

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
AUSTRIA	HUMAN & VET	Austrian Medicines and Medical Devices Agency (AGES) LCM Traisengasse 5 1200 Vienna Austria www.basg.gv.at	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: peter.platzer@ages.at	No specific provisions.
BELGIUM	HUMAN & VET	Federal Agency for Medicines and Health Products (FAMHP) Galileelaan – Avenue Galilée nr. 5 / PO box 03 B-1210, Brussels Belgium www.fagg.be	Phone: + 32 2 528 40 68 + 32 2 528 42 41 E-mail: innovationoffice@fagg-afmps.be (for innovation support and regulatory enquiries) sta@fagg-afmps.be (for medicinal and borderline products for human and veterinary use) sta.meddev@fagg-afmps.be (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

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			<p>medical device combination products, or medical devices or in vitro diagnostics used in conjunction with medicinal products).</p> <p>Web: https://www.famhp.be/en/innovationoffice</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.
BULGARIA	HUMAN	<p>Bulgarian Drug Agency (BDA) 8 Damyan Gruev Str. 1303 Sofia Bulgaria www.bda.bg</p>	<p>Phone: +359 28 90 35 55 E-mail: bda@bda.bg</p>	No specific provisions.
	VET	<p>Bulgarian Food Safety Agency (BFSA) 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_radoev@bfsa.bg</p>	No specific provisions.
CROATIA	HUMAN	<p>Agency for Medicinal Products and Medical Devices (HALMED)</p>	<p>Ms Maja Lovrek Romčević E-mail: Maja.LovrekRomcevic@halm.ed.hr Phone:</p>	No specific provisions.

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		Ksaverska cesta 4 10000 Zagreb Croatia www.halmed.hr	+ 385 1 4884 136	
	VET	Ministry of agriculture, Veterinary and Food Safety Directorate Planinska 2a 10000 Zagreb Croatia www.veterinarstvo.hr	Mr Boris Fabijanić E-mail: boris.fabijanic@mps.hr Phone: +385 1 6443 822	No specific provisions.
CYPRUS	HUMAN	Ministry of Health Pharmaceutical Services 15 Polyphemou St. Strovolos Industrial Estate 2033 Lefkosia Cyprus http://www.moh.gov.cy/moh/moh.nsf/index_en/index_en?OpenDocument	Mr Ioannis Kkolos Pharmaceutical Services Phone: +357 22 60 80 32 E-mail: jkkolos@phs.moh.gov.cy	No specific provisions.
	VET	Ministry of Agriculture, Rural Development and Environment	Dr Christodoulos Pipis Veterinary Services Phone: +357 22 80 52 00	No specific provisions.

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

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ESTONIA	HUMAN & VET	State Agency of Medicines 1 Nooruse Street 50411 Tartu Estonia www.ravimiamet.ee	Phone: +372 73 74 14 0 E-mail: info@ravimiamet.ee Mrs Kaili Semm Phone: +372 73 74 14 0 E-mail: kaili.semm@ravimiamet.ee	The Act 'Support of enterprise and state loan guarantees' (RT I 2003, 18, 96 as amended; Link) 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.
FINLAND	HUMAN & VET	Finnish Medicines Agency (FIMEA) P.O. Box 55 (Mannerheimintie 103b, Helsinki) 00034 FIMEA Finland http://www.fimea.fi	Phone: +358 29 522 3341	No specific financial provisions.
FRANCE	HUMAN	Agence nationale de sécurité du médicament et des produits de santé (ANSM) 143-147 bd Anatole France 93285 Saint-Denis CEDEX France www.ansm.sante.fr	Dr Guillaume Vaquer (Innovation Office) Phone: +33 1 55 87 30 00 E-mail: innovation@ansm.sante.fr Web : Innovation Office	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).

