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Three Steps Towards a European Health Union

Demands of the Conference on the Future of Europe due to start in the Spring

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The EU's competences are limited when it comes to health policy. The problems caused by this have been further highlighted by the COVID-19 pandemic. The "Conference on the Future of Europe", announced by the EU Commission, Council and European Parliament, should smooth the way for essential elements of a European Health Union.

Key Propositions

The European Treaties should be amended to give the EU the competence to introduce:

- **Clinical assessments of medicinal products and medical devices** to determine their therapeutic added value should be carried out in a uniform manner across the EU. This will strengthen the internal market, increase gains in efficiency and reduce bureaucracy costs.
- **Electronic health services** should be available across the EU. Binding EU standards must therefore ensure that services in the Member States are compatible in order to facilitate the cross-border exchange – with patient consent – of electronic health records, laboratory results and prescriptions.
- **Reliable recording of figures for infections, deaths and recoveries during a pandemic** is essential for an internal market without borders. This, as COVID-19 has shown, requires definitions, criteria and testing methods that are consistent and thus uniform across the EU.

Table of Contents

1 Introduction

The demarcation between national and EU responsibilities in the health sector has always been a highly controversial issue. In her State of the Union Address 2020, Commission President von der Leyen outlined the fact that the EU had achieved a great deal in the COVID-19 pandemic but that the task now was to become better equipped to deal with future crises and above all to react to cross-border health threats. Among other things, the European Centre for Disease Prevention and Control (ECDC) will be strengthened and a European agency for biomedical advanced research and development will be set up for this purpose.[1] The creation of a European Health Data Space has also been announced by the EU Commission.[2]

In addition, however, the EU's competences in the health sector should also be discussed. This is "clearer than ever" and a noble and urgent task for the Conference on the Future of Europe.[3] Vice President Šuica, who is responsible for this, had previously already indicated that the health sector must come to the fore in the discussion[4] about the future of the EU.[5] The European Parliament has already called for the creation of a European Health Union[6] and the EU Commission would also like such a Health Union.[7] Currently, however, it is the Member States that are mainly responsible for the health sector. This includes health policy, the organisation and delivery of health services and medical care as well their management and the allocation of resources [Art. 168 (7) TFEU].

This cep**Input** first sets out the legal basis for health policy measures by the EU (Section 2). It then submits three notions for introducing EU health competences to contribute to the debate at the Conference on the Future of Europe (Section 3).

2 Legal Basis for EU Health Policy Measures

The EU's responsibilities are basically determined according to the "principle of conferral". This states that the EU only acts where the Member States have empowered it to do so [Art. 5 (1) and (2) TEU]. The EU's health policy competences are in turn limited by the responsibility of the Member States for the health sector which is guaranteed under primary law [Art. 168 (7) TFEU]. Possibilities for EU legislation are principally based on four provisions of the Treaty on the Functioning of the European Union (TFEU)[8]:

(1) the competences shared between the EU and the Member States for certain common safety concerns in public health matters [Art. 4 (2) (k), 168 (4) TFEU] – see Section 2.1,
(2) the EU's competence to carry out actions to support, coordinate or supplement the protection and improvement of human health [Art. 6 (a), 168 (1) – (3), (5) – (6) TFEU] – see Section 2.2,

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1 See von der Leyen (2020), State of the Union Address 2020, p. 4 et seq. All sources last accessed on 9 February 2021.
2 European Commission, Letter of Intent to President David Maria Sassoli and to Chancellor Angela Merkel, p. 4.
3 See von der Leyen (2020), State of the Union Address 2020, p. 5.
4 One example of many: Politico, Coronavirus prompts calls for 'more Europe' on health care, 30 April 2020.
5 FT, Coronavirus re-sets agenda for Conference on Future of Europe, 13 April 2020.
6 See European Parliament resolution of 10 July 2020 on the EU's public health strategy post-COVID-19, No. 1.
7 See Communication on Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats.
8 This refers to competences for passing and harmonising laws. Other EU law, which does not relate directly to the health sector may have an effect on health policy and the health sectors of the Member States; see e.g. remarks by the CJEU on the connection between advertising by pharmacies and the Directive on electronic commerce [(EC) 2000/31] in: CJEU, Judgement of 1 October 2020, Case No. C-649/18, para. 28- 34. For this see also cep**Input** Advertising by Pharmacies. On fundamental freedoms see cep**Adhoc** Preiswettbewerb unter Apotheken, p. 7 et seq. On European Semester see e.g. Reho, O. (2020), Does the EU have sufficient healthcare competences to cope with COVID-19?, p. 1 et seq.

