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. 122/2021, 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(3) For applications rejected or withdrawn before the assessment of formal requirements has been completed, the amount payable shall be 10 percent of the applicable fee. For applications rejected or withdrawn after this time, the full fee shall be payable.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 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 for human use through distance selling pursuant to Article 59a of the Austrian Medicinal Products Act *(Arzneimittelgesetz,* AMG) (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 12 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 240.00 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 No. 51, 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 184.00.

(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 was first levied in 2014.

(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 owners of registered public pharmacies pursuant to Article 59a paragraph 2 AMG 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 2023.

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.

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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XI.2.a.1.c	Assessment by the competent ethics committee (Part II)	742
XI.2.a.2	With Austria as reporting Member State (multinational)	
XI.2.a.2.a	Assessment by BASG	1.829

XI.2.a.2.b	Assessment by the competent ethics committee (Part I)	972
XI.2.a.2.c	Assessment by the competent ethics committee (Part II)	742
XI.2.a.3	With Austria as concerned Member State (multinational)	
XI.2.a.3.a	Assessment by BASG	1.257
XI.2.a.3.b	Assessment by the competent ethics committee (Part I)	742
XI.2.a.3.c	Assessment by the competent ethics committee (Part II)	742
XI.2.b	Category B	
XI.2.b.1	With Austria as reporting Member State (national)	
XI.2.b.1.a	Assessment by BASG	1.942
XI.2.b.1.b	Assessment by the competent ethics committee (Part I)	1.371
XI.2.b.1.c	Assessment by the competent ethics committee (Part II)	1.371
XI.2.b.2	With Austria as reporting Member State (multinational)	
XI.2.b.2.a	Assessment by BASG	2.514
XI.2.b.2.b	Assessment by the competent ethics committee (Part I)	1.657
XI.2.b.2.c	Assessment by the competent ethics committee (Part II)	1.371
XI.2.b.3	With Austria as concerned Member State (multinational)	
XI.2.b.3.a	Assessment by BASG	1.257
XI.2.b.3.b	Assessment by the competent ethics committee (Part I)	1.314
XI.2.b.3.c	Assessment by the competent ethics committee (Part II)	1.371
XI.2.c	Category C	
XI.2.c.1	With Austria as reporting Member State (national)	
XI.2.c.1.a	Assessment by BASG	4.228

XI.2.c.1.b	Assessment by the competent ethics committee (Part I)	3.028
XI.2.c.1.c	Assessment by the competent ethics committee (Part II)	3.028
XI.2.c.2	With Austria as reporting Member State (multinational)	
XI.2.c.2.a	Assessment by BASG	5.485
XI.2.c.2.b	Assessment by the competent ethics committee (Part I)	3.714
XI.2.c.2.c	Assessment by the competent ethics committee (Part II)	3.028
XI.2.c.3	With Austria as concerned Member State (multinational)	
XI.2.c.3.a	Assessment by BASG	1.829
XI.2.c.3.b	Assessment by the competent ethics committee (Part I)	2.971
XI.2.c.3.c	Assessment by the competent ethics committee (Part II)	3.028
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	2.971
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	742
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	1.371
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	1.371
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	686
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	686
XI.2.e	Processing a split submission for authorisation pursuant to Article 11 of Regulation (EU) 536/2014 by BASG	228

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	514
XI.3.a.1.b	Assessment by the competent ethics committee	800
XI.3.a.2	With Austria as reporting Member State (multinational)	
XI.3.a.2.a	Assessment by BASG	629
XI.3.a.2.b	Assessment by the competent ethics committee	800
XI.3.a.3	With Austria as concerned Member State (multinational)	
XI.3.a.3.a	Assessment by BASG	514
XI.3.a.3.b	Assessment by the competent ethics committee	800
XI.3.b	Category B	
XI.3.b.1	With Austria as reporting Member State (national)	
XI.3.b.1.a	Assessment by BASG	514
XI.3.b.1.b	Assessment by the competent ethics committee	800
XI.3.b.2	With Austria as reporting Member State (multinational)	
XI.3.b.2.a	Assessment by BASG	629
XI.3.b.2.b	Assessment by the competent ethics committee	800
XI.3.b.3	With Austria as concerned Member State (multinational)	
XI.3.b.3.a	Assessment by BASG	514
XI.3.b.3.b	Assessment by the competent ethics committee	800

