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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the assessment of written guarantees provided by the United Kingdom to the Commission pursuing Article 8 of Regulation (EU) 2023/1182 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 in Northern Ireland

CONTENTS

EXECUTIVE SUMMARY

Regulation (EU) 2023/1182 ([1]) applies to and in the United Kingdom in respect of Northern Ireland under the Windsor Framework ([2]) pursuant to Withdrawal Agreement Joint Committee Decision 2/2023 ([3]). Regulation (EU) 2023/1182 provides for specific rules for medicinal products for human use intended to be placed on the market in Northern Ireland. It implements the joint solutions reached in February 2023 between the European Commission and the Government of the United Kingdom to ensure the continuous supply of medicines to patients in Northern Ireland in the same way and at the same time as in the rest of the United Kingdom.

According to these rules, novel medicines ([4]) for the Northern Ireland market will be authorised in accordance with UK rules and UK authorisation procedures only. In addition, prescription medicines placed on the Northern Ireland market should not carry the safety features ([5]) (unique identifier/barcode) that are obligatory in the Union to prevent circulation of falsified medicines within the internal market so that they are easily distinguishable from those placed on the Union market.

Pursuant to Regulation (EU) 2023/1182, the United Kingdom must put in place appropriate safeguards to ensure that UK-authorised medicines do not end up on the market of any EU Member State. This includes the requirement that individual packs of all medicines placed on the Northern Ireland market bear a label indicating "UK only".

In this respect, pursuant to Article 8 of Regulation (EU) 2023/1182, the United Kingdom provided the Commission on 20 November 2024 with written guarantees that the placing on the market in Northern Ireland of medicinal products for human use as referred to in Article 1(1) of Regulation (EU) 2023/1182 does not increase the risk to public health in the internal

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([1]) Regulation (EU) 2023/1182 of the European Parliament and of the Council of 14 June 2023 on specific rules relating to medicinal products for human use intended to be placed on the market in Northern Ireland and amending Directive 2001/83/EC (OJ L 157, 20.6.2023, p. 1).

([2]) The Windsor Framework is the new way in which the Protocol on Ireland/Northern Ireland is referred to in accordance with Joint Declaration No 1/2023 of the Union and the United Kingdom in the Joint Committee established by 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 of 24 March 2023 (OJ L 102, 17.4.2023, p. 87).

([3]) Decision No 2/2023 of the Joint Committee established by 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 of 3 July 2023 adding two newly adopted Union acts to Annex 2 to the Windsor Framework (OJ L 184, 21.7.2023, p. 109).

([4]) "Novel medicines" in this context should be understood as medicines belonging to the categories referred to in Article 3(1) and (2) of 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).

([5]) "Safety features" as referred to in Article 54, point (o) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

market and that such medicinal products will not be moved to a Member State. They also include guarantees to that effect that economic operators comply with the specific labelling requirements provided for in Article 5 of Regulation (EU) 2023/1182 and that effective monitoring, enforcement and controls of the new specific rules set in Articles 3, 4 and 5 of Regulation (EU) 2023/1182 are in place and are carried out, by means of, inter alia, inspections and audits.

Pursuant to the second subparagraph of Article 14 of Regulation (EU) 2023/1182, the Regulation is to apply from 1 January 2025 ([6]), provided that the United Kingdom has provided the written guarantees referred to in Article 8 of that Regulation and that the Commission has published prior to that date a notice in the Official Journal of the European Union indicating the date from which the Regulation applies.

The Commission carried out its assessment based on the information included in the written guarantees and also considering the legal instruments and related guidance the United Kingdom has adopted and published in relation to the implementation of Regulation (EU) 2023/1182. On this basis it can be concluded that the measures presented in the written guarantees, if fully implemented, provide reasonable assurance as to their conformity with the requirements of Article 8 of Regulation (EU) 2023/1182.

