vfa. Die forschenden Pharma-Unternehmen
Research-Based Pharmaceutical Companies

# Comment on the commission implementing regulation (EU) joint clinical assessment

## Key asks

- Improve the involvement of health technology developers to promote high quality assessments.
- Ensure a workable process with more predictability for health technology developers.
- Strengthen the protection of commercially confidential information.

## Introduction

The introduction of the Joint Clinical Assessment is intended to improve the availability of innovative therapies in the EU, reduce the bureaucratic burden for HTA authorities and health technology developers and should aim to achieve the highest level of quality of the assessment. Germany's Association of Research-Based Pharmaceutical Companies (vfa) has clear expectations regarding the implementation of the EU HTA Regulation. These revolve around establishing a predictable, workable, and efficient process, characterized by reduced bureaucracy. Such measures are aimed at fostering competitiveness within the sector.

The European Commission has presented the draft of the implementing regulation that lays down procedural rules for the joint clinical assessments of medicinal products for human use at the Union level for public consultation.

Vfa is concerned that the industry's expectations are not met. The implementation carries considerable risks due to a process that is little predictable, hardly workable, and not very efficient. This process restricts the fundamental rights of health technology developers to be heard, receive good administration, or protect commercially confidential information. The heightened bureaucracy will inevitably impact competitiveness, while lax regulations regarding the protection of trade secrets will undermine trust in the European process. Thereby, potentially jeopardizing Germany's, as well as the EU's attractiveness as a location for the pharmaceutical industry.

To achieve a predictable, workable, and efficient process safeguarding procedural rights of health technology developers with strong protection of trade secrets the following key recommendations must be considered:

- The HTA secretariat should always invite the health technology developer to provide further information relevant for the development of the assessment scope, including their view on the assessment scope (Article 2(3)).
- The HTA secretariat should share the input of Member States to the assessment scope proposal with the health technology developer (Article 9(3)).
- The HTA secretariat should share the consolidated assessment scope proposal with the health technology developer and give it the opportunity to provide input (Article 9(3)).
- The JCA Subgroup, should invite the health technology developer to provide their input during the assessment scope consolidation meeting (Article 10(1)).
- The HTA secretariat should always invite the health technology developer to an assessment scope explanation meeting no later than 10 days from the day on which the JCA Subgroup finalises the assessment scope (Article 11).
- The deadline to submit the dossier should be extended to 135 days (4.5 months) from the date of the notification of the first request to the health technology developer (Article 12(2)).

- A joint dossier advice should be implemented, to provide the health technology developer with the possibility to receive advice on the scope ahead of application for a marketing authorisation, thereby increasing predictability of the dossier submission process.
- The deadline to which the health technology developer should signal technical or factual inaccuracies and confidential information should be extended to 14 days from the date on which it received the revised draft joint clinical assessment and summary reports (Article 14(4)).
- To overcome the hurdles related to changes to therapeutic indications, the interaction between assessors and health technology developers should be strengthened and the deadline for submitting an updated dossier made more flexible (Article 16(1), 16(4)).
- The Commission should not publish the underlying documentation of the dossier of the health technology developer that contains confidential information (Article 20).
- The Commission should consider the views of the health technology developer on commercially confidential information and provide a conflict resolution mechanism (Article 20).

## On Article 2, Relevant information for the development of the assessment scope

### Regulation

Health technology developers shall provide the HTA secretariat with relevant information for developing the assessment scope of a joint clinical assessment of medicinal products. That information shall consist of: (a) the summary of the product characteristics proposed by the applicant; (b) the clinical overview section of the submission file to the European Medicines Agency (Article 2(1), 2(2)). If the JCA Subgroup considers it necessary, the HTA secretariat shall invite the health technology developer to provide further information relevant for the development of the assessment scope in a meeting with the JCA Subgroup or in writing (Article 2(3)).

### Comments

The development of the assessment scope is an essential element of the joint clinical assessment to ensure a high quality. The Regulation (EU) 2021/2282 (Article 8(6)) outlines that the scoping process includes details on the population, intervention, comparator, and outcomes (PICO), as well as information to be provided by the health technology developers and input from patient and clinical experts. The information provided by the health technology developers according to Article 2(1) and 2(2), i.e. the summary of the product characteristics proposed and the clinical overview section of the submission file to the European Medicines Agency are important inputs to the development of the assessment scope.

