

## National provisions for SMEs applicable to the pharmaceutical sector

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
<b>AUSTRIA</b>	HUMAN & VET	<b>Austrian Medicines and Medical Devices Agency (AGES)</b> LCM Traisengasse 5 1200 Vienna Austria <a href="http://www.basg.gv.at">www.basg.gv.at</a>	Information on fee reductions for Veterinary medicinal products and Medicinal products produced in pharmacies:  Dr Peter Platzer Phone: +43 50 55 53 65 70 E-mail: <a href="mailto:peter.platzer@ages.at">peter.platzer@ages.at</a>	No specific provisions.
<b>BELGIUM</b>	HUMAN & VET	<b>Federal Agency for Medicines and Health Products (FAMHP)</b> Galileelaan – Avenue Galilée nr. 5 / PO box 03 B-1210, Brussels Belgium <a href="http://www.fagg.be">www.fagg.be</a>	Phone: + 32 2 528 40 68 + 32 2 528 42 41  E-mail: <a href="mailto:innovationoffice@fagg-afmps.be">innovationoffice@fagg-afmps.be</a> (for innovation support and regulatory enquiries)  <a href="mailto:sta@fagg-afmps.be">sta@fagg-afmps.be</a> (for medicinal and borderline products for human and veterinary use) <a href="mailto:sta.meddev@fagg-afmps.be">sta.meddev@fagg-afmps.be</a> (for medicinal products and	Fee reductions (75%) for national scientific and technical, regulatory advice (STA) for medicinal products. and medicinal products and medical device combination products for SMEs. Fee waivers for STA on clinical trials if applicants commit at time of advice to submit a clinical trial application according to the Clinical Trial Regulation EU No 536/2014 within two years after receipt of the advice.  The above also apply to the simultaneous national scientific advice pilot project with two regulatory agencies, and accelerated COVID-19 national advice.  Support to SMEs through dedicated mailboxes to address innovation support, national advice and regulatory enquiries, and free of charge informal meetings: <i>project info meetings</i> (early dialogue to discuss a (pre)clinical research project and

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
			<p>medical device combination products, or medical devices or in vitro diagnostics used in conjunction with medicinal products).</p> <p>Web:  <a href="https://www.famhp.be/en/innovationoffice">https://www.famhp.be/en/innovationoffice</a></p>	provide high level guidance on scientific, technical and regulatory aspects to initiate a project; <i>portfolio meetings</i> to present and discuss products pipelines.
<b>BULGARIA</b>	HUMAN	<p><b>Bulgarian Drug Agency (BDA)</b>  8 Damyan Gruev Str.  1303 Sofia  Bulgaria  <a href="http://www.bda.bg">www.bda.bg</a></p>	<p>Phone:  +359 28 90 35 55  E-mail:  <a href="mailto:bda@bda.bg">bda@bda.bg</a></p>	No specific provisions.
	VET	<p><b>Bulgarian Food Safety Agency (BFSA)</b>  15A 'Pencho Slaveykov' Blvd  1606 Sofia  Bulgaria</p>	<p>Dr Antonio Radoev  Head of Department  "Control of Manufacturing, Trade and Use of VMPs"  Phone:  +359 8824 69555  E-mail:  <a href="mailto:a_radoev@bfsa.bg">a_radoev@bfsa.bg</a></p>	No specific provisions.
<b>CROATIA</b>	HUMAN	<p><b>Agency for Medicinal Products and Medical Devices (HALMED)</b></p>	<p>Ms Maja Lovrek Romčević  E-mail:  <a href="mailto:Maja.LovrekRomcevic@halm.ed.hr">Maja.LovrekRomcevic@halm.ed.hr</a>  Phone:</p>	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
		Ksaverska cesta 4 10000 Zagreb Croatia <a href="http://www.halmed.hr">www.halmed.hr</a>	+ 385 1 4884 136	
	VET	<b>Ministry of agriculture, Veterinary and Food</b> Safety Directorate Planinska 2a 10000 Zagreb Croatia <a href="http://www.veterinarstvo.hr">www.veterinarstvo.hr</a>	Mr Boris Fabijanić E-mail: <a href="mailto:boris.fabijanic@mps.hr">boris.fabijanic@mps.hr</a> Phone: +385 1 6443 822	No specific provisions.