[6] To be noted that, pursuant to Article 12 of Regulation (EU) 2023/1182, medicinal products that have been lawfully placed on the market in Northern Ireland before the date of application of that Regulation and that are not repackaged or relabelled after that date, may be further made available on the market in Northern Ireland until their expiry date without being required to comply with the specific rules laid down in Articles 3, 4 and 5 of that Regulation.

1. INTRODUCTION AND LEGAL FRAMEWORK

Regulation (EU) 2023/1182 applies to and in the United Kingdom in respect of Northern Ireland under the Windsor Framework and provides that novel medicines will be authorised and placed on the market in Northern Ireland in accordance with UK rules and UK authorisation procedures only. In order to easily distinguish the prescription medicines placed on the Northern Ireland market from those placed on the Union market, medicines placed on the Northern Ireland market should not carry the safety features (unique identifier/barcode) that are obligatory in the Union to prevent entry of falsified medicines into the supply chains.

The new rules go hand in hand with **appropriate safeguards** to ensure that UK-authorised medicines do not end up on the market of any EU Member State. Individual packs of all medicines placed on the Northern Ireland market should thus bear a label indicating "UK only" and the competent authority in the United Kingdom should continuously monitor their placing on the Northern Ireland market. The Commission will monitor the application of the rules by the United Kingdom and take appropriate measures in case of non-compliance.

In accordance with Article 8 of Regulation (EU) 2023/1182, the United Kingdom is to provide the Commission with written guarantees that the placing on the market of medicinal products does not increase the risk to public health in the internal market and that such medicinal products will not be moved to a Member State, including guarantees to the effect that:

(a) economic operators comply with the labelling requirements laid down in Article 5 of the Regulation;

(b) effective monitoring, enforcement and controls of the new specific rules in Articles 3, 4 and 5 of the Regulation are in place and are carried out, by means of, *inter alia*, inspections and audits.

In accordance with Article 14(4) of Regulation (EU) 2023/1182, the Commission is to provide the European Parliament and the Council with its assessment of these guarantees within one month from their submission.

On 20 November 2024, the United Kingdom provided to the Commission the written guarantees referred to in Article 8 of Regulation (EU) 2023/1182. This report provides the European Parliament and the Council with the Commission's assessment of these guarantees. The Commission carried out its assessment based on the information included in the written guarantees and also considering the legal instruments and related guidance the United Kingdom has adopted in relation to the implementation of Regulation (EU) 2023/1182.

2. ASSESSMENT OF THE WRITTEN GUARANTEES

The written guarantees submitted by the United Kingdom are structured in three key parts which are being analysed in turn in the following subsections.

In the introduction to the guarantees, the United Kingdom outlines the division of responsibilities and working arrangements between the relevant governmental departments responsible for the implementation and the enforcement of the rules applicable to medicinal products for human use as referred to in Article 1(1) of Regulation (EU) 2023/1182. These

involve the Department of Health and Social Care ("DHSC"), the Medicines and Healthcare Products Regulatory Agency ("MHRA") and the Medicines Regulatory Group ("MRG"), which is part of the Department of Health ("DOH") in the Northern Ireland Executive.

In accordance with Article 7 of Regulation (EU) 2023/1182, in its written guarantees, the United Kingdom refers to existing safeguards in the UK Human Medicines Regulation 2012 ([7]) which ensure that medicinal products for human use intended to be placed on the market in Northern Ireland will not be moved or placed on the market in a Member State. In accordance with the UK Human Medicines Regulation 2012, UK operators would also need to further act in compliance with Good Manufacturing Practice, Good Distribution Practice and the Marketing Authorisation (Regulations 37, 43 and 46). For companies with valid licences in Northern Ireland, the UK Human Medicines Regulation 2012 would require compliance with the EU principles and guidelines on Good Distribution Practice for medicinal products as laid down in Article 84 of Directive 2001/83/EC. The UK Human Medicines Regulation 2012 would also require wholesalers to take the appropriate measures to ensure that medicinal products authorised according to UK law do not enter the Union market. The Commission considers that these safeguards are adequate and necessary to ensure that UK authorised medicines will not be moved to the market of any EU Member State as provided for in Article 7(1) of Regulation (EU) 2023/1182.

