcher* [1989] AC 852 (CA).
[57] 1987 Act, s 6(4).
[58] Senior Courts Act 1981, s 69(1).
[59] CPR 35.3(1) provides: 'It is the duty of experts to help the court on matters within their expertise'.
[60] Consider the remarks in *Smith v McNair* [2008] CSOH 154, [81]–[82] (Lord McEwan).
[61] CPR 19.10.
[62] See A Zuckerman, *Principles of Civil Procedure* (3rd ed, Sweet & Maxwell, London, 2013) ch 13.

Group litigation under the Civil Procedure Rules is fundamentally different from US-style class actions. The latter are usually just a single proceeding. Conversely, in group litigation each claim comprises a separate proceeding. Where a group litigation order has been made, claims can be added to a group register. Judgments and orders in such claims in relation to a group litigation order issue are binding on all other claims that are on the group register.[63] Claims on the register will be managed together and some claims can be identified as 'test claims' for the purposes of particular issues.[64]

4.5. How long does it normally take to get to trial?

Generally speaking, the greater the complexity and value of a case, the longer it will take to be heard. Proceedings involving large numbers of claimants are likely to progress particularly slowly. The delay involved between the commencement of proceedings and the trial varies from case to case, but the average period is likely to be around three to five years, speaking very generally. Significantly, the Civil Procedure Rules that apply in England and Wales require disputants to engage in extensive correspondence prior to issuing proceedings. Although these procedures are designed to facilitate discussion between the parties and promote settlement in many cases they simply added significantly to the cost and delay of litigation.

4.6. What appeal options are available?

Most appeals will lie to the Court of Appeal of England and Wales, and its equivalents in the case of other jurisdictions within the United Kingdom. Appeals can be brought only with permission,[65] which can be granted by either the trial judge or the Court of Appeal.[66] Permission may be granted (in the case of a first appeal) only where the appeal has real prospects of success or there is some other compelling reason for the appeal to be heard.[67] In outline, an appeal will be allowed only where some error of law can be identified as having been committed by the court below. A finding of fact made by the trial judge will amount to an error of law only where the finding in question is plainly wrong,[68] which is a demanding requirement.

4.7. Does the court appoint experts to assist it in considering technical issues?

Consistently with the fundamentally adversarial way in which litigation is conducted in the United Kingdom, it falls to the parties to call expert witnesses, although they need the court's permission to do so.[69]

4.8. Are alternative methods of dispute resolution available (e.g. mediation, arbitration)?

Alternative dispute resolution is widespread in the United Kingdom and, indeed, is mandated by the Civil Procedure Rules that are applicable in England in Wales.[70] It is particularly

[63] CPR 19.12.
[64] CPR 19.13(b).
[65] CPR 52.3(1).
[66] CPR 52.3(2).
[67] CPR 52.6(1).
[68] *Yuill v Yuill* [1945] P 15 (CA), 19 (Lord Greene MR).
[69] CPR 35.4(1).

prominent in the consumer context.[71] The largely private nature of alternative dispute resolution means that there is no simple way of knowing with any confidence whether it plays a particularly significant role in connection with pharmaceutical claims.

5. Time Limits

Claims in respect of personal injuries are subject to a three-year limitation period.[72] This time limit applies irrespective of whether the claimant's action arose in the tort of negligence, in breach of contract, or under the 1987 Act. Time starts to run from the date of the damage (in the case of a claim in negligence and under the 1987 Act) or the date on which the breach of contract occurred (in the case of a claim in contract). However, if the 'date of knowledge' of the claimant is later, time will run from that point. The 'date of knowledge' is the subject of a complex definition[73] but, in essence, it is the date on which the claimant knew: (i) that the injury was 'significant'; (ii) that the injury was attributable to the relevant conduct of the defendant; and (iii) knew the defendant's identity.[74] Judges have a discretion to disregard the three-year limitation bar.[75] In the case of a claim under the 1987 Act, a ten-year bar applies in addition to the aforesaid three-year bar.[76] Pursuant to the ten-year bar, a defendant will also have a limitation defence in respect of a defective product if the claim was commenced ten years after the product concerned was put into circulation. This bar applies irrespective of whether and, if so, when, a cause of action under the 1987 Act accrued. Consequently, a claim under the 1987 Act may be time-barred even if the three-year limitation period had not yet started to run because no claim had accrued. Unlike the three-year time bar, the court does not have a discretion to disregard the 10-year bar.[77]

6. Damages

6.1. What remedies are available e.g. monetary compensation, injunctive/declaratory relief?

The principal remedy available to those who suffer damage due to defective pharmaceutical products is monetary compensation (compensatory damages). A claimant who establishes liability is in principle entitled to an award that will put him or her into the position that he or she would have occupied but for the defendant's wrong.[78] Recovery will not be permitted in proceedings in either tort or contract to the extent that loss is 'too remote'. Damage will be regarded as being remote if it was of a type that was not reasonably foreseeable (the tort test)[79] or not within the reasonable contemplation of the parties at the time of contracting (the

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[70] See, eg, CPR 1.4, which provides: '(1) The court must further the overriding objective by actively managing cases. (2) Active case management includes – … (e) encouraging the parties to use an alternative dispute resolution procedure if the court considers that appropriate and facilitating the use of such procedure'.

