This is a convenience translation of the German original. In case of discrepancy between the English and German versions, the German version shall prevail.

Ordinance of the Federal Office for Safety in Health Care *(Bundesamt für Sicherheit im Gesundheitswesen,* BASG) On the Schedule of Fees Pursuant to the Austrian Health and Food Safety Act *(Gesundheits- und Ernährungssicherheitsgesetz,* GESG)

Based on Article 6a paragraph 6 of the GESG, Federal Law Gazette *(Bundesgesetzblatt,* BGBl.) I No. 63/2002, last amended by Federal Law Gazette I No. 50/2025 , it is herewith ordained as follows:

Article 1. (1) The fees for services pursuant to Article 6a paragraph 6 of the Austrian Health and Food Safety Act (GESG) are set forth in the Annex to this Ordinance.

(2) All fees, with the exception of those referred to in Section VII of the Annex, shall be payable upon invoicing within the specified time following assessment of the formal requirements or receipt of documentation. The fees specified in Section VII of the Annex as well as fees for ex officio action shall be payable upon issuance of the administrative decision or after invoicing.

(3) For applications rejected or withdrawn before the assessment of formal requirements has been completed, the amount payable shall be 10 percent of the applicable fee. For applications rejected or withdrawn after this time, the full fee shall be payable.

(4) The fees for official actions as specified in Section X of the Annex shall be payable by the party that brings the product to market.

Article 2. (1) For the purposes of this Ordinance, "academic clinical study" shall be understood to mean the clinical trial of a medicinal product, the clinical investigation of a medical device, or the performance evaluation of an in-vitro diagnostic in which the investigator, a university or technical college, or a public hospital provider takes on the role of sponsor.

(2) If a clinical investigation of a medical device is submitted at the same time, in the same context, and by the same sponsor as the clinical trial of a medicinal product, the amount payable shall be equivalent to the full fee as specified in Section XII.1 or XII.2 of the Annex plus 35 percent of the applicable fee as specified in Section XI.1.a, XI.1.b, or XI.2 of the Annex.

(3) For academic clinical studies, the fees as specified in Section VII.6 of the Annex shall be waived.

(4) For fees payable for clinical trials in accordance with Regulation (EU) 536/2014 as specified in Section XI.2 of the Annex, the following categories have been defined:

- Category A: The investigational medicinal product (except placebos) is authorised in the European Economic Area (EEA), may have been modified, and
- is used in accordance with the terms of its marketing authorisation or in a manner considered evidence-based in Austria, and
- the study-related measures pose only a minimal additional risk to or impose only a minimal additional burden on the safety of the study participants compared to normal clinical practice.

- Category B: The investigational medicinal product (except placebos) is authorised in the EEA, may have been modified, and
  1) is not used in accordance with its marketing authorisation or in a manner considered evidence-based in Austria, and/or
  2) the study-related measures pose a more than minimal additional risk to or impose a more than minimal additional burden on the safety of the study participants compared to normal clinical practice.
- Category C: The investigational or auxiliary medicinal product is not authorised.

(5) For trials with a medicinal product authorised for use in patients in the EEA that investigate said product in healthy volunteers without a medical indication but otherwise comply with the terms of the marketing authorisation, a fee in accordance with category A shall be charged.

(6) The subsequent addition of a concerned Member State in accordance with Article 14 of Regulation (EU) 536/2014 where Austria is the additional Member State concerned shall be charged in accordance with the fees payable for an initial application with Austria as concerned Member State.

(7) The subsequent addition of a concerned Member State in accordance with Article 14 of Regulation (EU) 536/2014 where Austria is the reporting Member State shall be charged in accordance with the fees payable for a modification requiring authorisation.

(8) In the case of a split submission pursuant to Article 11 of Regulation (EU) 536/2014, the fees for the assessment of the global aspects (Part I) by BASG and the competent ethics committee and the fees for the assessment of the national aspects (Part II) by the competent ethics committee shall be charged separately. In addition, an extra service fee shall be charged by BASG as specified in Section XI.2.e. of the Annex.

(9) Depending on the types of documents modified as part of an application for the assessment of a substantial modification in accordance with Chapter III of Regulation (EU) 536/2014, fees may arise for the assessment by BASG, the competent ethics committee, or both. In case of a substantial modification that is subject to assessment by the competent ethics committee only (Part II), an additional service fee for tasks performed by BASG as specified in Section XI.3.e of the Annex shall apply.

