

Compounding Internationally
International Society of Pharmaceutical Compounding (ISPhC)
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If you will respond to the questions below, we will incorporate your answers in the ISPhC web page section Compounding Internationally, so we will have all the information in a uniform format. You will be listed as an author of the column for your country. Thank you very much for your help.

Is compounding permitted in your country?

*Yes, largely with medical prescription. But without prescription according to the formulations of European Pharmacopeias (if drugs permit without prescription).
Named “ officinalia”*

Who regulates compounding in your country?

Italian Pharmacopoeia XII.

Which are the Compounding Pharmacy Regulations or Guidelines in your Country? Please provide a description, a document or link to your country web page to use as a reference.

*Guidelines are the NBP (Norme di Buona Preparazione as Good Manufacture Practice) from 1992, but in fact from Januar 2004.
http://wiki.federfarmaroma.com/index.php?title=Norme_di_Buona_Preparazione_-_NBP*

List some difficulties you have with regulatory agencies regarding compounding:

The pharmacist compounder is "surrounded" by obstacles, and when there are, it has now been brought up to create obstacles alone!

In Italy, professional associations (FOFI) and the Associations of Owners have NEVER promoted the Compounder Pharmacy, indeed, trying to distract from the pharmacist to do, to avoid problems, especially with the Pharmaceal Industry.

*Inspectors apply rules subjective, often depending on the Province or Region.
Lack of clarity on the obligations. Afraid to decide for themselves.
Old method of charging tax (tariffazione), again of 1992! No desire to upgrade.*

What are you allowed to compound?

All with prescription, but drugs must be in a product in pharmaceutical market. Must be for the same disease. If this drug is for a particular different disease, can be prescribed but must indicate in the recipe the reason.

What are you not allowed to compound?

*Inability to unpack simple even harmless substances (like Aminoacid, Vitamin C – no API obviously).
Inability to compound a simple cream with Panthenol and Centella Asiatica glycolic extract , without prescription).*

Describe your compounding pharmacy.

*I don't work in a Pharmacy, but I know the reality of many Pharmacies.
Approximately 2500 are the Pharmacies compounders.
Dermatologies compounds are in the first place.
Recipe for hair (minoxidil with or without cortison)
For foot, nail, teeth.
FANS – Vaginal cream – Ovula and suppositories –
Many capsules (at second place) especially for obesity.
Many capsules with herbal remedies.
Syrups and suspensions for Pediatric and geriatric use.
Many veterinaries recipes. Recently the Veterinarians have discovered the possibility offered from the Compounder and they are very useful support from the Pharmacist.
Not all the 2500 pharmacies obviously, but 50 – 100 certainly.*

List some unique equipment that you commonly use.

*In Pharmacies that I know:
Water bath, capsules machine (Feton and Profill recently) – powder mixer (not many)
Few sieves (unfortunately) –
Some mixer for cream (like Topitec or Unguator) – Rare three roll mill for cream like Exakt (unfortunately, but very expensive) - Homogenizer like Ika Turrax T18 or 25, some Silverson machine. Rare isolator. Some laminar flow hoods (for Pharmacies that compound sterile eye drops).*

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

It is not officially allowed. But some pharmacy prepares for others, but only a simple prescription and unique

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

We have a section of the NBP fixing this. In my opinion, is a mix from USP BUD and other system!!

“Formulazioni solide, liquide non acquose o con un contenuto alcoolico non inferiore al 25 per cento : non oltre il 25 per cento del più breve periodo di validità dei componenti utilizzati; tale periodo non può comunque superare i 6 mesi.

Per tutte le altre formulazioni

Utilizzare entro 30 giorni dalla data di preparazione.”

Very cumbersome, given that we use only pure substances

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

There is great interest, but fear of being controlled and sanctioned

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

The technical and practical training that provides the University is not enough.

Shortly, laboratories not equipped well, do not allow to know and learn modern and current techniques.

Often I keep relations at the University of Rome, Perugia and Bologna, showing what the student, once graduate, will find in Pharmacies. If the Pharmacist wants to learn, and learn new ways to be updated, it must take additional training.

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

Yes, but only if the formula is in a European Pharmacopoeia (like Belgian, Italian, German, Spanish) nad the API is free from prescription.

Do you compound the following dosage forms?

A Pharmacy that compound, seriously:

	Yes	No
NONSTERILE		
Oral liquids (solutions, suspensions, emulsions)	yes	___
Topical liquids (solutions, suspensions, emulsions)	yes	___
Oral solids (capsules, tablets)	yes	___
Suppositories	yes	___
Troches/Lozenges	yes (specially veterinary)	
Ointments, Creams, Lotions	yes	___
STERILE		
Ophthalmic preparations	several	___
Nasal preparations	a few	___
Injections	I know only four pharmacies	

Intravenous admixtures

only in several Hospital

Do you compound for the following therapeutic categories?	<u>Yes</u>	<u>No</u>
Pain management	yes	_____
Dermatology	yes	_____
Hormone replacement therapy	several	_____
Veterinary	yes	_____
Neuropathy	a few	_____
Dental	yes	_____
Podiatry	several	_____
Ophthalmic	several	_____
Steroid therapy	a few	_____
Oncology	several	_____
Rheumatology	several	_____
Parenterals	a few (five)	_____
Inhalation/respiratory	a few	_____
Surgical	not	_____

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

References

Acknowledgment