

**EXPLANATORY MEMORANDUM TO
THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) AMENDMENT
REGULATIONS 2006**

2006 No. 2984

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Medicines and Healthcare products Regulatory Agency/Department of Health and is laid before Parliament by Command of Her Majesty.
- 1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Description

- 2.1 These Regulations amend the Medicines for Human Use (Clinical Trials) Regulations 2004 to provide an exception to the general rule that incapacitated adults can only participate in trials after the consent of their legal representative (as defined) has been obtained. The exception will apply in the context of trials of emergency medicines only e.g. first line treatment of cardiac arrest or car crash victims. The amendment will facilitate research into potentially life-saving emergency medicines in the UK.

3. Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None

4. Legislative background

- 4.1 The Clinical Trials Directive (Directive 2001/20/EC) regulates clinical trials of medicines, including medicines under development, across the European Community. The Clinical Trials Regulations of 1 May 2004 implemented the Clinical Trials Directive in the UK. The Parliamentary Scrutiny Committees considered the Clinical Trials Directive before agreement was reached by the Council of Ministers in 2001.
- 4.2 Article 5 (a) of the Clinical Trials Directive contains the general requirement that an incapacitated adult cannot be included in a clinical trial without the consent of his/her legal representative. Article 5(a) was implemented in the UK by Schedule 1 to the Clinical Trials Regulations so as to preclude an incapacitated adult being included in a trial without prior consent of a legal representative in the UK. The Clinical Trials Regulations include a specific provision for establishing who should act as the legal representative.

4.3 These Regulations amend Schedule 1 and in doing so derogate from the general rule at Article 5(a) of the Directive. The amendment will allow incapacitated adults to be entered in to a trial prior to consent having been obtained from a legal representative in trials of emergency medicines where certain conditions are met. This derogation from article 5(a) is justified on the basis that:

- The title of the Directive shows that it relates “to the implementation of good clinical practice in the conduct of clinical trials” and its underlying purpose is clearly to ensure trials are conducted in accordance with “good clinical practice” (see Article 1(4)). This is a set of internationally recognised requirements to be reflected in principles and detailed guidelines to be adopted and published by the Commission (see Article 1(2) and (3)).
- It is Directive 2005/28/EC (the Good Clinical Practice Directive) which lays down those principles. At recital (8) it states that the International Conference on Harmonisation’s 1996 “Guideline for Good Clinical Practice” should be taken into account.
- This guideline was adopted by the Committee for Proprietary Medicinal Products in 1997 as applicable in Europe, and specifically envisages (at paragraph 4.8.15) that there will be emergency situations in which neither the trials subject’s consent nor that of a legal representative can be obtained. The guideline is clear that trials may take place in such circumstances so long as suitable safeguards are contained in the trial protocol to protect the subject, and are approved by the relevant ethics committee.

4.4 The approach is also consistent with Commission correspondence with the UK which sees emergency situations as being for Member State to make provisions for and strongly implies that they are outside the scope of the Clinical Trials Directive. The approach is also consistent with that taken by France, Germany, Italy, Spain and Sweden.

5. Territorial extent and application

5.1 This instrument applies to all of the United Kingdom and Northern Ireland.

6. European Convention on Human Rights

6.1 The Secretary of State for Health has made the following statement regarding human rights:

“In my view the provisions of the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 are compatible with the Convention rights.”

7. Policy background

- 7.1 Since 1 May 2004, clinical trials conducted in the European Union are regulated under the Clinical Trials Directive. The Clinical Trials Directive aims to harmonise the laws and administrative provisions of Member States in relation to the regulation of clinical trials on medicines. The Clinical Trials Directive requires that all clinical trials are designed, conducted and reported in accordance with good clinical practice. This is to ensure that the rights, safety and well-being of those participating in clinical trials are protected and that the results of those trials are credible.
- 7.2 Article 5(a) of that Directive requires that an incapacitated adult cannot be included in a clinical trial without the consent of his/her legal representative. After consultation with representatives of those conducting emergency research, the UK implemented the Directive without modifying the requirement that informed consent must be obtained from a patient, or from his or her legal representative, prior to participation in a clinical trial.
- 7.3 Since the implementing Regulations came into force on 1 May 2004, researchers conducting a large international trial in cardiac arrest (the TROICA trial) concluded that the scheme for establishing the legal representative and obtaining his or her consent is unworkable for clinical trials set in the context of emergency medicine.
- 7.4 In January 2005, Lord Warner notified Parliament of the Government's proposals to consult on amending the requirements of the Clinical Trials Regulations 2004 for consent in emergency situations.
- 7.5 In 2005, the MHRA/DH consulted on a proposal to amend the Regulations so that an incapacitated person could be entered into a clinical trial involving emergency treatment prior to consent being obtained from his or her legal representative provided that certain conditions were met, including the approval of an ethics committee. The consultation period closed on 24 October 2005. The consultation document was distributed to over 2000 stakeholders, including the NHS, ethics committees, hospital trusts, industry trade associations and patient associations.
- 7.6 159 responses were received, of which 58 made no comment; 29 said only that they supported the proposed amendment; and 72 provided specific comments, within which 47 expressed overall support and 5 expressed concerns about the ethical acceptability of the proposals.
- 7.7 An analysis of the consultation responses is contained in the regulatory impact assessment (RIA) which accompanies this document.
- 7.8 Information about the amendment will be published on the DH and MHRA websites. The DH will provide specific guidance on the areas