Article 3. (1) For the purpose of this Schedule of Fees, a marketing authorisation of a known active substance is one where the proprietary medicinal product contains only such active substances as are contained in proprietary medicinal products

1. which, at the time of application, are authorised in one of the contracting parties to the Agreement on the EEA and
2. whose marketing authorisation relates to an application similar to that under review.

(2) For the purpose of this Schedule of Fees, a marketing authorisation of a new substance is one where not all of the conditions set forth in paragraph 1 are met.

(3) An extension of an existing marketing authorisation within the meaning of Regulation (EC) No 1234/2008 or a corresponding modification of an existing market authorisation in accordance with Article 62 Regulation (EU) 2019/6 that results in a new and separate authorisation number shall be charged as specified in Section I of the Annex.

Article 4. For applications for marketing authorisation of two or more proprietary medicinal products of the same product family in accordance with Sections I.1, I.2, or I.3., items a, b, c, and d, or in accordance with Section I.4 of the Annex

1. which are submitted simultaneously by the same applicant,

2. whose active substances are of the same kind, and

3. whose medical use has similar evaluation requirements,

the full fee shall be charged for the first of these applications, and 50 percent of that fee shall be charged for any additional application.

Article 4a. (1) If, in a mutual recognition or decentralised procedure with Austria as reference Member State (RMS), additional duplicate dossiers (i.e., dossiers which, with the exception of the name of the proprietary medicinal product, are identical) are submitted simultaneously or during an ongoing authorisation procedure, the fee payable for such duplicate dossiers and related subsequent applications in accordance with Section I.1.a, I.2.a, and IX.1.a of the Annex shall be reduced by 50 percent. This reduction applies only if the duplicate dossiers are submitted by the same applicant or marketing authorisation holder.

(2) If, at the time of notification of the intended distribution of proprietary medicinal products through distance selling pursuant to Article 59a of the Austrian Medicinal Products Act *(Arzneimittelgesetz,* AMG) or Article 50 of the Austrian Veterinary Medicinal Products Act (mail-order pharmacy), an identical notification regarding a website with identical content and purpose is submitted to BASG, the fee payable for such notification in accordance with Section VII.10 of the Annex shall be reduced by 50 percent.

Article 5. For Periodic Safety Update Reports (PSURs) (as defined in Article 2b paragraph 9 AMG) on two or more medicinal products which are

1. submitted simultaneously by the same marketing authorization holder,

2. deal with (an) identical active substance(s), and

3. whose medical use has similar evaluation requirements,

the full fee shall be payable for the most expensive of these applications, while any additional applications shall be charged at 50 percent of the applicable fee.

Article 6. (1) For authorisations and other activities pertaining to veterinary medicinal products, a fee amounting to 60 percent of the fee as specified in Sections I, IV, V.6, VI, VII, and VIII (except Sections VIII.6 and 7) of the Annex and in Article 8 paragraph 4 will be charged.

(2) For veterinary medicinal products, a fee amounting to 55 percent of that specified in Section II of the Annex will be charged.

(3) For marketing authorisations for limited markets and in exceptional circumstances pursuant to Articles 23 and 25 of Regulation (EU) 2019/6, respectively, a fee amounting to 45 percent of that specified in Section I of the Annex will be charged.

Article 7. (1) An "inspection half-day" is defined as a period of a maximum of 4 hours, or any fraction thereof, spent by an inspector working on site or in direct relation with an inspection.

(2) Travel expenses incurred in relation with an inspection outside of Austria in accordance with Section VII of the Annex are not included in the fees listed and shall be charged separately; for national inspections, a flat rate for travel expenses of EUR 265.00 shall be charged.

Article 8. (1) In case cash expenditures pursuant to Article 76 of the Austrian General Administrative Procedures Act *(Verwaltungsverfahrensgesetz)* 1991, Federal Law Gazette I No. 51/1991 as amended, are incurred in connection with either a procedure or other activities for which fees are payable in accordance with this Fees Ordinance, these cash expenditures shall be considered an integral part of the fee as stipulated by the Schedule of Fees, unless these cash expenditures exceed the fee payable. In the latter case, a fee of 20 percent of the fee specified in the Schedule of Fees plus the sum total of cash expenditures incurred shall be payable. If cash expenditures arise in relation to a procedure otherwise considered paid and settled by an annual flat fee as specified in Section II, such expenditures shall be settled in full by the applicant.

(2) Other services not listed in the Annex or additional services shall be charged, after consultation with the applicant, at an hourly rate of EUR 203.00.

