Draft bill

of the Federal Ministry of Health

Ordinance amending the Regulations on the Operation of Pharmacies and other regulations

A. Problem and objective

Pharmacies are a key pillar in the supply of medicines and an important, low-threshold point of contact for citizens regarding health issues. However, smaller and rural pharmacies in particular face challenges due to a shortage of skilled staff, structural change and declining profitability. In addition to legislative amendments, the reform of pharmacy law requires supplementary amendments to ordinances in order to achieve the overall reform objective of creating long-term, viable and economic framework conditions for pharmacies in order to maintain a comprehensive pharmacy network for local supply of medicinal products. The amendments to the regulations are intended to reduce bureaucracy, strengthen the personal responsibility of pharmacy owners and adjust pharmacy remuneration. At the same time, pharmacies need better opportunities to recruit skilled workers and must be able to deploy them more flexibly than before.

B. Solution

In order to maintain a comprehensive network of pharmacies, including in rural areas, framework conditions are required that enable pharmacies to operate more economically. To this end, the personal responsibility of pharmacy owners will be strengthened, bureaucracy reduced and pharmacy operations made more flexible. Changes are also being made to the remuneration of pharmacies.

C. Alternatives

None.

D. Budgetary expenditure without compliance expenditure

Federal government

No additional expenditure is justified for the federal government.

State government

No additional expenditure is justified for the state government.

Municipalities

No additional expenditure is justified for municipalities.

Statutory health insurance

For statutory health insurance, additional expenditure will arise due to the extension of the supply bottleneck surcharge for pharmacies to include cases where unavailable medicines are replaced with those listed in accordance with § 129(2b) sentence 1 of Book V of the Social Code. Since the number and scope of such supply bottlenecks and the perception of the simplified exchange by pharmacies cannot be estimated, the additional expenditure cannot be quantified. On the basis of the current number of reported supply bottlenecks for medicinal products included on the list drawn up in accordance with § 129(2b), first sentence, of Book V of the Social Code, additional expenditure in the low single-digit millions is expected.

E. Compliance expenditure

E.1 Compliance expenditure for citizens

For citizens, this ordinance creates an additional annual compliance cost of EUR 340 820 .

E.2 Compliance expenditure for businesses

For the economy as a whole, an annual compliance cost of -124,60 million euros and a one-off settlement cost of -684 000 euros could be incurred.

Otherwise, there will be no additional compliance costs for businesses.

This includes bureaucratic costs arising from information obligations.

Due to the documentation of the data provided by the transport service provider, the elimination of the obligation to adapt standardised and general preparation instructions from third parties to the relevant pharmacy operation, and the possibility to document batch numbers of imported medicines differently on wards, pharmacies will achieve relief of approximately -43,62 million euros per year in bureaucracy costs.

E.3 Compliance expenditure for government administrations

There are no compliance costs for the administration in federal government or state government. Remuneration negotiations result in additional, minor compliance costs for the federal government at regular intervals.

F. Additional costs

No impact is expected on individual prices or price levels, in particular consumer price levels.

Draft legislation of the Federal Ministry of Health

Ordinance amending the Regulations on the Operation of Pharmacies and other ordinances[1]

of ...

The Federal Ministry of Health decrees as follows by virtue of

– § 21(1) first sentence, (2) first sentence points 1, 1a, 1b, 2 and 4 to 8 of the Pharmacy Act as promulgated on 15 October 1980 (Federal Law Gazette I, p. 1993), as last amended by Article 2 of the Law of... [insert: Date and reference of the Further Development of Pharmacy Supply Act],

– of § 56(1)(1) of the Law on pharmaceutical technicians [PTA-Berufgesetz] of 13 January 2020 (Federal Law Gazette I, p. 66), as last amended by Article 4 of the Law of... [insert: Date and reference of the Further Development of Pharmacy Supply Act] in conjunction with § 1(1) of the Competences Amendment Act of 16 August 2002 (Federal Law Gazette I, p. 3165), as last amended by Article 7 of the Ordinance of 31 August 2015 (Federal Law Gazette I p. 1474) and the Organisational Order of 6 May 2025 (BGBl. 2025 I No. 131) in consultation with the Federal Ministry of Education, Family, Senior Citizens, Women and Youth and

– of the first sentence of § 54(1) and § 54(2)(1), (2), (6) and (7) of the Arzneimittelgesetz [Law on medicinal products], as promulgated on 12 December 2005 (Federal Law Gazette I, p. 3394), as last amended by Article 6 of the Law of... [insert: Date and reference of the Further Development of Pharmacy Supply Act], in agreement with the Federal Ministry for Economic Affairs and Energy and

the Federal Ministry for Economic Affairs and Energy decrees as follows, pursuant to § 78(1), first sentence, of the Law on medicinal products, as promulgated on 12 December 2005 (Federal Law Gazette I, p. 3394), as last amended by Article 6 of the Law of... [insert: Date and reference of the Further Development of Pharmacy Supply Act], in agreement with the Federal Ministry for health:

Artikel 1

Amendment to the Regulations on the Operation of Pharmacies

The Regulations on the Operation of Pharmacies, as promulgated on 26 September 1995 (Federal Law Gazette I, p. 1195), as last amended by Article 3 of the Law of... [insert: Date and reference of the Further Development of Pharmacy Supply Act], is amended as follows:

1. § 2 is amended as follows:

   a) The third sentence of paragraph 2 is replaced by the following sentences:

   ‘In addition to a responsible person appointed in accordance with § 2(5) sentence 1 point 2 or 3 of the Pharmacy Act, the operator is also responsible for compli-

[1] Notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17/9/2015, p. 1).

ance with the regulations applicable to the operation of pharmacies. The operator shall regularly personally satisfy himself that the designated responsible person fulfils his responsibility.'

b) Paragraph 5(2) is replaced by the following sentence:

'Except in the case of mutual representation of responsible persons who are designated for the same secondary pharmacy or subsidiary pharmacy in accordance with § 2(5) sentence 1 number 2 or 3 of the Pharmacy Act, representation may not exceed a total of three months per year.'

2. After § 2a paragraph 3, the following paragraph 4 is inserted:

(1) 'Where a pharmacy is managed by a responsible person designated pursuant to point 2 or 3 of the first sentence of § 2(5) of the Pharmacy Act, the quality management system shall be coordinated with the operator.'

3. § 3 is amended as follows:

a) The following sentences are inserted after paragraph 5, sentence 4:

'Pharmacists and pharmaceutical technicians who have obtained their professional qualification abroad and have applied for recognition may, until the recognition procedure has been completed, be employed in the same way as persons who are in training for the profession in question. The pharmaceutical activities of these persons shall be supervised by the pharmacy manager or by a pharmacist appointed by the pharmacy manager.'

b) Paragraph 5a sentence 1 is replaced by the following sentence:

'The transfer, including filling and packaging or labelling, of medicinal products may also be carried out, under the supervision of a pharmacist, by pharmacy assistants, pharmacy technicians, pharmacy retail employees, persons training to be pharmacy retail employees or by other non-pharmaceutical staff of the pharmacy with appropriate training and appropriate knowledge.'

4. § 4 is amended as follows:

a) After the fifth sentence of paragraph 2, the following sentence is inserted:

'Notwithstanding sentence 1, a pharmacy does not need to have a laboratory if the identification of medicinal products and starting materials pursuant to § 6(3a) sentence 1 and § 11(1) sentence 2 in conjunction with § 6(3a) sentence 1 is carried out by another pharmacy operated by the same operator.'

b) Paragraph 3 is replaced by the following Paragraph 3:

(1) 'A secondary pharmacy must have at least one dispensary and sufficient storage space. The first and third sentences of paragraph 2 do not apply. Additional rooms shall be provided in so far as individual and bulk formulations are prepared in the secondary pharmacy or other activities are carried out which require the presence of these rooms. Paragraphs 2b, 2c and 7 shall not apply if the secondary pharmacy does not prepare individual or bulk formulations of medicines itself but obtains them from another pharmacy operated by the same operator.'

c) Paragraph 4 sentence 1 point 1 is replaced by the following point 1:

1. ‘Storage spaces used exclusively for:

a) Storage of stocks exceeding the regular daily needs of the pharmacy,

b) supplying hospitals on the basis of a contract pursuant to § 14(3) or (4) of the Pharmacy Act; or

c) Provision of care to residents of residential institutions on the basis of a contract pursuant to the first sentence of § 12a(1) of the Pharmacy Act,’.

d) Paragraph 7 is replaced by the following Paragraph 7:

(1) ‘The pharmacy must be fitted with equipment in such a way that medicinal products can be properly prepared in the dosage forms normally prescribed. The preparation of sterile medicinal products shall be possible except for medicinal products for parenteral use. Where there is no device for producing water for injections, water for injection as a finished medicinal product must be kept in stock in sufficient quantities.’

5. § 5 is deleted.

6. § 6 is amended as follows:

a) Paragraph 3 sentence 1 point 3 is replaced by the following point 3:

1. ‘in a pharmacy operated by the same operator, or’.

b) After paragraph 3, the following paragraph 3a is inserted:

‘(3a) A pharmacy may carry out the identification of medicinal products for another pharmacy operated by the same operator. In this case, the pharmacy dispensing the medicinal product is exempt from the identity verification requirement set out in the first half of the fourth sentence of paragraph 3. It may only use or supply the medicinal product if:

1. the container of the medicinal product bears a mark indicating that identification has been carried out;

2. the container was sealed by the pharmacy which made the finding in such a way as to show if the container has been opened in the meantime; and

3. neither the container nor the seal are damaged.’

7. § 7(1a) sentence 3 is deleted.

8. § 11(1) sentence 2 is replaced by the following sentence:

‘§ 6(1), (3) and (3a) shall apply mutatis mutandis to the testing of starting materials.’

