Compounding Internationally International Society of Pharmaceutical Compounding (ISPhC) Please complete and e-mail to Ninfa Castellvi

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If you will respond to the questions below, we will incorporate your answers 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.

Is compounding permitted in your country? YES

Who regulates compounding in your country? AGENCY FOR MEDICINES

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.

www.fagg-afms.be / fr/ binaries /AR-KB-2009-01-02-guide-BPO-tcm291-31383.pdf

List some difficulties you have with regulatory agencies regarding compounding:

Limitations of active ingredients and excipients. Absence of modern products

What are you allowed to compound?

Magistral preparations=compounding prescriptions by M.D official or officinal preparations which the pharmacist prepare for the clients of his pharmacy. The compositions are mostly taken out of formularies. These preparations are under discussion??????

What are you not allowed to compound?

There is a lost of active ingredients which are not authorized to use.

Describe your compounding pharmacy.

List some unique equipment that you commonly use.

Unguator, ointment mill, homogenizacapsule filling machines

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

But Fagron started a NO compounding unit (outsourcing!)

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

The formulations published in Therapeutic Compounding Formulary (FTM) have a shelf life of maximum 2 months for officinal preparation the shelf life is usually limited to 1 year.

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

Improvement is necessary

Limitations on active ingredients to use should be abolished

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

Normally not. However young pharmacist who graduated now are not trained sufficiently and are not interested.

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

YES

Do you compound the following dosage forms?

NONSTERILE	Yes	No
Oral liquids (solutions, suspensions, emulsions)	_X	
Topical liquids (solutions, suspensions, emulsions)	_X	
Oral solids (capsules, tablets)	_X	
Suppositories	_X	
Troches/Lozenges		X
Ointments, Creams, Lotions	X	
STERILE		
Ophthalmic preparations	_X	
Nasal preparations	_X	
Injections		_X
Intravenous admixtures		X

Do you compound for the following therapeutic categories?	Yes	No
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. Belgiam Formulary

References

www.fagg-afmps.be/fr/binaries/FTM_pharmaciens_edition_2010_tcm291-121380.pdf

Acknowledgment