2.1. Guarantees as regards Article 5 of Regulation (EU) 2023/1182

This section addresses specifically the measures presented in the written guarantees to ensure application of the specific labelling requirements for medicinal products for human use intended to be placed on the market in Northern Ireland laid down in paragraphs (a) and (b) of Article 5 of the Regulation.

Article 5

Specific rules for the labelling of medicinal products as referred to in Article 1(1)

Medicinal products as referred to in Article 1(1) shall bear an individual label that complies with the following requirements:

(a) it shall be attached to the packaging of the medicinal product in a conspicuous place in such a way that it is easily visible, clearly legible, and indelible; it shall not in any way be hidden, obscured, detracted from, or interrupted by any other written or pictorial matter or any other intervening material;

(b) it shall state the words 'UK only'.

The Commission acknowledges that the written guarantees confirm that, according to the UK Human Medicines Regulation 2012, the inclusion of a "UK only" statement on the labelling on all medicines for human use placed on the market in Northern Ireland is a legal requirement applicable from 1 January 2025. It seems to be proportional that the United

([7]) The Human Medicines (Amendments relating to the Windsor Framework) Regulations 2024 (https://www.legislation.gov.uk/uksi/2024/832/contents/made).

Kingdom would allow a limited transition period of 6 months until 30 June 2025, during which the application of the "UK only" label could take the form of an indelible sticker compliant with the requirements set out in Article 5 of Regulation (EU) 2023/1182. After 30 June 2025, it would be mandatory for the "UK only" statement to be printed directly onto the packaging and the use of an indelible sticker would no longer be allowed. The written guarantees state that compliance with the requirements set out in Article 5 of Regulation (EU) 2023/1182 will be subject to effective monitoring, enforcement, and controls by the United Kingdom.

The written guarantees outline several measures to support compliance with the specific rules for the labelling of medicinal products for human use. They also provide information on regulatory oversight processes and on inspections and controls.

As part of the measures to support compliance, the written guarantees mention that guidance relating to labelling and packaging requirements has been published for the purpose of supporting industry compliance. ([8])

Moreover, the written guarantees also provide that, before implementing any changes to labelling or packaging, companies must notify the MHRA before 31 December 2024 of all intended artwork changes, the compliance of which with legal requirements will be checked by the MHRA. The written guarantees describe three regulatory options for companies to notify the MHRA of updates to the labelling or packaging:

1. a submission of the intended artwork changes together with and in the framework of another application (such as a variation) and implementation of artworks after formal approval;

2. a submission of a separate self-certification notification, allowing the marketing authorisation holder (MAH) to implement the proposed and submitted changes before receiving formal approval from the authority, before 1 January 2025;

3. a submission of a self-certification notification without initial update of the Electronic Common Technical Document (eCTD) by 31 December 2024, and submission of an updated eCTD sequence until 31 December 2025.

The progress of submission of these labelling changes would be monitored by the MHRA to identify cases of non-compliance after 1 January 2025 for further investigation and corrective regulatory action as necessary.

The Commission acknowledges that the MHRA's GMP inspections and control programme would be updated from 1 January 2025 to include the new labelling requirements set in

([8]) Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework).

Regulation (EU) 2023/1182. Good Manufacturing Practice / Good Distribution Practice (GMDP) inspections of pharmaceutical wholesalers, manufacturers and importers in Northern Ireland would be carried out by the MHRA. The MRG would inspect also other entities at the end of the medicinal product supply chain such as community and hospital pharmacies, private hospitals, and UK National Health Service (NHS) hospitals. Inspections would follow a risk-based approach and focus on change management, which includes the new specific labelling rules set in Article 5 of Regulation (EU) 2023/1182. The MHRA would further follow-up with and monitor economic operators who have not submitted the artwork changes. Should deviations be identified, the MHRA would inform the MRG and follow up with the respective economic operator requiring compliance actions, conduct follow-up inspections or suspend the authorisation should there be persisting non-compliance. The DOH would also provide assurances to the MHRA that appropriate monitoring and enforcement controls are in place as required by law, to ensure compliance with Article 5 of Regulation (EU) 2023/1182, in areas that are within DOH's responsibility. With regard to inspectors, the MHRA would provide relevant training to inspectors to assess compliance with Regulation (EU) 2023/1182 by 1 January 2025.

