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Euro exchange rates ([1])

28 December 2021

(2021/C 524/01)

1 euro =

	Currency	Exchange rate		Currency	Exchange rate
USD	US dollar	1,1331	CAD	Canadian dollar	1,4487
JPY	Japanese yen	130,16	HKD	Hong Kong dollar	8,8380
DKK	Danish krone	7,4362	NZD	New Zealand dollar	1,6602
GBP	Pound sterling	0,84248	SGD	Singapore dollar	1,5335
SEK	Swedish krona	10,2528	KRW	South Korean won	1 345,14
CHF	Swiss franc	1,0381	ZAR	South African rand	17,8113
ISK	Iceland króna	147,40	CNY	Chinese yuan renminbi	7,2159
NOK	Norwegian krone	9,9728	HRK	Croatian kuna	7,5175
BGN	Bulgarian lev	1,9558	IDR	Indonesian rupiah	16 126,51
CZK	Czech koruna	24,980	MYR	Malaysian ringgit	4,7369
HUF	Hungarian forint	369,08	PHP	Philippine peso	57,288
PLN	Polish zloty	4,6063	RUB	Russian rouble	83,4446
RON	Romanian leu	4,9500	THB	Thai baht	37,948
TRY	Turkish lira	13,3521	BRL	Brazilian real	6,3981
AUD	Australian dollar	1,5603	MXN	Mexican peso	23,4003
			INR	Indian rupee	84,6335

([1]) *Source*: reference exchange rate published by the ECB.

Commission Notice – Application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland

(2021/C 524/02)

DISCLAIMER

This guidance notice is intended to facilitate the application of the EU's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland after 1 February 2020 by indicating the manner in which the Commission will apply to this specific situation the relevant provisions of Directives 2001/82/EC ([1]), 2001/83/EC ([2]) and 2001/20/EC ([3]) as well as Regulations (EU) 2019/6 ([4]) and (EU) 536/2014 ([5]) and Commission Delegated Regulation (EU) 2016/161 ([6]). While this notice seeks to assist authorities and operators, only the Court of Justice of the European Union is competent to authoritatively interpret Union law. On 1 February 2020, the United Kingdom withdrew from the European Union and thereby became a 'third country' ([7]). The Withdrawal Agreement ([8]) provides for a transition period which ended on 31 December 2020. Until that date, Union law in nearly all areas applied to and in the United Kingdom ([9]). This included the pharmaceutical *acquis* of the Union, in particular Directive 2001/82/EC of the European Parliament and of the Council, Directive 2001/83/EC of the European Parliament and of the Council, Commission Delegated Regulation (EU) 2016/161, Article 13 of Directive 2001/20/EC of the European Parliament and of the Council and Chapter IX of Regulation (EU) 536/2014, which are of relevance for this Notice.

At the end of the transition period, Union law ceased to apply to the United Kingdom, whilst the main provisions of the Protocol on Ireland and Northern Ireland ('the IE/NI Protocol'), which forms an integral part of the Withdrawal Agreement, became applicable. In accordance with Article 5(4) of and point 20 of Annex 2 to the IE/NI Protocol, the pharmaceutical *acquis* of the Union including the abovementioned legal acts, as well as legal acts of the Union implementing, amending or replacing those legal acts apply to and in the United Kingdom in respect of Northern Ireland.

In practical terms, this means, in particular, that:

— Medicinal products (in the scope of the abovementioned legislation) placed on the market in Northern Ireland must comply with the regulatory requirements laid down in Union law;

— Medicinal products placed on the market in Northern Ireland must have a valid marketing authorisation granted by the Commission (EU wide authorisation) or by the competent authorities of the United Kingdom in respect of Northern Ireland, the holder of which is located in the Union or in Northern Ireland;

— Movements of medicinal products from parts of the United Kingdom other than Northern Ireland to Northern Ireland or to the Union constitutes an import within the meaning of applicable Union law;

— Movements of medicinal products from the Union or Northern Ireland to parts of the United Kingdom other than Northern Ireland or any other third country constitutes an export within the meaning of applicable Union law;

— Marketing authorisations issued by UK authorities are, in principle, not valid within the Union but only in Northern Ireland if adopted in accordance with applicable Union law (cf. Article 7(3) of the IE/NI Protocol);

([1]) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

([2]) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

([3]) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

([4]) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

([5]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).

([6]) Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

([7]) A third country is a country which is not a member of the EU.

([8]) Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 7) ('Withdrawal Agreement').

([9]) Subject to certain exceptions provided for in Article 127 of the Withdrawal Agreement, none of which is relevant in the context of this notice.

— Any action in the supply of medicines which must be carried out in the Union (e.g. batch testing) in order to allow for the placing on the market of medicinal products in accordance with Union law must occur in the Union or Northern Ireland, and only such actions that may be carried out in third countries may occur in parts of the United Kingdom other than Northern Ireland.

Since 2017, the Commission and the European Medicines Agency have actively been disseminating all relevant information in order to draw the attention of all relevant stakeholders to the impact of the United Kingdom's withdrawal and to alert them of the need to adapt in time before the end of the transition period. The necessary changes have notably been explained in BREXIT Notices as last amended and published on 7 May 2020 for clinical trials ([10]) and on 13 March 2020 for medicinal products ([11]).

Nonetheless, at the end of the transition period, operators in certain markets which have historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland) ([12]) still needed additional time to adapt supply chains and take account of the end of the transition period. Against that background and given that it was considered crucial that the Union's pharmaceutical *acquis* was implemented and enforced in a manner that both prevented shortages of medicines and ensured the high level of public health protection foreseen by Union law, on 25 January 2021 the Commission adopted a Notice explaining how it would apply, until 31 December 2021, the EU's pharmaceutical *acquis* in those markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland ([13]).

The period covered by that Commission Notice is now coming to an end, but the situation remains challenging in those markets which have historically relied on supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland). Supply chains of medicines have not yet been adapted, in particular those of suppliers of generics, over-the-counter medicinal products for human use and medicinal products for human use which are supplied on the basis of national marketing authorisations granted by the competent authorities in the United Kingdom. In addition, with regard to medicinal products for human use, certain new challenges have been identified during the past year.

In order to address this situation, and with the aim of preventing shortages of medicines and ensuring a high level of public health protection, with regard to medicinal products for human use, the Commission on 17 December 2021 adopted legislative proposals amending relevant provisions of Directive 2001/83/EC, Directive 2001/20/EC ([14]) and Regulation (EU) 536/2014 ([15]), as well as a delegated regulation amending Commission Delegated Regulation (EU) 2016/161 ([16]). It is necessary to bridge the gap between 31 December 2021 and the entry into force of these amendments. In this context, it should be noted that the Commission proposals for a directive amending Directive 2001/83/EC and Directive 2001/20/EC and for a Regulation amending Regulation (EU) 536/2014 provide for the application of those amendments from 1 January 2022 and 31 January 2022, respectively (the latter being the date on which Regulation (EU) 536/2014 becomes applicable). Likewise, the delegated regulation amending Commission Delegated Regulation (EU) 2016/161 provides that it shall apply from 1 January 2022.

([10]) https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/clinical-trials_en.pdf

([11]) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/notice-stakeholders-withdrawal-united-kingdom-eu-rules-medicinal-products-human-use-veterinary_en.pdf

([12]) These Member States are singled out in this Notice because of their historical dependence on the UK market for their supply of medicinal products and the fact that a large proportion of their imports of medicinal products is coming from UK.

([13]) Commission Notice – Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period, 2021/C 27/08 (OJ C 27, 25.1. 2021, p. 11).

([14]) Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC and Directive 2001/20/EC as regards derogations from certain obligations concerning certain nationally authorised medicinal products for human use made available in the United Kingdom in respect of Northern Ireland as well as in Cyprus, Ireland and Malta (COM (2021)997).

([15]) Commission proposal for a Regulation (EU) of the European Parliament and of the Council amending Regulation (EU) No 536/2014 as regards derogations from certain obligations concerning investigational medicinal products made available in United Kingdom in respect to Northern Ireland as well as in Cyprus, Ireland and Malta (COM (2021)998).

