Gníomhaireacht Bainistíochta an Chisteáin Náisiúnta
National Treasury Management Agency

An Ghníomhaireacht Stáit um Éilimh
State Claims Agency

Use of Unauthorised (Exempt) and Authorised Medicines Prescribed for an Unauthorised Indication (off-Label)

The Clinical Indemnity Scheme (CIS) was established in July 2002 and is managed by the State Claims Agency. Under the scheme, the State assumes full responsibility for the indemnification and management of all clinical negligence claims against enterprises and practitioners covered by the scheme. For more information on which enterprises are covered by the scheme, please go to www.stateclaims.ie.

The Clinical Indemnity Scheme (CIS) provides indemnity to hospitals/enterprises and, vicariously, practitioners in respect of a suit for personal injuries brought by a person alleging negligence, statutory or at common law, in respect of the provision of, or failure to provide, professional medical services.

CIS cover applies equally to the prescription/use of authorised or unauthorised (exempt) medicinal products (including the use of authorised medicinal products prescribed for an unauthorised indication) providing the latter are used with the express knowledge and consent of the enterprise's management.

It is a policy issue for the hospital/enterprise, and any regulatory body, to decide whether or not to use unauthorised (exempt) medicines and / or authorised medicines prescribed for an unauthorised indication. The CIS does not lay down any guidelines in relation to this.

More information on access to medicines prior to authorisation and a guidance note on Exempt Medicinal Products may be obtained from the Health Products Regulatory Authority at the following link: http://www.hpra.ie/homepage/medicines/regulatory-information/medicines-authorisation/access-to-medicines-prior-to-authorisation

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