European Parliament
2019-2024

Committee on Legal Affairs
The Chair

25.4.2023

Mr Pascal Canfin
Chair
Committee on the Environment, Public Health and Food Safety
BRUSSELS

Subject: Opinion on the legal basis on the proposal for a Regulation of the European Parliament and of the Council on specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland (COM(2023)0122 – C9-0033/2023 – 2023/0064(COD))

Dear Mr Chair,

By letter of 31 March 2023[1] you asked the Committee on Legal Affairs, pursuant to Rule 40(2) of the Rules of Procedure, to provide an opinion on the appropriateness of amending the legal basis of the proposal for a Regulation of the European Parliament and of the Council on specific rules relating to medicinal products for human use intended to be placed on the market of Northern Ireland (2023/0064(COD); ("the proposed Regulation"))[2].

JURI considered the above question at its meeting of 25 April 2023.

I - Background

Committee on the Environment, Public Health and Food Safety (ENVI) is dealing with the proposed Regulation, which is one of the three legislative proposals stemming from the Windsor Framework agreed between the United Kingdom and the Union on 27 February 2023.

The Commission based the proposed Regulation on Article 114 of the Treaty on the Functioning of the European Union (TFEU). ENVI did not question the appropriateness of that legal basis. However, ENVI understands that the Council intends to amend that legal basis by adding Article 168(4)(c) TFEU, arguing that this was necessary for the soundness of the proposed

[1] D(2023)12613.
[2] COM(2023) 122 of 27.02.2023.

Regulation.

Parliament's objective is to adopt all three proposals stemming from the Windsor Framework as a package at the first plenary sitting in May (8-11 May 2023). In order to enable a swift agreement and adoption of the proposed Regulation, ENVI is requesting the opinion of the Committee on Legal Affairs on the appropriateness of the amended legal basis ahead of the potential adoption of the proposed Regulation at the first plenary sitting in May 2023.

II - The relevant Treaty Articles

Chapter 3 of Title VII of Part three TFEU, on "Approximation of laws" reads, *inter alia*, (emphasis added):

Article 114
(ex Article 95 TEC)

1. ***Save where otherwise provided in the Treaties, the following provisions shall apply for the achievement of the objectives set out in Article 26. The European Parliament and the Council shall, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee, adopt the measures for the approximation of the provisions laid down by law, regulation or administrative action in Member States which have as their object the establishment and functioning of the internal market.***

2. *Paragraph 1 shall not apply to fiscal provisions, to those relating to the free movement of persons nor to those relating to the rights and interests of employed persons.*

3. ***The Commission, in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.***

4. *If, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them.*

5. *Moreover, without prejudice to paragraph 4, if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to introduce national provisions based on new scientific evidence relating to the protection of the environment or the working environment on grounds of a problem specific to that Member State arising after the adoption of the harmonisation measure, it shall notify the Commission of the envisaged provisions as well as the grounds for introducing them.*

6. *The Commission shall, within six months of the notifications as referred to in paragraphs 4 and 5, approve or reject the national provisions involved after having verified whether*

or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

In the absence of a decision by the Commission within this period the national provisions referred to in paragraphs 4 and 5 shall be deemed to have been approved.

When justified by the complexity of the matter and in the absence of danger for human health, the Commission may notify the Member State concerned that the period referred to in this paragraph may be extended for a further period of up to six months.

7. *When, pursuant to paragraph 6, a Member State is authorised to maintain or introduce national provisions derogating from a harmonisation measure, the Commission shall immediately examine whether to propose an adaptation to that measure.*

8. *When a Member State raises a specific problem on public health in a field which has been the subject of prior harmonisation measures, it shall bring it to the attention of the Commission which shall immediately examine whether to propose appropriate measures to the Council.*

9. *By way of derogation from the procedure laid down in Articles 258 and 259, the Commission and any Member State may bring the matter directly before the Court of Justice of the European Union if it considers that another Member State is making improper use of the powers provided for in this Article.*

10. *The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure.*

Title XIV of Part three TFEU, on "Public health" reads (emphasis added):

Article 168
(ex Article 152 TEC)

1. *A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*

Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.

The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention.

2. *The Union shall encourage cooperation between the Member States in the areas referred*

to in this Article and, if necessary, lend support to their action. It shall in particular encourage cooperation between the Member States to improve the complementarity of their health services in cross-border areas.