for which further clarification was sought during the consultation exercise in 2005.

7.9 The proposed amendment will provide an exception from the requirement for obtaining informed consent before an incapacitated adult is entered in to a clinical trial of emergency care medicines by deferring the informed consent requirement until it is reasonably practicable. While the amendment will be welcomed by researchers involved in emergency care medicine, it is possible that it will be viewed by some as reducing the level of protection afforded to an extremely vulnerable group of people (incapacitated adults in emergency situations). As a result, it is possible that there may be political interest in the amendment.

7.10 This exception to the requirement for prior consent would be consistent with the accepted international standards for conducting trials in emergency situations as set out in the International Conference on Harmonisation Guideline on Good Clinical Practice, and with the approach laid down in the Mental Capacity Act here in the UK.

8. Impact

8.1 A RIA is attached to this memorandum.

9. Contact

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REGULATORY IMPACT ASSESSMENT

1. TITLE OF PROPOSAL

Amendment of the Clinical Trials Regulations¹ as amended² (The Regulations) to allow clinical trials of emergency care for incapacitated adults.

2. PURPOSE AND INTENDED EFFECT OF MEASURE

(i) The objective

To amend the Regulations to allow clinical trials of emergency care for incapacitated adults by the addition of new regulations (the measure).

- (a) The amendments would allow the investigator or another member of the investigator's team to enter an incapacitated adult into a clinical trial without complying with the usual conditions of obtaining informed consent from the adult's legal representative. This exemption would be on condition that: (i) the nature of the trial requires urgent action, (ii) it is not reasonably practicable to meet the usual conditions in particular that the adult's legal representative has given informed consent and (iii) an ethics committee has given approval to the procedure under which action is taken.
- (b) When it is no longer necessary to take action as an as a matter of urgency this exemption would not apply and the usual conditions for obtaining informed consent would need to be met.

(ii) Background

- (a) The 2004 Clinical Trials Regulations implement the Clinical Trials Directive (2001/20/EC). In particular, they implement article 5(a) of the Directive which requires that the informed consent of an incapacitated adult's legal representative is obtained prior to his inclusion in a clinical trial.
- (b) The implementation of article 5(a) of the Directive caused problems for those seeking to conduct trials in emergency situations. This is because the trial drugs need to be administered urgently to a (usually) unconscious patient and time does not allow for the consent of a legal representative to be obtained first. Particularly affected was a large multi-centred trial requiring immediate administration of a clot busting drug to resuscitate patients following a heart attack (the TROICA trial).
- (c) An amendment to the Regulations was proposed that derogates from the express terms of article 5(a): the amendment would allow an incapacitated adult to participate in an emergency care clinical trial prior to consent having been obtained from his legal representative

¹ The Medicines for Human Use (Clinical Trials) Regulations 2004 SI [2004/1031

² The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 S.I. 2006/1928

providing that certain conditions are met, including the approval of an ethics committee. A consultation exercise on the proposed amendment took place from 1 August 2005 for comment by 24 October 2005. The proposal received wide support.