However, this input is not sufficient. For the joint work aiming to achieve the highest level of quality, the full range of the information of the health technology developer must be utilized. The health technology developer is uniquely placed to provide further information on its own technology, clinical trials, and availability of relevant data. Furthermore, they have a great overview about the disease, treatment practice across Member States and where the new technology is likely to be used in clinical practice, as well as insights on the burden of disease and important outcomes for patients and clinicians. As such, the health technology developer can easily provide information about the base-case PICO(s) as input for the development of the assessment scope based on empirical data on which patients are most likely to receive the new technology.

The inclusion of this information in the development of the assessment scope promotes a high-quality assessment. It may also contribute to a more streamlined scope, less complexity of the data requests and more workable process of dossier preparation (cf., On Article 12, Dossier and further data for joint clinical assessment provided by the health technology developer).

The importance of considering further information relevant for the development of the assessment scope is reflected in the provisions of Article 2(3). However, the provisions do not ensure that the information is considered systematically and in indiscriminatory manner, as the JCA Subgroups decides about the invitation to provide further information without objective and transparent criteria.

This is not in line with Regulation (EU) 2021/2282 (Article 8(6)), which provides that the development of the scope should include information provided by the health technology developers without further restrictions of access. It contradicts the fundamental principle of good administration (Art. 41 EU-Charta). In any event, it is not permissible to discriminate against applicants by granting procedural support just to a selected group of applicants while refusing such support to others.

Vfa has strong concerns that health technology developers will be treated unfairly under this regulation. Hence, vfa strongly recommends that the health technology developer is always invited to provide further information. Specifically, the health technology developers should be invited to provide the information about their view on the assessment scope. The provision and inclusion of this information in the development of the assessment scope promotes a high-quality dossier and assessment.

**Recommendation**

Article 2(3): The HTA secretariat should always invite the health technology developer to provide further information relevant for the development of the assessment scope, including the view of the health technology developer on the assessment scope.

## On Article 3, Exchange of information with the European Medicines Agency

**Regulation**

During the centralised procedure for medicinal products subject to a joint clinical assessment, the European Medicines Agency shall inform the HTA secretariat of (a) updates on steps in the centralised procedure, including changes in the envisaged timelines; (b) substantial questions or outstanding issues that might impact the therapeutic indication(s) of the medicinal products proposed by the applicant. The main steps for the exchange of the information, as well as the exact content of the information to be communicated at those steps, shall be agreed upon by the European Medicines Agency, the HTA secretariat and the JCA Subgroup (Article 3(4)).

**Comments**

The health technology developer is an important contributor in the joint clinical assessment process, essential for its success. To successfully contribute to the process, the health technology developer needs information from the European Medicines Agency (EMA) that is shared with the HTA secretariat. This enables health technology developers to prepare in due time their response to questions that might impact the therapeutic indication(s) or alters the envisaged timelines.

Therefore, any information from the EMA regarding changes in the envisaged timelines of the authorisation process and substantial questions or outstanding issues that might impact the therapeutic indication(s) should be communicated to the health technology developer. Not sharing the information with the health technology developer, would carry large risks of delay of the joint clinical assessment process, low quality assessments with limited usefulness for Member States.

The draft implementing regulation proposes that the main steps for the exchange of the information, as well as the exact content of the information to be communicated at those steps shall be agreed upon by the European Medicines Agency, the HTA secretariat and the JCA Subgroup. However, in view of the importance the health technology developers for process integrity, the health technology developers should be considered.

**Recommendation**

Article 3(4): The HTA secretariat should inform the health technology developer of the information received from the European Medicines Agency.

Article 3(4): The main steps for the exchange of the information, as well as the exact content of the information to be communicated at those steps, should be agreed upon by the European Medicines Agency, the HTA secretariat and the JCA Subgroup, and

should consider input from health technology developers.

## On Article 9 + 10, Assessment scope proposal + Finalization of the assessment scope

**Regulation**
The assessors prepare the assessment scope proposal considering the information provided by the health technology developer and input from the patients, clinical experts, and other experts (Article 9(1)). The assessors prepare a consolidated assessment scope proposal reflecting the member state's needs (Article 9(2)). Patients, clinical experts, and other experts are given the opportunity to provide input to the consolidated assessment scope proposal (Article 9(3). They may be invited to provide their input during a dedicated part of the assessment scope consolidation meeting (Article 10(1)).

