IMPORTANT ADDITION to the Position Paper: Pharmaceutical preparations: An Essential Part of Healthcare

Position paper: Outsourcing Compounding is Essential for Medicine Supply

It is important that the European Union will include Article 3, paragraph 1a – a crucial provision that provides a robust legal basis for outsourcing compounding – in the new pharmaceutical legislation. Failure to include this article would make it impossible for pharmacists (both community and hospital) to outsource compounding of medicinal products. This would have severe consequences for the availability of medicines. Vulnerable patient groups, including children and patients with rare diseases, are directly affected. In situations such as a pandemic or medicine shortages, outsourcing of compounding is also essential to ensure continuity of care. The Dutch Association of Hospital Pharmacists (NVZA), together with the Royal Dutch Pharmacists Association (KNMP) and the Dutch Network of Compounding Centres (NGB), therefore urgently call on European politicians to include Article 3, paragraph 1a in the legislation.

Call to action

The NVZA, KNMP, and the NGB urge the European Commission, the European Parliament, the Council of the EU, national governments, and all stakeholders to incorporate Article 3, paragraph 1a, of the Council proposal of 4 June 2025 into the European pharmaceutical legislation. This is crucial to ensure the continued availability of vital and essential medicines for patients.

Outsourcing of compounding is essential to ensure safe and sustainable supply of medicines to patients. In the Netherlands – as well as in other EU-member states – a significant number of medicines is only available through compounding.

Concerns about a so-called "shadow industry" or the quality of compounded preparations are unfounded. Article 3, paragraph 1a, imposes strict conditions for the circumstances under which a medicinal product may be compounded, as well as for the quality of the medicinal product itself. Moreover, the article contains clear requirements for the oversight of these preparations, thus ensuring safety and compliance with regulations.

Counsel proposal - Artikel 3 lid 1a
In justified cases a Member State may temporarily exclude from the scope of this Directive medicinal products prepared to mitigate or resolve a shortage in that Member State, or to address the specific needs of the patients in that Member State in a situation where a marketing authorisation holder has withdrawn the marketing authorisation of a medicinal product for reasons unrelated to quality, safety or efficacy or to address a situation, where there is an authorised medicinal product with a marketing authorisation which does not cover the specific strength, pharmaceutical form or formulation needed to address the specific needs of patients in that Member State.

The exceptions referred to in this paragraph shall apply only when no suitable alternative medicinal product is authorised and available within that Member State or can be supplied in accordance with paragraph 1 to meet the specific needs of the patients, and in the case of shortage, when the shortage in the relevant Member State cannot be resolved at that time through Union coordinated actions

For medicinal products prepared in accordance with this paragraph Member States shall ensure that:

a) *the preparation of the medicinal product is approved by the national competent authority on the basis of an assessment of the case and on public health grounds;*

b) *in the case of a shortage, the approval under point (a) is revoked when the shortage is resolved or the medicinal product can be supplied in accordance with paragraph 1;*

c) *in the cases other then shortages the approval is assessed at appropriate intervals for the necessity of the exemption;*

d) *appropriate oversight by the national competent authority is in place and in particular any issues with regards to quality and safety are monitored and evaluated;*

e) *the facility preparing the medicinal product complies with the requirements of the Good Manufacturing Practices referred to in Article 160;*

f) *the quality, safety and efficacy and the positive benefit-risk balance of the medicinal product is confirmed by the national competent authority;*

g) *the product is supplied to patients under the supervision of an authorised healthcare professional.*

Cause

The European pharmaceutical legislation is currently under revision, and final negotiations are underway between the European Commission, the European Parliament, and the Council. Article 3, paragraph 1a, has been added to the Council proposal to establish a robust legal basis for the outsourcing of compounding. It is crucial that this provision is included in the new EU pharmaceutical legislation.

Outsourcing of compounding is essential for the supply of essential pharmaceutical products in the Netherlands – and other European countries – as a complement to the available licensed medicines. Failure to include Article 3, paragraph 1a in the legislation will directly jeopardise patient care.

The NVZA, KNMP, and NGB therefore urgently call on the European Commission, the European Parliament, the Council of the EU, national governments, and all stakeholders to incorporate Article 3, paragraph 1a of the Council proposal into European pharmaceutical legislation.

Background

In recent decades, community and hospital pharmacies have increasingly collaborated on the preparation of medicines. They outsource (some of) these preparations to each other, as well as to pharmacies that have specialised in compounding of medicinal products. Nowadays, many pharmacies no longer have the facilities to prepare all medicines themselves, while some pharmacies have specialised in the preparation of particular types of medicinal products and outsource the compounding of other medicinal products.

Outsourcing of compounding is an essential part of both national and European healthcare. These medicines are indispensable when suitable licensed medicines are unavailable – due to inappropriate strengths or dosage forms, missing active substances, or temporary/permanent shortages of licensed

medicinal products. In such cases, compounded preparations offer an alternative and contribute to the continuity of care.

In the Netherlands and other EU member states, this practice has a long history and is embedded in a strict system of quality standards, legislation, regulations, and oversight. Outsourcing of compounding must meet strict quality requirements.

Compounding is not a substitute for licensed medicinal products, but a necessary complement when no adequate licensed alternative is available.

If such compounding were no longer possible following the revision of EU pharmaceutical legislation, this would pose serious risks to the availability of medicines for patients for whom no adequate licensed alternative is available. This is important not only for the quality of care but also for the efficient use of personnel and technical resources needed for the compounding.

Examples of peer-provided preparations in the Netherlands:

- Medicines specifically developed for newborns and children. For example, oral solutions such as clonidine (sedation in the ICU), amlodipine (high blood pressure), and midazolam (epilepsy).
- Desmopressin nasal spray: developed for patients with rare, serious clotting problems because the marketing authorization holder could not supply it.
- Flucytosine is used for life-threatening fungal infections and could no longer be supplied by the marketing authorization holder.
- Infusions with sodium chloride and glucose: a basic solution for every hospital patient, developed by hospital pharmacists when supply problems arose.
- Dipyridamole oral solution (anticoagulation after stroke or heart valve surgery): an oral solution developed for administration through a tube for patients who cannot swallow.
- Low-strength bosentan capsules for children with high blood pressure in the lungs.
- Sodium benzoate capsules for patients with high ammonia levels due to a rare metabolic disorder. There are 6,100 rare disorders; in Europe, between 27 and 36 million people have a rare disorder.
- Cardioplegia fluid: essential for stopping the heart during cardiac surgery and thus allowing the operation to be performed.
- Labetalol for severe pregnancy-related hypertension. During a temporary shortage of the registered product Trandate, there was no alternative available for the rapid control of severe hypertension during pregnancy. Pharmacy-prepared labetalol injections offered an immediate solution and protected the health of mother and fetus in emergency situations.
- Isoniazid oral solution for tuberculosis prevention in infants. Preventing tuberculosis in infants requires accurate dosing based on weight. Pharmacy-prepared isoniazid oral solutions make this life-saving treatment feasible and accessible.