(3) The annual flat fee as specified in Section II of the Annex shall be payable by the marketing authorisation holder, registration holder, or holder of a license pursuant to Article 7a AMG. The annual flat fee shall be invoiced, on a pro rata basis, at the end of each quarter for all medicinal products authorised, registered, approved, or licensed as per the last working day of the respective quarter. The annual flat fee as specified in Section II of the Annex is also payable for authorisations or registrations whose suspension has been ordered by BASG.

(3a) The annual flat fee as specified in Section III.2 of the Annex shall be payable by the holder of a parallel import license. This fee shall be invoiced, on a pro rata basis, at the end of each quarter for all (proprietary) medicinal products licensed for parallel import as per the last working day of the respective quarter.

(3b) The annual flat fee as specified in Section VII.11 of the Annex shall be invoiced to the person entitled to distance selling pursuant to Article 59a paragraph 2 AMG or Article 50 TAMG by May 31 of each subsequent year, with the invoice payable within the period specified therein.

(4) For applications, notifications, or other documentation not submitted electronically as required by the BASG Ordinance on the Electronic Submission of Applications and Notifications (Electronic Submission Ordinance, EEVO) of 2011 as amended, the prescribed fee increases by 5 percent.

Article 9. This Ordinance shall enter into force on 1. January 2026.

1 Explanatory note: On 15 January 2006, the Ordinance of the Federal Office for Safety in Health Care (BASG) On the Schedule of Fees Pursuant to the Austrian Health and Food Safety Act (GESG) (published on 18 January 2006 in the Official Gazette of the Republic of Austria's official newspaper for public announcements, i.e., *Amtsblatt zur Wiener Zeitung)* entered into force.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2006 *(BASG VO Nr. 02/2006)* entered into force on 15 January 2007.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2008 *(BASG VO Nr. 01/2008)* entered into force on 03 November 2008.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2009 *(BASG VO Nr. 01/2009)* entered into force on 26 March 2009.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2009 *(BASG VO Nr. 02/2009)* entered into force on 01 January 2010.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2011 *(BASG VO Nr. 01/2011)* entered into force on 28 November 2011.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2012 *(BASG VO Nr. 01/2012)* entered into force on 08 November 2012.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2013 *(BASG VO Nr. 01/2013)* entered into force on 24 January 2013.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2013 *(BASG VO Nr. 02/2013)* entered into force on 04 August 2013.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 03/2013 *(BASG VO Nr. 03/2013)* entered into force on 02 January 2014.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2015 *(BASG VO Nr. 01/2015)* entered into force on 04 May 2015.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2015 *(BASG VO Nr. 02/2015)* entered into force on 01 January 2016.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2016 *(BASG VO Nr. 01/2016)* entered into force on 31 January 2016.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2016 *(BASG VO Nr. 02/2016)* entered into force on 09 May 2016.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 03/2016 *(BASG VO Nr. 03/2016)* entered into force on 15 July 2016.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 04/2016 *(BASG VO Nr. 04/2016)* entered into force on 01 January 2017.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2017 *(BASG VO Nr. 01/2017)* entered into force on 01 June 2017.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2017 *(BASG VO Nr. 02/2017)* entered into force on 01 January 2018.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2018 *(BASG VO Nr. 02/2018)* entered into force on 01 September 2018.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 03/2018 *(BASG VO Nr. 03/2018)* entered into force on 01 January 2019.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2019 *(BASG VO Nr. 01/2019)* entered into force on 01 January 2020.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2020 *(BASG VO Nr. 02/2020)* entered into force on 01 July 2020.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 03/2020 *(BASG VO Nr. 03/2020)* entered into force on 01 January 2021.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2021 *(BASG VO Nr. 01/2021)* entered into force on 01 August 2021.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2021 *(BASG VO Nr. 02/2021)* entered into force on 01 January 2022.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 03/2021 *(BASG VO Nr. 03/2021)* entered into force on 28 January 2022.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2022 *(BASG VO Nr. 01/2022)* entered into force on 15 August 2022.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2022 *(BASG VO Nr. 02/2022)* entered into force on 01 January 2023.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 01/2023 *(BASG VO Nr. 01/2023)* entered into force on 01 January 2024.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 02/2024 *(BASG VO Nr. 02/2024)* entered into force on 01 June 2024.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 04/2024 *(BASG VO Nr. 02/2024)* entered into force on 01 January 2025.

The amendment to the Fees Ordinance as enacted by Federal Office for Safety in Health Care Ordinance No. 03/2024 *(BASG VO Nr. 03/2024)* entered into force on 01 March 2025.

