PCoC 20 (§§ 1-2)

# PROFESSIONAL CODE OF CONDUCT of the Pharmaceutical Society of Hesse, Public Corporation

resolved by the Delegates Assembly of the Pharmaceutical Society of Hesse (*Landesapothekerkammer Hessen*) on 4 March 2020, approved by decree of the Hessian Ministry for Social Affairs and Integration (*Hessisches Ministerium für Soziales und Integration*) on 30 April 2020, published in *Pharmazeutische Zeitung* (PZ) no. 20/2020, p. 72 and in *Deutsche Apotheker Zeitung* (DAZ) no. 20/2020, p. 81.

#### **Preamble**

Pharmacists are members of a liberal profession and serve the public good through their work. They attend to the health of the individual and hence to that of society as a whole. This Code sets out the fundamental principles of professional practice and conduct by pharmacists in their dealings with third parties and colleagues. Its aim is to prevent conduct that would be unbecoming of a member of this profession.

#### § 1 Professional practice

- (1) A pharmacist's mission is to ensure the orderly supply of pharmaceuticals to the public. In particular, that mission entails providing information and advice on pharmaceuticals, advising on all manner of health-related issues, developing, manufacturing, testing, storing and dispensing pharmaceuticals, as well as assessing their risks, and researching new substances and methods of delivery. There are many ways in which pharmacists can exercise their profession. They can work at public pharmacies, in industrial settings, at hospitals and research institutions, in the military (*Bundeswehr*), for the authorities or for corporations, at universities, teaching institutions and vocational schools.
- (2) Pharmacists have a duty to exercise their profession with due and proper care and to preserve the trust placed in them by virtue of their profession. They must conduct themselves in a manner befitting that trust.
- (3) Pharmacists have a duty to provide advice on the basis of their education and expertise. They are obligated to provide patients and practitioners with independent advice and information about pharmaceuticals. They have a more elevated duty to provide information and advice to patients seeking pharmaceuticals for the purpose of self-medication, or if the patients are children or adolescents.
- **(4)** Pharmacists have a duty of collegiality towards other members of their profession. Pharmacists must preserve the interests and the reputation of their place of business and their profession.
- (5) The exercise of medicine by a pharmacist constitutes a breach of professional duty unless doing so is permitted or mandated by law. Communicating objective readings or reference values and recommending a doctor's visit do not constitute the exercise of medicine.
- **(6)** Pharmacists are obligated to acquaint themselves and their employees with the applicable laws and regulations of pertinence to the exercise of their profession, as well as to abide by them and make them available for reference in the pharmacy. This includes in particular the Regulation Governing the Operation of Pharmacies (*Apothekenbetriebsordnung*), pharmaceuticals and narcotics law, the Regulation Governing Drug Pricing (*Arzneimittelpreisverordnung*), the Articles of Incorporation of the Pharmaceutical Society of Hesse, the Articles of Incorporation of the pension fund and any orders and guidelines issued on the basis thereof.
- (7) Because they exercise a liberal profession, pharmacists are subject not only to the statutory provisions, but also to this Professional Code of Conduct and fall under the special jurisdiction of the healing professions. Violations of this Professional Code of Conduct may be subject to disciplinary action for professional misconduct.

## § 2 Confidentiality and data protection

- (1) Pharmacists have a duty to keep confidential any and all information they become aware of in exercising their profession. They must also enter into confidentiality agreements with all of their employees, even if they are not governed by the terms of this Professional Code of Conduct.
- (2) Pharmacists must ensure compliance with the applicable provisions of data protection law. To the extent not permitted or compelled by statute or other regulations, the collection, processing and use of personal data requires the prior written consent of the data subject.

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(3) In the event that pharmacy operations are discontinued or handed over to a successor, it must be ensured that data cannot be improperly processed or used. Any further processing or use of personal data must also be effected in compliance with the applicable provisions of data protection law.

(4) It must be ensured that the statutory retention periods are complied with in relation to transactions subject to a duty of documentation.