**Comments**
According to Regulation (EU) 2021/2282 (Article 8(6)), the scoping process shall consider information provided by the health technology developer and input received from patients, clinical experts, and other experts. The Joint work should be produced following the principle of good administrative practice (Recital 12, Regulation (EU) 2021/2282).

However, while patients, clinical experts, and other experts are given the opportunity to provide input to the consolidated assessment scope proposal and may be invited to the assessment scope consolidation meeting, health technology developers are not given the same possibility and are excluded from the process of finalizing the assessment scope.

This provision is not in line with the principle of good administration (Art. 41 EU Charter), which the European Court of Justice has repeatedly recognised as a general legal principle in its established jurisprudence even before the EU Charter came into force. This includes the right to be heard (Art. 42(2) EU Charta), which is inadmissibly impaired with these provisions. It is important to note that the right to be heard goes beyond the mere technical possibility to give general views or comments during an administrative process. The health technology developer must have the possibility to effectively make known its views on the correctness and relevance of the facts and circumstances which are subject matter of an administrative procedure. This is precisely what is lacking in the proposed regulation, as the health technology developer is not given the possibility to effectively comment on important provisions of the process (i.e. the consolidated assessment scope proposal) that may have an essential impact on the result of the joint clinical assessment.

To avoid this infringement of fundamental EU-law, the health technology developer should be included in the process of finalizing the assessment scope.

**Recommendation**

Article 9(3): The HTA secretariat should share the consolidated assessment scope proposal with the health technology developer and patients, clinical experts and other relevant experts and give them the opportunity to provide input.

Article 10(1): The JCA Subgroup should invite the health technology developer and patients, clinical experts, and other relevant experts to provide their input during the assessment scope consolidation meeting.

## On Article 11, Assessment scope explanation meeting

**Regulation**
If the JCA Subgroup considers it necessary, the HTA secretariat shall invite the health technology developer to an assessment scope explanation meeting with the JCA Subgroup. The meeting shall take place no later than 30 days from the day on which the JCA Subgroup finalises the assessment scope.

**Comments**
The assessment scope explanation meeting is a very important instrument to ensure the high

quality of the dossier and the smooth conduct of the joint clinical assessment. The meeting provides the opportunity for both, health technology developers and assessors, to clarify requests and expectations on the desired scope and contents of the assessment. Importantly, it potentially reduces requests for further (missing) information and minimises the risk that a submitted dossier will be deemed incomplete later.

Given the importance of the meeting, it is incomprehensible why it is not offered to all health technology developers alike, but instead depends on the JCA Subgroups decision about its necessity. Further, the regulation cannot make sure that the invitation of the explanation meeting is issued systematically and in indiscriminatory manner, as the JCA Subgroups decides about the invitation without any objective, transparent criteria. The regulation invites for its arbitrary application, thus raising concerns about unfair treatment of health technology developers under this regulation.

Procedural rights of all health technology developers must be respected without discrimination, even in the face of possible capacity limitations of administrative bodies. It is not permissible to discriminate against health technology developers by granting procedural support just to a selected group of health technology developers while refusing such support to others out of capacity reasons.

To avoid the infringement, the health technology developer should be always invited to an assessment scope explanation meeting with the JCA Subgroup. Further, the meeting shall take place earlier, i.e., no later than 10 days from the day on which the JCA Subgroup finalises the assessment scope, to ensure the full positive effect of the instrument. Providing the assessment scope explanation meeting to all health technology developers will promote high-quality dossiers and assessments.

**Recommendation**

The HTA secretariat should always invite the health technology developer to an assessment scope explanation meeting with the JCA Subgroup. The meeting should take place no later than 10 days from the day on which the JCA Subgroup finalises the assessment scope.

## On Article 12, Dossier and further data for joint clinical assessment provided by the health technology developer

### Regulation

The deadline to submit the dossier shall be 90 days from the date of the notification of the first request to the health technology developer. The deadline shall be 60 days for applications for a marketing authorisation under the accelerated procedure and the joint clinical assessment, for which a variation to the terms of an existing marketing authorisation corresponds to a new therapeutic indication (Article 12(2)).

