Austria

Regulatory Submission – Austria (Summary of ethical and regulatory requirements)

Type of trial		Requirements by law					Approval required by				Time to approval	Insurance required
		A	B	C	D	E	Local EC [1]	Lead EC[2]	CA - AGES PharmMed	CA - MH		
Interventional	Medicinal product	X			X	X	X[1]	X[2]	X		35 d	yes
	Medical device		X		X	X	X[1]	X[2]	X		60 d	yes
	Gene therapy	X		X	X		X[1]	X[2]	X	X	90 + 90 d	yes
	Advanced therapy	X		X[3]	X		X[1]	X[2]	X[4]	X	90 + 90 d	yes
Non-interventional		X	X	X	X	X		X[5]	X[5]			no

Legends & Comments:

[1] In multicenter trials the local ethics committee of every site involved needs to be informed about the trial. There is no approval required from these local ECs in multicenter trials.
[2] One of the seven lead ECs in Austria needs to be chosen for a multicenter trial. Usually this is the EC of the site with the national coordinating investigator.
[3] If genetically engineered material is used.
[4] A formal approval of the CA is required for advanced therapies.

[5] The Competent Authority needs to be informed about non-interventional trials. It is also advised to submit a statement from a lead Ethics Committee documenting that the trial is of non-interventional nature to the CA in addition.

Submisison of an application for clinical trials with a **medicial product** to:
Bundesamt für Sicherheit im Gesundheitswesen (BASG)
Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES)
Institut Zulassung & LifeCycleManagement/KPPS
Traisengasse 5; A-1200 Wien

Submisison of an application for clinical trials with a **medical device** to:
Bundesamt für Sicherheit im Gesundheitswesen (BASG)
Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES)
Institut Inspektionen, Medizinprodukte und Haemovigilanz
Traisengasse 5; 1200 Wien

(3) Table 1. National Legislation

No.	Title	Type of document	Country	Year	URL | Translation
A	Medical drug act (Arzneimittelgesetz – AMG)	**Act**	Austria	1983	http://www.ris.bka.gv.at/defaultEn.aspx http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010441
B	Medical devices act (Medizinproduktgesetz – MPG)	**Act**	Austria	1996	http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10011003
C	Genetic engineering act (Gentechnikgesetz – GTG)	**Act**	Austria	1994	http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826&ShowPrintPreview=True http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010826
D	Data protection act (Datenschutsgesetz – DSG)	**Act**	Austria	1999	http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=bundesnormen&Gesetzesnummer=10001597 http://www.ris.bka.gv.at/Dokumente/Erv/ERV_1999_1_165/ERV_1999_1_165.pdf
E	Hospital act (Krankenanstalten und Kuranstaletengesetz – KAKuG)	**Act**	Austria	1957	http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285&ShowPrintPreview=True http://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10010285

(4) Table 2. Approval required by Organisations:

Abbr.	Title	Country	URL	URL language
Local EC	Local ethics committee [1]	Austria	http://www.ethikkommissionen.at/	German
Lead EC	Lead Ethics Committee (Leit-ethikkommission)	Austria	http://www.meduni-graz.at/ethikkommission/Forum/Mitglieder/frame.htm	German
CA – AGES PharMed	Compentent Authiority - AGES PharmMed	Austria	http://www.ages.at/ages/en/ages-austrian-agency-for-health-and-food-safety/	German, English
CA – MH	Competent Authroity - Ministry of Health	Austria	http://www.bmgf.gv.at/	German

[6] Table 4. (Additional) Questions and Answers (Country: Austria):

Q1	**How is the insurance of patients and treating physicians regulated in your country?**
A1	The treating physician needs to have insurance against malpractice. The sponsor of a clinical trial needs to take out insurance for patients within the clinical trial covering any harm that might be caused by the procedures, drugs, etc used in the trial
Q2	**Are submission timelines different for specific types of trials (medicinal product, medical device, gene therapy, advanced therapy, non-interventional)?**
A2	Gene therapy and advanced therapy trials need to be submitted to the Ministry of Health in addition to the EC and the CA (Ages PharmMed). Non-interventional trials need to have a statement from the EC that the trial is indeed non-interventional before submitting to the CA. The CA only needs be informed of the non-interventional trial and the participating sites need to be registered.
Q3	**Do you have special regulations for Orphan diseases?**
A3	No.