For the changes enacted with these amendments, see the respective ordinances as published by the Federal Office for Safety in Health Care (BASG) under "Official Announcements."

Any fees payable shall be based on the Fees Ordinance in force on the day an application is/was submitted.

Annex

Section	Service provided	EURO
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I.1.a.1	For a proprietary medicinal product containing a new active substance	53.731
I.1.a.2	For a proprietary medicinal product containing a known active substance	41.016
I.1.a.3	Repeat-use procedure or subsequent recognition procedure pursuant to Article 53 of Regulation (EU) 2019/6	8.204
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X.2	Classification procedure pursuant to Article 26 MPG as amended by Federal Law Gazette I No. 46/2021, pursuant to Article 51 (2) of Regulation (EU) 2017/745, or pursuant to Article 47 (2) of Regulation (EU) 2017/746, plus any expenses for external expert assessments	3.418
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X.4	Determination procedure pursuant to Article 5a MPG as amended by Federal Law Gazette I No. 46/2021 or Article 10 MPG 2021 as amended regarding the classification of a medical device, plus any expenses for external expert assessments	3.418
XI.	**Clinical trials on medicinal products**	
XI.1	**Clinical trial on medicinal products pursuant to AMG as amended by Federal Law Gazette I No. 23/2020**	
XI.1.a	Submission of a phase I, II, or III clinical trial on a medicinal product	4.081
XI.1.b	Submission of a phase IV clinical trial on a medicinal product	2.052
XI.1.c	Submission of a substantial modification of a clinical trial pursuant to Article 37a AMG	679
XI.1.d	Submission of a non-interventional study (NIS) pursuant to Article 2a paragraph 3 AMG or Article 2 paragraph 2 clause 4 of Regulation (EU) 536/2014	819
XI.1.e	Submission of a compassionate-use programme pursuant to Article 8a AMG	
XI.1.e.1	Based on an assessment report of the Committee for Medicinal Products for Human Use (CHMP)	684
XI.1.e.2	Not based on an assessment report of the CHMP	2.052
XI.2	**Application for authorisation of a clinical trial on a medicinal product pursuant to Article 5 of Regulation (EU) 536/2014**	
XI.2.a	Category A	
XI.2.a.1	With Austria as reporting Member State (national)	
XI.2.a.1.a	Assessment by BASG	1.392
XI.2.a.1.b	Assessment by the competent ethics committee (Part I)	821
XI.2.a.1.c	Assessment by the competent ethics committee (Part II)	821
XI.2.a.2	With Austria as reporting Member State (multinational)	
XI.2.a.2.a	Assessment by BASG	2.025

XI.2.a.2.b	Assessment by the competent ethics committee (Part I)	1.076
XI.2.a.2.c	Assessment by the competent ethics committee (Part II)	821
XI.2.a.3	With Austria as concerned Member State (multinational)	
XI.2.a.3.a	Assessment by BASG	1.392
XI.2.a.3.b	Assessment by the competent ethics committee (Part I)	821
XI.2.a.3.c	Assessment by the competent ethics committee (Part II)	821
XI.2.b	Category B	
XI.2.b.1	With Austria as reporting Member State (national)	
XI.2.b.1.a	Assessment by BASG	2.151
XI.2.b.1.b	Assessment by the competent ethics committee (Part I)	1.518
XI.2.b.1.c	Assessment by the competent ethics committee (Part II)	1.518
XI.2.b.2	With Austria as reporting Member State (multinational)	
XI.2.b.2.a	Assessment by BASG	2.783
XI.2.b.2.b	Assessment by the competent ethics committee (Part I)	1.835
XI.2.b.2.c	Assessment by the competent ethics committee (Part II)	1.518
XI.2.b.3	With Austria as concerned Member State (multinational)	
XI.2.b.3.a	Assessment by BASG	1.392
XI.2.b.3.b	Assessment by the competent ethics committee (Part I)	1.455
XI.2.b.3.c	Assessment by the competent ethics committee (Part II)	1.518
XI.2.c	Category C	
XI.2.c.1	With Austria as reporting Member State (national)	
XI.2.c.1.a	Assessment by BASG	4.682