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	VET	Agence Nationale du Médicament Vétérinaire (Anses-ANMV) 8 rue Claude Bourgelat Parc d'Activités de la Grande Marche CS 70611 35306 Fougères France www.anses.fr	Phone: +33 2 99 94 78 71 E-mail: sylvie.goby@anses.fr	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).
GERMANY	HUMAN	Federal Institute for Drugs and Medical Devices (BfArM) Kurt-Georg Kiesinger-Allee 3 53175 Bonn Germany www.bfarm.de	Wiebke Löbker (Innovation Office) Peggy Beinlich (Scientific Advice) Phone: +49 228 99 307 (4053; 3958) E-mail: innovation@bfarm.de advice@bfarm.de	Innovation Office support fees capped at 2000€ for SMEs. Fee reductions of 25% if a) the applicant cannot expect an adequate economic benefit corresponding to the development and authorisation costs and b) the placing of the medicinal product on the market is of public interest. The fee reduction is increased to 50% if the application is for a rare condition or the target group for which the medicinal product is intended is small, provided requirements a) and b) are also met.
	HUMAN & VET	Paul-Ehrlich-Institut Federal Institute for Vaccines and Biomedicines (PEI)	Innovation Office Phone: +49 61 03 772 772 E-mail: innovation@pei.de Web:	Fee reductions for national authorisations, including variations (25%) for a) entities with no expected economic benefit considering development, manufacturing, authorisation or licensing costs and b) there is a public interest in marketing the product; the fee reduction increased to 50% for products targeting rare conditions or small populations provided

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		Paul Ehrlich Str. 51-59 63225 Langen Germany www.pei.de	Innovation Office	requirements a) and b) are also met) (Fee Ordinance BMGBGebV).
	VET	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) Mauerstr. 39 - 42 10117 Berlin Germany www.bvl.bund.de	Dr Angelika Schadewinkel-Scherkl Phone: +49 30 184 4571 00 E-mail: 311@bvl.bund.de	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).
GREECE	HUMAN & VET	National Drug Organisation (EOF) Mesogion Avenue 284 Holargos Athens 15562 Greece www.eof.gr	Mr Farlopoulos Spiros Head of the Vet Dept Phone: +30 2132040297 +30 2132040537 E-mail: relation@eof.gr sfarlopoulos@eof.gr	No specific provisions.
HUNGARY	HUMAN	National Institute of Pharmacy and Nutrition Szabolcs u. 33. 1135 Budapest Hungary http://ogyei.gov.hu	Mr Mátyás Szentiványi Director General Phone: +36 1 886 9300 E-mail: szentivanyi.matyas@ogyei.gov.hu ogyei.gov.hu	No specific provisions.

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	VET	National Food Chain Safety Office Directorate of Veterinary Medicines Szállás utca 8. 1107 Budapest Hungary http://www.nebih.gov.hu	Dr Gábor Kulcsár Phone: +36 14 33 03 30 Email: kulcsarg@nebih.gov.hu	No specific provisions.
IRELAND	HUMAN & VET	Health Products Regulatory Authority (HPRA) Kevin O'Malley House Earlsfort Centre Earlsfort Terrace Dublin 2 D02 XP77 Ireland www.hpra.ie	Phone: +353 16 76 49 71 E-mail: info@hpra.ie	No specific provisions.
ITALY	HUMAN	Agenzia Italiana del Farmaco (AIFA) Via del Tritone 181 00187 Roma Italy www.agenziafarmaco.gov.it	Dr Paolo Foggi innovation.office@aifa.gov.it Alternate: Dr Luisa Camponeschi l.camponeschi@aifa.gov.it	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).

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				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 http://www.salute.gov.it	Dr Loredana Ragni l.ragni@sanita.it	No specific provisions.
LATVIA	HUMAN	State Agency of Medicines Jersikas iela 15 1003 Riga Latvia www.zva.gov.lv	Ms Ilze Bude Phone: +371 67 07 84 57 E-mail: ilze.bude@zva.gov.lv	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	Food and Veterinary Service 30 Peldu Street 1050 Riga Latvia www.pvd.gov.lv	Ms Zanda Auce Phone: +371 67084618 E-mail: Zanda.Auce@pvd.gov.lv	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.
LITHUANIA	HUMAN	State Medicines Control Agency Žirmūnų str. 139A 09120 Vilnius	Phone: +370 5 263 92 64 Mrs Irena Vaketaite Head of Inspections Unit Phone:	No specific provisions.