9. § 17 is amended as follows:

a) Paragraph 2 is replaced by the following Paragraph 2:

‘The delivery of medicines by pharmacy couriers is permitted without authorisation under § 11a of the Pharmacy Act. When delivered by pharmacy couriers, medicines must be packaged separately for each recipient and labelled with their

name and address. Paragraph 2a sentence 1 points 1, 2 and 8 and sentence 2 shall apply mutatis mutandis. In the case of delivery of medicinal products by pharmacy couriers, the pharmacy owner must ensure that the medicinal products are delivered to the recipient in a reliable manner and that the temperature requirements applicable to the medicinal product are met during delivery until delivery to the recipient. Delivery must be made by pharmaceutical staff of the pharmacy if, prior to delivery:

1. in the case of medicinal products subject to the prescription requirement under § 48 of the Medicinal Products Act or § 3(1) of the Medicinal Cannabis Act, the prescription was not available in the pharmacy, or

2. no advice was given on the use of the medicinal products.

If the prescription was not available in the pharmacy before delivery, it must be handed over at the latest at the time of delivery of the medicinal products. If no consultation took place prior to dispensing, this must be carried out when the medicinal product is dispensed. Advice can also be provided by means of telecommunication by the pharmacy. § 4(1) of the Drug Prescription Ordinance remains unaffected.'

b) Paragraph 2a sentence 1 point 1 is replaced by the following point 1:

'1. the medicinal product is packaged, transported and delivered in such a way that its quality and efficacy are preserved and the requirements of § 35b(1) to (3) are complied with, and that the contracted logistics company fulfils its obligations towards the pharmacy as agreed in the contract pursuant to § 35b(4);'.

c) After paragraph 4, the following paragraph 4a is inserted:

'(4a) A secondary pharmacy may purchase individual and bulk preparations of medicines from another pharmacy operated by the same operator instead of preparing them itself. Notwithstanding paragraph 4, the other pharmacy shall immediately prepare the prescribed medicinal products and deliver them to the secondary pharmacy or to the patient via the courier service of the secondary pharmacy or the preparing pharmacy.'

d) Paragraph 5a is replaced by the following Paragraph 5a:

'(5a) By way of derogation from the first sentence of paragraph 5, the pharmacist may, during the following periods, dispense another medicinal product identical to the prescribed medicinal product in terms of area of use and of the type and quantity of active ingredients, and comparable in pharmaceutical form and quality, if the prescribed medicinal product is not available and there is an urgent case requiring immediate use of the medicinal product:

1. Monday to Saturday from 00:00 to 08:00;

2. Monday to Friday from 6:30 p.m. to midnight,

3. Saturdays from 2 p.m. to midnight,

4. Sundays and public holidays from 0:00 a.m. to midnight; and

5. on 24 and 31 December from 2 p.m. to midnight.'

e) Paragraph 6c sentence 2 point 2 is replaced by the following point 2:

1. ‘ obtained from pharmacies operated by the same operator,’.

10. § 18 is amended as follows:

a) Paragraph 1(1) is replaced by the following sentence:

‘Where finished medicinal products are brought within the scope of this Ordinance pursuant to § 73(3) of the Medicinal Products Act, the following information shall be recorded by the pharmacy:

1. the name of the medicinal product brought within the scope of this Ordinance;

2. the name or company name and address of the pharmaceutical operator indicated on the packaging,

3. the batch name, quantity of the medicinal product and pharmaceutical formulation;

4. the name or company name and address of the pharmacy’s suppliers,

5. the name and address of the person for whom the medicinal product has been ordered;

6. the name and address of the prescribing doctor or veterinarian,

7. the date of the order and submission, and

8. the name of the pharmacist who dispensed the medicine or supervised its dispensing.’

b) After paragraph 1, the following paragraph 1a is inserted:

‘(1a) A hospital pharmacy may dispense with the recording of the information referred to in points 5 and 6 of the first sentence of paragraph 1 if, in the hospital it serves, it is ensured that a finished medicinal product which has been brought within the scope of this Ordinance pursuant to the first sentence of § 73(3) of the Law on medicinal products and which is ordered to a reasonable extent for the purpose of temporary stocking and supplied for the purpose of administration to a patient in the hospital is clearly assigned to the specific case of use by means of the following information at the latest at the time of administration to the patient:

1. the patient identification number or details that uniquely identify the person to be treated, such as surname, first name, date of birth and address;

2. information on the unique identification of the medicinal product, including its batch name.’

11. § 23 is replaced by the following § 23:

§ 1'

On-call duty

(1) The pharmacy owner shall keep the pharmacy available for on-call duty. To ensure the supply of medicines, the competent authority assigns pharmacies to provide

emergency services on a rotating basis, particularly during the night, on Sundays and on public holidays. The competent authority shall exempt the other pharmacies from the obligation to provide on-call duty throughout the day, except for a maximum of the following periods:

1. Monday to Friday for a period of six hours each during normal local business hours and

2. on Saturdays for a period of three hours during normal local business hours.

The authority may assign secondary pharmacies to provide emergency services for up to two hours between 9 a.m. and 10 p.m. It exempts secondary pharmacies outside of the emergency services from the obligation to be on call for the entire day, with the exception of a total of up to eight hours from Monday to Saturday during normal local business hours.

(2) The competent authority may grant exemption from the obligation to be on call during company holidays or, if there is a justified reason, for other periods, provided that the supply of medicines is ensured during this period by another pharmacy, which may also be located in another municipality.

(3) During the emergency services referred to in the second sentence of paragraph 1, it shall be sufficient to ensure that the pharmacy is on call if the pharmacy manager or a person authorised to represent the pharmacy is in close proximity to the pharmacy premises and can be contacted at any time. In justified individual cases, the competent authority may, upon request, exempt the director of a pharmacy from the obligation laid down in the first sentence if the director of the pharmacy or a person authorised to represent it is available at all times and the supply of medicinal products is ensured in a manner that is reasonable for patients and other customers.

(4) Pharmacies that are not on call must display clearly legible information about the nearest pharmacies on call in a clearly visible location for patients or other customers.

(5) Notwithstanding the provisions of paragraphs 1 to 3, pharmacies supplying hospitals shall agree on an on-call service arrangement with the hospital operator which ensures the proper supply of medicines to the hospital and advice from a pharmacist at the pharmacy.’

12. In § 26(2), the words ‘5 to 8’ are replaced by the words ‘6 to 8’ and the words ‘22 and 25a’ by the words ‘22, 23(5) and § 25a’.

13. After § 35a, the following § 35b is inserted:

‘§ 35b

Shipping of medicinal products

(1) In the case of the shipping of pharmacy-only medicinal products to end consumers, the director of the pharmacy shall, in particular, lay down requirements for the packaging, transport and delivery of medicinal products pursuant to point 1 of the first sentence of § 17(2a) in the quality management system pursuant to § 2a in relation to

1. a risk-based approach to transport planning,

2. the choice of appropriate transport packaging ensuring the protection of the medicinal product in question, in particular against breakage or deterioration;

3. appropriate transport conditions resulting from the requirements of the relevant medicinal product, in particular to ensure the quality, efficacy and integrity of the relevant medicinal product, and

4. the information to be provided to the contracted logistics company for the execution of an order, in particular with regard to the handling of the medicinal product to be delivered, the recipient and the instructions to be followed in the event of the recipient's absence.

(2) The pharmacy staff involved in dispensing must be sufficiently qualified for their respective tasks and must receive regular training on the requirements for dispensing medicines. The training measures must be documented.

(3) Packaging shall be chosen which ensures, in particular with regard to the temperature sensitivity of the medicinal product, the expected outside temperatures and the maximum duration of transport, that the respective medicinal product is not damaged or its quality or efficacy is not impaired during transport until it is delivered to the recipient, including possible interim storage. When dispatching chilled or cold-chain medicinal products, appropriate cooling systems must be used to ensure the quality and efficacy of the medicinal product throughout the transport period. Where necessary, valid detection shall be provided for temperature-sensitive medicinal products by means of temperature controls carried on board.

(4) The operator shall contractually ensure that the contracted logistics company complies with its obligations, and in particular that it:

1. complies with the shipping conditions laid down by the pharmacy, including transport and storage temperatures, including for the transitional period until successful delivery, if consignments cannot be delivered immediately;

2. carries out delivery to the recipient in accordance with the instructions of the pharmacy manager; and

3. communicates to the pharmacy any event that could have a negative impact on the quality or efficacy of the medicinal product.'

14. § 36 is amended as follows:

a) Point 2 is amended as follows:

a%6) Letter (h) is replaced by the following Letter (h):

a) ' contrary to the third or sixth sentence of § 3(5), does not supervise a pharmaceutical activity or have one supervised,'.

b%6) Letter (o) is replaced by the following Letter (o):

a) ' contrary to the first sentence of § 23(1), does not keep the pharmacy on call or'.

c%6) Letter (p) is deleted.

d%6) Letter (q) becomes Letter (p).

b) Point 4(c) is replaced by the following Letter (c):

a) ‘ contrary to § 28(3) in conjunction with the third or sixth sentence of § 3(5), does not supervise a pharmaceutical activity or have one supervised,’.

Artikel 2

Amendment to the Ordinance on the Pricing of Medicinal Products

The Ordinance on the Pricing of Medicinal Products of 14 November 1980 (Federal Law Gazette I p. 2147), last amended by Article 5 of the Act of 19 July 2023 (Federal Law Gazette 2023 I No. 197) is amended as follows:

1. After § 2(1) third sentence, the following sentence is inserted:

‘By way of derogation from the first sentence, the granting of commercial discounts shall also be permitted if the price charged for the supply of a finished medicinal product is thereby lower than the sum of the supply price of the pharmaceutical undertaking, the fixed surcharge referred to in the first sentence and VAT.’

