KNOW-HOW

Gleiss Lutz

23.04.2020

HEALTHCARE AND LIFE SCIENCES

COVID-19: FEDERAL MINISTRY OF HEALTH ISSUES EMERGENCY ORDINANCE TO ENSURE THE SUPPLY OF MEDICINAL PRODUCTS

On 21 April 2020, the Federal Ministry of Health issued the SARS-CoV-2 Medicinal Products Supply Ordinance (SARS-CoV-2-*Arzneimittelversorgungsverordnung*, 'SARS-CoV-2 AMVV') on the basis of the legal authorisation in section 5(2), no. 4, letters (a), (b), (e), and (f) and no. 7 Infection Protection Act (*Infektionsschutzgesetz*, 'IfSG'). The ordinance aims to ensure the supply of medicinal products to the population during the epidemic. It provides for various temporary exemptions from pharmacy, medicinal products, and narcotic drugs law as well as from the German Social Security Code, Book V (*Sozialgesetzbuch (SGB) Fünftes Buch*, 'SGB V') until 31 March 2021 or until the determination of epidemic situation of national importance is lifted.

I. Deviations from section 129 SGB V and the Framework Agreement on the Supply of Medicinal Products

The ordinance modifies the rules governing the sale of medicinal products in derogation of the provisions of section 129(1) and (2) SGB V and the Framework Agreement on the Supply of Medicinal Products (*Rahmenvertrag über die Arzneimittelversorgung*) in the interest of securing the supply.

- If a **prescribed medicinal product is unavailable**, pharmacies may now dispense to the insured person a **medicinal product with the same active ingredient** that is available or can be supplied to the pharmacy. If a medicinal product with the same active ingredient is unavailable, a pharmacy may – after consulting with the prescribing doctor – dispense a pharmacologically-theraputically comparable medicinal product (section 1(3), sentences 1 and 2 SARS-CoV-2-AMVV). This even applies if the prescribing doctor has ruled out exchanging one medicinal product for another (section 1(3), sentence 3 SARS-CoV-2-AMVV).
- Further, pharmacies may in such cases deviate from doctor's prescriptions in terms of **package size, package quantity, dispensing partial amounts of finished medicinal products,** and **strength** without consulting with the prescribing doctor provided there are no pharmaceutical concerns (section 1(3), sentence 4, nos. 1 to 4 SARS-CoV-2-AMVV).
- Health insurance funds' **right to contest and refuse reimbursement** of pharmacies' invoices when medicinal products are exchanged **is excluded** (section 1(4) SARS-CoV-2-AMVV). This arrangement aims to reduce pharmacies' risk from refusals to reimburse. The legislator therefore deliberately accepts both certain potential for abuse of the criteria of lack of availability and additional costs.
- However, pharmacists' authorisation to deviate from prescribed package size, package quantity, and strength does not apply if the prescription concerns narcotics in accordance with section 5(6) Narcotic Drugs Prescription Ordinance (*Betäubungsmittel-Verschreibungsverordnung*, 'BtMVV') (section 1(4), sentence 5 SARS-CoV-2-AMVV).
- If an active ingredient is not available at the price agreed or determined under section 129(5c), sentence 1 to 5 SGB V, the prices under section 129(5c), sentence 6 to 12 SGB V may be billed (section 1(5) SARS-CoV-2-AMVV).

II. Deviation from the provisions of pharmacy law

Section 2 of the ordinance **authorises the authorities charged** with executing the Pharmacy Act (*Apothekengesetz*, 'ApoG') and Ordinance on the Operation of Pharmacies (*Apothekenbetriebsordnung*, 'ApBetrO') to allow **deviations**

from the provisions of the ApoG on the **operation of pharmacies** and on the **dispensing of medicinal products as part of discharge management** and from the provisions of the **ApBetrO on the operation of pharmacies**, on staffing, on the **inspection of starting materials and containers**, on the **manufacture and inspection of medicinal products**, on the **purchase of medicinal products by pharmacies**, on **courier services**, and on **documentation** where this is required to ensure the proper supply of medicinal products, anaesthetics, medical devices, and other common pharmacy products to the population.

III. Amendment of the Medicinal Products Price Ordinance – introduction of a special flat fee of EUR 5.00 for pharmacy courier services

- Section 4 SARS-CoV-2 AMVV introduces a **temporary surcharge for pharmacies for dispensing medicinal products by courier** of **EUR 5.00** per delivery location and day, irrespective of the number of medicinal products delivered. If **partial amounts** are dispensed, then the surcharge applies **from the first dispensation**. When additional partial amounts are dispensed from the same package, pharmacies can charge only the surcharge of EUR 5.80 per dispensation. This amount is based on the remuneration for additional dispensing of a medicinal products already provided for under section 3(6) Medicinal Products Price Ordinance (*Arzneimittelpreisverordnung*, 'AMPreisV').
- This aims to reduce **insured persons' risk of infection** from visiting pharmacies. Patients must still hand in prescriptions to the pharmacy as normal. The courier fee does not apply to the delivery of medicinal products by pharmacies with a mail order permit.
- Pharmacies can charge statutory health insurance funds a **one-time fee of EUR 250.00 for the support of courier services**. The Federal Union of German Associations of Pharmacists (ABDA) and National Association of Statutory Health Insurance Funds will agree on the details about how to use and distribute these funds.