- (d) Proposed regulation 27(1) to (2) would amend Schedule 1, Part 1 paragraph 1 in relation to the conditions and principles of good clinical practice which apply in relation to an incapacitated adult. In particular the conditions set out in Schedule 1, Part 5, paragraphs (1) to (4) of the Regulations.
- (e) The amendments would allow the investigator or another member of the investigator's team to enter an incapacitated adult into a clinical trial without complying with the usual conditions of obtaining informed consent from the adult's legal representative (set out in paragraphs 1 to 4 of Part 5 of Schedule 1).
- (f) This exemption would be on condition that: (i) the nature of the trial requires urgent action, (ii) it is not reasonably practicable to meet the usual conditions in particular that the adult's legal representative has given informed consent and (iii) an ethics committee has given approval to the procedure under which action is taken.
- (g) When it is no longer necessary to take action as an as a matter of urgency this exemption would not apply and the usual conditions for obtaining informed consent would need to be met.
- (h) Similar provisions for deferral of consent for emergency research, (other than with medicines) in incapacitated adults were considered in detail and agreed as part of the implementation of the Mental Capacity Act 2005, in particular Section 32.

Current UK arrangements

- (i) The Regulations implement the Clinical Trials Directive (2001/20/EC). In particular, they implement article 5(a) of the Directive which requires that the informed consent of an incapacitated adult's legal representative is obtained prior to his inclusion in a clinical trial. This caused problems for those seeking to conduct trials in emergency situations. This is because the trial drugs need to be administered urgently to a (usually) unconscious patient and time does not allow for the consent of a legal representative to be obtained first. Particularly affected was a large multi-centred trial requiring immediate administration of a clot busting drug to resuscitate patients following a heart attack (the TROICA trial).

(iii) Risk Assessment

Risk to clinical trial subjects

- (a) One of the primary aims of the Regulations is to place the principles and detailed guidelines for good clinical practice on a statutory basis in order to protect subjects who volunteer for clinical trials. International guidance on good clinical practice³ recognises the need to include incapacitated adults in trials of emergency care prior to

³ Note for guidance on good clinical practice CPMP/ICH/95/135

obtaining consent (the hazard). While this could lead to the subjects experiencing considerable personal risk and inconvenience (the harm) this intervention would only be allowed for emergency situations, including examples such as severe head injury, cardiac arrest or septic shock, when there is insufficient time to contact a legal representative before treatment and any associated clinical trial must be started. In addition the anticipated benefit of the new treatment should be equal to or greater than the current standard treatment.

Risk to public health

- (b) Emergency care is an important part of public health. For example the immediate treatment of cardiac arrest, a common health hazard, can improve survival and subsequent health. Preventing research into new treatments for emergency care (the hazard) could lead to unnecessary deaths and morbidity from conditions requiring urgent treatment (the harm).

3. OPTIONS

(i) *Option 1: Continue to rely on existing arrangements.*

- (a) The Clinical Trials Regulations require that the informed consent of an incapacitated adult's legal representative is obtained prior to his inclusion in a clinical trial. Continuing to rely on these arrangements would prevent incapacitated adults from participating in certain trials of emergency care and therefore from benefiting from research into new treatments.
- (b) Investigators planning a trial of cardiac arrest (the TROICA trial) found it impracticable to obtain consent before entering such patients into the trial and therefore could not conduct it in the UK because of the existing regulations. Continuing to rely on these arrangements would prevent research into new medicines for this type of urgent treatment. Consequently, the pharmaceutical industry would reduce R&D investment in this type of research in the UK.

(ii) *Option 2: Amend the Clinical Trials Regulations.*

- (a) Under this option we would amend the Regulations to allow an incapacitated adult to participate in an emergency care clinical trial prior to consent having been obtained from his legal representative providing that it has not been reasonably practicable to obtain consent from his legal representative having regard to the nature of the trial and the circumstances of the case and that an ethics committee has approved the trial. Informed consent is still a requirement of participation in a clinical trial; but its absence does not preclude initial entry in to a trial. The normal arrangements for seeking consent must be met as soon as reasonably practicable or the subject be withdrawn from the clinical trial. The exception may not be used if there is no longer an emergency. Once the initial emergency is over, immediate steps must be taken by the investigator or clinician responsible for the care of the patient to obtain valid consent to the continuing participation of the subject in the trial.

4. **BENEFITS**

Option 1: Continue to rely on existing arrangements

- (a) Continuing to rely on existing arrangement would avoid the:
- effort of introducing change;
 - risk of harm to incapacitated adults being entered into trials of emergency care;
 - risk of challenge to the proposed amendment.

Option 2: Implement the Directive by amending the Regulations

- (b) The proposed amendments to the Regulations would benefit:
- incapacitated adults who require emergency care by allowing them to participate in clinical trials of new treatments that might improve their prospects of recovery and survival;
 - future incapacitated adults by improving treatments for conditions that require emergency care;
 - UK researchers by allowing them to participate in multinational trials of emergency care treatments;
 - Public health by providing the opportunity to reduce mortality and morbidity of conditions requiring urgent treatment; and
 - The pharmaceutical industry by allowing them to develop new essential medicines for emergency care as part of their business.