2. § 3 is amended as follows:

a) Paragraph 1(1) is replaced by the following sentence:

‘In the case of dispensing by pharmacies of finished medicinal products for use in human beings, a fixed surcharge consisting of a relative percentage of remuneration (relative share) equal to 3% of the pharmacy purchase price, a fixed remuneration (fixed sum) of EUR 8.35 and 41 cents to support the provision of emergency services, and VAT shall be charged in order to calculate the pharmacy retail price; in the case of dispensing of seasonal influenza vaccines by pharmacies to doctors, by way of derogation, a surcharge of EUR 1 per single dose, up to a maximum of EUR 75 per prescription item and VAT shall be charged.’

b) Paragraphs 1a and 2 are replaced by the following paragraphs 1a and 2:

‘(1a) In the case of replacement of a prescribed medicinal product by the pharmacy in accordance with § 129(2a) sentence 1 or § 129(2b) sentence 3 of Book V of the Social Code, a surcharge of 50 cents plus VAT shall be levied per replacement.

(2) The relative share is charged

1. except in the cases referred to in point 2, in the amount resulting from the sum of the pharmaceutical company's retail price excluding VAT applicable at the time of delivery to the wholesaler and the maximum wholesale mark-up applicable in accordance with § 2,

2. for finished medicinal products which, pursuant to § 52b(2) sentence 3 of the Medicinal Products Act, may only be obtained directly from the pharmaceutical company, the pharmaceutical company's supply price applicable at the time of delivery to the pharmacy, excluding value added tax.

In the cases referred to in point 2 of the first sentence, the third sentence of § 2(1) shall apply mutatis mutandis.’

c) Paragraph 5(2) is replaced by the following sentence:

‘Where, instead of the prescribed pack size, the prescribed quantity of the medicinal product is dispensed as a subset from a pack larger than the prescribed pack size, the pharmacy shall calculate the pack size corresponding to the prescribed pack size.’

3. After § 3, the following § 3a is inserted:

“§ 3a

Remuneration proposal agreement

(1) The National Association of Health Insurance Funds and the relevant umbrella organisation of pharmacists formed to represent their economic interests shall, in consultation with the Association of Private Health Insurance Companies, agree by ... [insert: 12 months after entry into force in accordance with Article 5] and thereafter until … [insert: 12 months after entry into force in accordance with Article 5, without year] of each year, a uniform proposal to adjust the relative share and the fixed sum. The proposal shall be submitted to the Federal Ministry of Health.

(2) When agreeing on the proposal, the parties to the agreement must take into account, in particular, the change in the consumer price index for Germany established by the Federal Statistical Office compared with the previous year, changes in the costs of pharmacies in terms of economic management and the principle of stability of contribution rates within the meaning of the first sentence of § 71(1) of Book V of the Social Code. § 71(2) of Book V of the Social Code shall apply mutatis mutandis.

(3) If an agreement pursuant to paragraph 1 is not concluded or is not concluded in part, it shall be determined in whole or in part by the Arbitration Board pursuant to § 129 (8) of Book V of the Social Code within eight weeks of the expiry of the period specified in paragraph 1 sentence 1 in each case. The costs of the arbitration proceedings shall be borne equally by the parties to the agreement referred to in paragraph 1.’

4. §4(2) is replaced by the following Paragraph 2:

(1) ‘ The basis for calculation shall be the pharmacy purchase price of the smallest package size required to dispense the substance in the relevant quantity.’

5. §5(2) is replaced by the following Paragraph 2:

(1) ' Pharmacy purchase prices for the quantities of substances and finished medicinal products required for the relevant preparation are to be taken as a basis. The definitive criteria are:

1. for substances, the purchase price of the smallest packaging required for preparation, and

2. for finished medicinal products, the purchase price of the smallest package size required for preparation, as determined in accordance with § 3(2), but not exceeding the pharmacy purchase price applicable to finished medicinal products when dispensed in public pharmacies.’

6. After § 7, the following § 7a is inserted:

“§ 7a

Medicinal products pursuant to § 48a and § 48b of the Medicinal Products Act

When dispensing a medicinal product in accordance with § 48a or § 48b of the Medicinal Products Act, pharmacies may charge an additional amount of 5 euros, including VAT.’

Artikel 3

Amendment to the Medicinal Products Trade Ordinance

The Medicinal Products Trade Ordinance of 10 November 1987 (Federal Law Gazette I p. 2370), as last amended by Article 2c of the Act of 18 November 2020 (Federal Law Gazette p. 2397) is amended as follows:

1. § 1 is replaced by the following § 1:

§ 1'

Scope

(1) This Ordinance shall apply to establishments and facilities in so far as they engage in the wholesale distribution of medicinal products, unless, pursuant to § 1 (2) of the Arzneimittel- und Wirkstoffherstellungsverordnung (Ordinance on the preparation of medicinal products and active substances), the provisions of that ordinance apply. The Ordinance also applies to persons who engage in the distribution of medicinal products within the meaning of § 4(22a) of the Medicinal Products Act and to logistics companies commissioned by pharmacies to ship pharmacy-only medicinal products to end consumers, insofar as this Ordinance so provides.’

2. After § 9, the following § 9a is inserted:

§ 9a Requirements for logistics companies commissioned by pharmacies

A logistics company appointed by a pharmacy to dispatch pharmacy-only medicinal products to end consumers must ensure that the quality and efficacy of the medicinal products are not impaired during storage and transport. In particular, the logistics company must:

1. use suitable vehicles equipped in such a way that the medicinal products being transported are not exposed to conditions that could impair their quality or efficacy or damage their packaging,

2. comply with the dispatch conditions laid down by the pharmacy, including transport and storage temperatures, including for the transitional period until successful delivery, where consignments cannot be delivered immediately;

3. record the temperature conditions and provide the pharmacy with evidence of this upon request, insofar as active cooling systems are used during transport, and

4. ensure that no unauthorised third party has access to the medicinal products during transport until they are handed over to the recipient.’

1. § 10 is amended as follows:

   a) In point 1, the words "orders or" are replaced by the text "orders,".

   b) In point 2, the words "takes or" are replaced by the text "takes,".

   c) in point 3(d), the words ‘informed’ are replaced by the words ‘informed or’.

   d) The following point 4 is inserted after point 3:

      ‘4. contrary to the first sentence of § 9a, does not ensure that the quality or efficacy of a medicinal product is not impaired.’

Artikel 4

Amendment to the Training and Examination Regulations for Pharmaceutical Technicians

The Training and Examination Regulations for Pharmaceutical Technicians of 23 September 1997 (Federal Law Gazette I p. 2352), last amended by Article 14 of the Ordinance of 7 June 2023 (Federal Law Gazette 2023 I No. 148), is amended as follows:

Annex 1 Part B Point (2)(d) is replaced by the following letter (d):

a) ‘ Produce medicinal products in the following dosage forms in accordance with medical instructions in accordance with recognised pharmaceutical rules, including labelling:

   a%6) solutions, emulsions, suspensions,

   b%6) ointments, creams, gels, pastes,

   c%6) capsules, powder,

   d%6) drug mixtures; and

   e%6) suppositories and ovules,’.

Artikel 5

Entry into force

Subject to the second sentence, this Ordinance shall enter into force on the day following promulgation. Article 1(2)(a) shall enter into force on ... [insert: date of the first day of the second quarter following promulgation].

The Bundesrat has agreed.

Justification

A. General part

I. Purpose and necessity of the provisions

Pharmacies are a key pillar in the supply of medicines and an important, low-threshold point of contact for citizens regarding health issues. However, smaller and rural pharmacies in particular face challenges due to a shortage of skilled staff, structural change and declining profitability. In addition to legislative amendments, the reform of pharmacy law requires supplementary amendments to ordinances in order to achieve the overall reform objective of creating long-term, viable and economic framework conditions for pharmacies in order to maintain a comprehensive pharmacy network for local supply of medicinal products. The amendments to the regulations are intended to reduce bureaucracy, strengthen the personal responsibility of pharmacy owners and adjust pharmacy remuneration. At the same time, pharmacies need better opportunities to recruit skilled workers and must be able to deploy them more flexibly than before.

II. Main content of the draft

In order to maintain a comprehensive network of pharmacies, including in rural areas, framework conditions are required that enable pharmacies to operate more economically. To this end, the personal responsibility of pharmacy owners will be strengthened, bureaucracy reduced and pharmacy operations made more flexible. Changes are also being made to the remuneration of pharmacies.

The Regulations on the Operation of Pharmacies shall include the following measures:

While maintaining constant availability, the opening hours of public pharmacies will be made more flexible. This will allow in particular pharmacies in rural areas to better adapt their business hours to local needs. The classification of pharmacies as emergency services by the competent authorities of the state government remains valid.

For more efficient operations, the production of medicinal products and the testing of medicinal products or starting materials are simplified. Laboratories will in future only have to be kept in one of several pharmacies operated by the same operator; medicinal product and raw material testing can be centralised in this pharmacy. The provision of equipment for the preparation of medicinal products, scientific aids and the adaptation of standard preparation instructions to the pharmacy operation in question are the responsibility of pharmacy management.

For secondary pharmacies in rural areas, the requirements for the provision of premises will be further reduced compared to the existing law. In addition, they will be able to have prescriptions dispensed by pharmacies belonging to the same chain. The use of secondary pharmacies for emergency services will be limited.

In order to make the use of personnel more flexible, skilled workers from abroad should already be able to carry out pharmaceutical activities as trainees during the recognition procedure. Professional groups with appropriate training may be employed for certain support activities in pharmacies.

Further exemptions from the room unit are being introduced.

The documentation of imported medicinal products in hospital pharmacies and pharmacies supplying hospitals will be facilitated, provided that tracing via the documentation on the ward is ensured.

The pharmacy fee is adjusted by means of amendments to the Ordinance on the Pricing of Medicinal Products. The following measures in particular are envisaged here:

Commercial discounts on prescription drugs should be made possible again. In February 2024, the Federal Court of Justice ruled that discounts on prescription drugs between wholesalers and pharmacies are only permitted within the variable wholesale surcharge of 3.15 percent – discounts or other benefits exceeding this amount are not permitted. Given the great economic importance of these discounts for pharmacies, commercial discounts for early payment should be possible again in the future.