IV. Precautions in the case of price increases of cytostatic agents

- If, due to short-term price increases by pharmaceutical companies, finished medicinal products for oncological preparations are no longer available at the prices agreed between the Federal Union of German Associations of Pharmacists and the National Association of Statutory Health Insurance Funds, section 1(5) SARS-CoV-2-AMVV applies. Under this provision, pharmacies may **bill** the health insurance funds their **actual cost prices** up to, as a maximum, the level of the prices indicated in the AMPreisV in order to avoid supply shortages.
- However, in order to check the billed price, the National Association of Statutory Health Insurance Funds and the relevant health insurance fund can require proof of the sources of supply and actually agreed purchase prices, including information on the discounts based on total turnover.

V. Market-regulating interventions relating to the distribution of medical products needed for the treatment of patients

For the benefit of the Federal Ministry of Health, SARS-CoV-2-AMVV not only provides for extensive **rights to obtain information** and **monitoring rights**, but also the legal basis for far-reaching interventions in market freedom and free pricing for medical products needed for the treatment of patients:

- Such products include **medicinal products** as well as their **active ingredients, starting materials and additives, medical devices, laboratory diagnostics, aids, PPE items** and **disinfectant products** whose essential importance for the needs-based provision of medical care has been determined and published by the Federal Ministry of Health in the Federal Gazette on a case-by-case basis (section 7(3) SARS-CoV-2-AMVV).
- The following duties are imposed on **manufacturers and distributors** of medical products whose relevance for supply has been determined (section 7(1) and (2) SARS-CoV-2-AMVV). They serve to maintain a regulated and needs-based supply of the population during pandemic situations and are intended to protect consumers by avoiding "crisis profiteering":
  - **information on stocks, storage location, production, distribution and prices upon request of the Federal Ministry of Health** (violations can be regarded as an administrative offence and subject to a **fine of up to EUR 25,000**);
  - **reasonable and continuous provision** of the products **within the limits of what is reasonable**;
  - pricing based on costs of providing the products;
  - **no mark-ups** vis-à-vis consumers **based on the epidemic** (violations can be regarded as an administrative offence and subject to a **fine of up to EUR 25,000**);
  - **precautions against apparent stockpiling or deliberately bringing about a shortage** when selling the

› products on the market.

› Manufacturers and distributors have a **claim to compensation** vis-à-vis the Federal Ministry of Health in the amount of those expenses incurred by them due to the fact that, as a result of a market-regulating decree of the Federal Ministry of Health pursuant to section 5(2), no. 6 IfSG, they can no longer satisfy the obligations they have entered into with other contracting partners.

VI. Increased powers within the scope of discharge management of the hospitals

› In order to reduce the number of visits to the doctor by patients following discharge from the hospital, hospitals are now allowed to prescribe medicinal products to such patients in **packs with up to the largest package size indicator** and not – as previously – only in packs with the smallest package size indicator (section 1(2) SARS-CoV-2-AMVV).

› For this reason, the **limited period** for which pharmacy-only medicinal products, surgical dressings, urine and blood test strips, balanced diets for enteral nutrition, as well as substances and preparations from substances that are used as medical devices, can be prescribed is also increased from a maximum of seven days **to up to 14 days**. The same applies when determining an **incapacity to work**.

VII. Objection period of the Federal Joint Committee for clinical studies on the off-label use of medicinal products shortened

If it wishes to object to clinical studies on the off-label use of medicinal products to treat COVID-19 illnesses, the Federal Joint Committee must now do so **within five work days** (instead of eight weeks, pursuant to section 35c(2), sentence 3 SGB V) after receiving notification of the planned study (section 1(1) SARS-CoV-2-AMVV). This is intended to speed up the process and in this way will protect an insured person's right to be treated with medicinal products outside their approved indication, provided that this is done in connection with **clinical studies** and a therapy-related improvement of the treatment of a serious illness as compared to existing treatment options is expected.

EXPERTISE

Corona Pandemic

Healthcare and Life Sciences

EXPERTS

Dr. Reimar Buchner

Dr. Enno Burk

Dr. Christina Fröb

Dr. Julia Hornung