([16]) Commission Delegated Regulation (EU) of 17 December 2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom (C (2021)9700).

As regards medicinal products for veterinary use, more time is needed for companies to adjust to the changes brought about by the provisions of the IE/NI Protocol referred to above. There is therefore currently still a risk of shortages of veterinary medicinal products in those markets which have historically depended on medicines supply from or through parts of the United Kingdom other than Northern Ireland. The Commission will continue to gather information on the current situation on the ground with a view to identifying any outstanding implementation issues and finding the most appropriate way forward for ensuring long-term continuity of veterinary medicines supply to Cyprus, Ireland, Malta and Northern Ireland. It is therefore necessary to allow more time for companies to adjust.

Therefore, the Commission considers it appropriate to explain in this Notice how it will apply, until 31 December 2022 or, as regards human medicines, until the date of entry into force of the amendments referred to above, if that date is before 31 December 2022, the Union's pharmaceutical *acquis* in those markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland (i.e. Cyprus, Ireland, Malta and Northern Ireland). In that regard, the following areas, which have been identified by the Commission as the principal difficulties currently still faced by Cyprus, Ireland, Malta and Northern Ireland in complying with the Union's pharmaceutical *acquis,* will be covered:

1. Lack of operators holding a manufacturing authorisation necessary for imports of medicinal products from third countries;

2. Difficulties to carry out quality control testing ('batch testing');

3. Difficulties to comply with the provisions of Directive 2001/83/EC and Delegated Regulation (EU) 2016/161 with respect to the placement and verification of the unique identifier;

4. Specifically with regard to medicinal products for human use for the Northern Irish market, difficulties for some operators holding a marketing authorisation for medicinal products as well as for qualified persons for the manufacturing and pharmacovigilance of these products which are currently established in parts of the United Kingdom other than Northern Ireland to transfer their sites to the EU/EEA or to Northern Ireland; and

5. Specifically with regard to medicinal products for human use for the Cypriot and Maltese markets, difficulties to ensure access for patients to certain medicinal products due to the reliance of supply chains on parts of the United Kingdom other than Northern Ireland.

Specifically for veterinary medicinal products, it should be noted that Regulation (EU) 2019/6 will start applying from 28 January 2022. Until that date, veterinary medicinal products will be governed by the relevant provisions of Directive 2001/82/EC. This Notice refers to the provisions of both instruments, with the understanding that references to provisions of Directive 2001/82/EC are to be read as applying until 28 January 2022, and reference to provisions of Regulation (EU) 2019/6 are to be read as applying as of 28 January 2022.

1. **Lack of operators holding a manufacturing authorisation required for importing medicinal products from third countries**

A. *Human and veterinary medicinal products*

According to Article 40(3) of Directive 2001/83/EC, Article 44(3) of Directive 2001/82/EC and Article 88(1)(c) of Regulation (EU) 2019/6, anyone placing medicinal products from third countries on the market in accordance with Union law (in the Union or in Northern Ireland) is an importer within the meaning of Union law, and must therefore hold a manufacturing authorisation issued by the Member State where the importer is established or, in the case of importers established in Northern Ireland, by the United Kingdom acting in respect of Northern Ireland, in accordance with Articles 41 and 42 of Directive 2001/83/EC for human medicines, Articles 45 and 46 of Directive 2001/82/EC and/or Articles 89 and 90 of Regulation (EU) 2019/6 for veterinary medicines. The conditions for such a manufacturing authorisation include, inter alia, the availability of a qualified person in the Union or Northern Ireland, the inspection of the manufacturer/importer and its compliance with Good Manufacturing Practices.

According to Articles 118 of Directive 2001/83/EC and Article 84(e) of Directive 2001/82/EC, competent authorities applying the Union's pharmaceutical *acquis* are obliged to suspend or revoke the marketing authorisation of a medicinal product where the holder of that authorisation does not have a valid manufacturing authorisation or does not comply with one of the conditions necessary to obtain such a manufacturing authorisation. According to Article 134(1)(d) of Regulation (EU) 2019/6, competent authorities are obliged to prohibit the supply of a veterinary medicinal product and require the marketing authorisation holder or suppliers to cease the supply of or recall the veterinary medicinal product from the market if the control tests referred to in Article 127(1) of that Regulation have not been carried out.

Regarding human medicinal products, in order to bridge the gap with the entry into force of the directive amending Directive 2001/83 referred to in the introduction of this Notice and regarding medicinal products for veterinary use, in order to provide more time for operators to adjust to the changes brought about by the IE/NI Protocol, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland could apply the following practice. This practice could be applied between 1 January 2022 and 31 December 2022, or, for human medicines, between 1 January 2022 and the date of entry into force of these amendments, if that date is before 31 December 2022:

— The competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland would allow medicinal products to be imported from other parts of the United Kingdom than Northern Ireland by wholesalers which are not in possession of a manufacturing authorisation as required by Article 40 of Directive 2001/83/EC, Article 44 of Directive 2001/82/EC and Article 88 of Regulation (EU) 2019/6; and they would not suspend or revoke the marketing authorisations of those medicinal products as required by Article 118 of Directive 2001/83/EC, Article 84(e) of Directive 2001/82/EC and Article 134(1)(d) of Regulation (EU) 2019/6, provided that the following conditions are fulfilled:

— The medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland and placed on the market in accordance with Union law (i.e. imported into the Union or Northern Ireland) have undergone batch testing ([17])) either in the Union, as provided for in Article 51(3) of Directive 2001/83/EC for human medicinal products and in Article 44(3) of Directive 2001/82/EC and Article 88(1)(c) of Regulation (EU) 2019/6 for veterinary medicinal products, or in parts of the United Kingdom other than Northern Ireland in compliance with Article 20(b) of Directive 2001/83/EC for human medicinal products and with Article 24(b) of Directive 2001/82/EC or the conditions set out in Section 2 of this Notice for veterinary medicinal products (see Section 2 of this Notice);

— The medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland and placed on the market in accordance with Union law (i.e. imported into the Union or Northern Ireland) have been subject to batch release by a Qualified Person (QP) in the Union or Northern Ireland or, for products authorised by the competent authorities of Cyprus, Ireland, Malta or the United Kingdom in respect of Northern Ireland, by a QP or a person having an equivalent qualification to a QP in parts of the United Kingdom other than Northern Ireland applying equivalent quality standards to those laid down in Union law, thus ensuring an equivalent level of protection of human and animal health;

— The operator importing medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland into Cyprus, Ireland, Malta or Northern Ireland holds a distribution authorisation issued in accordance with Article 77(1) of Directive 2001/83/EC for human medicinal products and Article 65(1) of Directive 2001/82/EC or Article 99(1) of Regulation (EU) 2019/6 for veterinary medicinal products;

— The marketing authorisation of the medicinal product concerned has been issued, based on and in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland in compliance with Union law;

— The medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland are made available to retailers or the end consumer in the same market historically dependent on medicines supply from parts of the United Kingdom other than Northern Ireland where they are imported, and they are not made available in other Member States;

— With regard to medicinal products for human use, they bear the safety features referred to in point (o) of Article 54 of Directive 2001/83/EC.

For veterinary medicinal products, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland would in this case also report to the Commission, on a monthly basis, as regards the progress made by wholesale distributors importing medicinal products in fulfilling the conditions necessary to obtain a manufacturing authorisation laid down in Article 45 of Directive 2001/82/EC and Article 89 of Regulation (EU) 2019/6.

([17]) According to Article 51(1)(b) of Directive 2001/83/EC, Article 55(1)(b) of Directive 2001/82/EC and Article 97(7) of the Regulation (EU) 2019/6, medicinal products imported into the EU have to undergo batch testing in the EU/EEA. These provisions prescribe that in the case of medicinal products coming from third countries, irrespective of whether the product has been manufactured in the Union, each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of medicinal products in accordance with the requirements of the marketing authorisation.