[71] 'Consumer ADR is highly developed in the UK, operating on a sectoral basis without unification or a single model, but with a number of different models': N Creutzfeldt-Banda, CJS Hodges and I Benöhr, 'The United Kingdom' in CJS Hodges, I Benöhr and N Creutzfeldt-Banda, *Consumer ADR in Europe* (Hart Publishing, Oxford, 2012) 253.

[72] Limitation Act 1980, ss 11–11A.

[73] Ibid, s 14(1).

[74] The leading case on the 'date of knowledge' is *AB v Ministry of Defence* [2012] UKSC 9; [2013] 1 AC 78.

[75] Limitation Act 1980, s 33(1).

[76] Ibid, s 11A(3).

[77] Ibid, s 33(1A)(a).

[78] *Robinson v Harman* (1848) 1 Exch 850, 855; 154 ER 363, 365 (Parke B); *Livingstone v Rawyards Coal Co* (1880) 5 App Cas 25 (HL), 39 (Lord Blackburn).

[79] *The Wagon Mound (No 1)* [1961] AC 388 (PC).

contract test).[80] The mere fact that harm is unforeseeably extensive does not render it too remote to be compensable.[81] It is unclear whether the doctrine of remoteness applies to claims under the 1987 Act.

Punitive damages are damages that are awarded to punish and deter rather than to compensate the claimant for the loss that he or she suffered. Exceptionally, punitive damages are available in claims in tort.[82] Cases of statutory authorisation aside, a punitive award can be made only in two situations.[83] The first is where the tort involves oppressive, arbitrary or unconstitutional action by government servants acting in that capacity. The other is where the defendant, in committing a tort, calculated that he or she could make a profit therefrom after paying compensatory damages. It seems likely that only the second of these categories has the potential to be relevant in pharmaceutical liability claims. Punitive damages cannot be awarded in proceedings for a breach of contract.[84] There seems to be no case law as to whether punitive damages can be awarded under the 1987 Act.[85] However, in principle, there is no reason why they should not be available.

6.2. What types of damage are recoverable e.g. damage to the product itself, bodily injury, mental damage, damage to property?

In the case of a claim in negligence, breach of contract and under the 1987 Act, compensation can be recovered in respect of physical and mental injury caused by a defective pharmaceutical product. Except in relation to proceedings for breach of contract, no compensation will be recoverable on account of the damage done to the product itself. In the case of a claim in negligence, that is because such loss is treated by English law as being purely economic in nature because a product that is defective is simply less valuable than the consumer thought it to be. English law withholds compensation in respect of pure economic loss save in exceptional situations.[86] The same outcome obtains in respect of actions under the 1987 Act by virtue of section 5(2), which provides that liability will not arise 'for the loss of or any damage to the product itself' (or to any subsequent product within which the product was incorporated). Under the 1987 Act, damages can be recovered in respect of damage caused to property by a defective product provided that the value of damage caused exceeds £275.[87] No similar restriction applies to claims in negligence or for breach of contract.

7. Costs / Funding

7.1. Is public funding e.g. legal aid, available?

[80] *Hadley v Baxendale* (1854) 9 Ex 341 at 354; 156 ER 145.
[81] *Hughes v Lord Advocate* [1963] AC 837 (HL), 845 (Lord Reid)
[82] Regarding the punitive damages award in English law generally, see J Goudkamp and E Katsampouka, 'An Empirical Study of Punitive Damages' (2018) *Oxford Journal of Legal Studies* (forthcoming).
[83] *Rookes v Barnard (No 1)* [1964] AC 1129 (HL).
[84] *Addis v Gramophone Co Ltd* [1909] AC 488 (HL).
[85] Punitive damages were claimed in *Shaw v Medtronic Corevale LLC* [2017] EWHC 54 (QB), which involved a claim under the 1987 Act. However, the punitive damages claim was barred because the action was brought under legislation providing for the survival of actions, and the legislation concerned provides that punitive damages do not survive for the benefit of the estate of a deceased person: see at [28]–[29]. For general discussion of the availability of punitive damages in claims under the 1987 Act, see CJS Hodges, 'Do Punitive Damages have any Place in Product Liability?' (1994) 16 *Product Liability International* 19.
[86] As to when damages can be recovered in respect of negligently inflicted pure economic loss, see, *Hedley Byrne & Co Ltd v Heller & Partners Ltd* (1964) AC 465 (HL).
[87] Section 5(4).

Since 2013, legal aid has been unavailable in personal injury claims in England and Wales.[88] Legal aid remains available in such cases in Scotland[89] and Northern Ireland. This situation means that, in the case of England and Wales at least, in which the vast majority of civil litigation in the United Kingdom takes place, any claims in respect of pharmaceutical products need either to be privately funded or funded by way of a conditional fee (i.e., no-win-no-fee) agreement.

[88] Legal Aid, Sentencing and Punishment of Offenders Act 2012, Sch 1, Pt 2, cl 1.
[89] Ibid, s 152(1).