XI.2.c.1.b	Assessment by the competent ethics committee (Part I)	3.353
XI.2.c.1.c	Assessment by the competent ethics committee (Part II)	3.353
XI.2.c.2	With Austria as reporting Member State (multinational)	
XI.2.c.2.a	Assessment by BASG	6.074
XI.2.c.2.b	Assessment by the competent ethics committee (Part I)	4.112
XI.2.c.2.c	Assessment by the competent ethics committee (Part II)	3.353
XI.2.c.3	With Austria as concerned Member State (multinational)	
XI.2.c.3.a	Assessment by BASG	2.025
XI.2.c.3.b	Assessment by the competent ethics committee (Part I)	3.290
XI.2.c.3.c	Assessment by the competent ethics committee (Part II)	3.353
XI.2.d	Fees for additional expenses in relation to clinical trial authorisations	
XI.2.d.1	For each additional investigational medicinal product not authorised within the EEA, the sum total of fees payable for positions XI.2a-d for services performed by BASG increases by	3.290
XI.2.d.2	For clinical trials consisting of several substudies (multiphase or integrated design), the sum total of fees payable for positions XI.2a-d for services performed by BASG increases by	821
XI.2.d.3	For clinical trials consisting of several substudies (multiphase or integrated design), the sum total of fees payable for positions XI.2a-d for services performed by the ethics committee increases by	1.518
XI.2.d.4	For investigational medicinal products considered advanced therapies pursuant to Article 1 paragraph 6a AMG, the sum total of fees payable for positions XI.2a-d for services performed by the ethics committee increases by	1.518
XI.2.d.5	For each substudy with a separate patient information document, the sum total of fees payable for positions XI.2a-d for services performed by the ethics committee increases by	760
XI.2.d.6	For each additional trial site, the sum total of fees payable for positions XI.2a-d for services performed by the ethics committee increases by	760
XI.2.e	Processing a split submission for authorisation pursuant to Article 11 of Regulation (EU) 536/2014 by BASG	253

XI.3	**Application for the authorisation of a substantial modification of a clinical trial pursuant to Chapter III of Regulation (EU) 536/2014**	
XI.3.a	Category A	
XI.3.a.1	With Austria as reporting Member State (national)	
XI.3.a.1.a	Assessment by BASG	569
XI.3.a.1.b	Assessment by the competent ethics committee	886
XI.3.a.2	With Austria as reporting Member State (multinational)	
XI.3.a.2.a	Assessment by BASG	697
XI.3.a.2.b	Assessment by the competent ethics committee	886
XI.3.a.3	With Austria as concerned Member State (multinational)	
XI.3.a.3.a	Assessment by BASG	569
XI.3.a.3.b	Assessment by the competent ethics committee	886
XI.3.b	Category B	
XI.3.b.1	With Austria as reporting Member State (national)	
XI.3.b.1.a	Assessment by BASG	569
XI.3.b.1.b	Assessment by the competent ethics committee	886
XI.3.b.2	With Austria as reporting Member State (multinational)	
XI.3.b.2.a	Assessment by BASG	697
XI.3.b.2.b	Assessment by the competent ethics committee	886
XI.3.b.3	With Austria as concerned Member State (multinational)	
XI.3.b.3.a	Assessment by BASG	569
XI.3.b.3.b	Assessment by the competent ethics committee	886

XI.3.c	Category C	
XI.3.c.1	With Austria as reporting Member State (national)	
XI.3.c.1.a	Assessment by BASG	821
XI.3.c.1.b	Assessment by the competent ethics committee	886
XI.3.c.2	With Austria as reporting Member State (multinational)	
XI.3.c.2.a	Assessment by BASG	1.076
XI.3.c.2.b	Assessment by the competent ethics committee	886
XI.3.c.3	With Austria as concerned Member State (multinational)	
XI.3.c.3.a	Assessment by BASG	821
XI.3.c.3.b	Assessment by the competent ethics committee	886
XI.3.d	Fees for additional expenses in relation to an application for authorisation of a clinical trial modification	
XI.3.d.1	Each addition of a new investigational medicinal product not authorised within the EEA increases the sum total of fees payable for above positions for services performed by BASG by	3.290
XI.3.d.2	The addition of a trial site in the course of another substantial modification of a clinical trial increases the sum total of fees payable for above positions for services performed by the ethics committee by	760
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XI.5.a.1	With Austria as reporting Member State (national)	317
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XI.5.b.3	With Austria as concerned Member State (multinational)	380
XI.5.c	Category C	
XI.5.c.1	With Austria as reporting Member State (national)	569
XI.5.c.2	With Austria as reporting Member State (multinational)	1.392
XI.5.c.3	With Austria as concerned Member State (multinational)	380
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XIII.1.c	Application for a free sales certificate for one country for single devices, accessories, and/or components (51 to 250 items)	1.054
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