B. *Investigational medicinal products*

According to Article 13 of Directive 2001/20/EC and Article 61 of Regulation (EU) 536/2014, the placing on the market of investigational medicinal products from third countries in accordance with Union law also requires the importer to hold a manufacturing and import authorisation. This also applies to the supply of investigational medicinal products from or through parts of the United Kingdom other than Northern Ireland to Cyprus, Ireland, Malta and Northern Ireland. Article 13(2) of Directive 2001/20/EC, Article 61 of Regulation (EU) No 536/2014 require the holder of the manufacturing and import authorisation to have, permanently and continuously, at his disposal the services of at least one qualified person in the scope of application of Union law, i.e. in the Union or in Northern Ireland.

In order to bridge the gap with the entry into force of the directive amending Directive 2001/20 and the regulation amending Regulation 536/2014, referred to in the introduction of this Notice, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland could apply the following practice between 1 January 2022 and 31 December 2022, or, between 1 January 2022 and the date of entry into force of these amendments, if that date is before 31 December 2022: The competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland would allow investigational medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by clinical trial sites or sponsors which are not in possession of a manufacturing and import authorisation as required by Article 13 of Directive 2001/20/EC and Article 61 of Regulation (EU) No 536/2014, provided that the following conditions are fulfilled:

— The medicinal products imported into Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland and approved for use in accordance with Union law have undergone certification of batch release either in the Union or in parts of the United Kingdom other than Northern Ireland in compliance with the requirements set out in Article 13(3) of Directive 2001/20/EC or Article 63 of Regulation (EU) No 536/2014;

— The medicinal products imported into Cyprus, Ireland, Malta or Northern Ireland from or through parts of the United Kingdom other than Northern Ireland are made available to clinical trial participants as the end consumer in the same market historically dependent on medicines supply from other parts of the United Kingdom than Northern Ireland where they are imported, and they are not made available in other Member States.

2.a) **Batch testing of human and veterinary medicinal products**

According to Article 51(1)(b) of Directive 2001/83/EC, Article 55(1)(b) of Directive 2001/82/EC and Article 97(7) of Regulation (EU) 2019/6, medicinal products imported into the EU have to undergo quality control testing ('batch testing') in the Union/EEA. The requirement of a batch testing site established in the Union is a fundamental pillar of the Union system of ensuring quality of medicinal products being placed on the Union market. However, with regard to batch testing, there may be objective reasons beyond the control of the marketing authorisation holders that may have prevented the timely transfer of such testing activities to be carried out in the Union or Northern Ireland.

In these cases, Article 20(b) of Directive 2001/83/EC and 24(b) of Directive 2001/82/EC allow importers placing medicinal products supplied from or through other parts of the United Kingdom than Northern Ireland on the market in Cyprus, Ireland, Malta or Northern Ireland or wholesale distributors placing such medicinal products on those markets as described under Section 1 above, to have, in justifiable cases, certain controls carried out in other parts of the United Kingdom than Northern Ireland. Taking into account the exceptional circumstances described in this Notice, with regard to medicinal products authorised by the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland, the Commission considers that a 'justifiable case' within the meaning of Article 20(b) Directive 2001/83/EC and 24(b) of Directive 2001/82/EC occurs when the following conditions are fulfilled:

— Each batch of the medicinal product concerned is released by a qualified person (QP) on a site in the Union or Northern Ireland or, in case the manufacturing authorisation holder declares that he does not have a qualified person established in the Union or Northern Ireland at his disposal, or in cases falling under Section 1 above, by a QP or a person having an equivalent qualification to a QP on a site in parts of the United Kingdom other than Northern Ireland applying equivalent quality standards to those laid down in Union law, thereby ensuring an equivalent level of protection of human or animal health;

— The establishment designated by the third party conducting the batch testing is regularly supervised by a competent authority of the Union/EEA or a Member State or the competent authority of the United Kingdom in accordance with Union law;

— For veterinary medicinal products under Directive 2001/82/EC, the marketing authorization holder takes tangible and credible steps towards transferring the batch testing sites to the Union or Northern Ireland by the 31 December 2022.

For veterinary medicinal products under Regulation (EU) 2019/6, importers placing veterinary medicinal products supplied from or through parts of the United Kingdom other than Northern Ireland on the market in Cyprus, Ireland, Malta or Northern Ireland or, in cases falling under Section 1 above, wholesale distributors placing such veterinary medicinal products on those markets, certain controls may be carried out in parts of the United Kingdom other than Northern Ireland until 31 December 2022, if the following conditions are fulfilled:

a) Each batch of the medicinal product concerned is released by a qualified person (QP) on a site in the Union or Northern Ireland or, in cases falling under Section 1 above, by a QP or a person having an equivalent qualification on a site in the parts of the United Kingdom other than Northern Ireland applying equivalent quality standards to those laid down in Union law, thereby ensuring an equivalent level of protection of human or animal health;

b) The establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including through on-the-spot checks.

c) The marketing authorization holder takes tangible and credible steps towards transferring the quality control testing site to the Union or Northern Ireland by 31 December 2022.

In order to make use of the derogation foreseen in Article 20(b) of Directive 2001/83/EC for human medicinal products and Article 24(b) of Directive 2001/82/EC for veterinary medicinal products, or of the derogation for veterinary medicinal products under Regulation (EU) 2019/6, marketing authorisation holders should notify the competent authority that granted the marketing authorisation of the product concerned (Cyprus, Ireland, Malta or Northern Ireland), specifying that – and for what reason – the above criteria of a 'justifiable case' within the meaning of Article 20(b) of Directive 2001/83/EC or of Article 24(b) of Directive 2001/82/EC, or the criteria for the derogation for veterinary medicinal products under Regulation 2019/6, are fulfilled.

Any such notification should be submitted without undue delay and should be received as soon as possible, and in no case later than by 31 January 2022 ([18]).

2b) **Batch testing for medicines for human use already carried out in the Union**

For batches of medicinal products for human use which are exported from a Member State to parts of the United Kingdom other than Northern Ireland and subsequently imported into Northern Ireland or into Cyprus, Ireland or Malta, the competent authorities of Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland may, until 31 December 2022, or, until the date of entry into force of the directive amending Directive 2001/83 referred to in the introduction of this Notice, if that date is before 31 December 2022 exceptionally not require additional controls upon importation as referred to in the first and second subparagraph of Article 51(1) of Directive 2001/83/EC, if those batches have already undergone these controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and if they are accompanied by the control reports referred to in the third subparagraph of Article 51(1) of Directive 2001/83/EC.

3. **Requirements relating to the placement of the unique identifier for medicinal products for human use**

The safety features (i.e. an anti-tampering device and unique identifier) are mandatory for medicinal products subject to prescription placed on the market in the EU, as laid down in Articles 54(o) and 54a(1) of Directive 2001/83/EC and in Commission Delegated Regulation (EU) 2016/161. Furthermore, to prevent the reintroduction of exported medicines into the EU Single Market, Article 22(a) of Commission Delegated Regulation (EU) 2016/161 obliges wholesalers to decommission the unique identifier on all medicines they export outside the EU before they are exported.

According to the IE/NI Protocol, the safety features laid down in Articles 54(o) and 54a(1) of Directive 2001/83/EC apply to medicinal products placed on the market in Northern Ireland. However, these safety features do not apply to medicinal products placed on the market in other parts of the United Kingdom.

As a consequence, from 1 January 2021, prescription medicinal products destined for parts of the United Kingdom other than Northern Ireland are not subject to the same requirements regarding safety features as products destined for Cyprus, Ireland, Malta or Northern Ireland, even where the supply route for the latter goes through parts of the United Kingdom other than Northern Ireland.

([18]) For human and veterinary medicinal products to be placed on the market in Northern Ireland, the competent authorities are the Medicines and Healthcare products Regulatory Agency (MHRA) and the Veterinary Medicines Directorate (VMD) respectively.

As from 1 January 2021, a derogation from the requirement to decommission the unique identifier on medicines exported to the United Kingdom was granted for one year ([19]). Subject to scrutiny by the European Parliament and the Council, by means of an amendment to Delegated Regulation 2016/161, a derogation from the obligation to decommission the unique identifier when medicines are distributed to the United Kingdom will continue to apply for a period of three years, coupled with additional safeguards, to ensure the continued supply of medicines Cyprus, Ireland, Malta and Northern Ireland.