<b>CYPRUS</b>	HUMAN	<b>Ministry of Health Pharmaceutical Services</b> 15 Polyphemou St. Strovolos Industrial Estate 2033 Lefkosia Cyprus <a href="http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument">http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument</a>	Mr Ioannis Kkolos Pharmaceutical Services Phone: +357 22 60 80 32 E-mail: <a href="mailto:jkkolos@phs.moh.gov.cy">jkkolos@phs.moh.gov.cy</a>	No specific provisions.
	VET	<b>Ministry of Agriculture, Rural Development and Environment</b>	Dr Christodoulos Pipis Veterinary Services Phone: +357 22 80 52 00	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
		<b>Veterinary Services</b> 1417 Nicosia Cyprus <a href="http://www.moa.gov.cy/vs">http://www.moa.gov.cy/vs</a>	E-mail: <a href="mailto:Director@vs.moa.gov.cy">Director@vs.moa.gov.cy</a>	
<b>CZECH REPUBLIC</b>	HUMAN	<b>státní i ústav pro kontrolu léčiv (SUKL)</b> Srobárova 48 100 41 Praha 10 Czech Republic <a href="http://www.sukl.cz">www.sukl.cz</a>	Phone: +420 27 21 85 11 1 E-mail: <a href="mailto:posta@sukl.cz">posta@sukl.cz</a>	SMEs fee reductions (50%) for expert activities and annual fees (government decree no. 327/2013 coll.)
	VET	<b>Ústav pro státní kontrolu veterinárních biopreparátů a léčiv (USKVBL)</b> Hudcova 56a 621 00 Brno - Medlánky Czech Republic <a href="http://www.uskvbl.cz">www.uskvbl.cz</a>	Phone: 420 54 12 10 02 20 24 E-mail: <a href="mailto:uskvbl@uskvbl.cz">uskvbl@uskvbl.cz</a>	No specific provisions.
<b>DENMARK</b>	HUMAN & VET	<b>Danish Medicines Agency (DKMA)</b> Axel Heides Gade 1 2300 Copenhagen Denmark <a href="http://www.lmst.dk">www.lmst.dk</a>	Phone: +45 44 88 95 95 E-mail: <a href="mailto:dkma@dkma.dk">dkma@dkma.dk</a>	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
<b>ESTONIA</b>	HUMAN & VET	<b>State Agency of Medicines</b> 1 Nooruse Street 50411 Tartu Estonia <a href="http://www.ravimiamet.ee">www.ravimiamet.ee</a>	Phone: +372 73 74 14 0 E-mail: <a href="mailto:info@ravimiamet.ee">info@ravimiamet.ee</a>  Mrs Kaili Semm Phone: +372 73 74 14 0 E-mail: <a href="mailto:kaili.semm@ravimiamet.ee">kaili.semm@ravimiamet.ee</a>	The Act 'Support of enterprise and state loan guarantees' (RT I 2003, 18, 96 as amended; <a href="#">Link</a> ) sets out state provisions for support to enterprises, guarantees for loan agreements and leasing contracts, and contains provisions for SMEs including those operating in the pharmaceutical sector.
<b>FINLAND</b>	HUMAN & VET	<b>Finnish Medicines Agency (FIMEA)</b> P.O. Box 55 (Mannerheimintie 103b, Helsinki) 00034 FIMEA Finland <a href="http://www.fimea.fi">http://www.fimea.fi</a>	Phone: +358 29 522 3341	No specific financial provisions.
<b>FRANCE</b>	HUMAN	<b>Agence nationale de sécurité du médicament et des produits de santé (ANSM)</b> 143-147 bd Anatole France 93285 Saint-Denis CEDEX France <a href="http://www.ansm.sante.fr">www.ansm.sante.fr</a>	Dr Guillaume Vaquer (Innovation Office)  Phone: +33 1 55 87 30 00 E-mail: <a href="mailto:innovation@ansm.sante.fr">innovation@ansm.sante.fr</a> Web : <a href="#">Innovation Office</a>	No specific financial provisions.  Free of charge support by the Innovation Office to SMEs developing innovative health products (early dialogue, scientific advice, pre-submission support for clinical trials).

