MEDICINES AND MEDICAL DEVICES

RELEVANT PROVISIONS: ARTICLES 2, 2a, 3k, 3l, 3ea, 5aa of COUNCIL REGULATION 833/2014

FREQUENTLY ASKED QUESTIONS – AS OF 1 FEBRUARY 2023

1. **Do EU economic operators or economic operators doing business in the EU have to comply with Council Regulation (EU) 833/2014 when providing medicinal products, medical devices and certain related assistance and services to natural or legal persons, entity or body in Russia or for use in Russia?**
   Last update: 29 July 2022

Yes, EU economic operators or economic operators doing business in the EU must comply with Council Regulation (EU) 833/2014, including when exporting medicinal products or medical devices to Russia. Pursuant to Article 13 of Council Regulation (EU) No 833/2014, EU sanctions apply, among others, within the territory of the Union, to any person inside or outside the territory of the Union who is a national of a Member State, to any legal person, entity or body, inside or outside the territory of the Union, which is incorporated or constituted under the law of a Member State and to any legal person, entity or body in respect of any business done in whole or in part within the Union.

This also includes subsidiaries in the EU of Russian parent companies. Russian subsidiaries of EU parent companies are incorporated under Russian law, not under the law of a Member State, hence they are not bound by the measures in Council Regulation (EU) No 833/2014. However, EU parent companies cannot use their Russian subsidiaries to circumvent the obligations that apply to the EU parent, for instance by delegating to them decisions which run counter the sanctions, or by approving such decisions through the Russian subsidiary.

2. **What are the most relevant restrictions under Council Regulation (EU) No 833/2014 that EU economic operators or economic operators doing business in the EU should be aware of when providing medicinal products, medical devices and certain related assistance and services to natural or legal persons, entity or body in Russia or for use in Russia?**
   Last update: 29 July 2022

While all restrictions under Council Regulation (EU) No 833/2014 must be complied with by EU economic operators or economic operators doing business in the EU, the economic operators indicated in the question should pay particular attention to the following restrictions.

Article 2	Restriction on sale, supply, transfer or export of dual-use goods and technology to any natural or legal person, entity or body in Russia or for use in Russia, or related provision of certain assistance and services.

Article 2a	Restriction on sale, supply, transfer or export of goods and technology in Annex VII to any natural or legal person, entity or body in Russia or for use in Russia, or related provision of certain assistance and services.
Article 3k	Restriction on sale, supply, transfer or export of the goods in Annex XXIII to any natural or legal person, entity or body in Russia or for use in Russia, or related provision of certain assistance and services.
Article 3l	Restriction on transport of goods within the territory of the Union by a road transport undertaking established in Russia, including in transit.
Article 3ea	Restriction on vessels registered under the flag of Russia to access EU ports.
Article 5aa	Restriction to directly or indirectly engage in transactions with the entities referred to in Article 5aa.

This list is not exhaustive. It is an obligation on EU economic operators or economic operators doing business in the EU to verify which restrictions are relevant for their business and comply with them. To do that, they can seek guidance from their national competent authority (NCA).

3. **Are there exceptions to restrictions under Council Regulation No 833/2014 for providing medicinal products, medical devices and certain related assistance and services to natural or legal persons, entity or body in Russia or for use in Russia?**
   Last update: 29 July 2022

Yes. Council Regulation 833/2014 includes a number of exceptions that can be relevant for those actions. Exceptions encompass 'exemptions' and 'derogations' (authorisations)[1]. The exceptions provided in Council Regulation No 833/2014 include the following:

[1] Derogations' should not be confused with 'exemptions'. Exemptions mean that a restriction does not apply when the purpose of the action matches the one exempted. Operators can carry out the action at hand without any delay or further action. Derogations mean that a restricted (prohibited) action can be carried out only after the NCA has granted an authorisation for the indicated purpose. Exemptions are generally phrased along the following lines: '(The prohibitions laid down in) Article... shall not apply to...'. Derogations are generally phrased along the following lines: 'By way of derogation from the (prohibitions in) Article..., the competent authorities may authorise, under the conditions they deem appropriate...'.

