Magistral preparation of Athroposophic Medicinal Products
A systematic collection of FAQ`s and international experiences
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Introduction

Henrik Szőke 31. 08. 2024.

The International Federation of Anthroposophic Doctors Associations (IVAA) stated in it`s new strategy 2024-2028 as a strategic objective the “Implementation and recognition of the system of AM” regarding the „Availability of anthroposophic medicinal products (AMPs)” to „identify, support, promote, and communicate regional magistral preparations best practice models (as shared toolkit, internal "handbook"). On this topic a European Call took place on 27. 05. 2024 with Henrik Szoke (IVAA), Marek Roszkiewicz (IAAP); Annette Greco (Wala), and Monica Mennet - von Eiff (Weleda) and several country representatives of AM. The meeting concluded by highlighting the need for a systematic collection of experiences, protocols, and legal requirements. As a conclusion, the creation of a working group was initiated, involving companies (Weleda Monica Mennet - von Eiff, Wala Annette Greco), stakeholders (IAAP also Marek Roszkiewicz, and IMKA), and IVAA (Henrik Szőke, Stefano Milani), along with securing funding and enhancing local production capabilities, was considered crucial for sustainable production and distribution of finished medicinal products, magistral preparations.

Supplies of starting materials by manufacturers to pharmacies - important points to clarify in advance

Dr. M. Mennet-von Eiff 08.08.2024 added by Annette Greco 12.08.2024

Important questions:

1. What are the requirements at national level for the manufacture of AM outside industrial scale?

a. Is it possible to produce on individual prescription? Or is a prescription always required?

b. Is it possible to stockpile magisterially produced medicines? If so, are there any special requirements, e.g. quantities to be achieved?

c. Is it possible to ship manufactured medicines within the country?

d. Does the pharmacy have to carry out tests on a starting material (identity, purity, content) or is the recognition of an AZ sufficient?

e. What dosage forms may be manufactured in a pharmacy? Which are technically possible?

f. What are the requirements for the quality of the manufactured drug - official release at specification level? Are stability tests required according to the pharmacopoeia?

g. Do imported starting materials have to comply with a pharmacopoeia monograph?

2. Is the pharmacy authorised to purchase alcoholic products? In other words, is it authorised to receive products containing untaxed alcohol?

3. What dosage forms does the pharmacy intend to use?

4. Does the pharmacy have a VAT number?

5. Orders and documentation
a. Order quantities are planned?
b. How often does the pharmacy plan to order?
c. Will the pharmacy provide a business forecast/plan? If so, for what period?
d. What additional documentation will the pharmacy require? Just a release certificate from the QC (certificate of analysis) and a general GMP confirmation for production?
e. Which pharmacopoeias are recognised in the country (Ph Eur, HAB, Ph. Helv., APC)?
f. What are the pharmacy's delivery times?
g. Will the order language/certificates be accepted in English?

6. What are the contractual arrangements?

7. Customs clearance is done by the pharmacy in the destination country.

8. We will not always have everything available, so we need to be aware that if a raw material is out of stock, we may not be able to supply it for over a year. How do we deal with this?

9. Costs for additional documentation and testing can be passed on to pharmacies

10. Does the pharmacy produce for itself for dispensing or is it planned to pass on to other pharmacies? For the finished product? For the starting material?

11. What is the intended name of the preparations? Name of the supplying manufacturer? Free naming?

12. Are there any considerations for dealing with starting materials with a very short shelf life?

13) Are the specifications, e.g. of the HAB, for the further processing of the raw materials complied with? If not, on what evidence is further processing based?

14) Are professionals other than pharmacists authorised to manufacture? Is this done in the country?

15. has the possibility of importing finished products been considered and weighed against extemporaneous formulation?

Customs:
Export to third countries:
- For products containing alcohol, creation of an eVD (electronic administrative document)
- Customs documents must be prepared (e.g. export accompanying document from €1,000). Alternatively, proof must be provided that the goods were actually exported.
- Possible preference check at customs to allow the customer to import the goods duty free. This option is only available if the recipient country has an agreement with the EU.
- Check that the goods are not dangerous. Dangerous goods cannot be sent by air freight or courier services.
- The national regulations of the importing country must be observed. In some cases, special documentation may be required for certain products in the importing country.
- It should also be noted that import duties may apply in the receiving countries. For example, the import duty for tinctures into India is 30%. The 30% is calculated on the value of the goods + freight (e.g. €100 value of goods + €30 freight = €130 = €39 duty).

Shipping:
Overseas / EU Air Freight:
- Hazardous materials/dangerous goods are not permitted as air freight by courier. Must be sent via a freight forwarder. This can be very expensive. And the goods are x-rayed! Is this a problem for the substances?
- Dangerous goods documents must also be completed for overseas shipments.
- Shipping costs: Several 100 Euros (varies by country)
- Sea freight - very long journey (4-6 weeks minimum)
- Thermal shipping would need to be checked on a per item basis, quite difficult!
- If a shipment is to be made, please inform customs / export / VL abroad in advance.
- Transport and customs costs can be passed on to the pharmacies in accordance with the contract!