### Comments

The health technology developer must submit a dossier, as well as additional information, data, analyses, and other evidence for joint clinical assessment, in accordance with the template in Annex I of the draft regulation. This template holds extensive requirements.

Together with the extensive dossier template, the assessment scope reflecting the Member State's needs, result in an extremely complex assessment process. According to EUnetHTA21 exercises and industry experts' investigations large numbers of PICO (range: 5 to 26) are expected to be part of the assessment scope. The large scope creates the potential for very large sets of data analyses in submission dossiers. Health technology developers cannot reliably predict the final scope, which creates substantial uncertainty and complexity. Unlike the German health technology assessment process, Regulation (EU) 2021/2282 does not incorporate a procedure for dossier advice ahead of application for a marketing authorisation. However, such a procedure would substantially reduce complexity and increase the predictability for the health technology developers.

Given these complexities of the dossier and shortcomings of Regulation (EU) 2021/2282 regarding

the lack of provision of a joint dossier advice, one of the most important success factors for health technology developers is sufficient time for dossier preparation. However, the provisions of 90 and 60 days are clearly unfeasible and carry large risks for low-quality or even incomplete dossiers. According to the vfa survey, experience shows that the dossier preparation for the German Health Technology Assessment procedure takes between 9 and 12 months for marketing authorisation applications of new products and new indications. Rule of procedures in Germany provide 3 months (plus 2 months for dossier advice), relating only to update assessments that are generally characterised by higher predictability and less complexity.

Thus, more time is required to ensure a high-quality dossier. The time should be extended to 135 days (4.5 months). This may be accomplished by allocating the timelines between health technology developer and assessors more fairly, as the proposed provisions clearly favour the assessors. The time for the accelerated marketing authorisation procedure and the authorisation procedure corresponding to a new therapeutic indication should be extended to 90 days. A longer preparation time for the dossiers promotes the quality of dossiers and facilitates high-quality joint clinical assessment processes for the assessors.

To reduce complexity, an alignment of common evidence requirements should be sought, focusing on what is common to the Member States. This process should consider the view of the health technology developer on the assessment scope (cf., On Article 2, Relevant information for the development of the assessment scope). This may contribute to a more streamlined scope, less complexity of the data requests and more workable process of dossier preparation, while promoting higher quality of the assessment.

Further, to increase predictability, the health technology developer should be timely informed about the input of Member States to the assessment scope proposal (Article 9(3)).

Furthermore, a joint dossier advice should be implemented, providing the possibility for advice ahead of application for a marketing authorisation.

**Recommendation**

Article 12(2): The deadline to submit the dossier should be 135 days (4.5 months) from the date of the notification of the first request to the health technology developer and 90 days for the accelerated or new therapeutic indication marketing authorisation procedure.

Article 9(3): The HTA secretariat should share the input of Member States to the assessment scope proposal with the health technology developer.

A joint dossier advice should be implemented, providing the possibility for the health technology developer to receive advice on the scope ahead of application for a marketing authorisation.

## On Article 14, Draft joint clinical assessment and summary reports (Factual accuracy check)

**Regulation**

The health technology developer shall signal any purely technical or factual inaccuracies and any information it considers to be confidential within 7 days from the date on which it received the revised draft joint clinical assessment and summary reports. The health technology developer shall demonstrate the commercially sensitive nature of the information it considers to be confidential. The deadline shall be 5 days for the accelerated marketing authorisation procedure, for a marketing authorisation which corresponds to a new therapeutic indication, and in case of changes to the therapeutic indication (Article 14(4)).

**Comments**

According to Regulation (EU) 2021/2282, the joint clinical assessment should be factual and include a description of the relative effects observed for the health outcomes analysed, including numerical results and confidence intervals, and an

analysis of scientific uncertainty and strengths and limitations of the evidence (for example, internal and external validity) (Recital 28). The health technology developer shall signal any purely technical or factual inaccuracies and shall not provide any comments on the results of the draft assessment (Article 11(5), Regulation (EU) 2021/2282). Thus, while the health technology developer should not comment on the results of the draft assessment (e.g., the assessment result of the degree of certainty of the relative effects), it should comment on inaccuracies that relate to the technical and factual basis of this assessment.