Medical or pharmaceutical purposes	
Article 2(3)(b):	Exemption for the sale, supply, transfer or export of dual-use goods and technology, or related provision of certain assistance and services, for non-military use and for a non-military end user, intended for medical or pharmaceutical purposes. This exemption does not apply where the end-user is a person, entity or body listed in Annex IV.
Article 2a(3)(b):	Exemption for the sale, supply, transfer or export of the goods and technology in Annex VII, or related provision of certain assistance and services, for non-military use and for a non-military end-user, intended for medical or pharmaceutical purposes. This exemption does not apply where the end-user is a person, entity or body listed in Annex IV.
Article 3k(5)(a):	Authorisation for the sale, supply, transfer or export of the goods in Annex XXIII, or related provision of certain assistance and services, intended for medical or pharmaceutical purposes, unless the NCA has reasonable grounds to believe that the goods might have a military end-use.

Pharmaceutical and medical products	
Article 3l(4)(b):	Authorisation for the transport of goods within the territory of the Union by a road transport undertaking established in Russia after having determined that such transport is necessary for the purchase, import or transport of pharmaceutical and medical products, whose import, purchase and transport is allowed under Council Regulation No 833/2014.
Article 3ea(5)(b)	Authorisation for a vessel to access a EU port after having determined that the access is necessary for the purchase, import or transport of pharmaceutical and medical products, whose import, purchase and transport is allowed under

	Council Regulation No 833/2014.
Article 5aa(3)(f):	Exemption for transactions which are necessary for the purchase, import or transport of pharmaceutical and medical products, whose import, purchase and transport is allowed under this Regulation, as well as humanitarian purposes.

4. **Is there a definition of 'medical' or pharmaceutical purposes' as per the exceptions under Article 2(3)(b), Article 2a(3)(b), Article 3k(5)(a)?**
   Last update: 1 February 2023

EU sanctions do not include a definition of 'medical' or 'pharmaceutical purposes'. It is for economic operator to assess, and prove, if the goods and technology under Article 2 and Article 2a are sold, supplied, transferred or exported to, or the related assistance and services are provided for, a person, entity or body in Russia or for use in Russia for those purposes. The economic operator retains responsibility in case the exported goods and technology are not used for such purposes.

In the case of Article 3k(5)(a), it is for the NCA to assess, on a case-by-case basis, if goods are sold, supplied, transferred or exported to, or the related assistance and services is provided for, a person, entity or body in Russia or for use in Russia for those purposes. This assessment should be conducted on the basis of the information submitted in the request for derogation by the economic operator and on the basis of the NCA knowledge. The recipient of an authorisation retains responsibility for complying with the terms and conditions in the derogation.

It must be recalled that exceptions should be applied narrowly in order not to undermine the goal of EU sanctions (see Point 3.8. Humanitarian exceptions, Commission Guidance Note on the provision of humanitarian aid in compliance with EU restrictive measures (sanctions))[2]. Economic operators can seek guidance from their NCA.

This said, the categories of 'medical' or 'pharmaceutical purposes' should encompass, first and foremost, trade in goods and technology that fall under the scope of application of the following EU legislation:

- Regulation (EU) 2017/745 (Medical Devices Regulation) and Regulation (EU) 2017/746 (*In Vitro* Diagnostic Devices);
- Directive 2001/83/EC (Directive on medicinal products for human use).

[2] C(2022) 4486 final available at https://ec.europa.eu/info/sites/default/files/business_economy_euro/banking_and_finance/documents/220630-humanitarian-aid-guidance-note_en.pdf

Subject to the assessment of the NCA and provided that the applicant has solid evidence in relation to the medical or pharmaceutical purposes of the action, the exceptions at hand *may* include:

- spare parts of and components to be assembled into medical devices;
- ingredients of and compounds to be further processed into medicines;
- medicinal products intended for research and development trials;
- intermediate products intended for further processing into medicinal products;
- machineries and equipment, including protective ones, that are strictly necessary for the production of medicines, administration of medicinal products or use of medicinal products.

Cosmetics, biocidal products, herbal medicines, food supplements and other borderline products, as well as chemical substances other than ingredients of and compounds to be further processed into medicinal products, and other goods, including if used in healthcare facilities, do not have, in principle, medical or pharmaceutical purposes. Veterinary medicinal products, as defined in Regulation (EU) 2019/6 of 11 December 2018 are not covered by the exceptions under Articles 2, 2a and 3k of Council Regulation (EU) 833/2014. This is because those exceptions do not include the word "veterinary"; therefore, they do not cover items for "medical" or "pharmaceutical" purposes specifically for animal use (not human use).