A negotiated solution is established as a new element of pharmacy remuneration. The contracting parties of the self-governing body are tasked with negotiating adjustments to pharmacy remuneration. The pharmacy population is thus given the opportunity to help shape their own remuneration, as is the case with other healthcare providers. In order to promote constructive negotiations, legally binding guidelines are laid down in the form of certain indices.

In order to strengthen locations in rural areas in particular, the current surcharge for pharmaceutical services of 20 cents per pack of prescription drugs is to be reallocated to night and emergency service remuneration.

Expenses of pharmacies related to the exchange of non-available medicinal products in the case referred to in § 129(2b) of Book V of the Social Code shall also be remunerated.

In addition, potentially increased expenditure associated with the dispensing of medicinal products in accordance with § 48a and § 48b of the Medicinal Products Act is additionally reimbursed.

Other requirements:

The responsibility of pharmacy operators for individual processes, including in secondary pharmacies, is made more specific and thus emphasises their personal responsibility for the operation.

For the dispatch of medicinal products by pharmacies, specific requirements are laid down with regard to the provisions necessary in the quality management system and the carrying out of transport operations, in particular to ensure the quality and efficacy of the medicinal products dispatched. To this end, guidelines are also being drawn up for contracts between pharmacies and transport service providers. In addition, requirements are laid down for logistics companies commissioned by pharmacies to dispatch pharmacy-only medicinal products to end consumers. It is also clarified that an obligation to ensure the quality and efficacy of a medicinal product also exists in relation to the courier service.

III. Executive footprint

The state government, local government associations, expert groups and associations were consulted.

IV. Alternatives

None.

V. Regulatory competence

The amendments to the Regulations on the Operation of Pharmacies are based on § 21(1) first sentence and § 21(2) first sentence points 1, 1a, 1b, 2, 4, 5, 6, 7 and 8 of the Pharmacy Act.

The amendments to the Ordinance on the Pricing of Medicinal Products are based on § 78(1), first sentence, of the Medicinal Products Act.

The amendments to the training and examination regulations for pharmaceutical technicians are based on § 56(1)(1) of the Law on pharmaceutical technicians.

The amendments to the Medicinal Products Trade Ordinance are based on § 54(1), first sentence, and § 54(2), points 1, 2, 6 and 7 of the Medicinal Products Act.

The consent of the Bundesrat is required.

VI. Compatibility with European Union law and international treaties

The draft Ordinance is compatible with the international agreements concluded by the Federal Republic of Germany.

The draft falls within the scope of Directive (EU) 2018/958 of the European Parliament and of the Council of 28 June 2018 on a proportionality test before adoption of new professional regulations. The proportionality test was carried out in accordance with § 42a of the Joint Rules of Procedure of the Federal Ministries of 26 July 2000 (Joint Ministerial Gazette 2000 page 526), as last amended by Article 1 of the Decision of 15 May 2024 (Joint Ministerial Gazette 2024 No 19, p. 386), with regard to the rules regulating the pharmaceutical professions. The rules comply with the principle of proportionality. In particular, simplifications will be introduced, including in relation to staffing in pharmacies and on-call duty. In particular, the regulations do not contain any discrimination on the basis of nationality or residence.

The requirements for the dispatch of pharmacy-only medicinal products by the dispatching pharmacy and the logistics company contracted by it are intended to protect the health and life of humans within the meaning of Article 56 of the Treaty on the Functioning of the European Union and are also proportionate. The requirements for the dispatching pharmacy also constitute proportionate requirements within the meaning of Directive (EU) 2018/958 . In particular, the regulations do not contain any discrimination on the basis of nationality or residence.

The adjustments to the fee in the Ordinance on the Pricing of Medicinal Products are also proportionate within the meaning of Directive (EU) 2018/958. These serve to maintain a comprehensive network of pharmacies including in rural areas. Adjustment of fees is appropriate and necessary to improve the economic situation of pharmacies. Since the rules apply to all pharmacists in Germany, they are also not discriminatory on the basis of nationality or place of residence.

VII. Consequences of the legislation

The purpose of this Ordinance is to continue to ensure the supply of medicinal products to the general public through pharmacies.

1. Legal and administrative simplification

The draft does not provide for legal and administrative simplification.

2. Sustainability aspects

The Ordinance is in line with the guiding principles of the Federal Government on sustainable development in the spirit of the German Sustainability Strategy and specifically supports the objective of Sustainability Goal 3, ‘Good Health and Well-being’. The draft Ordinance will ensure that pharmacies remain open, thereby guaranteeing comprehensive supply of medicines to patients throughout Germany. The draft also introduces simplifications for pharmacy operations, for example with regard to on-call duty, staff deployment and reduced requirements for secondary pharmacies. Thus, the draft contributes to Sustainable Development Goal 8 ‘Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all’.

3. Budgetary expenditure excluding compliance costs

Federal government, state government and municipalities

Article 2(2)(a)

The 20-cent increase in the surcharge for ensuring emergency services (emergency service surcharge) will not result in any additional costs for the federal, state or local authorities responsible for funding the subsidy. Due to the simultaneous cancellation of the surcharge for financing pharmaceutical services in the same amount, this surcharge will be redistributed in a cost-neutral manner.

Statutory health insurance

Article 2(2)(a)

For the statutory health insurance scheme, there are no additional costs resulting from the increase of 20 cents in the packaging-related supplement to support the provision of the emergency service (emergency service supplement). Due to the simultaneous cancellation of the surcharge for financing pharmaceutical services in the same amount, this surcharge will be redistributed in a cost-neutral manner.

Article 2(2)(b)

Extending the supply bottleneck surcharge for pharmacies to include cases where unavailable medicines are substituted in accordance with § 129(2b) of Book V of the Social Code will result in additional expenditure for statutory health insurance funds in an amount that cannot be quantified. The amount depends, on the one hand, on the number and extent of supply shortages and, on the other hand, on pharmacies’ perception of simplified exchanges. Due to the current number of reported supply bottlenecks for medicinal products on the list drawn up in accordance with the first sentence of § 129(2b) of Book V of the Social Code, additional expenditure on statutory health insurance in the low single-digit millions could be incurred as a result of the ordinance.

Article 2(3)

The agreement between the National Association of Health Insurance Funds and the umbrella organisation of pharmacists formed to represent their economic interests, which is enshrined in the new § 3a of the Ordinance on the Pricing of Medicinal Products, is purely advisory in nature. Any additional costs for statutory health insurance will only arise if the recommendation is implemented as a result of a subsequent amendment of the Ordinance on the Pricing of Medicinal Products.

4. Compliance costs

4.1. Compliance costs for citizens

Article 2(6)

The possibility for pharmacists to charge up to €5 for dispensing medicines in accordance with § 48a and § 48b of the Medicinal Products Act results in additional compliance costs for citizens. The amount depends on the specific amount claimed by pharmacies for dispensing and on the number of times citizens make use of the dispensing service in accordance with § 48a and § 48b of the Medicinal Products Act. Furthermore, utilisation will be determined by the contents of the future statutory instrument pursuant to § 48b(2) of the Medicinal Products Act.

Since the details of charges under § 48b of the Medicinal Products Act must be determined solely by ordinance, no fulfilment costs can be estimated in this regard.

Assuming that a levy pursuant to § 48a of the Medicinal Products Act occurs four times a year in all pharmacies (17 041) (4 levies x 17 041 pharmacies = 68 164 levies per year) and in each case the maximum amount of the special surcharge of EUR 5 is claimed, this results in an annual compliance cost of EUR 340 820 (5.00 x 68 164 levies = EUR 340 820 per year).

4.2. Compliance costs for businesses

Article 1(1)

It is stipulated that when two persons are appointed to manage a secondary or subsidiary pharmacy, they may deputise for each other for longer than the usual three months. It is estimated that there will be savings as there is no need to hire a substitute pharmacist for representations going beyond the three months.

Assuming average opening hours for a pharmacy of 44 hours per week (5 days of 8 hours each, 4 hours on Saturday = 44 hours/week) and a wage of 64.2 euros/hour (economic sector: M, high) as well as the assumption that a further representation period of three months full-time could occur, would result in a saving of approximately -33 897,6 Euro per individual case (64.2 Euro x 44 hours = 2 824.8 Euro/week; 12 x 2 824.8 Euro/week = 33 897.6 Euro/3 months).

In 2024, there were 4,511 subsidiary pharmacies and 10 secondary pharmacies. It is estimated that approximately 1,000 secondary managers are represented by two designated representatives and benefit from the extended representation arrangement.

This results in an overall saving for 1 000 cases of approximately EUR 33,9 million per year (EUR 33 897.6/3 months x 1 000 cases = EUR 33 897 600).

Article 1(3)(a)

The regulation serves to address the shortage of skilled workers and ensure earlier involvement of foreign skilled workers. Due to the low number of cases, the compliance costs are expected to be negligible, at less than € 100 000 .

Article 1(5)(c)

The regulation makes it possible to derogate from the specification of the room unit for certain storage rooms. Due to the low number of cases, it is assumed that there will be a slight saving of less than EUR 100 000 due to lower room rent.

Article 1(4)(b), (6)(b), (8)

The possibility that a pharmacy operated by the same operator can carry out identity checks on medicinal products and starting materials for a pharmacy results in savings on the personnel, material and equipment centralised in for subsidiaries. The savings depend heavily on the respective requirements in the pharmacy.

The one-off material costs for the purchase of basic equipment with laboratory equipment for analysis and chemicals are estimated to be around 20 000 euros. Identity checks using spectroscopy may incur costs of approximately € 20 000 for the basic equipment required to perform near-infrared spectroscopy or mid-infrared spectroscopy in pharmacies, approximately € 400 for maintenance of the equipment every two years, and approximately €150 per month for the equipment software. In total, a one-off saving of € 40 000 (€20,000 + €20,000 = €40,000) can be made on material costs when setting up a new secondary pharmacy.

4 million euros in one-off material costs were thus incurred for basic equipment in laboratory devices for analysis, chemicals and spectroscopes (100 pharmacies x 40,000 euros) for 100 newly established subsidiary pharmacies.