In view of the above guarantees provided by the United Kingdom with respect to the specific labelling rules for medicinal products for human use intended to be placed on the market in Northern Ireland set out in Article 5 of Regulation (EU) 2023/1182, the Commission considers that the measures taken by the United Kingdom address appropriately all the relevant aspects of Article 5 given that the required legal measures have been taken , adequate guidance to all concerned stakeholders has been published and appropriate procedures to ensure the update/introduction of the artworks are in place. In this respect, the provided guarantees therefore seem to be adequate to ensure that economic operators comply with those requirements, in line with the objectives set out in Article 8 of Regulation (EU) 2023/1182. Also, effective monitoring, enforcement and controls of the specific rules laid down in Article 5 are in place and are carried out, by means of, inter alia, inspections and audits.

2.2. Guarantees as regards Article 3 of Regulation (EU) 2023/1182

This section addresses specifically the measures presented in the written guarantees to comply with the requirement that effective monitoring, enforcement and controls of the specific rules laid down in Article 3 of Regulation (EU) 2023/1182 are in place and are carried out, by means of, inter alia, inspections and audits, including to ensure that the safety features referred to in Article 54, point (o), of Directive 2001/83/EC do not appear on the outer packaging or, where there is no outer packaging, on the immediate packaging of medicinal products placed on the market in Northern Ireland, as referred to in Article 3 of Regulation (EU) 2023/1182.

Article 3

Specific rules for medicinal products as referred to in Article 1(1)

1. The competent authorities of the United Kingdom in respect of Northern Ireland may allow medicinal products as referred to in Article 1(1) of this Regulation to 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, provided that the conditions laid down in Article 40(1a), first subparagraph, points (a) to (d), of Directive 2001/83/EC are fulfilled.

2. The safety features referred to in Article 54, point (o), of Directive 2001/83/EC shall not appear on the outer packaging or, where there is no outer packaging, on the immediate packaging of medicinal products as referred to in Article 1(1) of this Regulation.

3. Where a medicinal product as referred to in Article 1(1) of this Regulation bears the safety features referred to in Article 54, point (o), of Directive 2001/83/EC, those features shall be fully removed or covered.

4. The qualified person referred to in Article 48 of Directive 2001/83/EC shall, in the case of a medicinal product as referred to in Article 1(1) of this Regulation, ensure that the safety features referred to in Article 54, point (o), of that Directive have not been affixed on the packaging of the medicinal product.

5. Holders of a wholesale distribution authorisation shall not be required to:

(a) verify medicinal products as referred to in Article 1(1) of this Regulation in accordance with Article 80, first paragraph, point (ca), of Directive 2001/83/EC;

(b) keep records as regards the information referred to in Article 80, first paragraph, point (e), last indent, of Directive 2001/83/EC.

6. For all supplies of medicinal products as referred to in Article 1(1) of this Regulation to a person authorised or entitled to supply medicinal products to the public, as referred to in Article 82 of Directive 2001/83/EC, as regards the United Kingdom in respect of Northern Ireland, the authorised wholesaler shall not be required to enclose a document that makes it possible to ascertain the batch number of the medicinal products in accordance with Article 82, first paragraph, last indent, of that Directive.

According to the written guarantees, pursuant to the revised UK Human Medicines Regulations 2012, as of 1 January 2025, safety features within the meaning of Article 54, point (o), of Directive 2001/83/EC will be prohibited on the outer packaging or, where there is no outer packaging, on the immediate packaging of medicinal products. Any features included for the purposes of compliance with EU Falsified Medicines Directive (EU FMD) requirements would have to be removed or covered. MAHs would have to update their artwork accordingly at the next regulatory opportunity.