5. **Is there a definition of pharmaceutical and medical products as per the exceptions under Articles 3l(4)(b), Article 3ea(5)(b) and Article 5aa(3)(f)?**
   Last update: 1 February 2023

EU sanctions do not include a definition of 'pharmaceutical and medical products'. In the cases concerning Article 3l(4)(b) and Article 3ea(5)(b), it is for the NCA to assess, on a case-by-case basis, if the products transported by a road undertaking or vessels qualify as pharmaceutical and medical products. This assessment should be conducted on the basis of the information submitted in the request for derogation by the economic operator and other information available. The recipient of a derogation retains responsibility for complying with the terms and conditions of the authorisation. The NCA may also authorise the entry into the EU of an empty road undertaking or vessel that can demonstrate that the purpose of its entry into the EU is to transport back a good that is assessed by the NCA as being pharmaceutical and medical product.

In case of Article 5aa(3)(f), it is for the economic operator to assess in the first place, and prove, if the relevant transaction concerns pharmaceutical and medical products. The economic operator retains responsibility in case the transaction does not concern those products.

It must be recalled that exceptions should be applied narrowly in order not to undermine the goal of EU sanctions (see Point 3.8. Humanitarian exceptions, Commission Guidance Note on the provision of humanitarian aid in compliance with EU restrictive measures (sanctions))[3]. Economic operators can seek guidance from their NCA.

[3] C(2022) 4486 final available at https://ec.europa.eu/info/sites/default/files/business_economy_euro/banking_and_finance/documents/220630-humanitarian-aid-guidance-note_en.pdf

This said, the categories of pharmaceutical and medical products should include first and foremost products that fall under the scope of application of the following EU legislation:

- Regulation (EU) 2017/745 (Medical Devices Regulation) and Regulation (EU) 2017/746 (*In Vitro* Diagnostic Devices);
- Directive 2001/83/EC (Directive on medicinal products for human use).

Subject to the assessment of the NCA and provided that the applicant has solid evidence these are medical or pharmaceutical products, the exemption at hand *may* include:

- spare parts of and components to be assembled into medical devices;
- ingredients of and compounds to be further processed into medicines;
- medicinal products intended for research and development trials; and
- intermediate products intended for further processing into medicinal products.

Cosmetics, biocidal products, herbal medicines and food supplements and other borderline products, chemical substances other than ingredients of and compounds to be further processed into medicinal products as well as other goods, including if used in healthcare facilities, do not qualify, in principle, as pharmaceutical and medical products.

Veterinary medicinal products, as defined in Regulation (EU) 2019/6 of 11 December 2018 are not covered by the exceptions under 3l(4)(b), Article 3ea(5)(b) and Article 5aa(3)(f) of Council Regulation (EU) 833/2014. This is because those exceptions do not include the word "veterinary"; therefore, they do not cover pharmaceutical and medical products specifically for animal use (not human use).

6. **Who can grant authorisations under Article 3l(4)(b) and 3ea(5)(b)?**
   Last update: 29 July 2022

NCAs grant authorisations under Article 3l and 3ea. See, in this respect, sections Road Transport and Access to EU ports of these FAQs.

7. **Can a commercial company make use of an exemption/apply for a derogation for humanitarian purposes, when it comes to medical or pharmaceutical supplies/products?**
   Last update: 29 July 2022

Commercial companies should in principle avail themselves of the exceptions provided for medical and pharmaceutical products and purposes, and not of the humanitarian exception. These fall under different requirements and should not be considered interchangeable. An authorisation for humanitarian purposes under EU sanctions can be obtained only if the action is intended to provide assistance, relief and protection to persons in need, in accordance with International Humanitarian Law and the principles of humanity, neutrality, impartiality and independence and that other relevant conditions, are met and subject to the terms and conditions determined by the NCAs. Commercial companies, such as manufacturers of medicinal products and medical devices, can benefit from a derogation for humanitarian purposes.

However, since the core business of commercial companies is not humanitarian *per se*, such companies must show that the concerned action has humanitarian purposes only. The NCA must then assess on a case-by-case basis if the specific action has indeed humanitarian purposes (namely whether such action is intended to provide assistance, relief and protection to persons in need, in accordance with International Humanitarian Law and the principles of humanity, neutrality, impartiality and independence). The fact that in certain cases the provision of medical or pharmaceutical products can qualify as humanitarian aid does not mean that every supply of them is inherently humanitarian. NCAs and economic operators should also consider that exceptions should be applied narrowly in order not to undermine the goal of EU sanctions (see Point 3.8. Humanitarian exceptions, Commission Guidance Note on the provision of humanitarian aid in compliance with EU restrictive measures (sanctions)) [4] and that circumvention of sanctions is prohibited.

