

Unit 4: Regulatory Aspects of QUM in India

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4.1 Regulation as a QUM building block

Regulation is the legal machinery that sets the floor under quality use: which medicines may be sold at all, of what quality, by whom, to whom, on whose authority, with what information and what promotion. It cannot by itself create excellent prescribing, which is why Units 1 to 3 are about practice, but its absence reliably permits the worst use: unregistered and substandard products, unrestricted sale of medicines that need supervision, misleading promotion and no accountable professional at the point of supply. The Indian framework is taught here at the level the syllabus sets, the areas of regulation and their QUM purpose, naming governing instruments only in their standard textbook form. Specific schedule contents, licensing conditions and penalties are set by the current law and rules and are checked there, not memorised from notes.

4.2 Regulation including scheduling

The core statute is the Drugs and Cosmetics Act and its Rules, under which medicines are licensed for manufacture, import, sale and distribution, quality is policed through standards, sampling and laboratories, and misbranded, adulterated and spurious medicines are offences. Scheduling is the Rules' device for grading control to risk: medicines are placed in schedules that prescribe the conditions of their sale and supply, prominently including schedules whose medicines may be supplied only on the prescription of a registered medical practitioner, schedules adding record keeping and warning requirements for medicines with dependence or misuse potential, and provisions governing labels, warnings and the particulars a lawful supply must carry. The QUM logic of scheduling is proportionality: the greater the risk in unsupervised use, the tighter the gate, prescription only supply, records, warnings, restricted advertising, and the pharmacist at the counter is where the schedule becomes real, by insisting on the prescription the law requires and keeping the records it prescribes. The central and state division of labour, central authority over standards, imports and new medicines, state authorities over much manufacture and sale licensing and inspection, explains why enforcement experience varies and why professional standards must not.

Regulatory area	What it controls	QUM purpose
Licensing and quality control	Manufacture, import, sale, standards and testing	Only quality assured medicines enter use
Scheduling	Conditions of sale, prescription only status, records and warnings	Supervision graded to the risk of unsupervised use
Complementary medicines regulation	Licensing, quality and claims of traditional and complementary products	The same honesty and safety floor for every product used as a medicine
OTC regulation	Which medicines may be self selected, labelling and advertising	Safe self care inside stated limits
Professional regulation	Registration, conduct and accountability of the pharmacist	An accountable professional at the point of supply

4.3 Regulation of complementary medicines

Complementary medicines in India span the recognised traditional systems, principally Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy, together with a wide market of supplements and herbal products, and they are regulated through their own statutory channels: the traditional systems under the ministry and regulatory structures for those systems, with their own pharmacopoeias, licensing and good manufacturing requirements, and homoeopathy under its own council and pharmacopoeial tradition, beside the Drugs and Cosmetics framework where its provisions apply. The QUM questions are the same as for any medicine, and regulation exists to make them answerable: is the product what its label claims, made to a quality standard, free of undeclared potent ingredients and contamination, labelled with honest claims that do not promise cure where evidence does not, and used with its interactions and limits in view. The pharmacist's duty at the counter is integration in the Unit 3 sense: ask, record, screen for interaction and duplication, and never treat a product as harmless merely because it is traditional or natural.

4.4 Regulation of OTC medicines

Over the counter medicines are those the regulatory system permits a person to obtain without a prescription, for self recognised, minor and self limiting conditions, inside the limits their labelling states. India has historically operated this area principally by exclusion, medicines not placed in prescription only schedules being in practice available without prescription, with labelling, advertising and pharmacy sale provisions supplying the safeguards, rather than through a single published OTC list of the kind some other systems maintain; the student should present that position carefully, as a framework description, and check the current rules and any current list or amendment at the time of practice, because this is an actively reformed area. The QUM stakes are high because self medication is the largest volume of medicine use there is. Its benefits are real, timely treatment of minor illness, professional time saved, patient autonomy, and its risks are the syllabus risks of rational use in the home: masking a serious condition, wrong product for the condition, duplication of an ingredient across products, unsafe use in pregnancy, childhood and chronic disease, and interaction with prescribed therapy. The pharmacist is the safety net of the OTC system: structured questioning about the symptom, the person and their other medicines, advice with clear limits and referral triggers, and refusal to supply where supply would be unsafe are professional acts, not retail courtesies.

4.5 Professional responsibility of the pharmacist

Professional responsibility is where regulation becomes personal. The pharmacist in India practises under registration with the pharmacy council system established by the Pharmacy Act, is bound by the pharmacy practice regulations and the professional code they express, and answers, professionally and in law, for the medicines supplied under their supervision. In QUM terms the responsibilities are concrete: to supply only quality, lawfully sourced medicines and store them properly; to dispense against a valid prescription where one is required and never to treat that requirement as optional; to check prescriptions and intervene on error and irrationality, because silent supply of a prescription known to be wrong is a professional failure, not neutrality; to counsel patients and protect their confidentiality; to keep the records the law and good practice require; to refuse participation in misleading promotion or sale driven practice; and to keep competence current through continuing learning. Responsibility also runs upward: reporting quality defects and adverse reactions through the systems of Unit 5 is a professional duty, and a pharmacist who sees a system producing errors owes the service the report and the improvement proposal, not only private concern.

4.6 Role of industry in QUM in medicine development

Industry enters QUM first as the developer and manufacturer of the medicines themselves, and its development duties are quality duties: evidence generated honestly across the trial programme of the sister

subject MPP104T, a product dossier that states benefit and risk as the data show them, manufacture to good manufacturing practice so that the medicine supplied is the medicine studied, labelling and product information that state indications, warnings and use accurately, and post marketing safety work, collecting, evaluating and reporting adverse reactions and acting on signals with the regulator. A medicine developed and labelled well arrives in practice with quality built in; a medicine oversold at launch, with marginal benefit presented as breakthrough and risks minimised, loads the prescriber and pharmacist with repair work for its whole life. Industry is therefore a named QUM partner in Unit 1 and a regulated actor in Unit 4 at once, and both framings are true.

4.7 Industry, information and promotion: the QUM boundary

The second industry interface is promotion: representatives, sponsored education, advertising where permitted, samples and digital marketing, all of which demonstrably shape prescribing and none of which is independent education, however useful individual items may be. The regulatory and ethical boundary, expressed in India through drug advertising controls, prescription medicine promotion restrictions and the industry's uniform code for pharmaceutical marketing practices in its current form, together with institutional and professional codes, draws a consistent line: promotion must be accurate, balanced and consistent with the approved product information; prescription medicines are promoted to professionals, not advertised to the public; inducements that purchase prescribing are prohibited in principle; and hospitality and sponsorship carry disclosure and restraint obligations. The pharmacist's and prescriber's QUM defence is critical appraisal applied to commercial information with the same rigour as to a paper: what is the comparator, what outcome, in which patients, and what does the independent source say. A service that teaches that defence has done more for prescribing quality than one that merely complains about promotion.

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