4. **The location of the marketing authorisation holder and the qualified persons for manufacturing and pharmacovigilance with regard to medicinal products for human use**

In accordance with Article 8(2) of Directive 2001/83/EC, read in conjunction with the IE/NI Protocol, a marketing authorisation may only be granted to an applicant established in the Union or in Northern Ireland.

Article 48 of Directive 2001/83/EC, read in conjunction with Article 49 of that Directive and the IE/NI Protocol, requires the qualified person for manufacturing to reside in and operate from the Union or Northern Ireland.

In accordance with Article 104(3) of Directive 2001/83/EC, read in conjunction with the IE/NI Protocol, the qualified person responsible for pharmacovigilance must be established in and operate from the Union or Northern Ireland. In addition, in accordance with Article 7 of the Commission Implementing Regulation (EU) No 520/2012 ([20]) the pharmacovigilance system master file must be located either at the site in the Union where the main pharmacovigilance activities of the marketing authorisation holder are performed or at the site in the Union where the qualified person responsible for pharmacovigilance operates.

In order to bridge the gap until the entry into force of the amendments to Directive 2001/83/EC referred to in the introduction of this Notice, the competent authorities of the United Kingdom in respect of Northern Ireland could apply the following practice between 1 January 2022 and 31 December 2022, or, between 1 January 2022 and the date of entry into force of the amendments to Directive 2001/83/EC, if that date is before 31 December 2022:

1. The holders of marketing authorisations issued by the authorities of the United Kingdom in respect of Northern Ireland may be located in parts of the United Kingdom other than Northern Ireland;

2. For the mutual recognition and decentralised procedures as referred to in Articles 28 to 39 of Directive 2001/83/EC, the holders of marketing authorisations issued by the national authorities of the United Kingdom in respect of Northern Ireland, or by the competent authorities of Cyprus, Ireland and Malta may be located in parts of the United Kingdom other than Northern Ireland;

3. Where the marketing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person responsible for pharmacovigilance, as well as the pharmacovigilance system master file, may exceptionally be allowed to be located and operate in parts of the United Kingdom other than Northern Ireland. This shall not apply to situations where the marketing authorisation holder already has at its disposal a qualified person established in the Union;

4. Where the marketing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person for manufacturing may reside in and operate from parts of the United Kingdom other than Northern Ireland. This shall not apply to situations where the manufacturing authorisation holder already has at his disposal a qualified person who is established in the Union.

5. **Marketing authorisations granted by the Cypriot and Maltese competent authorities under Article 126a of Directive 2001/83/EC**

Until the end of the transition period, the competent authorities of Cyprus and Malta could for justified public health reasons, grant marketing authorisations based on marketing authorisations issued by the United Kingdom, in accordance with Article 126a of Directive 2001/83/EC and under the conditions specified therein.

In order to bridge the gap with the entry into force of the proposed amendments to Directive 2001/83/EC referred to in the introduction of this Notice, the competent authorities of Cyprus and Malta could apply the following practice between 1 January 2022 and 31 December 2022, or between 1 January 2022 and the date of entry into force of the amendments referred to above, if that date is before 31 December 2022.

The competent authorities of Cyprus and Malta could for justified public health reasons validly maintain in force, extend and grant marketing authorisations pursuant to Article 126a of Directive 2001/83/EC which are based on marketing authorisations granted by the competent authority of the United Kingdom.

([19]) Commission Delegated Regulation (EU) 2021/457 of 13 January 2021 amending Delegated Regulation (EU) 2016/161 as regards a derogation from the obligation of wholesalers to decommission the unique identifier of products exported to the United Kingdom (OJ L 91, 17.3.2021, p. 1).

([20]) Commission Implementing Regulation (EU) No 520/2012 of 19 June 2012 on the performance of pharmacovigilance activities provided for in Regulation (EC) No 726/2004 of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council (OJ L 159, 20.6.2012, p. 5).

Where the competent authorities of Cyprus or Malta maintain in force, extend or grant such marketing authorisations, they shall ensure compliance of such marketing authorisations with Union law and in particular with the requirements of Directive 2001/83/EC.

Before granting such a marketing authorisation, the competent authorities of Cyprus or Malta:

a) should notify the marketing authorisation holder in parts of the United Kingdom other than Northern Ireland of the granting or the extension of a marketing authorisation in respect of the medicinal product concerned being envisaged;

b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.

EUROPEAN DATA PROTECTION SUPERVISOR

Summary of the Opinion of the European Data Protection Supervisor on the anti-money laundering and countering the financing of terrorism (AML/CFT) package of legislative proposals

(The full text of this Opinion can be found in English, French and German on the EDPS Internet: www.edps.europa.eu)

(2021/C 524/03)

The European Commission adopted on 20 July 2021 a package of legislative proposals aiming to strengthen the EU's anti-money laundering and countering the financing of terrorism (AML/CFT) rules (the 'AML legislative package'), consisting of: a Proposal for a Regulation of the European Parliament and of the Council on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing; a Proposal for a Directive of the European Parliament and of the Council on the mechanisms for the prevention of the use of the financial system for the purposes of money laundering or terrorist financing and repealing Directive (EU) 2015/849; a Proposal for a Regulation of the European Parliament and of the Council establishing the European Authority for Countering Money Laundering and Financing of Terrorism, amending Regulations (EU) No 1093/2010, (EU) 1094/2010 and (EU) 1095/2010; and a Proposal for a Regulation of the European Parliament and of the Council on information accompanying transfers of funds and certain crypto-assets.

The EDPS welcomes the objectives pursued by the AML legislative package, namely to increase the effectiveness of anti-money laundering and countering the financing of terrorism in particular via greater harmonization of the applicable rules and enhanced supervision at the EU level (including the establishment of the European Authority for Countering Money Laundering and Financing of Terrorism, 'AMLA').

The EDPS highlights that the risk-based approach to the monitoring of the use of the financial system for money laundering, which is at the core of the AML legislative package, while welcome, needs further specifications and clarifications.

Against this background, to ensure compliance with the principles of necessity and proportionality, as well as to enhance legal certainty for obliged entities on their duties, the EDPS makes a number of remarks and recommendations, in particular:

The AML legislative package should identify the categories of personal data to be processed by the obliged entities to fulfil the AML/CFT obligations, instead of systematically leaving this specification to regulatory technical standards, as well as better describe conditions and limits for the processing of special categories of personal data and of personal data relating to criminal convictions and offences.

The AML legislative package should specify in particular which types of special categories of personal data should be processed by the obliged entities, taking into account the necessity and proportionality principles, having regard to the different activities and measures to be taken (identification, customer due diligence, reporting to FIUs), and to the specific purpose pursued (namely anti-money laundering or countering the financing of terrorism). In particular, the EDPS considers that the processing of personal data related to sexual orientation or ethnic origin should not be allowed.

Concerning beneficial ownership registers, the EDPS:

— welcomes the obligation for Member States to notify the Commission the closed list of competent authorities and self-regulatory bodies and of the categories of obliged entities that are granted access to the beneficial ownership registers. However, the EDPS invites the legislator to specify that access to beneficial ownership registers, by tax authorities as well as by self-regulatory bodies, should be limited to the purpose of the fight against money-laundering and financing of terrorism and thus authorized only for this purpose;

— in relation to access by 'any member of the general public' to the beneficial ownership registers, the EDPS reiterates his earlier position that the necessity and proportionality of such generalised access for the purposes of prevention of money laundering and terrorism financing has not been clearly established so far. In principle, such access should be limited to competent authorities who are in charge of enforcing the law and to obliged entities when taking customer due diligence measures. The EDPS is of the view that access to beneficial ownership information motivated by other

objectives of general interest (such as enhancing transparency) should rather be considered as right to obtain information. Such public access would require a separate necessity and proportionality assessment, and be subject to a separate set of rules laying down the necessary safeguards. Hence, the EDPS recommends the legislator to assess the necessity and proportionality of such a 'general access' and, on the basis of this assessment, if considered appropriate, to lay down a specific legal framework in this regard, distinct from the one related to access by competent authorities;

Moreover, the EDPS strongly recommends adding, among the risks to be considered by Member States when establishing the criteria for granting exemptions to access to beneficial ownership information, an express reference to the risks to the protection of the personal data of the individuals concerned.