If the identity check for all pharmacies operated by the same operator is carried out only in a pharmacy, maintenance and software of near-infrared spectroscopy or medium-infrared spectroscopy devices are required only in one subsidiary. As a result, running costs of 2 000 annual euros can be saved (400 euros / 2 years = 200 euros / year; 150 euros / month x 12 months / year = 1 800 euros / year). It is estimated that this applies to 20 percent of the approximately 4 511 subsidiary pharmacies (0.2 x 4 511 subsidiary pharmacies = 902 pharmacies; 902 pharmacies x EUR 2 000/year = EUR 1 804 400/year).

In total, around €1,8 million in running costs can be saved each year.

In addition, working hours are saved if the identity check in a subsidiary is carried out only in a pharmacy. The identity check is usually carried out by employees with a medium wage level (pharmaceutical technician, economic sector: 40.9 euros/hour on average). Assuming that centralising this task would eliminate half of the 2.5 hours of work per week typically required in a pharmacy, this would result in a reduction of 1.25 hours per week or 65 hours per year per pharmacy. It is estimated that this applies to 20 percent of the approximately 4 511 secondary pharmacies (65 hours/year x 40.9 euros/hour = 2 658.5 euros/year for one pharmacy; 2 658.5 euros/year per pharmacy x 902 pharmacies = 2 397 967 euros/year).

Overall, around -2,4 Millionen EUR in annual personnel costs can therefore be saved.

Article 1(4)(b), (9)(c)

By waiving the requirement for secondary pharmacies to have a prescription workstation and a night duty room, newly established secondary pharmacies can save money through reduced rent and energy costs and because certain equipment and technical facilities are no longer necessary.

The estimated costs of renting new premises for commercial spaces vary depending on the location. For secondary pharmacies, good locations in non-urban areas are assumed,

where rents in the range of € 10-20 /square metre can be expected; on average, € 15 / square metre is assumed.

For rental of 5 square meters, assumed as the minimum size for prescription formulation, therefore, on average 900 Euro net basic rental costs are incurred annually. Room costs (ancillary costs) are assumed to be EUR 6 per square metre per month. They amount to EUR 360 per year for a formulation station of 5 square metres. The net rent for a 5 square metre formulation station amounts to € 1 260 /year (5 sqm x €15/sqm = €75/month net rent for formulation station; 75 euros/month x 12 = 900 euros/year net rent excluding heating for formulation station; 5 square metres x 6 euros/square metre = 30 euros/month ancillary costs; 30 euros/month x 12 = 360 euros/month; 75 euros + 30 euros = 105 euros/month net rent including heating for formulation station; 105 euros/month x 12 months/per year = 1,260 euros per year net rent including heating for formulation station).

In addition, there are no acquisition costs for preparation equipment (averaging around € 5 500) or for technical equipment such as extractor hoods and sinks (averaging around €1,335), which are necessary for a formulation station. In total, this amounts to €6,835 in one-off acquisition costs for the formulation station (€5,500 + €1,335 = €6,835 for preparation equipment and technical equipment for the formulation station).

For the rental of around 7 square meters for a night service room, on average, 1 260 net basic rental costs are incurred annually. The room costs (ancillary costs) for the night duty room, which measures 7 square metres, amount to € 504 . The net rent for a 7 square metre night duty room amounts to € -1 764 /year (7 sqm x €15/sqm = €105/month net rent for the prescription area; 105 euros/month x 12 = 1,260 euros/year net rent excluding heating for night duty room; 7 square metres x 6 euros/square metre = 42 euros/month ancillary costs; 42 euros/month x 12 = 504 euros/month ancillary costs for night duty room; 105 euros + 42 euros = 147 euros/month net rent including heating for night duty room; 147 euros/month x 12 = 1,764 euros/year net rent including heating for night duty room).

These costs will no longer be incurred by secondary pharmacies in future, resulting in savings in annual rental costs of approximately €1 260 for the elimination of the prescription workstation and approximately € 1 764 for the elimination of the night duty room, as well as a one-off cost of approximately6 840 s for setting up the prescription workstation (1,260 euros/year + 1,764 euros/year = 3,024 euros net rent for prescription workstation + night duty room).

With 100 newly established secondary pharmacies, this could result in savings of around €302 400 /year in net rent costs including heating and a one-off saving of around €684 000 in equipment costs (€1,260/year + €1,764/year = €3,024 net rent including heating for prescription dispensing + night duty room; 100 x €3,024 = €302,400 net rent for dispensing + night duty room in total).

Re Article 1(4)(d)

It is regulated that devices for individual prescription formulation no longer have to be kept in stock in pharmacies. The decision takes into account the environment and the pharmacy’s usual prescription requirements. It is assumed that most prescriptions are formulated regularly in pharmacies and therefore, due to the low number of cases, the compliance costs are expected to be negligible, at less than €100,000.

Article 1(5)

It is made possible that free information can be used, for example, instead of the relevant legal texts in paper or digital form. This eliminates regular acquisition costs for updates, for example. It is assumed that this is 95 percent of all 17 041 pharmacies and that savings of EUR -100 per pharmacy per year can be achieved in this way.

In 16 000 the case of pharmacies, the savings thus amounted to a total of -1,6 Millionen euro per year (16 000 x 100 euro/year = 1 600 000 euro/year).

Article 1(7)

The obligation to adapt standardised and general preparation instructions of third parties to the respective pharmacy establishment no longer applies. The decision on this is left to pharmacy management.

On average, a pharmaceutical technician spends 10 minutes on this task (economic sector: M 40.9 euros/hour on average) and a subsequent 5-minute consultation with a pharmacist (economic sector: EUR 64.2/hour high) per adjustment of a preparation instruction. The number of individual and bulk formulations to be prepared varies between pharmacies. It is likely that the adjustment will only take place if necessary as soon as a formulation is requested for the first time. An adjustment may still be necessary in some cases. It is therefore assumed that there will no longer be any need to adapt 15 production permits per pharmacy per year in the future. It is assumed that all 17 041 pharmacies are affected.

This means that each pharmacy can save 2.5 hours of working time per year at a medium quality level, amounting to around € 102 , and 1.25 hours of working time at a high quality level, amounting to € 80 (10 minutes/preparation licence, medium qualification x 15 preparation licences/year = 150 minutes per year, medium qualification = 2.5 hours/year, medium qualification; 2.5 hours/year x €40.9/hour = €102.25/year medium qualification for adjusting 15 preparation licences; 5 minutes/preparation licences high qualification x 15 preparation authorisations/year = 75 minutes per year high qualification = 1.25 hours/year high qualification; 1.25 hours/year x €64.2/hour = €80.25/year high qualification for the adaptation of 15 preparation authorisations; €102.25/year medium qualification + €80.25/year high qualification = €182.50 total personnel costs).

Overall, for all 17 041 pharmacies, there will be an overall saving in personnel costs of around -3,1 Millionen EUR per year (EUR 182.5 x 17 041 pharmacies = EUR 3 109 982.5).

Article 1(9)(b) and Article 3

As it is assumed that transport companies are already commissioned to ship medicinal products, the additional compliance costs are expected to be negligible, at less than € 100 000 , due to the low number of cases.

The requirement that pharmacies and carriers must conclude a contract results in a minor annual compliance burden. Assuming that such contracts already exist as standard contracts at the companies and are regularly signed by both parties upon conclusion of a contract, a minor annual compliance burden is assumed, which can be considered part of the normal operation of a company.

For 2024, it can be assumed that approximately 32,7 million medicines requiring refrigeration and cold chain storage were dispensed by pharmacies. These are likely to be almost exclusively prescription-only medicinal products. With a mail order share of currently about 1.5 percent for prescription drugs, it can be assumed that these 490 000 drugs, for example, are shipped from mail-order pharmacies. Actively temperature-led shipping

could be carried out for an estimated 20 percent of these medicinal products. The data transmitted by the transport service provider shall as far as possible be transferred automatically. A random check of 5 percent of the relevant data is estimated to take 1 minute per case, which can be carried out by pharmaceutical technicians (average wage level, €34.20/hour). Thus, the total cost of the review process can be estimated at around €3,000 per year (490,000 medicinal products x 0.2 x 0.05 x €34.20/hour / 60 minutes = €2,793).

Article 1(10)(b)

The regulation allows hospital-supplying pharmacies and hospital pharmacies to document the batch name of imported medicinal products on a ward by way of derogation. Imported medicines are used in hospitals in particular when medicines for the relevant area of application are not available within the scope of the Medicinal Products Act and are temporarily stockpiled to ensure proper supply (§ 73(3) of the Medicinal Products Act). The amount of the savings depends, in particular, on the nature and scope of the supply bottlenecks; use of the amended documentation option and the associated savings can therefore only be estimated. In Germany, for example, 477 000 hospital beds are to be assumed. It is estimated that an average of approximately 10 imported medicines are used per bed per year. The documentation effort to date is estimated to take around 15 minutes due to the necessary consultations between pharmacy and ward and checks to determine in which cases the medicine in question was used. It can be assumed that the task can be performed on both sides by persons with a medium level of qualification (EUR 34.20/ hour). In approximately 4.77 million cases, annual savings of around €40.8 million can therefore be expected (477,000 beds x 10 medicines x 0.25 hours x €34.20/hour = €40,783,500).

Article 1(11)

The abolition of on-call duty and the greater flexibility for opening hours of public pharmacies result in savings for pharmacies through the possibility of lower staffing. If full use were made of the more flexible opening options, it would in principle be possible to reduce the weekly opening times by around 25.5 hours. However, in regions where no relevant customer flows are to be expected at certain times, many pharmacies have already been exempted from on-call service by the competent authorities at those times. Since it is not possible to estimate how many pharmacies will additionally take this option through the new rules, to what extent and what staffing levels will not be used as a result, the savings cannot be precisely quantified.