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
	VET	<b>Agence Nationale du Médicament Vétérinaire (Anses-ANMV)</b> 8 rue Claude Bourgelat Parc d'Activités de la Grande Marche CS 70611 35306 Fougères France <a href="http://www.anses.fr">www.anses.fr</a>	Phone: +33 2 99 94 78 71 E-mail: <a href="mailto:sylvie.goby@anses.fr">sylvie.goby@anses.fr</a>	Free of charge support to SMEs developing innovative veterinary products (early dialogue, scientific advice).  Annual fees for marketing authorisations are proportionate to the turnover of a company and capped at 35,000€ (Article D. 5141-60 of public health code).
<b>GERMANY</b>	HUMAN	<b>Federal Institute for Drugs and Medical Devices (BfArM)</b> Kurt-Georg Kiesinger-Allee 3 53175 Bonn Germany <a href="http://www.bfarm.de">www.bfarm.de</a>	Wiebke Löbker (Innovation Office) Peggy Beinlich (Scientific Advice)  Phone: +49 228 99 307 (4053; 3958) E-mail: <a href="mailto:innovation@bfarm.de">innovation@bfarm.de</a> <a href="mailto:advice@bfarm.de">advice@bfarm.de</a>	Innovation Office support fees capped at 2000€ for SMEs.  Fee reductions of 25% if the applicant cannot expect an adequate economic benefit corresponding to the development and authorisation costs, and the placing of the medicinal product on the market is of public interest. Fee reduction of 50% if the application is for a rare condition or the target group for which the medicinal product is intended is small.
	HUMAN & VET	<b>Paul-Ehrlich-Institut Federal Institute for Vaccines and Biomedicines (PEI)</b>	Innovation Office Phone: +49 61 03 772 772 E-mail: <a href="mailto:innovation@pei.de">innovation@pei.de</a> Web:	Fee reductions for national authorisations, including variations (25% for entities with no expected economic benefit considering development, manufacturing, authorisation or licensing costs. and there is a public interest in marketing the product; up to 50% for products targeting rare conditions or small populations) (Fee Ordinance BMGBGebV).

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
		Paul Ehrlich Str. 51-59 63225 Langen Germany <a href="http://www.pei.de">www.pei.de</a>	<a href="#">Innovation Office</a>	
	VET	<b>Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)</b> Mauerstr. 39 - 42 10117 Berlin Germany <a href="http://www.bvl.bund.de">www.bvl.bund.de</a>	Dr Angelika Schadewinkel-Scherkl Phone: +49 30 184 4571 00 E-mail: <a href="mailto:311@bvl.bund.de">311@bvl.bund.de</a>	Fee reductions for national authorisations, including variations (25% for entities with no expected economic benefit considering development, manufacturing, authorisation or licensing costs and there is a public interest in marketing the product; up to 50% for products targeting rare conditions or small groups). (Fee Ordinance BMGBGebV).
<b>GREECE</b>	HUMAN & VET	<b>National Drug Organisation (EOF)</b> Mesogion Avenue 284 Holargos Athens 15562 Greece <a href="http://www.eof.gr">www.eof.gr</a>	Mr Farlopoulos Spiros Head of the Vet Dept Phone: +30 2132040297 +30 2132040537 E-mail: <a href="mailto:relation@eof.gr">relation@eof.gr</a> <a href="mailto:sfarlopoulos@eof.gr">sfarlopoulos@eof.gr</a>	No specific provisions.
<b>HUNGARY</b>	HUMAN	<b>National Institute of Pharmacy and Nutrition</b> Szabolcs u. 33. 1135 Budapest Hungary <a href="http://ogyei.gov.hu">http://ogyei.gov.hu</a>	Mr Mátyás Szentiványi Director General Phone: +36 1 886 9300 E-mail: <a href="mailto:szentivanyi.matyas@ogyei.gov.hu">szentivanyi.matyas@ogyei.gov.hu</a>	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
	VET	<b>National Food Chain Safety Office</b> <b>Directorate of Veterinary Medicines</b> Szállás utca 8. 1107 Budapest Hungary <a href="http://www.nebih.gov.hu">http://www.nebih.gov.hu</a>	Dr Gábor Kulcsár Phone: +36 14 33 03 30 Email: <a href="mailto:kulcsarg@nebih.gov.hu">kulcsarg@nebih.gov.hu</a>	No specific provisions.