The EDPS also recommends providing in the AML legislative package for a reporting mechanism on the use of the beneficial ownership registers in the fight against money laundering and the financing of terrorism, in order to gather fact-based evidence as to the effectiveness of the system, as well as support possible future legislative initiatives.

Moreover, the EDPS notes the extensive access powers conferred to FIUs and invites the legislator to reassess the necessity and proportionality of these access rights, in relation in particular to the 'law enforcement information' listed under Article 18(1)(c) of the Proposal for a Directive.Having regard to the system for the exchange of information between FIUs, the FIU.net, the EDPS recommends that the Proposal for a Regulation establishing AMLA is amended to clearly define the roles of all involved stakeholders (AMLA, FIUs) from a data protection perspective in relation to this communication channel, as this impacts on the applicable data protection framework and has implications for the supervision model.

Having regard to sources of information for CDD, including 'watch lists', the AML legislative package should clarify in particular in which cases obliged entities should have recourse to such lists. In this respect, the EDPS invites the legislator to consider whether such access should only take place in case of high risk of money laundering or financing of terrorism.

Furthermore, in order to foster the adoption of codes of conducts and certifications to be adhered to by providers of databases and watch lists used for AML/CTF purposes, the EDPS invites the legislator to include in the AML legislative package a reference to codes of conduct under Article 40 GDPR and to certifications under Article 42 GDPR, to be developed taking into account the specific needs in this sector.

1. **Background**

1. The European Commission adopted on 20 July 2021 a Proposal for a Regulation of the European Parliament and of the Council on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing ('the Proposal for a Regulation') ([1]); a Proposal for a Directive of the European Parliament and of the Council on the mechanisms for the prevention of the use of the financial system for the purposes of money laundering or terrorist financing and repealing Directive (EU) 2015/849 ('the "Proposal for a Directive') ([2]); a Proposal for a Regulation of the European Parliament and of the Council establishing the European Authority for Countering Money Laundering and Financing of Terrorism, amending Regulations (EU) No 1093/2010 (EU) 1094/2010 and (EU) 1095/2010 ('the Proposal for a Regulation establishing AMLA') ([3]); and a Proposal for a Regulation of the European Parliament and of the Council on information accompanying transfers of funds and certain crypto-assets ('the Proposal for a Regulation on crypto-assets') ([4]). Hereinafter, we also refer to the four draft Proposals as 'the AML legislative package'.

2. The AML legislative package is proposed pursuant to the Action Plan for a comprehensive Union policy on preventing money laundering and terrorism financing of 7 May 2020 ([5]). The EDPS has issued the Opinion on the Action Plan on 23 July 2020 ([6]).

([1]) COM(2021) 420 final.
([2]) COM (2021) 423 final.
([3]) COM(2021) 421 final.
([4]) COM(421) 422 final. The EDPS notes in this regard that the Proposal for Regulation expands to crypto-assets traceability requirements for the purpose of AML/CFT; the obligation for the crypto-asset service provider to provide the information under Articles 14-18; the inclusion of crypto-asset service providers under Article 20, Data protection, and 21, Record retention. The EDPS has recently issued his Opinion on crypto-assets, *EDPS Opinion on the Proposal for a Regulation on Markets in Crypto-assets, and amending Directive (EU) 2019/1937*, on 24 June 2021.
The Opinion is available at: https://edps.europa.eu/data-protection/our-work/publications/opinions/edps-opinion-proposal-regulation-markets-crypto_en
([5]) Communication on an action plan for a comprehensive Union policy on preventing money laundering and terrorism financing (C (2020)2800 final).
([6]) Opinion 5/2020 on the European Commission's action plan for a comprehensive Union policy on preventing money laundering and terrorism financing, available at: https://edps.europa.eu/sites/default/files/publication/20-07-23_edps_aml_opinion_en.pdf

3. The objectives of the Action Plan, as referred to in particular in the Regulation ([7]), are:

   — ensuring effective implementation of the existing EU AML/CFT framework;

   — establishing an EU single rulebook on AML/CFT;

   — bringing about EU-level AML/CFT supervision;

   — establishing a support and cooperation mechanism for FIUs;

   — enforcing EU-level criminal law provisions and information exchange;

   — strengthening the international dimension of the EU AML/CFT framework.

4. The AML legislative package, including the Proposal for a Regulation incorporating elements (provisions) of Directive (EU) 2018/843 ([8]), is an ambitious legislative initiative aiming at increasing the effectiveness of the fight against money laundering. It aims to do so in particular through the centralisation of enforcement, including the newly established European Authority for Countering Money Laundering and Financing of Terrorism ('AMLA'), a standardisation of the obligations for obliged entities, streamlining a supra-national and national risk-based approach, as well as laying down rules on cooperation between competent oversight authorities and on relevant databases and infrastructure for the exchange of information, notably FIU.net, to be hosted and managed by AMLA.

5. On 21 July 2021, the European Commission requested the EDPS to issue an opinion on the Proposal, in accordance with Article 42(1) of Regulation (EU) 2018/1725. These comments are limited to the provisions of the Proposal that are most relevant from a data protection perspective.

4. **Conclusions**

In light of the above, the EDPS:

— welcomes the AML legislative package's aims to increase the effectiveness of anti-money laundering and countering the financing of terrorism in particular via greater harmonization of the applicable rules and enhanced supervision at the EU level (including the establishment of the European Authority for Countering Money Laundering and Financing of Terrorism, AMLA);

— and welcomes the risk-based approach followed to prevent the use of the financial system for money laundering, which is at the core of the AML legislative package;

However, to ensure compliance with the data protection principles of necessity and proportionality, as well as with applicable Union and Member State data protection law, the EDPS observes and recommends in particular the following:

— the AML legislative package (notably, the Proposal for a Regulation) should identify the categories of personal data to be processed by the obliged entities to fulfil the AML/CFT obligations;

— in particular, the Proposal for a Regulation should provide clear indications on conditions and limits for the processing of special categories of personal data and of personal data relating to criminal convictions and offences;

— concerning special categories of personal data, the AML legislative package should specify in particular which type of data (within the broader category of special categories of personal data under Article 9 of the GDPR) should be processed by the obliged entities, and at what exact stage of the process, for the purpose of anti-money laundering and countering the financing of terrorism. In this regard, the EDPS considers that the processing of personal data related to sexual orientation or ethnic origin should not be allowed;

— concerning beneficial ownership registers, the EDPS:

   — welcomes the specification of beneficial ownership information to be held in the beneficial ownership registers. However, the EDPS recommends specifying that the list of information under Article 44 of the Proposal for a Regulation is an exhaustive list;

   — welcomes the obligation for Member States to notify the Commission the list of competent authorities and self-regulatory bodies and of the categories of obliged entities that are granted access to the registers. However, the EDPS invites the legislator to specify that access to beneficial ownership registers, by tax authorities as well as by self-regulatory bodies, should be limited to the purpose of the fight against money-laundering and financing of terrorism and thus authorized only for this purpose;

([7]) See at page 1 of the Explanatory Memorandum.

([8]) Directive (EU) 2018/843 of the European Parliament and of the Council of 30 May 2018 amending Directive (EU) 2015/849 on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, and amending Directives 2009/138/EC and 2013/36/EU (OJ L 156, 19.6.2018, p. 43).