The European Medicines Verification Organisation (EMVO) would disconnect the UK(NI) National Medicines Verification System (NMVS) from the European Medicines Verification System (EMVS) on 1 January 2025 and SecurMed (UK(NI) Medicines Verification Organisation) would decommission the UK(NI) NMVS on the same date. As all data for historically uploaded UK packs will be deleted and no longer accessible in the system, any attempt to scan a historic Northern Ireland pack elsewhere in the Union should return an error message.

In this respect, packs released after 1 January 2025 should not carry a barcode that is recognised by the Union system, and any such code present would need to be fully removed or covered, in line with the relevant guidance published by the MHRA. ([9]) The MHRA has also published appropriate guidance on the legal obligations for Qualified Persons in this respect. ([10])

Pharmaceutical wholesalers and manufacturers in Northern Ireland would be inspected by GMDP inspectors to ensure the labelling requirements are met. Where deviations would be identified, compliance actions would be required by MHRA inspectors and MRG would be informed. Furthermore, MRG Inspectors would inspect other entities at the end of the supply chain such as community and hospital pharmacies, private hospitals and NHS hospitals. Part of these visits would assess medicines in stock and ensure that all medicines are appropriately labelled. Where deficiencies would be identified, corrective actions would be taken to ensure compliance, including seizure of non-compliant products. This information would be shared with the MHRA to ensure the integrity of the medicines supply chain and compliance with applicable Union Regulations.

The DOH would also provide assurances to the MHRA that appropriate monitoring and enforcement controls are in place as required by law, to ensure compliance with Article 3 of Regulation (EU) 2023/1182, in areas that are within DOH's responsibility.

In view of the above guarantees, the Commission considers the measures taken by the United Kingdom in respect of Northern Ireland adequate, as the appropriate legal measures have been taken, guidance has been published for stakeholders and appropriate procedures are in place to ensure that the Union safety features do not appear on the outer or immediate packaging of medicinal products or, where they appear, that they are fully removed or covered. This would ensure conformity with the specific rules set out in Article 3 of Regulation (EU) 2023/1182, which is necessary to effectively reach the public health aim pursued and to ensure that the medicinal products placed on the market in Northern Ireland are easily

([9]) Labelling and packaging of medicinal products for human use following agreement of the Windsor Framework (https://www.gov.uk/government/publications/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework/labelling-and-packaging-of-medicinal-products-for-human-use-following-agreement-of-the-windsor-framework).

([10]) Wholesalers & manufacturers guidance following agreement of the Windsor Framework (https://www.gov.uk/government/publications/wholesalers-manufacturers-guidance-following-agreement-of-the-windsor-framework/wholesalers-manufacturers-guidance-following-agreement-of-the-windsor-framework#guidance-for-qps).

distinguishable from those placed on the Union market, Also, effective monitoring, enforcement and controls of the specific rules laid down in Article 3 of Regulation (EU) 2023/1182 have been put in place and are carried out, by means of, inter alia, inspections and audits"

2.3. Guarantees as regards Article 4 of Regulation (EU) 2023/1182

This section addresses specifically the measures presented in the written guarantees to comply with the requirement that effective monitoring, enforcement and controls of the specific rules laid down in Article 4 of Regulation (EU) 2023/1182 are in place and are carried out, by means of, inter alia, inspections and audits.

Article 4

Specific rules for medicinal products as referred to in Article 1(1) of this Regulation belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004

1. A medicinal product as referred to in Article 1(1) of this Regulation belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004 that has been granted a marketing authorisation in accordance with Article 10 of that Regulation shall not be placed on the market in Northern Ireland.

2. Notwithstanding paragraph 1 of this Article, a medicinal product as referred to in Article 1(1) of this Regulation belonging to the categories referred to in Article 3(1) and (2) of Regulation (EC) No 726/2004 may be placed on the market in Northern Ireland provided that all of the following conditions are fulfilled:

(a) the competent authorities of the United Kingdom have authorised the placing on the market of the medicinal product in accordance with the law of the United Kingdom and under the terms of the authorisation granted by them;

(b) the medicinal product concerned is labelled in accordance with Article 5 of this Regulation;

(c) written guarantees are provided by the United Kingdom to the Commission in accordance with Article 8 of this Regulation.