The factual basis relates to medical, scientific, and statistical information, data, analyses, other evidence, and methods used in the draft assessment. In view of the broad factual basis of the assessment, the factual accuracy check by the health technology developer is a time-consuming task, especially as it may also include comments on deviations from medical, scientific, and statistical conventions or standards. Health technology developers need sufficient time for these comments. The proposed 7 days is clearly insufficient and restricts the health technology developers right to be heard (Art. 42 para. 2 EU-Charta). Germany's rules of procedures for the health technology assessment process allow for a 3-week possibility to comment on the draft assessment with similar scope. Health technology developers need at least 14 days for factual accuracy check (or 10 days, e.g., for the accelerated marketing authorisation procedure).

The proposed 7 days are also insufficient regarding the possibility for the health technology developer to demonstrate the commercially sensitive nature of the information it considers to be confidential. The right of the health technology developer to protect business and trade secrets should not be restricted by providing too little time to comment. Health technology developers need at least 14 days (or 10 days) for demonstrating the commercially sensitive nature of the information.

**Recommendation**

Article 14(4): The deadline to which the health technology developer should signal any technical or factual inaccuracies and any information it considers to be confidential should be 14 days from the date on which it received the revised draft joint clinical assessment and summary reports.

Article 14(4): The deadline should be 10 days for the accelerated marketing authorisation procedure, for a marketing authorisation which corresponds to a new therapeutic indication, and in case of changes to the therapeutic indication.

## On Article 16, Changes to the therapeutic indication(s)

**Regulation**

Where during the centralised procedure, there is a change of the therapeutic indication(s) initially submitted to the European Medicines Agency that affects the assessment scope, the HTA secretariat shall inform the health technology developer of the new assessment scope and shall request the health technology developer to submit an updated dossier. The deadline shall be set at minimum 7 days and maximum 30 days counting from the date of notification of the request to the health technology developer (Article 16(1), 16(4)).

**Comments**

Changes to therapeutic indications can have a strong impact on the clinical assessment as these changes can affect the assessment scope and data requests can substantially change. According to a vfa survey, in approximately 8 to 12 % of the assessment procedures in Germany, changes in label occur that lead to a substantial change in data requirements. To overcome this hurdle in the interest of producing a high-quality joint clinical assessment report, the interaction between assessors and health technology developers needs to be strengthened and the deadline for submitting an updated dossier should be more flexible.

Specifically, the assessors should organise a meeting with the European Medicines Agency and health technology developer to assess whether that change affects the assessment scope and to discuss an updated project plan for the assessment. Further, a maximum of 30 days to prepare

a full dossier after change of scope is not possible. Hence, the HTA secretariat should have the possibility to extend the deadline beyond 30 days, considering the timetable for the evaluation and the outcomes of the meeting. Allowing a pragmatic approach with more interaction and flexibility are success factors in handling the difficult situation and to ensure a joint clinical assessment report useful for Member States.

**Recommendation**

Article 16(1): Where, there is a change of the therapeutic indication(s), the assessor, should organise a meeting with the European Medicines Agency and health technology developer to assess whether that change affects the assessment scope, to discuss an updated project plan for the assessment, and inform the JCA Subgroup.

Article 16(4): The HTA secretariat should be able to extend the deadline referred to in Article 12(5), considering the timetable for the evaluation and the outcomes of the meeting.

## On Article 20, Confidentiality request

**Regulation**

The Commission shall publish the joint clinical assessment and summary reports, together with other documentation listed in Article 30(3), points (d) and (i) of Regulation (EU) 2021/2282, thereof, after having considered the views of the JCA Subgroup as to the commercially sensitive nature of the information contained in that documentation, which the health technology developer has requested to be treated as confidential.

With reference to Regulation (EU) 2021/2282, the Commission thus shall publish the dossier of the health technology developer (Article 10(2)) including the underlying documentation (Article 9(3) point (d)). Annex I of the proposed implementing Regulation outlines the template of the dossier of the joint clinical assessment for medicinal products, thereby specifying "Appendix D. Underlying documentation" that contains amongst others:

- D.4. Study reports for original clinical studies, including study protocols and statistical analysis plans,
- D.6. Clinical safety and efficacy data included in the submission file to the EMA, i.e., Modules 2.5, 2.7.3 and 2.7.4 of the CTD (format of submission to the EMA) and CSRs,
- D.9. Information on Joint Scientific Consultations.