<b>IRELAND</b>	HUMAN & VET	<b>Health Products Regulatory Authority (HPRA)</b> Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 D02 XP77 Ireland <a href="http://www.hpra.ie">www.hpra.ie</a>	Phone: +353 16 76 49 71 E-mail: <a href="mailto:info@hpra.ie">info@hpra.ie</a>	No specific provisions.
<b>ITALY</b>	HUMAN	<b>Agenzia Italiana del Farmaco (AIFA)</b> Via del Tritone 181 00187 Roma Italy <a href="http://www.agenziafarmaco.gov.it">www.agenziafarmaco.gov.it</a>	Dr Paolo Foggi <a href="mailto:innovation.office@aifa.gov.it">innovation.office@aifa.gov.it</a>  Alternate: Dr Luisa Camponeschi <a href="mailto:l.camponeschi@aifa.gov.it">l.camponeschi@aifa.gov.it</a>	Reduced fees (25%) for public entities and SMEs meeting the EU definition and services (i.e. national scientific advice, training and continuing education for industry professionals, analysis of research and field studies, publishing activities) (Article 4, paragraph 6, of Decree of the Ministry of Health of 29 March 2012, no. 53, Article 6 of Decree of the Minister of Health of 6 December 2016; -Updating of existing tariffs and determination of tariffs relating to services not yet tariffed).

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
				Free of charge innovation meetings to SMEs by the innovation office to promote early interaction developing new methodologies and technologies applied to medicinal products developments, and receive scientific and regulatory support.
	VET	Ministero della Salute Via G. Ribotta 5 00144 - Rome Italy <a href="http://www.salute.gov.it">http://www.salute.gov.it</a>	Dr Loredana Ragni <a href="mailto:l.ragni@sanita.it">l.ragni@sanita.it</a>	No specific provisions.
<b>LATVIA</b>	HUMAN	<b>State Agency of Medicines</b> Jersikas iela 15 1003 Riga Latvia <a href="http://www.zva.gov.lv">www.zva.gov.lv</a>	Ms Ilze Bude Phone: +371 67 07 84 57 E-mail: <a href="mailto:ilze.bude@zva.gov.lv">ilze.bude@zva.gov.lv</a>	Exemptions from annual post-authorisation maintenance fees for medicinal products authorised via national, mutual recognition or decentralised procedure and distributed in a pharmacy or healthcare institution in Latvia where the turnover of the said medicine did not exceed 3000€ the previous calendar year, and amounts sold did not exceed 49 packs.
	VET	<b>Food and Veterinary Service</b> 30 Peldu Street 1050 Riga Latvia <a href="http://www.pvd.gov.lv">www.pvd.gov.lv</a>	Ms Zanda Auce Phone: +371 67084618 E-mail: <a href="mailto:Zanda.Auce@pvd.gov.lv">Zanda.Auce@pvd.gov.lv</a>	Exemption from annual fees for post-authorisation surveillance of veterinary medicinal products unless the turnover of the product distributed in Latvia the previous calendar year exceeds 2000€.  Veterinary medicinal products authorised for sole use by veterinarians (e.g. immunologicals, anaesthetics) might be exempted from the obligation to have a labelling in the national language by Food and Veterinary Service decision.
<b>LITHUANIA</b>	HUMAN	<b>State Medicines Control Agency</b> Žirmūnų str. 139A 09120 Vilnius	Phone: +370 5 263 92 64 Mrs Irena Vaketaite Head of Inspections Unit Phone:	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
		Lithuania <a href="http://www.vvkt.lt">www.vvkt.lt</a>	+370 5 263 98 91 E-mail: <a href="mailto:irenavaketaite@vvkt.lt">irenavaketaite@vvkt.lt</a>	
	VET	<b>State Food and Veterinary Service</b> Siesikų str. 19 07170 Vilnius Lithuania E-mail: <a href="mailto:info@vmvt.lt">info@vmvt.lt</a> <a href="https://vmvt.lt">https://vmvt.lt</a>	Mr Sigitas Siriukaitis Head of Veterinary Medicines and Feed Division Phone: +370 5 249 1626 E-mail: <a href="mailto:sigitas.siriukaitis@vmvt.lt">sigitas.siriukaitis@vmvt.lt</a>	No specific provisions.