Member States shall, in liaison with the Commission, coordinate among themselves their policies and programmes in the areas referred to in paragraph 1. The Commission may, in close contact with the Member States, take any useful initiative to promote such coordination, in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.

3. *The Union and the Member States shall foster cooperation with third countries and the competent international organisations in the sphere of public health.*

4. ***By way of derogation from Article 2(5) and Article 6(a) and in accordance with Article 4(2)(k) the European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, shall contribute to the achievement of the objectives referred to in this Article through adopting in order to meet common safety concerns:***

   (a) *measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; these measures shall not prevent any Member State from maintaining or introducing more stringent protective measures;*

   (b) *measures in the veterinary and phytosanitary fields which have as their direct objective the protection of public health;*

   (c) measures setting high standards of quality and safety for medicinal products and devices for medical use.

5. *The European Parliament and the Council, acting in accordance with the ordinary legislative procedure and after consulting the Economic and Social Committee and the Committee of the Regions, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonisation of the laws and regulations of the Member States.*

6. *The Council, on a proposal from the Commission, may also adopt recommendations for the purposes set out in this Article.*

7. *Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood.*

III – CJEU case law on the choice of legal basis

The Court of Justice has traditionally viewed the question of the appropriate legal basis as an issue of constitutional significance, guaranteeing compliance with the principle of conferred powers (Article 5 TEU) and determining the nature and scope of the Union's competence[3].

According to well-established case law, the legal basis of a Union act does not depend on an institution's conviction as to the objective pursued, but must be determined according to objective criteria amenable to judicial review, including in particular the aim and the content of the measure[4].

If examination of a measure reveals that it pursues a twofold purpose or that it has a twofold component and if one of those is identifiable as the main or predominant purpose or component, whereas the other is merely incidental, that measure must be based on a single legal basis, namely that required by the main or predominant purpose or component[5]. Only exceptionally, if it is established that the act simultaneously pursues a number of objectives, inextricably linked, without one being secondary and indirect in relation to the other, may such an act be founded on the various corresponding legal bases[6]. This would however only be possible if the procedures laid down for the respective legal bases are not incompatible with and do not undermine the right of the European Parliament[7].

IV – Aim and content of the proposed Regulation

In order to assess the appropriateness of adding Article 168(4)(c) as the legal basis of the proposed Regulation in the light of the case law of the Court of Justice on the choice of legal basis, it is necessary to examine its main aim and the content.

The explanatory memorandum of the proposed Regulation first recalls the context which requires its adoption. It refers to the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community[8] ("Withdrawal Agreement"), and in particular to Article 5(4) of the Protocol on Ireland/Northern Ireland ("the Protocol"). In accordance with that Article and in conjunction with Annex 2 to the Protocol, Regulation (EC) No 726/2004[9] and Directive 2001/83/EC[10], as

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[3] Opinion 2/00 *("Cartagena Protocol")*, ECLI:EU:C:2001:664, paragraph 5.
[4] Case C-300/89*, Commission v Council ("Titanium dioxide")*, ECLI:EU:C:1991:244, paragraph 10.
[5] Ibid. paragraph 30 and Case C-137/12, *Commission v Council*, ECLI:EU:C:2013:675, paragraph 53 and case-law cited.
[6] Case C-300/89, paragraphs 13 and 17; Case C-42/97, *Parliament v Council*, ECLI:EU:C:1999:81, paragraph 38; *Opinion 2/00*, paragraph 23; Case C-94/03, *Commission v Council ("Rotterdam Convention")*, ECLI:EU:C:2006:2 and Case C-178/03, *Commission v Parliament and Council*, ECLI:EU:C:2006:4, paragraphs 36 and 43.
[7] Case C-300/89, paragraphs 17-25; Case C-268/94 *Portugal v Council*, ECLI:EU:C:1996:461.
[8] OJ L 29, 31.1.2020, p. 7.
[9] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
[10] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community

well as the Commission acts based on them, apply to and in the United Kingdom in respect of Northern Ireland. In concrete terms, this means that medicines placed on the market in Northern Ireland must be covered by a valid marketing authorisation issued by the Commission (EU-wide authorisation) or by the United Kingdom in respect of Northern Ireland in accordance with the abovementioned Regulation and Directive.