— observes that Article 12 of the Proposal for a Directive incorporates provisions, already included in the Directive (EU) 2015/849, as amended by Directive (EU) 2018/843, according to which '*any member of the general public*' has access to the beneficial ownership registers. The EDPS thus reiterates his position expressed in the EDPS Opinion 1/2017 on such generalised access, namely that beneficial ownership information shall be accessed - for the purpose of identification and prevention of money-laundering and terrorist financing - only by competent authorities who are in charge of enforcing the law and by obliged entities when taking customer due diligence measures ([9]). The EDPS remarks that the access to beneficial ownership information (for instance, by NGOs) would come into play as, different, right to obtain and to provide information. Such public access, responding to a different function/purpose, should be subject to a different test of necessity and proportionality, and to a separate, different set of rules. Hence, the EDPS recommends the legislator to assess the necessity and proportionality of such a 'general access' and, on the basis of this assessment, if appropriate, to lay down a specific legal framework in this regard, distinct from the one related to access by competent authorities;

— moreover, the EDPS strongly recommends adding, among the risks to be considered by Member States when establishing criteria for providing exemptions to access to beneficial ownership information, an express reference to the risks to the protection of the personal data of the individuals concerned. The EDPS also recommends deleting the term 'exceptional' in the first and in the second sentence of Article 13;

— finally, the EDPS would recommend inserting a provision in the AML legislative package establishing a mechanism for reporting on the effectiveness of the use of the beneficial ownership registers in the fight against money laundering and the financing of terrorism;

— having regard to the processing of personal data relating to criminal convictions and offences, the reference to 'allegations' (in addition to 'investigations', 'proceedings' and 'convictions') in Article 55(3)(b) of the Proposal for a Regulation is vague and should therefore be deleted or specified;

— remarks the extensive access powers conferred to FIUs under Article 18 of the Proposal for a Directive, and hence invites the legislator to reassess the necessity and proportionality of these access rights, in relation in particular to the 'law enforcement information' listed under Article 18(1)(c). In the same vein, the EDPS recommends to clearly and exhaustively delineate the categories of personal data to which FIUs may have access pursuant to Article 18(1)(a) ('financial information') and Article 18(1)(b) ('administrative information');

— reiterates that a legal configuration of the powers and activities of FIUs as 'investigation-based', rather than 'intelligence-based', would be more in line with the data protection principles of proportionality and purpose limitation, and thus recommends deleting wording in recital 51 of the Directive related to the detection of 'subjects of interest';

— having regard to FIU.net, recommends that the Proposal for a Regulation establishing AMLA, or at least an implementing technical standard to be adopted by the Commission pursuant to Article 24(3) of the Proposal for a Directive, clearly provides for the roles of all involved stakeholders (AMLA, FIUs) from a data protection perspective, as this impacts on the applicable data protection framework and on the supervision model;

— having regard to the central AML/CFT database, the EDPS recommends specifying a storage limitation period for the personal data contained therein, in particular due to the collection by FIUs and transmission to the central AML/CFT database of 'results from supervisory inspections of files concerning Politically Exposed Persons their family members and associates';

([9]) See paragraphs 61 and 62 of the EDPS Opinion 1/2017: 'As seen in the introduction to this Opinion, the AML Directive reserves the investigation and enforcement of criminal activities to the public competent authorities. In this respect, private parties active in the financial markets are merely requested to provide information to the competent authorities in charge. Under no circumstance, a private subject or entity is, either formally or informally, directly or indirectly, entrusted with an enforcement role.' 62. 'It can be acknowledged that NGOs working on financial crimes and abuses, the press and investigative journalism de facto contribute to drawing attention of the authorities to phenomena that may be relevant for criminal enforcement. If this is the case, however, the legislator should conceive the access to beneficiary information as a component of the right to obtain and to provide information, by citizens and the press respectively. This would assign a new purpose to public access, with the consequence that the proportionality of such rule would be assessed against that right and not against policy purposes (e.g. fight against terrorism or tax evasion) that cannot be associated to private action.'
We also recall, on this point, the jurisprudence of the Court of Justice in the case *Österreichischer Rundfunk*, where the Court held that it was necessary to examine whether the policy objective served by publicity 'could not have been attained equally effectively by transmitting the information as to names to the monitoring bodies alone' [para. 88, emphasis added, Judgment of the Court of 20 May 2003. *Rechnungshof* (C-465/00) *v Österreichischer Rundfunk and Others and Christa Neukomm* (C-138/01) *and Joseph Lauermann* (C-139/01) *v Österreichischer Rundfunk*, ECLI:EU:C:2003:294]. This question should be carefully considered when assessing the proportionality of measures consisting of public access to personal information.

— having regard to the sources of information for CDD, including 'watch lists', the AML legislative package should clarify in particular in which cases obliged entities should have recourse to such lists. In this respect, the EDPS invites the legislator to consider whether such access should only take place in case of high risk of money laundering or financing of terrorism. Moreover, a recital could specify that obliged entities should duly verify information from watch lists, having regard in particular to their reliability and accuracy.

— furthermore, in order to foster the adoption of codes of conducts and certifications to be adhered to by providers of databases and watch lists used for AML/CTF purposes, the EDPS invites the legislator to include in the AML legislative package a reference to codes of conduct under Article 40 GDPR and to certifications under Article 42 GDPR, to be developed taking into account the specific needs in this sector;

— Article 32(3) of the Proposal for a Regulation provides that AMLA shall issue guidelines on the criteria for the identification of persons falling under the definition of persons known to be a close associate [of 'politically exposed person']. In this regard, the EDPS considers that the category of 'persons known to be close associate' should be specified in the Proposal for a Regulation itself, rather than (only) by AMLA's guidance;

— the EDPS recommends specifying the categories of employees falling under the 'integrity screening' required under Article 11 of the Proposal for a Regulation;

— the EDPS recommends including, in a more explicit way, among the criteria for consideration of the competent authority when publishing administrative sanctions and measures, the risks to the protection of the personal data of the individuals concerned;

— finally, the EDPS recommends some changes (additions and deletions) to the wording of articles and recitals of the AML legislative package referring to the GDPR and the EUDPR.

Brussels, 22 September 2021

Wojciech Rafał WIEWIÓROWSKI

NOTICES FROM MEMBER STATES

Commission notice pursuant to Article 16(4) of Regulation (EC) No 1008/2008 of the European Parliament and of the Council on common rules for the operation of air services in the Community

Public service obligations in respect of scheduled air services

(Text with EEA relevance)

(2021/C 524/04)

Member State	Italy
Routes concerned	Alghero - Rome Fiumicino and vice versa Alghero - Milan Linate and vice versa Cagliari - Rome Fiumicino and vice versa Cagliari - Milan Linate and vice versa Olbia - Rome Fiumicino and vice versa Olbia - Milan Linate and vice versa
Date of entry into force of the public service obligations	15 May 2022
Address from which the text and any information and/or documentation relating to the public service obligations can be obtained	For further information: Autonomous Region of Sardinia Department of Transport Directorate-General for Transport Unit for Maritime and Air Transport and Territorial Continuity Via XXIX Novembre 1847, 27- 41 09123 Cagliari ITALIA Tel. +39 0706067331 Fax +39 0706067309 Internet: http://www.regione.sardegna.it Email: trasporti@pec.regione.sardegna.it trasp.osp@regione.sardegna.it

V

(Announcements)

ADMINISTRATIVE PROCEDURES

EUROPEAN COMMISSION

Call for proposals 2022 - EAC/A09/2021

Erasmus+ Programme

(2021/C 524/05)

1. **Introduction and Objectives**

This call for proposals is based on the Regulation (EU) No 2021/817 of the European Parliament and of the Council of 20 May 2021 establishing 'Erasmus+': the Union Programme for education, training, youth and sport. The Erasmus+ Programme covers the period 2021 to 2027. The programme objectives of the Erasmus+ Programme are listed in Article 3 of the Regulation.

2. **Actions**

This call for proposals covers the following actions of the Erasmus+ Programme:

Key Action 1 (KA1) – Learning mobility of individuals:

— Mobility of individuals in the fields of education, training and youth

— Youth participation Activities

— DiscoverEU – Inclusion Action

— Virtual exchanges in higher education and youth

Key Action 2 (KA2) - Cooperation among organisations and institutions

— Partnerships for Cooperation:

  — Cooperation Partnerships

  — Small-scale Partnerships

— Partnerships for Excellence:

  — Centres for Vocational Excellence

  — Erasmus+ Teacher Academies

  — Erasmus Mundus Action

— Partnerships for Innovation:

  — Alliances for innovation

  — Forward-looking projects

— Capacity building in higher education, vocational education and training, youth and sport

— Not-for-profit European Sport Events

Key Action 3 (KA3) - Support to policy development and cooperation

— European Youth Together

Jean Monnet actions:

— Jean Monnet in the field of higher education

— Jean Monnet in other fields of education and training

3. **Eligibility**

Any public or private body active in the fields of education, training, youth and sport may apply for funding within the Erasmus+ Programme. In addition, groups of young people who are active in youth work, but not necessarily in the context of a youth organisation, may apply for funding for learning mobility of young people and youth workers, youth participation activities and DiscoverEU inclusion action.