<b>LUXEMBOURG</b>	HUMAN & VET	<b>Direction de la Santé Villa Louvigny Division de la Pharmacie et des Medicaments</b> Allée Marconi 2120 Luxembourg <a href="http://www.Msetat.lu">www.Msetat.lu</a>	Human E-mail: <a href="mailto:luxdpm@Msetat.lu">luxdpm@Msetat.lu</a> Veterinary Email: <a href="mailto:luxvet@Msetat.lu">luxvet@Msetat.lu</a>	No specific provisions.
<b>MALTA</b>	HUMAN	<b>Malta Medicines Authority (MMA)</b> Sir Temi Zammit Buildings Life Sciences Park San Gwann SGN3000 Malta <a href="http://www.medicinesauthority.gov.mt">www.medicinesauthority.gov.mt</a>	Medicines Authority Phone: +356 23 43 90 00 E-mail: <a href="mailto:info.medicinesauthority@gov.mt">info.medicinesauthority@gov.mt</a> Malta Enterprise Phone: +356 2542 0000 E-mail:	Assistance and incentives to enterprises engaged in pharmaceuticals manufacturing (including packaging) subject to approval by <a href="#">Malta Enterprise</a> – the Maltese entity responsible for foreign direct investment, internationalisation of companies and the promotion of entrepreneurship and business start-ups.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
	VET	<b>Animal Health and Welfare Department</b> Abattoir Street, Albert Town, Marsa MRS 1123, Malta	<a href="mailto:info@maltaenterprise.com">info@maltaenterprise.com</a>  Animal Health and Welfare Department Phone: +356 2095 3791 Email: <a href="mailto:infoahwd.mafa@gov.mt">infoahwd.mafa@gov.mt</a>  Malta Enterprise Phone: +356 2542 0000 E-mail: <a href="mailto:info@maltaenterprise.com">info@maltaenterprise.com</a>	See under Human.
<b>NETHERLANDS</b>	HUMAN & VET	<b>College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board (CBG-MEB)</b> Graadt van Roggenweg 500 P.O.Box 8275 3531 AH Utrecht The Netherlands <a href="http://www.cbg-meb.nl">www.cbg-meb.nl</a>	Phone: +31 88 224 8000 Contact: <a href="https://english.cbg-meb.nl/contact">https://english.cbg-meb.nl/contact</a>	SME fee reductions for customised advice, a type of scientific advice for SMEs and academic entities on pharmaceutical or non-clinical aspects in early phases of development (see <a href="https://english.cbg-meb.nl/topics/mah-scientific-and-regulatory-advice">https://english.cbg-meb.nl/topics/mah-scientific-and-regulatory-advice</a> and <a href="https://english.cbg-meb.nl/topics/mah-fees-and-product-types">https://english.cbg-meb.nl/topics/mah-fees-and-product-types</a> ).
<b>POLAND</b>	HUMAN & VET	<b>Office for Registration of Medicinal Products,</b>	Phone: +48 22 49 21 10 0 E-mail: <a href="mailto:urpl@urpl.gov.pl">urpl@urpl.gov.pl</a>	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
		<b>Medical Devices and Biocidal Products</b> Al. Jerozolimskie 181c 02-222 Warsaw Poland <a href="https://urpl.gov.pl/en">https://urpl.gov.pl/en</a>		
<b>PORTUGAL</b>	HUMAN	<b>National Authority of Medicines and Health Products, I.P. (INFARMED, I.P.)</b> Portugal Parque de Saúde de Lisboa, Avenida do Brasil n° 53 1749-004 Lisboa Portugal <a href="http://www.infarmed.pt">www.infarmed.pt</a>	Ms Helena Baião Regulatory and Scientific Advice Coordinator Regulatory and Scientific Advice Office (GARC)  Phone: +351217987139  E-mail: <a href="mailto:garc@infarmed.pt">garc@infarmed.pt</a>	Fee exemptions or reductions for medicines on grounds of public health interest and/or company category (SMEs) for pre- and post-marketing scientific and regulatory advice by GARC.  Fee exemptions for SMEs that do not have products on the market yet.  (references: Nos. 12 and 13 of annexes to Portaria No. 377/2005 of 4 April; Portaria No. 317-A/2000 of 31 May; incentives for small business (SIPIE Sistema de Incentivos a Pequenas Iniciativas Empresariais; IAPMEI Instituto de Apoio às Pequenas e Médias Empresas e ao Investimento).