For a pharmacist, wage costs of 64.2 euros/hour (economic sector: M EUR 64.2/hour), for a pharmaceutical technician EUR 40.9/hour (economic sector: M EUR 40.9/hour average) and for a pharmacy retail employee EUR 25.5/hour (economic sector: M 25.5 euros/hour low) are assumed. Assuming that pharmacies tend not to open during off-peak hours and therefore employ on average one specialist at €48.50 per hour (a pharmacist or a pharmaceutical technician; average value of ([€64.2 + €40.9]/2 = €52.55) and 0.5 pharmacy retail employees at €12.72 per hour (€25.5/2 = €12.75), €65.3/hour (€52.55 + €12.75 = €65.3) could be saved.

If 1 000 pharmacies reduced their opening hours by twelve hours per week, around €40.8 million in personnel costs could be saved annually (€65.3/hour x 12 hours/week = €783.6/week per pharmacy; €783.6 per pharmacy/week x 52 weeks = €40,747.2/year per pharmacy; 1,000 pharmacies x €40,747.2/year = €40,747,200/year).

The savings are offset by lost revenue if the pharmacy does not open, which varies greatly from pharmacy to pharmacy due to different conditions such as customer frequency and the number and type of medicines dispensed, and therefore cannot be quantified.

Article 1(13)

The training of staff involved in dispatching entails minor additional costs for the dispatching pharmacies.

The regulatory provision concerns, in principle, pharmacies which have a licence to sell pharmacy-only medicinal products by mail order in accordance with Paragraph 11a of the Pharmacy Act. There are about 3 250 pharmacies. However, mail order is operated to a relevant extent only by 150 pharmacies, for example. It can be assumed that, on average, five persons in these 150 pharmacies must be trained internally by a pharmacist for these activities each year. For the remaining pharmacies, it can be assumed that only minimal training will be required, as the dispatch of medicines in individual cases is carried out by the responsible pharmacist themselves.

For a pharmacist, wage costs of 64.2 euros/hour (economic sector: M EUR 64.2/hour), for a pharmaceutical technician EUR 40.9/hour (economic sector: EUR 40.9/h) is assumed. Assuming that two pharmacists and four pharmaceutical technicians are involved and that training, including documentation, takes about one hour, a minor cost of EUR 43 800 is to be assumed. (Calculation method: 64.2 euros x 2 + 40.9 euros x 4 x 1 hour = 292 euros/ year per pharmacy; 150 pharmacies x 292 euros/year = 43 800 euros.

Article 2(2)(c)

For private health insurance companies, there are no additional costs resulting from the intermediate increase of 20 cents in the packaging-related supplement to support the provision of emergency services (emergency service supplement). Due to the simultaneous cancellation of the surcharge for financing pharmaceutical services in the same amount, this surcharge will be redistributed in a cost-neutral manner.

Article 2(3)

The agreement to adjust the fixed packaging surcharge (fixed sum and relative share) creates a non-quantifiable compliance burden for the relevant top organisation of pharmacists. The specific amount will depend on the outcome of negotiations with the National Association of Statutory Health Insurance Funds. Assuming that several rounds of negotiations with a total duration of one hundred hours and three representatives each are necessary to reach an agreement, the compliance costs would amount to EUR 18 600 (Calculation method: 100 hours x 3 persons x EUR 62.00/hour). The frequency of the compliance costs depends on the frequency of the negotiations, which is not specified by the legislator.

In addition, the Association of Private Health Insurance will incur compliance costs of EUR 931 in the context of the consultation process (calculation method: 10 hours x EUR 93.10/hour). The frequency of the compliance costs depends on the frequency of the negotiations, which is not specified by the legislator.

4.3. Compliance costs for the authorities

Federal government

Article 2(2)(c)

For the aid from the Federal Government, the state government and municipalities, there are no additional costs from the interim increase in the package-related surcharge to promote compliance with the emergency service (emergency service surcharge) by 20 cents. Due to the simultaneous cancellation of the surcharge for financing pharmaceutical services in the same amount, this surcharge will be redistributed in a cost-neutral manner.

Article 2(3)

As a result of the agreement to adjust the package-related fixed surcharge (fixed amount and relative share), the Central Federal Association of Health Insurance Funds incurs non-quantifiable implementing costs. The specific amount depends on the course of the negotiations with the relevant umbrella organisation for pharmacists set up to protect their economic interests. Assuming that several rounds of negotiations with a total duration of one hundred hours and three representatives each are necessary to reach an agreement, the compliance costs would amount to EUR 21 960 (Calculation method: 100 hours x 3 persons x EUR 73.20/hour). The frequency of the compliance costs depends on the frequency of the negotiations, which is not specified by the legislator.

5. Other costs

Article 2(3)

The agreement between the National Association of Health Insurance Funds and the umbrella organisation of pharmacists formed to represent their economic interests is purely advisory in nature. Additional costs for the relevant umbrella organisation of pharmacists set up to protect their economic interests may arise only if the recommendation is implemented through a subsequent amendment of the Ordinance on the Pricing of Medicinal Products.

6. Other consequences of the legislation

The draft ordinance helps to ensure medical care, safeguards the continued operation of pharmacies and thus contributes to the nationwide supply of medicines for all citizens, including those in rural areas. In doing so, the draft ordinance strengthens the equivalence of people's living conditions, in particular the factors of 'healthcare', 'economy and innovation' and 'engagement, cohesion and participation'.

The ordinance has no discernible gender impact, as it does not contain rules that influence the specific life situation of women and men. No impact on issues relating to demographics are expected.

The introduction of an experimental clause is not considered necessary. On the one hand, the proposed amendments give the parties concerned further room for manoeuvre; on the other hand, in the light of patient safety, further possibilities for derogations are not appropriate.

VIII. Time limit; evaluation

The regulatory proposal is not time-bound. The regulatory proposal leads mainly to savings and is therefore not subject to evaluation.

B. Special part

Re Article 1 (Amendment to the Regulations on the Operation of Pharmacies)

Re Number 1

Re Letter a

It is clarified that the pharmacy operator is obliged to regularly visit the pharmacies they operate to ensure that pharmacy management is fulfilling its responsibility to manage the

pharmacy within the legally prescribed framework. The regulation emphasises the personal responsibility of the operator for their pharmacies.

Re Letter b

The restricted period of three months during which a director of a pharmacy may be represented shall not apply where the holder of the licence appoints two persons to be responsible for the management of the subsidiary or secondary pharmacy and they represent each other. This improves the integration of part-time workers as pharmacy managers and helps to address the shortage of skilled workers.

Re Number 2

The quality management system of a pharmacy contains the respective operational procedures and is therefore the central tool to ensure the quality of the services provided and of the pharmaceutical products prepared by the pharmacy. It is clarified that the quality management system to be maintained by the pharmacy must be agreed upon by the management of a subsidiary pharmacy with the operator of the pharmacy. The regulation thus emphasises the personal responsibility of the operator for their pharmacies.

Re Number 3

Re Letter a

In order to counteract the shortage of skilled workers, pharmacies will be given more flexibility in terms of staffing. The addition enables the use in the pharmacy of persons in respect of whom the recognition procedure for professional qualifications as a pharmacist or as a pharmaceutical technician acquired abroad has not yet been completed. This allows them to gain professional experience and technical language expertise in German pharmacies at an early stage and helps to alleviate the shortage of skilled workers. In order to continue to ensure the quality of patient care, these persons can only be employed as persons in training under supervision and must be supervised accordingly.

Re Letter

The amendment will enable the pharmacy to employ additional staff with appropriate training and familiarity with certain activities. They should be allowed to assist with auxiliary tasks in pharmacies under supervision. Depending on the job, this may include, for example, pharmaceutical technicians or chemical technicians. This is intended to counteract the shortage of skilled workers and give pharmacies more flexibility in terms of staffing.

Re Number 4

Re Letter a

In future, as a result of the introduction of the first sentence of § 6(3a) and the amendment of the second sentence of § 11(1) in conjunction with the first sentence of § 6(3a), the identification of medicinal products and starting materials may, under certain conditions, be carried out by one pharmacy for another pharmacy operated by the same operator. Therefore, it is no longer necessary for all pharmacies operated by the same person to have a testing laboratory. This is intended to facilitate the economic operation of pharmacies and to maintain a comprehensive network of pharmacies. The provision does not apply to the provision of a preparation station (formulation); this remains necessary in all pharmacies (except secondary pharmacies, where according to § 17(4a) individual and bulk preparations of medicines are not made on the premises).

Re Letter b

Secondary pharmacies [Zweigapotheken] are to be further developed as a form of care provision. Reduced requirements for secondary pharmacies are provided to reduce bureaucracy and facilitate the establishment of secondary pharmacies to provide locations and districts with a limited supply of medicinal products. The reduced requirements allow for flexible and cost-effective operation of a secondary pharmacy.

An office and sufficient storage room remain mandatory as operating rooms of a secondary pharmacy. Further rooms and equipment are only required to the extent that activities are carried out in the secondary pharmacy for which such rooms and equipment are required, such as for the production of individual and bulk preparations of medicinal products. Paragraphs 2b, 2c and 7, which prescribe the premises and equipment for the preparation of medicinal products not intended for parenteral use, as well as drugs and drug mixtures, shall not apply if the secondary pharmacy does not make its own individual and bulk preparations in accordance with § 17(4a), but instead has them prepared by another pharmacy operated by the same operator.

Re Letter c

In order to make things more flexible, a further exception is introduced in point 1. Stocks that exceed the daily requirements for medicines and medical devices regularly dispensed in the pharmacy may be stored in a separate room. This may be appropriate, for example, for stockpiling medicines that are in greater demand during certain seasons. This exception also stipulates that the room must be located within reasonable proximity to the other operating rooms.

Re Letter d

As part of the drive to reduce bureaucracy, the regulations governing the provision of equipment for the preparation of prescription medicines are simplified. The pharmacy shall be equipped with equipment in such a way as to allow the proper preparation of medicinal products in the forms normally prescribed. The need may differ, for example, due to the specialisations of medical practices in the vicinity. The devices may continue to include, in particular, those for the production of dosage forms such as solutions, emulsions, suspensions, ointments, creams, gels, pastes, capsules, powders, drug mixtures, suppositories and ovules.