Business sectors affected

- (c) The innovative pharmaceutical industry will be affected. There will be a limited impact on the generic sector. The NHS, universities, charities and others who undertake non-commercial clinical trials of emergency care will also be affected.

Issues of Equity or Fairness

- (d) The proposed Option 2 will provide incapacitated adults with the same opportunities as adults with capacity to benefit from advances in treatments for conditions that could cause prolonged disability or death.
- (e) Is it fair under Option 1:
- to exclude incapacitated adults who need emergency care from clinical trials that might improve their chance of recovery or survival?
 - to exclude future incapacitated adults from advances in treatments for emergency care that derive from clinical trials?
 - to prevent UK researchers from participating in multinational trials of emergency care treatments?
 - to prevent the pharmaceutical industry from developing new medicines for emergency care as part of their business?

5. **COSTS**

(i) Anticipated Costs under option 1

Option 1: Continue to rely on existing arrangements

- (a) This option would not change the current direct costs for pharmaceutical companies, medical research charities, universities or NHS Trusts but would prevent incapacitated adults from participating in clinical trials of emergency care.
- (b) It would result in an indirect cost by preventing UK investigators participating in international multicentre trials of emergency medicines and therefore reduce their ability to compete for grants and support for their research. For example investigators planning to conduct the trial of a clot busting drug (TROICA) anticipated that the emergency research amendment would be introduced shortly after January 2005. The window for UK investigators to participate in the TROICA trial has now passed but it is being conducted in several other EEA countries.
- (c) It would result in an indirect cost by preventing the pharmaceutical industry from developing new medicines for emergency care as part of their UK business. Consequently it would reduce investment in research and development of this type of medicine in the UK. This type of research is currently permitted in several other EEA countries (see subparagraph 7(ii)2 below for details).

(ii) Anticipated costs under option 2

Option 2: Implement the Directive by amending the Regulations

Activities for which fees are proposed

- (a) The proposed amendment would not trigger any additional fees.
Costs of commencing and conducting a clinical trial to conform with the amended Regulations
- (b) The proposed amendment would remove the requirement for immediate consent from the legal representative of an incapacitated adult prior to entering him into a trial of medicine for emergency care, which should not involve additional costs. It would also require that consent is sought from the incapacitated adult's legal representative as soon as practicably possible. As this is the current requirement before entering an incapacitated adult into a trial it should not involve any additional costs.
Costs of implementing requirements for ethics committees
- (c) Under the proposed amendment it would be a condition that an ethics committee would have given a favourable opinion before the trial could commence. As this is a current requirement of the Regulations before a clinical trial involving incapacitated adults can commence it should not lead to any additional costs.

6. CONSULTATION WITH SMALL BUSINESS: THE SMALL FIRMS' IMPACT TEST

We included small businesses in the groups to whom we distributed the consultation letter. They did not raise any issues of increased costs

or other impacts in the responses. Since we did not anticipate any added burden resulting from the proposed amendment we did not consult small businesses separately.

7. COMPETITION ASSESSMENT

(i) Market affected

- (a) The proposed amendment to the Regulations will affect the innovative pharmaceutical industry. There will be a limited impact on the generic sector. The NHS, universities, charities and others who undertake non-commercial clinical trials will also be affected

(ii) The clinical trials market

- (a) Organisations such as research-based pharmaceutical companies, commercial trial centres acting under contract, and a range of non-commercial bodies such as universities, the NHS, and medical research charities undertake most clinical trials. Trials undertaken by or on behalf of pharmaceutical companies comprise the majority of trials and are conducted on a commercial basis. The impact of the amendment is likely to affect competition because the innovative pharmaceutical industry and non-commercial trialists are currently prevented from conducting clinical trials of new medicines for emergency care in the UK yet they can conduct them in other EEA countries.