(3) the EU's competence to adopt measures for the approximation of laws in the internal market [Art. 114 TFEU] – see Section 2.3,
(4) the so-called flexibility clause as a possibility for further development of EU law "below" a formal treaty amendment [Art. 352 TFEU] – see Section 2.4.

2.1 Common Safety Concerns in Certain Areas

In the case of certain common safety concerns in public health matters, the EU shares its competences with the Member States [Art. 4 (2) (k), 168 (4) TFEU]. This allows for: (1) measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives; (2) measures for the protection of public health in the veterinary and phytosanitary fields and (3) measures setting high standards of quality and safety for medicinal products and devices for medical use.[9] The latter arise primarily in provisions on market authorisation[10] such as those contained in the Medical Devices Regulation[11] and other European legislation.[12]

2.2 Supporting, Coordinating and Supplementing

The legal bases for the protection and improvement of human health [Art. 6 (a) TFEU] are set out in Art. 168 (1-3) and (5-6) TFEU. These provisions permit measures for improving public health, preventing human diseases, and obviating sources of danger to physical and mental health.[13] In such areas, the EU can support or coordinate the measures of the Member States or supplement their policies.

Art. 168 (5) TFEU is of particular importance. It empowers the EU to adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, as well as measures concerning the monitoring, early warning of and combating serious cross-border threats to health. However: In contrast to the approximation of laws – which the provision explicitly prohibits – the measures must be those which motivate the Member States and private actors to behave in a certain way through positive incentives.[14] Possible examples include support schemes such as "EU4Health"[15] and the creation and subsidisation of networks[16] as well as the formulation of health policy action plans.[17]

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[9] See also Walter/Obwexer, in: von der Groeben/Schwarze/Hatje (Hg.), Europäisches Unionsrecht, 7th Edn. 2015, Art. 4 TFEU, para. 32.
[10] See cep**Input** Joint Clinical Assessment of Health Technologies, p. 10.
[11] See cep**Adhoc** Deadline extension for medical devices, p. 2 et seq.
[12] E.g. Directive on the Community code relating to medicinal products for human use [(EC) 2001/83]; Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [(EC) 726/2004]; Regulation on in vitro diagnostic medical devices [(EU) 2017/746].
[13] See altogether Walter/Obwexer, in: von der Groeben/Schwarze/Hatje (Hg.), Europäisches Unionsrecht, 7th Edn. 2015, Art. 6 TFEU, para. 13, which however – unlike this study – includes Art. 168 (7) TFEU in the list.
[14] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Hg.), Das Recht der Europäischen Union, August 2020, Art. 168 TFEU, para. 69.
[15] This provides funding for measures by the Member States, health organisations and non-governmental organisations; see EU Commission (2021), "EU4Health 2020–2027 – a vision for a healthier European Union".
[16] See altogether Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Hg.), Das Recht der Europäischen Union, August 2020, Art. 168 TFEU, para. 70.
[17] These are generally Communications from the EU Commission in which it sets out how it intends to address a particular health problem. E.g.: Action Plan against Antimicrobial Resistance, see cep**PolicyBrief** No. 2018-01 Antimicrobial Resistance and in a broader sense also the Strategic Approach to Pharmaceuticals in the Environment, see cep**PolicyBrief** No. 2020-02 Pharmaceuticals in the Environment.