Re Number 5

As part of the drive to reduce bureaucracy and promote digitalisation, the requirements for the provision of scientific and other aids are being abolished. The decision as to whether and in what form these aids will continue to be stocked in pharmacies is left to the discretion of the pharmacy management.

Re Number 6

Re Letter a

In the past, there have been repeated uncertainties as to whether the reference to § 1(2) relates to the Pharmacy Act or the Regulations on the Operation of Pharmacies. The rewording is intended to create legal certainty.

Re Letter b

By way of derogation from the fourth sentence of paragraph 3, it shall be possible for a pharmacy to carry out the examination and determination of the identity of medicinal prod-

ucts for another pharmacy operated by the same person. The decision is left to the professional discretion of pharmacy operators.

In order to protect patients, precautions must be taken to prevent and detect manipulation. In particular, impurities or confusion should be prevented by sealing. The dispensing pharmacy may only use the medicinal products if it is excluded that changes have been made to the medicinal product after the examination. This includes a label indicating the identity check carried out and the corresponding sealing applied by the pharmacy of the subsidiary that carried out the check.

Centralised identity verification within a chain of subsidiaries facilitates the operation of secondary and subsidiary pharmacies, enables the targeted deployment of skilled workers and helps reduce bureaucracy for pharmacies.

Re Number 7

As part of the reduction of bureaucracy, the explicit obligation to adapt standardised and general preparation instructions from third parties to the respective pharmacy business is no longer applicable. The decision as to whether an adjustment is necessary is now left to the professional judgement of pharmacy managers.

Re Number 8

It is a consequential amendment to the repeal of § 6(3)a.

The central identification procedure pursuant to § 6(3a) sentence 1 also applies to starting materials.

Re Number 9

Re Letter a

It is clarified that the courier service must also comply with the temperature requirements applicable to the medicinal product during delivery until delivery to the consignee.

In addition, two corrections are made. The prescription requirement under the Medical Cannabis Act is supplemented and a reference to a deleted regulation is removed.

Re Letter b

This is a consequential amendment to the introduction of § 35b, which specifies in detail the requirements to be observed by pharmacy management when shipping medicines with regard to packaging, transport and delivery, as well as compliance with contracts concluded by the operator with logistics companies in accordance with § 35b.

Re Letter c

Reduced requirements for secondary pharmacies are provided to reduce bureaucracy and facilitate the establishment of secondary pharmacies to provide locations and districts with a limited supply of medicinal products. The reduced requirements allow for flexible and cost-effective operation of a secondary pharmacy.

Individual and bulk preparations of medicinal products may be prepared in the pharmacy itself or may in future also be obtained from another pharmacy operated by the same operator.

The care of patients must continue to be ensured. The obligation of the secondary pharmacy to contract for prescription medicines remains in place. However, the medicinal

product is prepared by another pharmacy operated by the same operator. The latter delivers the prepared prescription medicinal product to the secondary pharmacy or to the patient via the pharmacy's messenger service. The decision as to whether a secondary pharmacy prepares its own individual or bulk preparations or obtains them from another pharmacy operated by the same operator is left to the professional discretion of the pharmacy operators.

Re Letter d

This is a consequential amendment to the amendment of § 23.

As a result of the amended provisions on the on-call service, the reference to § 23(1), second sentence, is deleted and the periods currently in force are included directly in the regulation without any changes.

Re Letter e

All pharmacies operated by the same operator shall be included.

Re Number 10

Re Letter a

An editorial correction is made by deleting the reference to the deleted § 73(3b) of the Medicinal Products Act. In addition, the list provides clarifications in terms of terminology.

Re Letter b

According to § 73(3) sentence 1 alternative 2 of the Medicinal Products Act, hospital pharmacies and pharmacies supplying hospitals may, in the event of a supply shortage, temporarily stock imported medicines as an exception. In these cases, documentation at the supplying pharmacy is difficult because extensive consultation with the supplying wards is required to determine who received a particular medicine in each individual case. As part of the drive to reduce bureaucracy, the new regulation stipulates that only certain parameters that are independent of the use of the medicinal product need to be documented in the hospital pharmacy, provided that the documentation in the relevant hospital ward ensures clear traceability to the patient and to the medicinal product used. The medicinal product shall be identified, for example, by reference to the central pharmaceutical number or, alternatively, by reference to the name, designation or business name of the pharmaceutical company, quantity and strength, and the batch name.

Under § 14(2) sentence 1 points 1 and 2 of the Transfusion Act, hospital wards are already subject to a partially corresponding documentation requirement, meaning that the persons involved are in principle familiar with the procedure. Traceability must be clear and immediate for the hospital pharmacy in order to allow for short-term contact with affected patients, for example in cases of medicinal product risks. As regards the corresponding application of the provision in § 26(2), the provision also applies to hospital pharmacies.

Re Number 11

As part of the drive to reduce bureaucracy, new rules are being introduced for pharmacy duty rosters. The basic on-call service currently provided for, where pharmacy operators must ensure the supply of medicinal products, is maintained. However, the new regulation provides for further exemptions from the on-call service to be ordered by the competent authority. The duty to be on call at all times applies to all pharmacies that have not been exempted by the competent authority in accordance with sentence 3. On-call duty must be maintained by the pharmacies designated by the competent authority to provide emer-

gency services, so they are not exempted. Where pharmacies are not classified for emergency services, the competent authority shall exempt them from on-call duty. However, as an exception to this, it lays down the opening periods provided for in the provision. Provided that the supply of medicinal products is ensured, it may specify periods shorter than those provided for in the regulation. As a result, the legal opening hours for pharmacies will be significantly liberalised and pharmacies will be able to determine when to open their pharmacy much more freely than before. This allows pharmacies to deploy their staff much more flexibly.

Secondary pharmacies [Zweigapotheken] are to be further developed as a form of care provision. Reduced requirements for secondary pharmacies are provided to reduce bureaucracy and facilitate the establishment of secondary pharmacies to provide locations and districts with a limited supply of medicinal products. The reduced requirements allow for flexible and cost-effective operation of a secondary pharmacy. In the case of secondary pharmacies, the requirements for the periods during which secondary pharmacies must be available for on-call duty will be reduced. Since secondary pharmacies do not have to provide a night service room, these can be provided for partial emergency services, but not for services at night. Secondary pharmacies are exempt from on-call duty at other times, although the authorities may stipulate on-call duty totalling up to eight hours per week between Monday and Saturday during normal local business hours.

Under paragraph 2, the competent authority may exempt a pharmacy from on-call duty for the other specified periods, provided that the supply of medicinal products is guaranteed. Paragraph 3 has been amended to reflect the changes in paragraph 1 and is otherwise identical to the previous paragraph 3.

Paragraph 4 corresponds to the previous paragraph 5. 1

Paragraph 5 corresponds in substance to the previous paragraph 6. In order to provide legal clarity, the term ‘hospital pharmacy’ was used and the applicability of the paragraph to hospital pharmacies was regulated in § 26(2).

Re Number 12

This is a consequential amendment to the deletion of § 5, which is therefore omitted from the list. In addition, a consequential amendment is made to § 23(5) for clarification purposes, and the applicability of this paragraph to hospital pharmacies is also clarified.

Re Number 13

The new § 35b standardises detailed logistical requirements for the dispatch of medicinal products by pharmacies to end consumers. The provision specifies the existing general obligation of pharmacies to maintain quality during shipping in § 17(2a) sentence 1 number 1; the addressees are specified in § 17(2a) sentences 1 and 3. The guidelines are based on process specifications from the Good Distribution Practice (GDP) guidelines. The other provisions in § 17(2a) shall continue to apply.

Paragraph 1 regulates requirements for the definition of transport processes in the quality management system. The existing obligation to establish corresponding processes is thus clarified. Accordingly, procedures based on risk-based transport planning, in particular, are necessary. Depending on the requirements of the medicinal product (e.g. cold chain, refrigerated medicinal product, low-vibration transport, etc.), these procedures include, in particular, choosing appropriate transport packaging and defining appropriate transport conditions, which, together with the data required for performance of the contract, are also passed on to the contracted logistics company.

Paragraph 2 stipulates that the personnel involved in the dispatch must be sufficiently qualified for the activities and be regularly trained on the shipping requirements. The training measures must be documented.

Paragraph 3 clarifies the requirements imposed on the dispatching pharmacy. This concerns ensuring shipping conditions so that the quality and efficacy of the dispatched medicinal product is not compromised. The focus here is on temperature conditions that must be complied with in relation to the medicinal product during transport to the end consumer. Firstly, suitable transport packaging must be used, the selection of which must be based not only on the requirements of the medicinal product but also on the outside temperatures. For example, in the case of temperature-sensitive medicines, a decision must be made as to whether measures should be taken during periods of expected high or low outside temperatures to prevent any negative impact on the quality and efficacy of the medicine, for example by using insulated bags or gel packs. In the case of medicinal products subject to refrigeration or to a cold chain obligation, appropriate cooling measures shall be taken; depending on the medicinal product and transport time, the addition of passive cooling elements or transport with active cooling may be considered. Where necessary, valid detection shall be provided for temperature-sensitive medicinal products by means of temperature controls carried on board.

Paragraph 4 lays down an obligation for the pharmacy operator to contractually ensure the contracted logistics company complies with the notified shipment requirements. This includes compliance with temperature conditions during transport and storage and delivery to the consignee in accordance with the notified requirements. In addition, it must be ensured that the transporter informs the pharmacy of any events that could have a negative impact on the medicinal product so that the pharmacy can make a risk-based decision on how to proceed. Further requirements, which are addressed directly to the contracted logistics company, are laid down in the newly introduced § 9a of the Medicinal Products Trading Ordinance.

Re Number 14

Re Letter e a

Re Double letter aa

In order to ensure the use of foreign professionals in the recognition procedure, such as persons in training under supervision, a corresponding administrative offence is introduced.

