

Our National Association of Pharmacies- ANF (non-governmental institution) also published the Portuguese Galenic Formulary (FGP) which includes guidelines for preparations, standard procedures, rules for beyond-use dates assignment (adapted from USP), etc.. Portuguese Galenic Formulary (FGP) is an official compendia recognized by the Portuguese regulatory agency (INFARMED)

List some difficulties you have with regulatory agencies regarding compounding:
Mainly, the lack of proper updating and clarifying of some regulations

What are you allowed to compound?

Compounded medicines can only include substances described in the Portuguese pharmacopoeia, in the pharmacopoeias of other states of European Pharmacopoeia Convention or from scientific compendiums

What are you not allowed to compound?

a) Animal organ extracts;

b) Active pharmaceutical ingredients (of systemic compounded medicines) in dosages higher than those authorized for commercially human medicines (for systemic use);

c) The following active pharmaceutical ingredients:

Amfepramone;

Benzphetamine;

Secbutabarbitol;

Clobenzorex;

Ethylamphetamine;

Fenbutazate;

Fencamfamin;

Flenfuramine and dexfenfluramine;

Fenproporex;

Flunitrazepam;

Fluoxetine;

Lefetamine;

Levothyroxine and similar substances;

Mefenorex;

Norpseudoephedrine;

d) Other active pharmaceutical ingredients included in medicines which respective marketing authorisations were suspended or withdrawn, for reasons concerning public health issues

Describe your compounding pharmacy.

Not applicable

List some unique equipment that you commonly use.

Regulations include minimal equipment that all pharmacies must have, e.g: mortars and pestles, graduated glass material, hot water baths, electronic scales, ph-indicator strips, etc.

Some community pharmacies also have mixing equipment (Unguator ®, Topitec ®) and capsules machines.

Can you compound or manufacture large quantities to provide to other pharmacies?

Regulations do not describe the possibility of community pharmacies compound and provide to other pharmacies for resale.

How do you assign beyond-use dates, or expiration dates to your compounded preparations?

Beyond-use dates are assigned according to published stability studies (in the Portuguese Galenic Formulary (FGP), books, IJPC, etc.) or according to the quality control made in our laboratory (LEF) when pharmacies demand us.

When there is not any stability studies data, beyond-use dates are assigned according to the rules for beyond-use dates assignment (included in the Portuguese Galenic Formulary (FGP) and adapted from USP criteria).

What do you think is unique about the way compounding is done in your country?

There are not compounding-only pharmacies.

There is only one pharmaceutical compounding information center

Do all pharmacists have the ability to compound? Or, does it take additional special training?

All the pharmacists have the ability to compound since the curriculum of their graduated education includes pharmaceutical compounding. Nevertheless, all the pharmacists must undergo continuous education and seek post-graduation education as well as training on job.

Are you allowed to compound non-prescriptions medications for sale?

Regulations do not clearly distinguish non-prescriptions and prescribed compounded medicines, instead distinguish compounded medicines prepared according to a physician's prescription (in Portuguese *fórmula magistral*) or prepared according to the directions in a compendium, a pharmacopoeia or a formulary (in Portuguese *preparado oficial*).

Do you compound the following dosage forms?

NONSTERILE	<u>Yes</u>	<u>No</u>
Oral liquids (solutions, suspensions, emulsions)	X	_____

Topical liquids (solutions, suspensions, emulsions)	X	_____
Oral solids (capsules, tablets)	X	_____
Suppositories	X	_____
Troches/Lozenges	_____	X
<i>we are not aware if any community pharmacy compound troches and lozenges</i>		
Ointments, Creams, Lotions	X	_____
STERILE		
Ophthalmic preparations	_____	X
Nasal preparations	_____	X
Injections	_____	X
Intravenous admixtures	_____	X
<i>we are not aware if any community pharmacy compound sterile dosage forms(sterile compounding is usually done by hospital pharmacies)</i>		

Do you compound for the following therapeutic categories?	<u>Yes</u>	<u>No</u>
Pain management	X	___
Dermatology	X	___
Hormone replacement therapy	X	___
Veterinary	X	___
Neuropathy	X	___
Dental	X	___
Podiatry	X	___
Ophthalmic	___	X
Steroid therapy	X	___
Oncology	X	___
Rheumatology	___	X
Parenterals	___	X
Inhalation/respiratory	___	X
Surgical	___	X

Other information you would like to share with compounding pharmacists internationally about compounding in your country? Please add here.

References

Acknowledgment