#### § 3 Collaboration with third parties

- (1) In exercising their profession, pharmacists are obligated to work together with persons and institutions operating within the healthcare system. They are not permitted to enter into agreements, arrangements or implied contracts which concern or could result in the preferential supply of certain pharmaceuticals, the referral of patients, the assignment of prescriptions or the dispensing of pharmaceuticals without full disclosure of their composition.
- **(2)** Furthermore, pharmacists are forbidden from offering advice, support, organisational assistance or inducements resulting in the restriction or elimination of freedom of choice with respect to pharmacies by persons and institutions operating within the health care system, by carers for the elderly or by social services providers.

#### § 4 Dispensing prescriptions

Pharmacists have a duty to dispense medical, dental and veterinary prescriptions within a period of time that is appropriate for the prescription. Should it not be possible to dispense the prescription within an appropriate period of time, pharmacists must notify the patients of this fact without undue delay and offer them the necessary assistance in procuring the pharmaceuticals. This applies also to the compounding of drugs in the pharmacy.

#### § 5 Standby duty

- (1) In accordance with the statutory provisions and by the order of the Pharmaceutical Society of Hesse, pharmacists are required to participate in the pharmacy emergency service. This includes duly notifying the other pharmacies on the standby duty roster for the local area of any changes in hours of availability and duly posting information on the pharmacies participating in the emergency service.
- (2) Pharmacists must ensure that their pharmacies are prepared to meet the special requirements for supplying pharmaceuticals during emergency service.
- (3) If it is not possible to dispense a prescription during emergency service, pharmacists must provide patients with the necessary assistance in obtaining their pharmaceuticals within an appropriate period of time. Specifically, they must call the nearest pharmacy operating on standby to enquire about the availability of the prescribed medication, or if the prescription was issued by the emergency medical service, consult with the emergency medical service to ascertain whether a substitution would be appropriate in accordance with section 17 (5) of the Regulation Governing the Operation of Pharmacies (*Apothekenbetriebsordnung*).
- (4) Any exemption from standby duty, including as the result of swapping with another pharmacy, requires the prior consent of the Pharmaceutical Society of Hesse, which may be obtained by submitting a written request stating the grounds for exemption. The request must be received in advance in due time.

## § 6 Social responsibility

- (1) When training their employees, pharmacists must comply with the regulations existing with respect to professional training.
- (2) Upon terminating their employment relationship, pharmacy operators must document in writing the material terms of their contracts in accordance with the provisions of the German Act on the Disclosure of Employment Conditions (*Nachweisgesetz*).
- (3) Upon entering into an agreement governing training as a pharmaceutical/commercial assistant, the pharmacy operator must without undue delay, and no later than prior to commencing their professional training, document in writing the material terms of their contracts in accordance with the provisions of the German Vocational Training Act (*Berufsbildungsgesetz*). Training contracts must be submitted to the Pharmaceutical Society of Hesse without undue delay upon entry into the agreement for entry into the register of training contracts.

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(4) To the extent they are capable of doing so from a personal and operational standpoint, pharmacists should be involved in the training and continuing education of their staff.

(5) Pharmacists should exercise the necessary due diligence in issuing work references and expert opinions, including references for employees in training.

#### § 7 Quality assurance

- (1) Pharmacists have a duty to implement and comply with quality assurance measures and to demonstrate such implementation and compliance at the Pharmaceutical Society's request. These measures must adequately ensure that the quality of their professional training and workplace meets the state of the scientific and technological art. They include cooperation with external quality assurance measures, such as round robin tests and test purchases in particular. This has no bearing on voluntary participation in the official certification processes of the Pharmaceutical Society of Hesse.
- (2) Pharmacists may not make unauthorised use of the quality certificate issued by the Pharmaceutical Society of Hesse in the context of creating a quality management system.
- (3) Pharmacists must ensure that their pharmacy is staffed at all times by sufficiently qualified personnel. They must appoint a branch pharmacy manager for the branch pharmacies and notify the Pharmaceutical Society of Hesse of such appointment. The pharmacy operator must comply with the applicable statutory provisions when employing staff. The pharmacy operator and the pharmacy manager must exercise due care in staffing the branch pharmacies.
- **(4)** Pharmacists have a duty to continue their professional training and to keep abreast of the regulations applicable to their profession.

