



Clinical Indemnity Scheme



State Claims Agency

### **Unlicensed and Off License Use of Licensed Medicinal Products**

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](http://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 licensed and unlicensed medicinal products (including the off-license use of licensed medicinal products) providing the latter is 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 sanction the use of unlicensed medicines (including the off-license use of licensed medicinal products) The CIS does not lay down any guidelines in relation to this.

The CIS does not provide representation for clinical staff in relation to fitness to practice issues. In this regard, the State Claims Agency advises clinical staff to purchase additional benefits cover, specifying cover in respect of criminal and fitness to practice matters from a relevant defence organisation.

For any queries on this matter please contact [info@stateclaims.ie](mailto:info@stateclaims.ie)

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