XI.3.c	Category C	
XI.3.c.1	With Austria as reporting Member State (national)	
XI.3.c.1.a	Assessment by BASG	742
XI.3.c.1.b	Assessment by the competent ethics committee	800
XI.3.c.2	With Austria as reporting Member State (multinational)	
XI.3.c.2.a	Assessment by BASG	972
XI.3.c.2.b	Assessment by the competent ethics committee	800
XI.3.c.3	With Austria as concerned Member State (multinational)	
XI.3.c.3.a	Assessment by BASG	742
XI.3.c.3.b	Assessment by the competent ethics committee	800
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	2.971
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	686
XI.3.e	Processing a split submission for authorisation of a modification pursuant to Article 20 of Regulation (EU) 536/2014 by BASG	228
XI.4	**Notification of BASG of clinical trial changes not requiring authorisation**	
XI.4.a	With Austria as reporting Member State (national and multinational)	400
XI.5	**Assessment of the annual safety report pursuant to Article 43 of Regulation (EU) 536/2014 by BASG**	
XI.5.a	Category A	
XI.5.a.1	With Austria as reporting Member State (national)	286
XI.5.a.2	With Austria as reporting Member State (multinational)	514

XI.5.a.3	With Austria as concerned Member State (multinational)	343
XI.5.b	Category B	
XI.5.b.1	With Austria as reporting Member State (national)	286
XI.5.b.2	With Austria as reporting Member State (multinational)	514
XI.5.b.3	With Austria as concerned Member State (multinational)	343
XI.5.c	Category C	
XI.5.c.1	With Austria as reporting Member State (national)	514
XI.5.c.2	With Austria as reporting Member State (multinational)	1.257
XI.5.c.3	With Austria as concerned Member State (multinational)	343
XI.6	Corrective measures taken by BASG pursuant to Article 77 of Regulation (EU) 536/2014	972
XI.7	Application for transition of a clinical trial authorised pursuant to Directive 2001/20/EC to Regulation (EU) 536/2014	276
XI.8	Application for authorisation of a clinical trial on a veterinary medicinal product pursuant to Article 9 of Regulation (EU) 2019/6	
XI.8.a	Application for authorisation of a clinical trial on a veterinary medicinal product without specifying waiting periods	2.212
XI.8.b	Application for authorisation of a clinical trial on a veterinary medicinal product, with waiting periods specified	3.525
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XII.1.a	Notification of a substantial modification of a clinical investigation or performance evaluation pursuant to Article 40a MPG as amended by Federal Law Gazette I No. 46/2021	608
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XII.2.a	Application for authorisation of a clinical investigation of a medical device pursuant to Article 70 paragraph 7b of Regulation (EU) 2017/745 or Article 13 paragraph 3 MPG 2021 as amended, where at least one of the medical devices used does not bear a valid CE marking or has been modified	7.542
XII.2.b	Application for authorisation of a clinical investigation of a medical device pursuant to Article 70 paragraph 7b of Regulation (EU) 2017/745 or Article 13 paragraph 3 MPG 2021 as amended, where all medical devices used bear a valid CE marking and have not been modified	2.742
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XII.2.d	Notification of a clinical investigation pursuant to Article 70 paragraph 7a of Regulation (EU) 2017/745, where all medical devices used bear a valid CE marking and have not been modified	2.057
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XII.2.f	Notification of a clinical investigation pursuant to Article 13 paragraph 3 MPG 2021 as amended	857
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XII.3.c	Notification of the performance study of an IVD pursuant to Article 66 paragraph 7a of Regulation (EU) 2017/746, where at least one of the IVDs used does not bear a valid CE marking or has been modified	2.057

XII.3.d	Notification of the performance study of an IVD pursuant to Article 66 paragraph 7a of Regulation (EU) 2017/746, where all of the IVDs used bear a valid CE marking and have not been modified	857
XII.3.e	Notification of a performance study pursuant to Article 70 paragraph 1 of Regulation (EU) 2017/746 ("post-market performance follow-up [PMPF] study")	857
XII.3.f	Notification of a performance study involving a companion diagnostic pursuant to Article 58 paragraph 2 of Regulation (EU) 2017/746, where only left-over samples are used	857
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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)	951
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