The following countries can fully take part in all Erasmus+ Programme actions ([1]):

— the 27 Member States of the European Union and overseas countries and territories,

— third countries associated to the Programme:

  — the EFTA/EEA countries: Iceland, Liechtenstein and Norway,

  — EU candidate countries: the Republic of Turkey, the Republic of North Macedonia and the Republic of Serbia ([2]).

In addition, certain Erasmus+ Programme actions are open to organisations from

third countries non-associated to the Programme.

Please refer to the 2022 Erasmus+ Programme Guide for further details on the modalities of participation.

4. **Budget and duration of projects**

The total budget earmarked for this call for proposals is estimated at EUR 3 179 million:

Education and Training:	EUR	2 813,11 million
Youth:	EUR	288,13 million
Sport:	EUR	51,89 million
Jean Monnet:	EUR	25,8 million

The total budget earmarked for the call for proposals as well as its repartition is indicative and may be modified subject to an amendment of the Erasmus+ Annual Work Programme. Potential applicants are invited to regularly consult the Erasmus+ Annual Work Programme and their amendments, published on:

https://ec.europa.eu/programmes/erasmus-plus/resources/documents/annual-work-programmes_en

as regards the available budget for each action covered by the call.

The level of grants awarded as well as the duration of projects vary depending on factors such as the type of project and the number of partners involved.

Beneficiaries may declare costs for the work carried out by volunteers under an action or work programme on the basis of unit costs authorised and defined in a Commission Decision (2019) 2646. Please refer to the Erasmus+ Programme Guide for detailed instructions for the eligibility of volunteer's costs.

([1]) Jean Monnet activities are open to organisations from the whole world.
([2]) Subject to the signature of the bilateral Association Agreements.

5. **Deadline for the submission of applications**

All deadlines for submission of applications specified below are set at Brussels time.

Key Action 1	
Mobility of individuals in the field of higher education	23 February at 12:00
Mobility of individuals in VET, school education and adult education fields	23 February at 12:00
International mobility involving third countries not associated to the programme	23 February at 12:00
Erasmus Accreditations in VET, school education and adult education	19 October at 12:00
Erasmus Accreditations in the field of youth	19 October at 12:00
Mobility of individuals in the field of youth	23 February at 12:00
Mobility of individuals in the field of youth	4 October at 12:00
DiscoverEU inclusion Action	4 October at 12:00
Virtual exchanges in the field higher education and youth	20 September at 17:00

Key Action 2	
Cooperation partnerships in the fields of education, training and youth, except for those submitted by European NGOs	23 March at 12:00
Cooperation partnerships in the fields of education, training and youth submitted by European NGOs	23 March at 17:00
Cooperation partnerships in the field of sport	23 March at 17:00
Cooperation partnerships in the field of youth	4 October at 12:00
Small-scale partnerships in the fields of school education, vocational education and training, adult education and youth	23 March at 12:00
Small-scale partnerships in the fields of school education, vocational education and training, adult education and youth	4 October at 12:00
Small-scale partnerships in the field of sport	23 March at 17:00
Centres of Vocational Excellence	7 September at 17:00
Erasmus+ Teacher Academies	7 September at 17:00
Erasmus Mundus Action	16 February at 17:00
Alliances for Innovation	15 September at 17:00
Forward-looking projects	15 March at 17:00
Capacity building in the field of Higher Education	17 February at 17:00
Capacity building in the field of Vocational Education and Training	31 March at 17:00
Capacity building in the field of Youth	7 April at 17:00
Capacity building in the field of Sport	7 April at 17:00
Non-for-profit European Sport Events	23 March at 17:00

Key Action 3	
European Youth Together	22 March at 17:00

Jean Monnet Actions and Networks	1 March at 17:00

Please refer to the Erasmus+ Programme Guide for detailed instructions for the submission of applications.

6. **Full details**

The detailed conditions of this call for proposals, including priorities, can be found in the 2022 Erasmus+ Programme Guide at the following internet address:

http://ec.europa.eu/programmes/erasmus-plus/resources/programme-guide

The Erasmus+ Programme Guide constitutes an integral part of this call for proposals and the conditions for participation and funding expressed therein apply in full to this call.

OTHER ACTS

EUROPEAN COMMISSION

Publication of a communication of approval of a standard amendment to a product specification for a name in the wine sector referred to in Article 17(2) and (3) of Commission Delegated Regulation (EU) 2019/33

(2021/C 524/06)

This communication is published in accordance with Article 17(5) of Commission Delegated Regulation (EU) 2019/33 ([1]).

COMMUNICATION OF A STANDARD AMENDM\ENT TO THE SINGLE DOCUMENT

'Charentais'

PGI-FR-A1196-AM02

Date of communication: 28 October 2021

DESCRIPTION OF AND REASONS FOR THE APPROVED AMENDMENT

1. **Volatile acidity**

The volatile acidity has been revised for white wines.

The limit for volatile acidity is now 0,65 grams per litre in H2SO4 for white wines with a sugar content in excess of 5 grams per litre.

With the climate becoming warmer, sugar levels are increasing, as are volatile acidity levels. This is why these levels have been adjusted.

Point 4 of the [single] document has been amended as a result of this amendment.

2. **Geographical area**

The geographical area and the area in immediate proximity have been revised. The list of municipalities is now included, having been brought into line with the official geographical code.

Points 6 and 9 of the document have been amended as a result of this amendment.

3. **Grape varieties**

The following varieties have been added to the specification:

Syrah N; Gros Manseng B; Petit Manseng B; Cabernet Cortis N; Monarch N; Pinotin N; Prior N; Vidoc N; Artaban N; Bronner B; Johanniter B; Floreal B; Souvignier Gris Rs; Solaris B; Soltis B.

These varieties have been added in order to adapt more effectively to climate change, as well as to reduce the use of plant health products. The aim is also to preserve the organoleptic character of the wine.

Ugni Blanc has been withdrawn from the list of grape varieties as it no longer matches the desired organoleptic character of the wines of the PGI. A transitional measure has been agreed for this variety until the 2022 harvest.

Point 7 of the document has been amended as a result of this amendment.

([1]) OJ L 9, 11.1.2019, p. 2.

4. **Agri-environmental measures**

The following agricultural and environmental measures have been added to the specification.

Permanent grass cover is required along parcel boundaries: headlands and areas between parcels not planted or cultivated. This requirement does not apply to headlands being restored, in particular following erosion or exceptional climatic events.

Full chemical weed control on parcels is prohibited.

Between the rows, naturally occurring and/or planted vegetation is managed by mechanical or physical means.

It is not permitted to use sprayers which do not have nozzles directed to both sides of the rows, such as fan turbines mounted on high-clearance tractors or oscillating cannons. In the case of air-assisted sprayers, it is only permitted to use air injection nozzles registered for treating vines in the most recent register of means to reduce spray drift of plant health products, as published in the official bulletin of the Ministry responsible for agriculture.

Application of synthetic mineral nitrogen is limited to 30 units per hectare per year.

These amendments are intended to take better account of the environment and of general demands for less use of plant protection products.

These amendments do not require any amendments to the single document.

5. **Link**

The link to the origin has been revised in order to update the surface areas and production volumes.

Point 8 of the document has been amended as a result of this amendment.

6. **Reference to the inspection body**

The wording referring to the inspection body has been revised to make it consistent with the wording in other specifications for protected geographical indications. This amendment is solely a matter of wording.

This amendment does not require any amendment to the single document.