Re Double letter bb

The administrative offence relating to on-call service will be amended.

Re Double letter ee

The offence of failing to display or of improperly displaying information about the nearest pharmacies on call does not apply.

Re Letter b

In order to ensure the use of foreign professionals in the recognition procedure, such as persons in training under supervision, a corresponding administrative offence is introduced.

Re Article 2 (Amendment to the Ordinance on the Pricing of Medicinal Products)

Re Number 1

Wholesalers should be able to award further discounts in addition to the relative wholesale surcharge of up to 3.15 percent regulated in the first sentence. Only commercial discounts granted in return for a payment made before the due date (‘genuine discounts’) are allowed. Discounts which are made when payments are made in accordance with the contract (‘unreasonable discounts’) are not included; these remain inadmissible in accordance with the case law of the Federal Court of Justice.

Pharmaceutical wholesalers compete for pharmacies not only through the relative share of their remuneration or delivery conditions, but also by granting price reductions in the form of discounts. The provision allows this normal commercial competition again in a clearly defined framework. Such discounts are common in wholesale trade and can contribute to the economic stabilisation of pharmacies without undermining price maintenance. The requirements of § 52b(3) sentence 1 of the Medicinal Products Act with regard to demand-based and continuous supply by fully supplying wholesalers remain unaffected.

Re Number 2

Re Letter a

The newly introduced definitions of the components of the fixed surcharge ‘fixed sum’ and ‘relative share’ serve to clearly delineate these two components of remuneration. They contribute to legal certainty by ensuring uniform and binding use of terms and facilitating standard references to the respective component of the fine. The newly introduced and legally defined term ‘fixed sum’ corresponds to the common name of the absolute proportion of remuneration. The other components of the fixed surcharge result from a relative percentage share of currently 3% of the pharmacy purchase price and a share to support the provision of emergency services.

The previous contribution of 20 cents for the promotion of pharmaceutical services pursuant to § 129(5e) of Book V of the Social Code will no longer be levied as a fixed surcharge component in light of further developments in the financing structure for these services. To date, the surcharge has been paid into the fund for pharmaceutical services managed by the night and emergency service fund, from which the fees for completed pharmaceutical services were subsequently paid out. The fund currently has large financial reserves. The continued levying of the surcharge on the financing base would lead to further growth without any prospect of the funds being skimmed off in a comparable amount in the foreseeable future.

The surcharge of 21 cents to promote the security of the emergency service will be increased to 41 cents. This is to support pharmacies in rural areas. In the sense of a redistribution, the increase corresponds to the amount of the previous share for the financing of pharmaceutical services pursuant to § 129(5)e of Book V of the Social Code in the amount of 20 cents. This increases the annual payout volume for the emergency service flat-rate determined by the night and emergency service fund by around EUR 160 million for the corresponding period. The night and emergency services provided by pharmacies ensure that the population has access to medicines outside regular opening hours. Night and emergency services therefore make an important contribution to the supply of medicines to the population. Pharmacies located in regions with a low density of pharmacies must provide night and emergency services more frequently than pharmacies located in regions with a high density of pharmacies. The increase in the surcharge to support the provision of emergency services will therefore particularly benefit pharmacies in rural areas.

Re Letter b

With the Act to Strengthen Nursing Training of 12 December 2023 (Federal Law Gazette 2023 I No 359), a new § 129(2b) was inserted into Book V of the Social Code. In addition to § 129(2a) of Book V of the Social Code, this provides for a further possibility of exchanging medicinal products in the event of unavailability. Pharmacies should also be able to charge the 50 cent surcharge in accordance with § 3(1a) for this exchange. It is also clarified that the supplement relates to the respective exchange of a medicinal product and cannot be charged more than once for the same exchange of the same medicinal product, regardless of how many packs are dispensed as part of the exchange. The organisational effort for which the surcharge is granted, for example through consultations with the prescribing doctor or queries to the pharmaceutical wholesaler, is not caused by the number of packages dispensed, but by the exchange itself.

Paragraph 2 has been adjusted accordingly on the basis of the new definition of the relative share introduced in the first sentence of paragraph 1.

Re Letter c

The new sentence 2 is intended to make it clear that the package size corresponding to the quantity actually delivered must be used as the basis for the billing. If a subset is dispensed from a larger package, the package size corresponding to the dispensed quantity shall be decisive for billing. If, for example, a corresponding quantity is taken from an N3 package when dispensing an N2 package, the N2 package shall be used as the basis for calculation. The same applies to the supply of an N1 pack from an N2 or N3 pack; here too, the packaging of the quantity actually supplied, i.e. in this case the N1 pack, is decisive.

Re Number 3

The aim of the regulation is to establish a procedure for the regular review and further development of the fixed surcharge components by the self-governing body. The agreement partners, the National Association of Health Insurance Funds and the relevant umbrella organisation of pharmacists formed to represent their economic interests are thus tasked with agreeing on a joint proposal for adjusting the price components in consultation with the Association of Private Health Insurance Companies and submitting this proposal to the regulator in accordance with § 78(1) sentences 1 and 2 of the Medicinal Products Act.

Paragraph 2 serves to establish a robust yet flexible basis for agreements that takes into account both economic developments and the maintenance of financial viability within the statutory health insurance system. The opening clause for other suitable indices is intended to enable the contracting parties to take into account other factors that are relevant from their point of view.

Failing agreement within the period referred to in paragraph 1, the dispute resolution mechanism shall be the arbitration body referred to in § 129(8) of Book V of the Social Code, which shall decide on the proposal within eight weeks.

Re Number 4

The purpose of the amendment is to specify that, in the event of the supply of a substance in accordance with Paragraph 4, the actual purchase price of the smallest packaging required for the quantity to be supplied is decisive for the calculation of the pharmacy fee. The packaging should also be able to be fully invoiced in the event that only a partial quantity from the packaging is used for the delivery. The reference to the purchase price of the smallest packaging required for supply is intended to avoid imposing an excessive financial burden on payers and at the same time to ensure an appropriate, demand-led price basis.

Re Number 5

The purpose of the Ordinance is to determine in a uniform and transparent manner the prices to be charged in pharmacies for making up preparations made from substances (formulations). Paragraph 1 stipulates that for substances in formulations (in accordance with § 4(2)), the actual purchase price of the smallest package required for the preparation is decisive. Paragraph 2 provides that, for finished medicinal products in formulations, the pharmacy purchase price referred to in Paragraph 3(2), and thus not the actual purchase price but the list price, is to be taken into account, the smallest package size required for the preparation being decisive. By focusing on the smallest packaging or pack size required, a fair, demand-oriented price base is ensured.

Re Number 6

When dispensing medicinal products in accordance with § 48a and § 48b of the Medicinal Products Act, pharmacies may incur increased costs. The increased expenditure arises in particular from the review of the exclusion criteria pursuant to § 48a(2) of the Medicinal Products Act and from compliance with the requirements of the Ordinance pursuant to § 48b of the Medicinal Products Act. The pharmacies should be allowed to claim an amount of 5 euros.

Re Article 3 (Amendment to the Medicinal Products Trade Ordinance [Arzneimittelhandelsverordnung])

Re Number 1

The provision extends the scope of the Medicinal Products Trade Ordinance to logistics companies commissioned by pharmacies to transport medicinal products to end customers via mail order. Requirements with which the contracted logistics company must comply are laid down in § 9a.

Logistics companies are subject to supervision by the competent federal state authorities pursuant to § 64(1)(1) of the Medicinal Products Act with regard to the requirements under § 9a.

Re Number 2

The new § 9a regulates requirements for logistics companies contracted by pharmacies for the transport of medicinal products subject to sale in a pharmacy to end consumers via mail order. The logistics company must ensure that the quality and efficacy of the medicinal products is not impaired during transport. This also applies to the extent that interim storage becomes necessary on the way to the end consumer because delivery is delayed or the medicinal product cannot be delivered at a certain time of delivery. The relevant shipping conditions must be communicated by the dispensing pharmacy to the logistics company; these must be complied with by the logistics company in accordance with § 35b(3) of the Regulations on the Operation of Pharmacies. Particular attention should be paid to the temperature conditions specified by the pharmacy. If an active cooling system is used during transport, the logistics company must continuously record the temperature conditions and make them available to the pharmacy upon request. The logistics company must use suitable vehicles which are equipped in such a way that the dispatched medicinal products are not subjected to conditions which could affect their quality and efficacy or damage their packaging. The medicinal products must also be secured against unauthorised access during transport and delivered to the final customer in accordance with the pharmacy's instructions. Where packing stations are used for collection in accordance with this instruction, the quality maintenance requirement also applies to this delivery step.

The regulations are intended to ensure that the quality and efficacy of medicinal products remain guaranteed during transport by pharmacies via mail order and that unauthorised access to such shipments is prevented.

Logistics companies are subject to supervision by the competent federal state authorities pursuant to § 64(1)(1) of the Medicinal Products Act with regard to the requirements under § 9a.

Re Number 3

In order to ensure that a logistics company ensures that the quality and efficacy of a dispatched medicinal product is not impaired during a transport operation commissioned by a pharmacy, a corresponding administrative offence is introduced.

Re Article 3 (Amendment to the Training and Examination Regulations for Pharmaceutical Technicians)

This is a consequential amendment.

The amendment to § 4(7) of the Apothekenbetriebsordnung removes the list of pharmaceutical forms, so the reference in Annex 1, Part B, point 2(d) would be meaningless. The reference to the pharmaceutical forms previously referred to in § 4(7) of the Regulations on the Operation of Pharmacies is therefore included in the text of the Annex without change.

Re Article 4 (Entry into force)

Subject to the second sentence, this Ordinance shall enter into force on the day following promulgation. Article 1(2)(a) shall enter into force on the first day of the quarter following its promulgation in order to enable the technical implementation of the changes to the emergency service surcharge and the surcharge for financing additional pharmaceutical services pursuant to § 129(5e) of Book V of the Social Code required by the regulation.