#### § 8 Drug risks

Pharmacists have a duty of cooperation with respect to ascertaining, identifying and recording drug risks. They must report without undue delay their findings or observations to the competent authority, the Regional Council in Darmstadt. Due to the particular urgency of the matter, notification should be submitted by fax, e-mail or telephone. Furthermore, pharmacists must notify the Medicines Committee (*Arzneimittelkommissionen der deutschen Apotheker*) without undue delay.

#### § 9 Manufacturing of pharmaceuticals

- (1) When manufacturing pharmaceuticals, pharmacists have a particular duty to ensure that the pharmaceuticals are properly manufactured, stored and labelled.
- (2) Pharmacists responsible for quality control have a particular duty to monitor and manage the testing of pharmaceuticals.
- (3) Pharmacists employed as knowledgeable experts are responsible for ensuring that each batch of pharmaceuticals is manufactured, tested and approved for release in accordance with the regulations on the marketing of pharmaceuticals.

## §10 Liability protection

Pharmacists must ensure that they and their employees are adequately protected against liability claims arising in the course of their professional activity. Evidence of liability protection must be submitted to the Pharmaceutical Society of Hesse upon request.

### § 11 Competition and advertising

(1) All conduct in connection with competition and advertising must be compatible with the special nature of the profession and must not harm the integrity of pharmacists or the trust placed in them as members of the health care profession.

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Advertising and competition must not give the impression that pharmacists place their own financial interests above their public duty to ensure the orderly supply of pharmaceuticals to the public.

- (2) Advertising and competition must not cause or favour additional or improper consumption of pharmaceuticals.
- (3) Regardless of the foregoing, pharmacists must refrain from any advertising or competitive actions that contravene statutory provisions or other provisions of law concerning pharmacists, specifically the German Act on Unfair Competition (Gesetz über den unlauteren Wettbewerb) or the German Medical Products Advertising Act (Heilmittelwerbegesetz).

Specifically, the following competitive activities are prohibited:

- 1. falsely implying a preferential or special status on the part of one's own pharmacy, one's own person or pharmacy staff; in particular through misleading naming, references or use of designations and qualifications;
- collecting prescriptions from persons authorised to practice medicine, dentistry or veterinary medicine, and dispensing in contravention of the provisions of the German Pharmacy Act (*Apothekengesetz*) and the Regulation Governing the Operation of Pharmacies (*Apothekenbetriebsordnung*), as well as advertising such;
- 3. dispensing pharmaceuticals free of charge;
- 4. offering and providing services not falling under the remit of care, which are not related to products commonly associated with pharmacies or which are not based on pharmacy training;
- 5. giving inappropriate inducements and gifts, particularly to customers, members of other health care or paramedical professions, payers, convalescent homes, homes for the elderly, hospitals and similar institutions as well as their managers and employees, which may impair the patient's freedom of choice;
- 6. demanding, being promised and accepting gifts or other benefits for oneself or third parties, if this can influence pharmacists' independence;
- 7. providing exhibition space in pharmacies, including shop windows, showcases, shelves, etc. in return for payment, products or other services;
- 8. waiving, in whole or in part, payment of statutory co-pays or additional costs for insured persons, or indicating such:
- 9. deviating from the pharmacy dispensing prices indicated in the Regulation Governing Drug Pricing (*Arzneimittelpreisverordnung*) and advertising such;
- 10. entering into agreements and arrangements and implementing measures having the purpose or the effect of excluding other pharmacies from the supply or dispensing of pharmaceuticals, in whole or in part.

#### § 12 Free movement of services within the EU

This Professional Code of Conduct shall also apply to pharmacists who are nationals of a member state of the EU if they only temporarily provide free cross-border services within the scope of this Professional Code of Conduct, but remain resident in an EU state.

#### § 13 Entry into force

This Professional Code of Conduct shall enter into force on the day after its promulgation.

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