SINGLE DOCUMENT

1. **Name(s)**

Charentais

2. **Geographical indication type**

PGI - Protected geographical indication

3. **Categories of grapevine products**

1. Wine

4. **Description of the wine(s)**

Still red, rosé and white wines

BRIEF WRITTEN DESCRIPTION

Wines entitled to the protected geographical indication ‘Charentais’ are still red, rosé and white wines.

The red wines generally have notes of red fruit and very ripe fruit which may also include notes of spices. These are light wines which nevertheless are well structured thanks to the supple tannins giving them a certain roundness. These wines are suitable for moderate ageing.

The white and rosé wines make a characteristically strong impact which generally gives way to a sensation of balance and fruity notes. They are made to be placed on the market without delay while still young.

The maximum volatile acid content is 11,22 milliequivalents per litre, with the exception of wines that have undergone full malolactic fermentation, and white wines with residual sugars exceeding 5 grams per litre, in which case the maximum figure is 13,26 milliequivalents per litre.

GENERAL ANALYTICAL CHARACTERISTICS

General analytical characteristics	
Maximum total alcoholic strength (in % volume)	
Minimum actual alcoholic strength (in % volume)	11
Minimum total acidity	in milliequivalents per litre
Maximum volatile acidity (in milliequivalents per litre)	
Maximum total sulphur dioxide (in milligrams per litre)	

5. **Wine-making practices**

5.1. *Specific oenological practices*

1. Cultivation method

For vines suitable for producing wines entitled to the PGI 'Charentais' planted in or after the 2001-2002 crop year, the required planting density is at least 4 000 plants per hectare with a space no larger than 2,5 metres between the rows.

5.2. *Maximum yields*

1. PGI 'Charentais'

90 hectolitres per hectare

6. **Demarcated geographical area**

The harvesting of the grapes, and the vinification and processing of PGI 'Charentais' wines must take place in the departments of Charente and Charente Maritime.

7. **Main wine grape variety(-ies)**

Alicante Henri Bouschet N

Arinarnoa N

Arriloba B

Artaban N

Bronner B

Cabernet Cortis N

Cabernet Franc N

Cabernet Sauvignon N

Chardonnay B

Chasan B

Chenin B

Colombard B

Cot N - Malbec

Egiodola N

Floreal B

Folle Blanche B

Gamay N

Gros Manseng B

Johanniter B

Jurançon Noir N - Dame Noire

Merlot N

Monarch N

Montils B

Mourvèdre N - Monastrell

Muscadelle B

Négrette N

Petit Manseng B

Pinot Noir N

Pinotin N

Prior N

Sauvignon B - Sauvignon Blanc

Sauvignon Gris G - Fié Gris

Semillon B

Solaris B

Souvignier Gris Rs

Syrah N - Shiraz

Tannat N

Trousseau Gris G - Chauché Gris

Vidoc N

Voltis B

8. **Description of the link(s)**

The geographical area of the PGI 'Charentais' covers the whole of the departments of Charente and Charente Maritime. It corresponds to the northern end of the Aquitaine Basin.

The PGI 'Charentais' vineyards are intrinsically linked to the history of Cognac. Production of PGI 'Charentais' wines was able to develop thanks to the presence of these prestigious vineyards. The difficult economic circumstances that first arose in 1973 meant that Cognac production was constrained and limited, leading wine-growers to diversify their production. Since then, they have invested in the production of higher-quality still wines, recognised by the 'Vin de Pays Charentais' Decree of 1981, with 2 000 hectares of vines involved. At first, wine-makers concentrated on making wines from the most common white varieties, such as Ugni Blanc and Colombard. However, they soon turned to some of the more aromatic varieties grown locally, such as Sauvignon, Chardonnay and Chenin. Since 1985, 'Vin de Pays Charentais' has been produced in three colours. The development of red wines also involved selection of the more 'noble' varieties, such as Merlot, Cabernet Sauvignon, Cabernet Franc, Gamay and Pinot Noir. This selection of grape varieties is part of a wider movement towards quality, involving the selection of better adapted rootstocks, a more strategic approach to planting vines, and the acquisition of new wine-making skills by the wine-growers.

The additional designations 'Ile de Ré' and 'Saint-Sornin' were recognised at the same time in 1992. The 'Ile de Ré' vineyards now enjoy a high reputation.

The vineyards for 'Saint-Sornin' are unusual in that they are entirely dedicated to the production of PGI wines unlike other parts of the area covered by the designation, which can also be used for 'Cognac' and 'Pineau des Charentes'. Furthermore, these vineyards also benefit from a strong sense of unity among producers organised around the 'Saint-Sornin' cooperative winery.

Another designation, 'Ile d'Oléron', was recognised in 1999. This designation covers vineyards that, historically, were very extensive: around 1 000 hectares in 1950. The cooperative movement has a strong presence and enjoys a significant reputation locally.

The white and rosé wines are characterised by their freshness and fruity notes, largely citrus. In the mouth, they make a strong impact which generally gives way to a sensation of balance and fruity notes. They are made to be placed on the market without delay while still young.

The red wines generally have notes of red fruits and very ripe fruit which may also include notes of spices. These are light wines which nevertheless are well-structured thanks to supple tannins giving them a certain roundness. These wines are suitable for moderate ageing.

The wines produced on Ile de Ré and Ile d'Oléron are light and lively, often with notes of iodine. The wines produced in the Saint-Sornin area, on the other hand, have more spiced notes, together with a more complex structure.

The PGI 'Charentais' represents 1 500 hectares, with production between 70 000 and 90 000 hectolitres depending on the year.

There has been significant work in varietal selection and in acquiring new oenological skills. As a result, PGI 'Charentais' wines have become a product in their own right in the regional wine-growing landscape. The appropriate soil and climate conditions, in conjunction with selection of the best soils for producing moderate yields, are also positive factors in the development of wine production under the PGI 'Charentais'.

The quality of the wines has been enhanced and adapted to market developments thanks to a combination of the aforementioned intelligent use of the natural environment, skills acquired by the wine-growers, planting of more aromatic varieties alongside the traditional varieties and the development of economic and commercial operators. As a result, the wines have sensory and aromatic characters that consumers find easy to appreciate, and which are especially popular with tourists.

Today, the marketing of the PGI 'Charentais' is particularly dynamic at regional level, and adds to the attraction of the coastal area for tourists in the summer season. In addition, there is a well-developed distribution network for these wines, covering supermarkets, catering and direct sale from the wineries.

Together these factors have contributed to sustaining the reputation of the Charentes region for wine-making, and of the wines themselves placed on the market under this designation.

9. **Essential further conditions (packaging, labelling, other requirements)**

Area in immediate proximity

Legal framework

National legislation

Type of further condition

Derogation concerning production in the demarcated geographical area

Description of the condition

The area in immediate vicinity, defined by derogation for the making and processing of the wines, comprises the following municipalities, which border the geographical area: Fontenay-le-Comte, Niort, Montmorillon, Rochechouart, Bellac, Nontron, Périgueux, Blaye and Libourne.

Labelling terms

Legal framework

National legislation

Type of further condition

Additional provisions relating to labelling

Description of the condition

The protected geographical indication ‘Charentais’ may be supplemented by the name of one of the following smaller geographical units, according to the conditions set out in the specification:

‘Ile de Ré’

‘Saint-Sornin’

‘Ile d’Oléron’

‘Charente’

‘Charente-Maritime’

The protected geographical indication ‘Charentais’ may be supplemented by the terms ‘primeur’ (early) or ‘nouveau’ (new).

The protected geographical indication ‘Charentais’ may be supplemented by the name of one or more of the grape varieties mentioned in the specification, with the exception of Alicante Henri Bouschet N, Mourvèdre N (Balzac Noir) and Jurançon Noir N (Folle Noire).

The European Union PGI logo must appear on the label if the words ‘Indication géographique protégée’ (Protected Geographical Indication) are replaced by the traditional expression ‘Vin de pays’.

Link to the product specification

https://info.agriculture.gouv.fr/gedei/site/bo-agri/document_administratif-d607839b-69a8-4575-80f5-0f6490e9ea52

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