In combating cross-border diseases and threats to health, the EU therefore has a coordinating function: Thus it can set up bodies such as the "Health Security Committee" in which Member States exchange information with each other and with the EU Commission on risk assessments in the event of a crisis. The actual national risk and communications management cannot be delegated to the EU Commission though.[18] The EU can also set up its own EU institutions – such as the ECDC. The purpose of such institutions must, however, be the collection and administration of data. Anything beyond the collection of data – e.g. the formulation of strategies with binding effect for the Member States – is not yet covered.[19]

2.3 Approximation of Laws in the Internal Market

Under Art. 114 TFEU, the EU can adopt measures for the approximation of laws whereby legislation in the Member States is harmonised with an EU standard. This serves to reduce and eliminate differences between the laws in the Member States.[20] The provision stipulates that: (a) the aim of the envisaged European law is approximation; (b) laws, regulations or administrative actions in the Member States are to be approximated and (c) the approximation has as its object the establishment and functioning of the internal market.[21] In principle, the EU can also adopt measures – and thus adopt legal provisions – that have a significant effect on the health sector. In doing so, however, it must not circumvent the responsibility of the Member States for their health sector. Thus, the responsibility of the Member States for defining their health policy and for organising their health services and medical care must be preserved [Art. 168 (7) TFEU].[22] This involves unspecified legal terms, the details of which are difficult to ascertain[23]: Health policy is understood to mean the political arrangement of the healthcare framework – including planning, organisation, management and financing of the health system. The health services includes the institutions and organisations tasked with promoting health and the prevention and treatment of diseases and injuries. As distinct from the organisation of health services, medical care means the standard of medical care, i.e. the scope of services provided according to national regulations.[24] To that extent, this can be regarded as the "limit" of the possibility for harmonisation,[25] although this legal basis has been used for some – broadly health policy related – laws.[26]

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[18] Art. 168 (5) TFEU. See Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Hg.), Das Recht der Europäischen Union, August 2020, Art. 168 TFEU, para. 70. See in particular also the remarks by Niggemeier, in: von der Groeben/Schwarze/Hatje (Hg.), Europäisches Unionsrecht, 7th Edn. 2015, Art. 168 TFEU, para. 60.

[19] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Hg.), Das Recht der Europäischen Union, Mai 2020, Art. 168 TFEU, para. 70.

[20] Frenz (2016), "Europarecht", 2nd Edn., para. 733.

[21] Korte, in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 114 TFEU, para. 1, 20, 21, 34, 38.

[22] See also cep**Input** Joint Clinical Assessment of Health Technologies, p. 11.

[23] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Hg.), Das Recht der Europäischen Union, August 2020, Art. 168 TFEU, para. 78.

[24] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Hg.), Das Recht der Europäischen Union, August 2020, Art. 168 TFEU, para. 79- 81.

[25] See cep**Input** Joint Clinical Assessment of Health Technologies, p. 11.

[26] E.g. Directive on the Community code relating to medicinal products for human use [(EC) 2001/83]; Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [(EC) 726/2004]; Directive on the application of patients' rights in cross-border healthcare [(EU) 2011/24]; Regulation on medical devices [(EU) 2017/745] and the Regulation on in vitro diagnostic medical devices [(EU) 2017/746].

2.4 Flexibility Clause

The so-called flexibility clause [Art. 352 TFEU] aims to make up for the discrepancies and gaps, which exist between the EU's objectives and the powers of its institutions, by stretching the competences of EU institutions in order to bring about a gradual integration. This facilitates the further development of EU law "below" a formal amendment of the treaties.[27]

3 Three Notions for EU Competences in the Health Sector

Even if health policy is essentially the sole responsibility of the Member States, there are areas in which regulation at EU level would be beneficial. As a contribution to the debate about EU health competences, three notions indicating the advantages of European action will be presented. Subsequently, it will be assessed whether such action can be achieved at EU level within the existing division of legislative competences or whether this should be discussed at the Conference on the Future of Europe as possible amendments of the treaties.

3.1 Notion 1: Joint Clinical Assessment of Health Technologies

(1) Content and Objective

The clinical assessment of health technologies – i.e. particularly medicinal products and medical devices – is a process whereby these technologies are subject to a multidisciplinary, comparative assessment. The aim is to determine the added value of a new health technology. The assessment currently takes place at national level. The EU Commission wants to change this and has therefore proposed a corresponding Regulation for an EU-wide assessment[28]. Moving clinical assessment to EU level would have an impact on national health policy as the assessment is generally a basis for the pricing and reimbursement of the health technology under assessment. A joint clinical assessment would, however, strengthen the internal market, provide the healthcare sector with significant gains in efficiency and reduce bureaucracy costs. Its introduction at European level is therefore appropriate.[29]