The Commission notes that with the revision of the UK Human Medicines Regulation of 2012 the United Kingdom has taken the necessary measures to ensure that medicines falling within the scope of Regulation 726/2004 would be placed on the market in Northern Ireland only if they are authorised by the authorities of the United Kingdom.

The Commission acknowledges that, according to the written guarantees, the routine inspection programme would be updated to include compliance and enforcement actions that would be undertaken to ensure compliance with Good Manufacturing and Distribution Practices. In accordance with Article 4(1) of Regulation (EU) 2023/1182, medicinal products authorised under Union law would no longer be authorised for supply in Northern Ireland and

would have to comply with UK law as of 1 January 2025, which would be verified during routine GMDP inspections. Furthermore, the UK's inspections programme would be updated to include the requirements of Regulation (EU) 2023/1182 and inspectors would be trained to assess the implementation of these new requirements accordingly. The United Kingdom would include in their risk-rating of inspections a focus on MAH who have not changed their artwork with the "UK only" label and related requirements accordingly.

The written guarantees include several enforcement options should a breach of the applicable rules be identified during enforcement or inspections actions, which would be carried according to a risk-based approach. The Commission considers the proposed actions adequate and necessary. The United Kingdom reported that enforcement actions would be carried out in proportion to the potential harm or severity of the breach. These enforcement options would include written warnings, advice or guidance to the economic operator and implementation of an inspection programme at first instance. Should the economic operator fail to comply with the UK legislative requirements for medicinal products for human use and not take corrective actions, formal actions would be taken by involving Professional Regulatory bodies to decide on a potential prosecution.

In view of the above guarantees, the Commission considers that the measures taken by the United Kingdom in respect of Northern Ireland appear to provide for the effective monitoring, enforcement and controls of the specific rules laid down in Article 4 of Regulation (EU) 2023/1182 as the appropriate legal measures have been taken, related guidance has been published and appropriate procedures are in place.

3. CONCLUSION

The written guarantees submitted by the United Kingdom pursuant to Article 8 of Regulation (EU) 2023/1182 provide reasonable assurance that, subject to effective enforcement by the authorities of the United Kingdom, the placing on the market of medicinal products as referred to in Article 1(1) will not increase the risk to public health in the internal market and that such medicinal products will not be moved to a Member State.

The written guarantees also provide reasonable assurance that:

i. economic operators will comply with the labelling requirements laid down in Article 5 of Regulation (EU) 2023/1182;

ii. the safety features referred to in Article 54, point (o), of Directive 2001/83/EC will not appear on the outer packaging or, where there is no outer packaging, on the immediate packaging of medicinal products as referred to in Article 1(1) of Regulation (EU) 2023/1182.

iii. effective monitoring, enforcement and controls of the specific rules laid down in Articles 3, 4 and 5 of Regulation (EU) 2023/1182 will be in place and carried out, by means of, inter alia, inspections and audits.

As provided for in Article 9(1) of Regulation (EU) 2023/1182, the Commission will continuously monitor the application by the United Kingdom of the specific rules relating to

medicinal products for human use intended to be placed on the market in Northern Ireland, in particular those laid down in Articles 3, 4 and 5 of the Regulation. In this respect the United Kingdom has committed in the written guarantees to supply, upon request, relevant information related to the activities undertaken in support of the written guarantees.

Article 9 of Regulation (EU) 2023/1882 also provides for a specific mechanism to address any serious or repeated infringements of those specific rules and empowers the Commission to take appropriate measures if those infringements are not remedied.

In light of the above conclusions and in accordance with the fifth subparagraph of Article 14 of Regulation (EU) 2023/1182, the Commission will publish a notice in the Official Journal of the European Union indicating that the Regulation will apply as from 1 January 2025.