Despite the transitional period provided for in the Withdrawal Agreement, it proved difficult for certain economic operators based in parts of the UK other than Northern Ireland to adapt and move relevant regulatory compliance functions to Northern Ireland or the Union in respect of nationally authorised medicines, as required by the Protocol.

To ensure uninterrupted supply of medicines with the United Kingdom national authorisations to, *inter alia*, Northern Ireland, the Union adopted Directive (EU) 2022/642[11], which introduced certain derogations from obligations concerning certain medicinal products for human use. That Directive also introduced a bridging solution on novel medicines that under Union law are authorised through the centralised procedure provided by Regulation (EC) No 726/2004, so they can be be supplied to patients in Northern Ireland.

Against this background, the purpose of the proposed Regulation is to lay down "*specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland in accordance with Article 6 of Directive 2001/83/EC*" (Article 1). The need for the specific marketing rules is described in recitals (5) and (6): "*[i]n order to take account of the specific situation of Northern Ireland, it is appropriate to adopt specific rules relating to the placing on the market of Northern Ireland of medicinal products for human use...*".

Concretely, the proposed Regulation provides, for example, that certain medicinal products may, under certain conditions laid down in Directive 2001/83/EC, "*be imported into Northern Ireland from other parts of the United Kingdom by holders of a wholesale distribution authorisation that are not in possession of a relevant manufacturing authorisation*" (Article 3(1)). It also provides for other derogations concerning safety features on the "*outer packaging*" or "*immediate packaging*" of medicinal products (Article 3(2)), etc.

The proposed Regulation also prohibits/allows the placing on the market of Northern Ireland of medical products belonging to certain categories provided for in Regulation (EC) No 726/204 (Article 4).

It furthermore provides for some specific "*labelling requirements*" (Article 5), continued monitoring of the placing of medicinal products covered by the proposed Regulation on the maket of Northern Ireland (Article 6) and prohibits the movement of the medicinal products concerned from Northern Ireland to the market in a Member State (Article 7).

Articles 8 and 9 provide for written guarantees by the United Kingdom to the Commission, and for suspension of Articles 3, 4 and 5 by the Commission. The rest are final provisions.

By contrast, health concerns are mentioned only generally in the recitals, for example in recital

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code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

[11] Directive (EU) 2022/642 of the European Parliament and of the Council of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta (OJ L 118, 20.4.2022, p. 4).

(7): "*[it] is important to lay down rules which ensure that the application of the specific rules laid down in this Regulation does not lead to an increased risk to public health in the internal market*" or, again, in recital (10): "*At the same time, appropriate safeguards for the Union should be put in place in order to ensure that the application of the specific rules does not increase risks to public health in the internal market...*", and finally in recital (13): "*In order to ensure an effective and swift reaction to any increased risk for public health, this Regulation should provide for the possibility for the Commission to adopt delegated acts in accordance with an urgency procedure*."

In the Articles, health is only mentioned once, in the introductory wording in Article 8: "*The United Kingdom shall provide the European Commission with written guarantees that the placing on the market of the medicinal products referred to in Article 1(1) does not increase the risk to public health in the internal market and that those medicinal products will not be moved to a Member State, including...*".

V – Analysis

Although the Commission intended the proposed Regulation to be an exclusively internal market measure it should be recalled that the legal basis of a Union act does not depend on an institution's conviction as to the objective pursued but must be determined according to objective criteria.

It is clear from the typically internal market elements of the proposed Regulation, such as placing on the market, authorisations, packaging and labelling requirements, market monitoring etc., combined with the specific context of the withdrawal of the United Kingdom from the Union that the measure is intended to preserve the internal market of the Union while allowing at the same time for certain products to be made available in the very specific market of Northern Ireland.

The proposed Regulation does not seem to pursue genuine health concerns. The focus of both the recitals and Articles as it transpires from the proposed Regulation appears to be on the internal market. The element that seems to call into question Article 114 as the sole legal basis for the proposed Regulation appears to be the nature of the products in question, which are medicinal products. But the proposed Regulation does not seem to be aimed at "*setting high standards of quality and safety for medicinal products*" as such, as required by Article 168(4)(c). Both the explanatory memorandum and the recitals of the proposed Regulation refer to health concerns only occasionally and the recitals concerned only seem to give a wider context and are not reflected in the operative part by specific normative provisions. The health concerns therefore seem to be only ancillary to the objectives pursued by the proposed Regulation.