(2) EU Competence

A binding joint clinical assessment cannot be adopted on the basis of the existing EU competences for common safety concerns [Art. 168 (4) TFEU]. The EU can adopt rules aimed directly at ensuring the quality and safety of a medicinal product or a medical device with respect to the patient, but such rules serve as a means of dealing with common safety concerns regarding these products. This is achieved principally by way of general provisions relating to the market authorisation of products, such as those set out in the Medical Devices Regulation. The market authorisation and the assessment of health technologies have different remits and answer different questions, even if they base their answers on common evidence. The provisions on joint clinical assessment form the basis for a case-by-case assessment of a specific health technology with respect to the clinical added value, i.e. the relative

[27] Which is very unlikely to succeed mainly due to the parliamentary reservation in Section 8 German Integration Responsibility Act (IntVG). See altogether Rossi in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 352 TFEU, para. 10. On this see also Frenz (2016), "Europarecht", 2nd Edn., para. 749.

[28] Proposal COM(2018) 51 of 31 January 2018 for a Regulation of the European Parliament and of the Council on health technology assessment and amendingDirective 2011/24/EU.

[29] See cepInput Joint Clinical Assessment of Health Technologies.

effectiveness and relative safety in comparison with one or more other technologies which reflect the current standard of care. They are thus intended for use by the Member States as a scientific basis on which to determine the price of the health technology and for deciding on cost reimbursement, and not for dealing with general safety concerns regarding these products.[30]

The binding nature of a joint clinical assessment at EU level means that such action certainly cannot be based on the competence to support, coordinate or supplement [Art. 168 (1-3), (5-6) TFEU]. Their introduction would not be a measure aimed at motivating Member States and private actors to behave in a certain way through positive incentives but a legally binding procedure.

Due to the obligations to carry out joint clinical assessments and their mandatory use in further-going national proceedings, the competence to adopt measures for the approximation of laws in the internal market [Art. 114 TFEU] does not facilitate the introduction of such a joint clinical assessment either. It will not be possible to avoid intervening in the health policy of the Member States because the clinical assessment is a significant component of health policy, the approach and design of which expresses the preferences of the Member States, such in the setting of scientific standards.[31]

The introduction of a binding joint clinical assessment – without diverging national assessments – by means of the so-called flexibility clause [Art. 352 TFEU] is also impossible because it cannot be used to circumvent the exclusion of harmonisation contained elsewhere in the Treaties [Art. 352 (3) TFEU].[32] Art. 168 (7) TFEU rules out the harmonisation of the laws of the Member States relating to health policy.[33]

Thus an extension of competence by an amendment to the European treaties is the only possibility remaining. This should be taken up at the Conference on the Future of Europe.

3.2 Notion 2: Electronic Cross-Border Health Services

(1) Content and Objective

The current efforts to develop electronic cross-border health services are based on voluntary cooperation between the health authorities of the Member States.[34] The EU supports the Member States inter alia in establishing the cross-border interoperability of national electronic health records (eHR). In this regard, the specifications and standards for electronic health services and those of the underlying national electronic health record systems are issued by the board of the competent authorities of the Member States ("eHealth Network")[35] and "recommended" by the EU Commission.

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30 See cep**Input** Joint Clinical Assessment of Health Technologies, p. 10 et seq.

31 See cep**Input** Joint Clinical Assessment of Health Technologies, p. 11. This is presumably the reason why, during the current legislative proceedings on the proposed Regulation, the European Parliament has proposed a right for the Member States to carry out – national – "complementary" assessments. This bridge aims to ensure that the Regulation does not intervene in the Member States' sphere of responsibility [Art. 168 (7) TFEU]. However, the broader the scope of the – so far very unspecific – right, and the more the Member States make use of it, the smaller the gains in efficiency will be; see cep**Input** Joint Clinical Assessment of Health Technologies, p. 11 et seq.

32 Rossi, in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 352 TFEU, para. 89.

33 Rossi, in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 352 TFEU, para. 89. See also Fehling, M., "Gesetzgebungskompetenzen im Verfassungsrecht und im Unionsrecht", in: JURA (2016), p. 505 et seq.

34 See EU Commission (2018), "Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society", p. 5.

35 See cep**PolicyBrief** No. 2019-15 European Electronic Health Record Exchange Format and cep**PolicyBrief** No. 2020-8 EU-Data Strategy - Part 2.

