

- categories of over-the-counter (OTC) pharmaceuticals
- advertising

➤ Discuss the regulation of wholesalers and pharmacies. Please consider:

- entry requirements for new pharmacies
- generic substitution
- mail-order/Internet pharmacies
- regulation of counterfeit drugs
- any clawback systems

➤ Discuss policies to improve cost-effective use of pharmaceuticals. Please consider:

- measures aimed at influencing physician prescribing behaviour
- measures aimed at influencing pharmacists
- measures aimed at informing patients
- how these policies are monitored and any penalties applied (in theory and practice) by regulatory bodies (e.g. fines)

➤ Describe the system for pricing prescription pharmaceuticals. Please consider:

- profit-control scheme, reference pricing scheme or direct price controls
- composition of prices of medicines, i.e. ex-factory/manufacturer price, wholesaler (profit) margin, pharmacy margin (or profit) and any taxes
- regulation of OTC products

e.g. general sales list, pharmacy supervised

Generic substitution is the substitution of a product, whether marketed under a trade name or generic name, by an equivalent product that contains the same active ingredients and is usually cheaper.

Clawback is a process by which the relevant authority can recoup some of the profits made by pharmacies on their dispensing margins.

e.g. information, prescribing by active ingredient, prescribing budgets, prescribing guidelines, prescribing feedback

e.g. substitution by pharmacists, dispensing budgets, margins that encourage generic dispensing

Cross-reference to Chapter 3 *Financing*.