It may be useful to also examine the fact that the proposed Regulation provides for derogations from Directive 2001/83/EC and Regulation (EC) No 726/2004. The former was based on Article 95 TEC alone (now Article 114 TFEU) but recent amendments to it were based on either Article 114 TFEU alone or on the dual legal basis of Article 114 and Article 168(4)(c) TFEU. The Regulation was from the outset on based on Article 95 and Article 152(4)(b) TEC (now Article 114 and 168(4)(b) TFEU) and has recently been amended on the basis of Articles 114 and 168(4)(c) TFEU. In relation to legal bases chosen in previous related or similar acts, it

should be recalled that the Court held that the legal basis for an act must be determined having regard to its own aim and content[12].

In light of the above analysis and considering the very specific context of the withdrawal of the United Kingdom from the Union, in the aftermath of which comes the proposed Regulation, the heath concerns, that would require the addition of Article 168(4)(c) as the legal basis, seem to fail the centre of gravity test and Article 114 TFEU appears to be the appropriate and sufficient legal basis for the proposed Regulation. Even more so when considering that paragraph 3 of Article 114 TFEU expressly provides that the Commission proposals based on that Article concerning, *inter alia*, health will take as a base a high level of protection. In this regard, provided that the conditions for recourse to Article 114 TFEU as a legal basis are fulfilled "*the EU legislature cannot be prevented from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made*".

It is unfortunate that in the context of the general urgency accompanying the proposed Regulation the Council did not consult Parliament beforehand regarding the appropriateness of its position to add Article 168(4)(c) as the second legal basis of the measure to be jointly adopted by Parliament and the Council, which puts Parliament in front of a *fait accompli* if it is not to block the swift final adoption of the proposed Regulation.

However, it is nevertheless proposed that, although not necessary from a legal point of view, adding Article 168(4)(c) as the second legal basis of the proposed Regulation would not adversely affect its legality, since (1) the two legal bases are compatible, (2) the co-legislators have sometimes had recourse to such double legal basis in the past for amending legislative acts which would be derogated from under the proposed Regulation, and (3) according to the case-law, even if the recourse to a second legal basis might possibly be incorrect, it would not entail the annulment of the act by the Court of Justice, to the extent that one of the legal basis is appropriate and sufficient, and that the other legal basis is procedurally compatible with that legal basis[13].

VI – Conclusion and recommendation

In light of the foregoing, and to facilitate the swift adoption of the proposed Regulation, the Committee on Legal Affairs decided at its meeting of 25 April 2023, by 25 votes in favour, none against and no abstention[14], to recommend to the Committee on the Environment, Public Health and Food Safety that the addition of Article 168(4)(c) TFEU as second legal basis for the proposed Regulation can be considered acceptable.

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[12] Case C-187/93, *Parliament v Council*, ECLI:EU:C:1994:265, paragraph 28. See also Case C-411/06, *Commission v Parliament and Council* (*"Shipments of waste"*), ECLI:EU:C:2009:518, paragraph 77, and Case C-81/13, *UK v Council*, ECLI:EU:C:2014:2449 paragraph 36.

[13] Case C-491/01, *British American Tobacco*, ECLI:EU:C:2002:741, paragraphs 97-99.

[14] The following were present for the final vote: Sergey Lagodinsky (Vice-Chair), Marion Walsmann (Vice-Chair), Lara Wolters (Vice-Chair), Raffaele Stancanelli (Vice-Chair), Pascal Arimont, Manon Aubry, Gunnar Beck, Daniel Buda, Ibán García Del Blanco, Ilana Cicurel, Pascal Durand, Angel Dzhambazki, Agnes Jangerius (for Tiemo Wőlken pursuant to Rule 209(7)), Virginie Joron, Heidi Hautala, Pierre Karleskind, Maria-Manuel Leitão-Marques, Gilles Lebreton, Antonius Manders, Karen Melchior, Maite Pagazaurtundúa (for Adrián Vázquez Lázara pursuant to Rule 209(7)), Sabrina Pignedoli, Jiří Pospíšil, Axel Voss and Javier Zarzalejos.

Yours sincerely,

Adrián Vázquez Lázara