This means that they are not legally binding.[36] Voluntary cooperation between Member States in the "eHealth Network" is based on the so-called Patients' Rights Directive[37]. So far, five standards for electronic health services are planned of which only two have been implemented: Standards for the exchange of (1) patient summaries and (2) electronic prescriptions. Standards for the exchange of (3) laboratory results, (4) medical imaging and reports and (5) hospital discharge reports are currently being drafted. National eHRs are based on electronic health record systems, i.e. information systems for recording, retrieving and managing health records. Existing electronic health record systems are often incompatible due to varying formats and technical standards.[38] The cross-border standards are currently set through a non-binding recommendation[39] of the EU Commission under its general competence to adopt Recommendations [Art. 292 (4) TFEU].[40] The whole process is lengthy and so far only citizens of few Member States are actually able to use the first two health services.[41] The establishment of binding standards for electronic health services at European level could speed up the existing process and increase legal certainty thereby enabling – with patient consent – the EU-wide cross-border exchange of e.g. electronic health records, laboratory results and prescriptions.

(2) EU Competence?

Binding EU-wide standards cannot be introduced on the basis of existing EU competences for common safety concerns [Art. 168 (4) TFEU] as the areas covered[42] are not materially affected. The EU competences to support, coordinate or supplement do not allow for this either. The establishment of such EU-wide technical standards would not be a measure aimed at motivating Member States and private actors to behave in a certain way through positive incentives but a legally binding standard. The competence to adopt measures for the approximation of laws in the internal market does not permit their introduction either because the establishment of such binding standards – particularly those for the national electronic health record systems – would directly affect health policy which is part of the Member States' sphere of responsibility [Art. 168 (7) TFEU]. The EU is not permitted to use the internal market competence to circumvent the Member States' protected sphere of responsibility.[43] Its introduction by means of the so-called flexibility clause [Art. 352 TFEU] is also impossible because that clause cannot be used to circumvent the exclusion of harmonisation contained elsewhere in the Treaties [Art. 352 (3) TFEU].[44] Art. 168 (7) TFEU rules out the harmonisation of the laws of the Member States relating to health policy.[45] Thus an extension of competence by an amendment to the European treaties is the only possibility remaining. This should also be taken up at the Conference on the Future of Europe.

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36 See Recommendation (EU) 2019/243 of 6 February 2019 on a European Electronic Health Record exchange format.

37 Directive on the application of patients' rights in cross-border healthcare [2011/24/EU].

38 cep**PolicyBrief** No. 2019-15 European Electronic Health Record Exchange Format.

39 As a result of their legal nature, recommendations cannot interfere with the Member States' responsibility for the organisation and delivery of their health services and medical care; see Berg/Augsberg, in: Schwarze/Becker/Hatje/Schoo (Hg.), EU-Kommentar, 4th Edn. 2019, Art. 168 TFEU, para. 36.

40 See altogether cep**PolicyBrief** No. 2019-15 European Electronic Health Record Exchange Format.

41 See EU Commission (2021), "Electronic cross-border health services": Croatia, Luxembourg, Malta, Portugal, Czechia, Finland, Estonia.

42 Organs and substances of human origin; blood and blood derivatives; veterinary and phytosanitary fields or high standards of quality and safety for medicinal products and devices for medical use; see Section 2.1.

43 See altogether cep**Input** Joint Clinical Assessment of Health Technologies, p. 11.

44 Rossi, in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 352 TFEU, para. 89.

45 Rossi, in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 352 TFEU, para. 89. See also Fehling, M., "Gesetzgebungskompetenzen im Verfassungsrecht und im Unionsrecht", in: JURA (2016), p. 505 et seq.

3.3 Notion 3: EU-wide Fight Against Pandemics

(1) Content and Objective

The EU has a coordinating role when it comes to combating cross-border diseases and threats to health.[46] Even if EU fundamental freedoms – especially freedom of movement[47] – and fundamental rights may to be restricted during a pandemic, restrictions should be kept as slight and as short as possible. Above all, it must be evident to EU citizens what applies, where and when so that they can actually assert their rights. This is not only to facilitate planning certainty for citizens and companies but is a necessary condition to ensure legal certainty for all involved.