8. **The exemption under Article 2(3)(b) and Article 2a(3)(b) can apply under the condition that the goods and technology are intended for non-military use and for a non-military end user. What does that mean?**
   Last update: 29 July 2022

The exemptions in Articles 2(3) and 2a(3) allow exports of dual-use and advanced technologies intended for humanitarian purposes, health emergencies and medical purposes from the relevant restrictions, as long as such exports are destined for non-military use and for a non-military end-user. Therefore, where the items are destined for a civilian facility as the end-user, the exemption could apply unless there are reasonable grounds to believe that the items could be diverted to a military end-use or end-user.

9. **According to Article 3k(6), an NCAs can grant derogations under Article 3k(5) unless it has reasonable grounds to believe that the goods might have a military end-use. What does that mean?**
   Last update: 29 July 2022

The term military end-use is addressed in Article 4(1)(b) of the Regulation (EU) 2021/821 of the European Parliament and of the Council (Dual Use Regulation). The fact that goods for medical or pharmaceutical purposes are sold, supplied, transferred or exported to military hospitals in Russia or for the use in military hospitals in Russia does not mean automatically that they are intended for a military end user.

10. **How can a company verify if the goods and technology it is exporting for medical or pharmaceutical purpose are subject to restrictions under Article 2, 2a or 3k?**
    Last update: 29 July 2022

Dual-use goods and technology subject to the restriction under Article 2 means the items listed in Annex I to Dual Use Regulation.

[4] C(2022) 4486 final available at https://ec.europa.eu/info/sites/default/files/business_economy_euro/banking_and_finance/documents/220630-humanitarian-aid-guidance-note_en.pdf

Goods and technology subject to the restriction under Article 2a means the items listed in Annex VII to Council Regulation (EU) 833/2014.

Goods subject to the restriction under Article 3k means the items listed in Annex XXIII to Council Regulation (EU) 833/2014.

To ascertain if the goods and technology are subject to restrictions under Article 2, 2a or 3k, the company should check if the goods are classified under the 8-digit CN codes included in the afore-mentioned annexes. For that, they can seek guidance from their NCA. The Commission has also published a correlation table between the CN codes and the dual use codes, extracted from the TARIC database. This table, compatible with the harmonized System 2022[5], is available on the public CIRCABC site "TARIC and Quota data and information" under "reference documents"[6].

11. What does Council Regulation (EU) No 269/2014 entail for EU economic operators or economic operators doing business in the EU when exporting medicinal or pharmaceutical products or providing financing or technical assistance to natural or legal persons, entity or body in Russia or for use in Russia?
Last update: 29 July 2022

Under Council Regulation (EU) No 269/2014, the EU has designated a number of individuals and legal persons as subject to asset freezes and a prohibition to make funds available. This means, inter alia, that it is prohibited for EU economic operators or economic operators doing business in the EU to make funds or economic resources available to designated persons or persons owned/controlled by them. Economic resources encompass assets of every kind, whether tangible or intangible, movable or immovable, which are not funds but may be used to obtain funds, goods or services; as such, medicinal or pharmaceutical products can qualify as economic resources (see point 3, Syria chapter, Commission guidance note on the provision of humanitarian aid to fight the Covid-19 pandemic in certain environments subject to EU restrictive measures[7]). Note that for an asset to qualify as an 'economic resource', it is not necessary to prove that it will be used to obtain funds (see Point 3.3. Prohibition to make funds and economic resources available to designated persons or for their benefit, Commission Guidance Note on the provision of humanitarian aid in compliance with EU restrictive measures (sanctions))[8]. By way of example, this means that no further trade with those persons is possible as of the moment of their designation. Economic operators should therefore make sure that they take the necessary contractual measures to that end (Russia FAQs, Section 'Horizontal as well as Circumvention and Due diligence, Section 'Individual financial measures' and Section

[5] http://www.wcoomd.org/en/topics/nomenclature/instrument-and-tools/hs-nomenclature-2022-edition/hs-nomenclature-2022-edition.aspx

[6] https://circabc.europa.eu/ui/group/0e5f18c2-4b2f-42e9-aed4-dfe50ae1263b

[7] C(2021) 5944 final https://ec.europa.eu/info/sites/default/files/business_economy_euro/banking_and_finance/documents/210813-humanitarian-aid-guidance-note_en.pdf

[8] C(2022) 4486 final available at https://ec.europa.eu/info/sites/default/files/business_economy_euro/banking_and_finance/documents/220630-humanitarian-aid-guidance-note_en.pdf

'Execution of contracts and claims'). Exceptions to this prohibition may however apply for exclusively humanitarian purposes in Ukraine[9].

[9] See Article 2a of Council Regulation 269/2014.