	VET	<b>Direção-Geral de Alimentação e Veterinária (DGAV)</b> Campo Grande, n.º 50 1700-093 Lisboa Portugal <a href="http://www.dqv.min-agricultura.pt">www.dqv.min-agricultura.pt</a>	Dr Susana Guedes Pombo Head of Vet Medicines Agency Phone: +351213239655/6 E-mail: <a href="mailto:spombo@dgav.pt">spombo@dgav.pt</a>	Fee exemptions or reductions for pre- and post-marketing scientific and regulatory advice on mutual recognition or decentralised procedures, for cases of lack of availability and limited use of veterinary medicines.  (references: Article 2 and No. 21 of annexes of Portaria No. 27/2011 of 10 January; Portaria No. 317-A/2000 of 31 May); Portaria No. 317-A/2000 of 31 May; incentives for small business (SIPIE Sistema de Incentivos a Pequenas Iniciativas Empresariais; IAPMEI Instituto de Apoio às Pequenas e Médias Empresas e ao Investimento).

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
ROMANIA	HUMAN	<b>National Agency for Medicines and Medical Devices of Romania (NAMMDR)</b> 48, Av. Sanatescu Str. Sector 1 011478 Bucharest Romania <a href="https://www.anm.ro/en/">https://www.anm.ro/en/</a>	Ms Felicia Ciulu Costinescu General Directorate For Pharmaceutical Inspection Phone: +40 21 317 11 00 E-mail: <a href="mailto:Felicia.Costinescu@anm.ro">Felicia.Costinescu@anm.ro</a>	No specific provisions.
	VET	<b>Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar</b> Str. Dudului 39 Sector 6 060603 Bucharest Romania <a href="http://www.icbmv.ro/">www.icbmv.ro/</a>		No specific provisions.
SLOVAK REPUBLIC	HUMAN	<b>State Institute for Drug Control (SUK)</b> Kvetná 11 825 08 Bratislava 2 Slovak Republic <a href="http://www.sukl.sk">www.sukl.sk</a>	Phone: +42 1 2 50 70 11 11 E-mail: <a href="mailto:sukl@sukl.sk">sukl@sukl.sk</a>	No specific provisions.
	VET	<b>Institute for State</b>	Phone: +421 37 65 15 50 6	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
		<b>Control of Veterinary Biologicals and Medicaments</b> Biovetska 34 949 01 Nitra Slovak Republic <a href="http://www.uskvbl.sk">www.uskvbl.sk</a>	E-mail: <a href="mailto:uskvbl@uskvbl.sk">uskvbl@uskvbl.sk</a>	
<b>SLOVENIA</b>	HUMAN & VET	<b>Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)</b> Slovenčeva ulica 22 1000 Ljubljana Slovenia <a href="http://www.jazmp.si">www.jazmp.si</a>	Mrs Barbara Kovač Phone: +386 8 2000 500 E-mail: <a href="mailto:info@jazmp.si">info@jazmp.si</a>	No specific provisions.
<b>SPAIN</b>	HUMAN & VET	<b>Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)</b> Parque Empresarial Las Mercedes Edificio 8 C/Campezo 1 28022 Madrid España <a href="http://www.aemps.gob.es">www.aemps.gob.es</a>	Innovation Office E-mail: <a href="mailto:innov_spain@aemps.es">innov_spain@aemps.es</a>	No specific provisions.

Country	Human & Veterinary medicines	National competent authority	Contact point	Existing national provisions for SMEs applicable to pharmaceutical sector
<b>SWEDEN</b>	HUMAN & VET	<b>Medical Products Agency (MPA)</b> Dag Hammarskjölds väg 42 751 03 Uppsala Sweden <a href="http://www.lakemedelsverket.se">www.lakemedelsverket.se</a>	Ms Anna Mäkinen Salmi Ms Gunilla Andrew-Nielsen Innovation Support Office Phone: +46 18 17 46 00 E-mail: <a href="mailto:InnovationOffice@lakemedelsverket.se">InnovationOffice@lakemedelsverket.se</a>	Assistance to SMEs and academia by the innovation support office on regulatory and scientific topics.  Dedicated webpage ('the SME guide' <a href="http://www.lakemedelsverket.se">www.lakemedelsverket.se</a> ), to help SMEs navigate the website.