As the COVID-19 pandemic has shown, even a comparison of the situations in the Member States is difficult. This is primarily due to the differing approaches to data collection and data reporting. Thus a reliable picture of the spread of the virus at any one time has not always been possible.[48] During a pandemic, it should be possible to lay down binding definitions, methods and criteria[49] at EU level. This applies to the definition of a positive case of infection, a death by infection and a recovery from infection[50] as well as establishing test procedures and mutual recognition of test results.[51]

(2) EU Competence?

Common binding EU-wide definitions, methods and criteria cannot be introduced on the basis of existing EU competences for common safety concerns [Art. 168 (4) TFEU] as the areas covered[52] are not materially affected. With regard to EU competences to support, coordinate and supplement [Art. 168 (1-3) and (5-6) TFEU], one might initially think of Art. 168 (5) TFEU, which permits incentive measures designed to protect and improve human health and combat the major cross-border health scourges, but this provision expressly prohibits any approximation of laws. Measures are limited to those which motivate the Member States and private actors to behave in a certain way through positive incentives.[53] In the case of a pandemic, however, only common binding EU definitions, methods and criteria are appropriate. Likewise, the Council can for example recommend mutual recognition of COVID-19 test results [Art. 168 (6) TFEU] but cannot make this a mandatory requirement. Even the competence to adopt measures for the approximation of laws in the internal market does not make this possible because such binding rules would have a direct effect on health policy which is part of the Member States' sphere of responsibility [Art. 168 (7)TFEU]. The EU is not permitted to use the internal market competence to circumvent the Member States' protected sphere

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46 In the context of its competences to support, coordinate and supplement [Art. 168 (5) TFEU]; see Section 2.2. Possible measures in the field of civil protection [Art. 196 TFEU] and based on the so-called solidarity clause [Art. 222 TFEU] are not considered in this study.

47 See on this also cep**Input** Limits for frontier workers in the internal market due to COVID-19.

48 See e.g. European Parliament resolution of 17 September 2020 on COVID-19: EU coordination of health assessments and risk classification, and the consequences for Schengen and the single market, para. G, H and No. 9.

49 The EU-Commission has also recently made proposals for this on 19 January 2021: A united front to beat COVID-19, p. 8 et seq.

50 See European Parliament resolution of 17 September 2020 on COVID-19: EU coordination of health assessments and risk classification, and the consequences for Schengen and the single market, No. 18.

51 Thus, on 21 January 2021, the Council recommended mutual recognition of the results of COVID-19 tests carried out by certified health bodies in other Member States; see Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU, No. 17.

52 Organs and substances of human origin; blood and blood derivatives; veterinary and phytosanitary fields or high standards of quality and safety for medicinal products and devices for medical use; see Section 2.1.

53 Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Hg.), Das Recht der Europäischen Union, August 2020, Art. 168 TFEU, para. 69.

of responsibility.[54] The so-called flexibility clause [Art. 352 TFEU] cannot be relied upon either because it cannot be used to circumvent the exclusion of harmonisation contained elsewhere in the Treaties [Art. 352 (3) TFEU].[55] Art. 168 (7) TFEU rules out the harmonisation of the laws of the Member States relating to health policy.[56]

Thus an extension of competence by an amendment to the European treaties is the only possibility remaining. This should also be taken up at the Conference on the Future of Europe.

4 Summary

The forthcoming Conference on the Future of Europe will bring competences relating to the health sector to the fore. The three notions contained herein are intended as a contribution to this discussion. The consideration of joint clinical assessment, electronic cross-border health services and the EU-wide fight against pandemics present areas of health policy for which it would be appropriate to regulate them at EU level but which, due to the current division of competences, cannot be made subject to binding EU legislation. Corresponding amendments to the European treaties should be debated at the Conference on the Future of Europe.

[54] See altogether cepInput Joint Clinical Assessment of Health Technologies, p. 11.
[55] Rossi, in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 352 TFEU, para. 89.
[56] Rossi, in: Calliess/Ruffert (Hg.), EUV/AEUV, 5th Edn. 2016, Art. 352 TFEU, para. 89. See also Fehling, M., "Gesetzgebungskompetenzen im Verfassungsrecht und im Unionsrecht", in: JURA (2016), p. 505 et seq.

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