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

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	VET	Animal Health and Welfare Department Abattoir Street, Albert Town, Marsa MRS 1123, Malta	info@maltaenterprise.com Animal Health and Welfare Department Phone: +356 2095 3791 Email: infoahwd.mafa@gov.mt Malta Enterprise Phone: +356 2542 0000 E-mail: info@maltaenterprise.com	See under Human.
NETHERLANDS	HUMAN & VET	College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board (CBG-MEB) Graadt van Roggenweg 500 P.O.Box 8275 3531 AH Utrecht The Netherlands www.cbg-meb.nl	Phone: +31 88 224 8000 Contact: https://english.cbg-meb.nl/contact	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 https://english.cbg-meb.nl/topics/mah-scientific-and-regulatory-advice and https://english.cbg-meb.nl/topics/mah-fees-and-product-types).
POLAND	HUMAN & VET	Office for Registration of Medicinal Products,	Phone: +48 22 49 21 10 0 E-mail: urpl@urpl.gov.pl	No specific provisions.

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		Medical Devices and Biocidal Products Al. Jerozolimskie 181c 02-222 Warsaw Poland https://urpl.gov.pl/en		
PORTUGAL	HUMAN	National Authority of Medicines and Health Products, I.P. (INFARMED, I.P.) Portugal Parque de Saúde de Lisboa, Avenida do Brasil n.º 53 1749-004 Lisboa Portugal www.infarmed.pt	Ms Helena Baião Regulatory and Scientific Advice Coordinator Regulatory and Scientific Advice Office (GARC) Phone: +351217987139 E-mail: garc@infarmed.pt	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	Direção-Geral de Alimentação e Veterinária (DGAV) Campo Grande, n.º 50 1700-093 Lisboa Portugal www.dgv.min-agricultura.pt	Dr Susana Guedes Pombo Head of Vet Medicines Agency Phone: +351213239655/6 E-mail: spombo@dgav.pt	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).

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ROMANIA	HUMAN	National Agency for Medicines and Medical Devices of Romania (NAMMDR) 48, Av. Sanatescu Str. Sector 1 011478 Bucharest Romania https://www.anm.ro/en/	Ms Felicia Ciulu Costinescu General Directorate For Pharmaceutical Inspection Phone: +40 21 317 11 00 E-mail: Felicia.Costinescu@anm.ro	No specific provisions.
	VET	Institutul pentru Controlul Produselor Biologice si Medicamentelor de Uz Veterinar Str. Dudului 39 Sector 6 060603 Bucharest Romania www.icbmv.ro/		No specific provisions.
SLOVAK REPUBLIC	HUMAN	State Institute for Drug Control (SUK) Kvetná 11 825 08 Bratislava 2 Slovak Republic www.sukl.sk	Phone: +42 1 2 50 70 11 11 E-mail: sukl@sukl.sk	No specific provisions.
	VET	Institute for State	Phone: +421 37 65 15 50 6	No specific provisions.

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		Control of Veterinary Biologicals and Medicaments Biovetska 34 949 01 Nitra Slovak Republic www.uskvbl.sk	E-mail: uskvbl@uskvbl.sk	
SLOVENIA	HUMAN & VET	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) Slovenčeva ulica 22 1000 Ljubljana Slovenia www.jazmp.si	Mrs Barbara Kovač Phone: +386 8 2000 500 E-mail: info@jazmp.si	No specific provisions.
SPAIN	HUMAN & VET	Agencia Española de Medicamentos y Productos Sanitarios (AEMPS) Parque Empresarial Las Mercedes Edificio 8 C/Campezo 1 28022 Madrid España www.aemps.gob.es	Innovation Office E-mail: innov_spain@aemps.es	No specific provisions.

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SWEDEN	HUMAN & VET	Medical Products Agency (MPA) Dag Hammarskjölds väg 42 751 03 Uppsala Sweden www.lakemedelsverket.se	Ms Anna Mäkinen Salmi Ms Gunilla Andrew-Nielsen Innovation Support Office Phone: +46 18 17 46 00 E-mail: InnovationOffice@lakemedelverket.se	Assistance to SMEs and academia by the innovation support office on regulatory and scientific topics. Dedicated webpage ('the SME guide' www.lakemedelsverket.se), to help SMEs navigate the website.