**Comments**

The proposed regulation provides that the commission should publish the dossier of the health technology developer including the underlying documentation. The underlying documentation's purpose is clearly designated in Regulation (EU) 2021/2282, as to allow the assessor and co-assessor to verify the accuracy of the dossier contents. This purpose can be fulfilled without publishing it. However, the draft implementing regulation includes the publication of the underlying documentation.

Commercially confidential information in the documentation must be protected. According to the definition of the EMA, commercially confidential information refers to any information contained in the clinical reports submitted to EMA by the applicant which is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant. This includes the following aspects: trade secrets (including e.g. formulas, programs, process, or information contained or embodied in a product, unpublished aspects of trademarks, patents, etc), structures, chemical analytics, development plans of a company, and pricing details.

The underlying documentation contains many documents that are highly likely to contain commercially confidential information. Especially the study reports for original clinical studies, including study protocols and statistical analysis plans, the CTD documents of the submission to EMA, and importantly, the documentation on joint scientific consultations may contain many commercially confidential information. Documents related to joint scientific consultations must be seen

confidential in their entirety, as they reveal the development plans of a company. Methodological aspects of the study design and respective clinical analyses can be part of these developmental plans. Thus, study reports, protocols and statistical analyses plans may contain methodological information and clinical data that must be therefore treated as commercially confidential information as they might reveal the global strategy decisions of the health technology developer.

It is paramount that the right of pharmaceutical companies for protection of their trade secrets legally protected by Directive EU 2016/943, is ensured. Trade secrets allow creators and innovators to derive profit from their innovation and, therefore, are particularly important for business competitiveness as well as for research and development, and innovation-related performance. Trade secrets are the currency of the innovative pharmaceutical industry (Directive (EU) 2016/943). Any breach of this protection or even uncertainties about the protection have potential detrimental effects on health technology developers' business models and the trustworthiness of the European Union's innovative pharma market, and can profoundly harm Germany, and the EU as a pharmaceutical industry location.

Given the paramount importance of protection of commercially confidential information for industry, the regulation should follow Germany's example, where strong protection is in place.

In Germany, the documents that are confidential for the company, i.e. in particular the underlying documentation in Module 5 of the German submission dossier, are not published. The German "Module 5" compares very much to "Appendix D. Underlying documentation" of Annex I of this regulation. Further, the dossier and the benefit assessment are only published to the extent that no marked trade and business secrets conflict with this (Rules of Procedure of the Federal Joint Committee). Still, the published information adheres to the principles of the assessment. This approach provides sufficient transparency whilst guaranteeing the protection of important business secrets.

The protection of commercially confidential information envisaged by the Commission in this Regulation is weak and leaves large uncertainty about the effectiveness of the mechanism of the protection. This is because the proposed regulation provides that the commission only considers the views of the JCA Subgroup on commercially confidential information, after the JCA Subgroup decided on the commercially sensitive nature of the information, that have been requested by the health technology developer. Therefore, commercially confidential information designated by the health technology developer might be published without giving the health technology developer the possibility to respond to opinions expressed by the JCA Subgroup regarding their classification. There is an urgent need for a process of meaningful interaction by which the health technology developer can effectively respond to the opinions of the assessors with a subsequent exchange on unresolved issues, to prevent trade secrets from being published. The process must also include a conflict resolution mechanism for cases where different opinions between the health technology developer and the assessors of the JCA Subgroup persist.

It is necessary that the decision on a disputed issue of confidentiality of information can be taken within the European framework (following established EU jurisprudence) and is not left to the individual judgement of the Member States. This means that uniform decision-making standards are required, which are applied by an independent European institution – the Commission – in the event of conflicting interests.

Vfa strongly recommends that the protection of confidential information, which is crucial for health technology developers, be given the necessary priority. This can be achieved through the standardised application of a specifically defined term, the protection of the procedural rights of health technology developers and the provision of a conflict resolution mechanism.

**Recommendation**

The Commission should not publish the underlying documentation of the dossier of the health technology developer that contains confidential information.

The Commission should consider the views of the health technology developer on commercially confidential information and provide a conflict resolution mechanism for disputed issues of confidentiality within a European framework.

The Commission should provide a definition of commercially confidential information.

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Version 28th March 2024