COVID-19 VACCINE INJURIES

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3 Covid-19 Vaccines Primarily used in Europe

- Pfizer/BioNTech Vaccine
- AstraZeneca
- Moderna

Vaccination Levels in UK / Europe up to 2024

- Over 50 million doses of Pfizer/BioNTech
- Over 15 million doses of AstraZeneca – withdrawn from EU in March 2024
- Over 950 million doses in Europe up to 2024

General Adverse Side Effects of all Covid-19 vaccines-No Cause of Action

- Injection site reactions (sore arms)
- Flu like illnesses
- Headaches
- Chills
- Fatigue
- Nausea
- Rapid Heart Beat

- Reflect normal immune response triggered by the body to the vaccines
- Usually resolved within a few days

Severe allergic reactions

- Anaphylaxis;
- Moderna vaccine – reports of anaphylaxis in UK very rare- 0.5 yellow cards per 1,000 doses
- Potential side effect of the vaccine
- Those with known hypersensitivity to the ingredients in the vaccine should not receive it
- AstraZeneca vaccine – 868 anaphylaxis reactions reported

Facial Nerve Palsy (Bells Palsy)

- Possible adverse effect of the Pfizer/BioNTech vaccine
- Bells Palsy can be caused by viral infections, traumatic injury, cancers or hormonal changes during pregnancy
- Isolated facial paralysis after vaccination has been reported for decades with almost all viral vaccines
- Thought to be immune mediated or induced by viral reactivations
- EudraVigilance data (EU) indicates a much higher frequency of facial paralysis after Pfizer/BioNTech vaccine than the AstraZeneca vaccine
- Risk of developing Bells Palsy could be 2-3 times higher in individuals receiving MRNA vaccines than those in receiving traditional vaccines
- This should be considered when selecting a vaccine for patients with a history of Bells Palsy

Other neurological injuries

- Transverse Myelitis
- GBS
- CIDP
- Myocarditis

What is Myocarditis and Pericarditis?

- Inflammation of the heart muscle

- MHRA Yellow Cards;
- 1,200 of Myocarditis and Pericarditis following Pfizer/BioNTech vaccine up to 2022

- AstraZeneca – over 221 reports of Myocarditis up to 2022
- 216 reports of Pericarditis

Guillain Barre Syndrome (GBS)

A rare condition – causes inflammation on the nerves

- Can lead to numbness, weakness and pain
- Usually occurs in the feet, hands and limbs
- Can spread to the chest and face
- Also associated with Covid-19 infection
- Pericarditis is inflammation of the pericardium
- Miller/Fisher Syndrome / variation of GBS

How are cases pursued?

- All records must be obtained
- Check the consent process for known risks
- Choose expert carefully
- May need a selection of experts
- Check when symptoms first started
- Rule out any pre-existing condition
- Vaccination should be 6 months after Covid infection

The Law

- Liability for Defective Products
- Directive A5/374/EEC
- EU wide no fault liability regime for defective products
- Most product liability claims in the EU rely on this Directive
- Medical Negligence – lack of informed consent and breach of duty
- State Vaccine Compensation Schemes – first call.

Product Liability Directive

- Product Liability Directive does not exclude national laws to provide for product liability by other causes of action
- Must not be inconsistent with the operation of the product liability directive
- Directive expressly leaves several matters to the National Law of member states –
- Implementation of the development risk Defence
- Introduction of a ceiling for damages resulting in death or personal injury by identical products
- Recovery of non-material damages

How do you establish liability under the Directive?

- To establish liability, the injured person must prove the defect, the damage and the causal link between the two
- A producer is liable for damages caused by a defect in the product
- A product is considered defective when it does not provide the level of safety that a person is entitled to expect taking all the circumstances into account including;
- The presentation of the product
- The use to which it can reasonably be expected that the product will be put
- The time the product was put into circulation. A product is not defective for the sole reason that a better product is subsequently put into circulation

- Article 4 – Claimant must establish the cause and link between the defect and the damage

Burden of Proof can differ across EU Member States

- **N.W. L.W en C.W v Sanofi' Pasteur MSD SNC 2017 ECJ**
- Each Member State can determine the most just evidentiary rules
- Provided this does not result in the Burden of Proof set out in Article 4 of the Product Liability Directive being disregarded
- The effectiveness of the System of Liability introduced by the Product Liability Directive cannot be undermined
- Defect of a Vaccine and it's causal link can be demonstrated by serious, specific and consistent evidence in the absence of scientific consensus about a causal relationship

What are the Defences to a product liability claim?

A producer is not liable under the Product Liability Directive if they can prove any of the following;

- They did not put the product into circulation
- It is probable that the defect that caused the damage did not exist at the time when they put the product into circulation or that the defect came into being after;
- They did not manufacture the product for sale or distribute the product in the course of their business
- The State of Scientific and Technical Knowledge, at the time when they put the product in circulation was not such as to enable the discovery of a defect (development risks defence)
- In the case of a manufacture of a component, the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacture of the product

Conclusions

Developing Litigation

- Expert driven
- Stick to core principles
- Can be product or medical negligence claims
- Always check pre-existing medical history for auto immune disorders
- State Vaccine Compensation Schemes

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