The EU Directive On Clinical Research: Present Status Of Implementation With Regard To The Incompetent Patient
Lemaire F, Bion J, Blanco J et al. ICM 2005 ; 31 : 476-9

Country	Drug research only	Emergency research consent			
		Waiver	Deferred	Only if 'direct benefit'	Surrogate (LR) consent
Austria	Y	Y	Y	Y	Y
Belgium	No	Y	Y	No	Y
Czech R	Y	No	No	-	Y
France	No	Y	Y	No	Y
Germany	Y	Y	Y	Y	Y
Greece	Y	No	No	-	Y
Ireland	Y	N	N	-	Y
Italy	Y	Y	-	-	Y
NL	N	Y	Y	Y	Y
Norway		Y	Y	Y	Y
Portugal	Y	N	N	N	-
Spain	Y	Y	Y	N	Y
UK	N	N	N	N	Y

- (b) The table above, published by the President of the European intensive care society, indicates that Austria, Belgium, France, Germany, Italy, Netherlands, Norway and Spain currently have provision for emergency care research while Czech R, Greece, Portugal and UK do not.

- (c) The proposed amendment would remove this barrier to competition in the UK and thus encourage additional investment in R&D for emergency care medicines.

8. RESULT OF CONSULTATION

(i) Summary of responses to consultation document on emergency research (MLX 326)

- (a) The MHRA consulted on the proposed amendments during a 12-week period ending 24 October 2005. It distributed the consultation document (MLX 326) to over 2000 stakeholders and received responses from small and large pharmaceutical companies, contract research organisations, quality assurance organisations, industry associations, laboratory services, ethics committees, NHS hospital trusts, primary care trusts, ambulance trusts, Royal Colleges, organisations representing academic researchers, nurses, and pharmacists, charities supporting publicly funded research, individual investigators and patient associations.
- (b) Of the 159 responses, 58 said no comment, 29 only said they supported the proposed amendment and 72 provided specific comments within which 47 expressed overall support and 5 voiced concerns about the ethical acceptability of the proposals. The summary below lists the issues and concerns raised in the responses.

Further guidance

- (c) Most of the comments asked for additional guidance on the following issues:
- Definition of “legal representative” and guidance on relevant procedures (18)⁴;
 - Withdrawal from the trial if informed consent not provided within 24 hours (34);
 - Scope of the exemption from immediate informed consent (14);
 - Consideration of the trial by an ethics committee (10);
 - Use of the data when consent not given (7);
 - Application of the exemption to children (9);
 - Procedures when patient does not survive (2);
 - Changes to the law in Scotland (3);
 - Ethical concerns about lack of consent (5);
 - Trials with novel medicines (2);
 - Impact on trials in emergency situations not involving medicines (5); and
 - Responsibility for harm in trials with no consent (3).
- (d) In response to these requests DH has agreed to provide further guidance on the areas that need clarification.

Specific issues

- (e) Respondents indicated that further consideration should be given to the following issues:

⁴ The number in brackets indicates the number of respondents commenting on that issue.

- The proposal to require informed consent within 24 hours of entering an incapacitated adult into a trial. Most said that this was not practicable and might not be in the subjects best interests. In response this requirement has been omitted so that consent must be obtained when it is reasonably practicable.
- The acceptability of relatives giving informed consent in emergency situations (1); The Regulations provide for alternative arrangements where a relative is not willing to act a legal representative (See subparagraph 2(a)(i)(bb) of Part 1 of Schedule 1)
- The role of NHS Trusts in allowing such trials to proceed (1). Specific guidance will be provided on the procedures for clinical trials of emergency care medicines.

Concerns

- (f) Five respondents said that they could not accept that it was ethical to enter a subject into a trial without prior informed consent. One felt that a third party could not know the will of the patient and therefore could not give informed consent.
- (g) Policy leads have considered these concerns and accept that there is an ethical question where a person is to be entered into a clinical trial without their prior consent. However the proposals are in line with the ICH GCP guidance, which is the accepted standard for conducting clinical trials in Europe, United States and Japan and other countries throughout the world. The provision that an ethics committee must approve the procedure provides a safeguard to prevent inappropriate inclusion of patients into medical research projects in emergency situations.

9. ENFORCEMENT AND SANCTIONS

The MHRA will be responsible for monitoring and enforcement of the proposed amendments to the Regulations. The powers for this will be provided by the Medicines Act 1968 which will be extended to cover the amended provisions. Compliance with GCP will generally be monitored through the regular inspection programmes. Appropriate enforcement provisions will cover offences concerning the amended provisions. Penalties will be commensurate with those specified in the Medicines Act.

10. MONITORING AND REVIEW

- (a) The impact of the Clinical Trial Regulations is being monitored by three groups that have direct access to Government to promote growth and innovation and have a specific interest in the Government's performance in regulating clinical trials in the UK
- (b) First, the Pharmaceutical Industry Competitiveness Task Force (PICTF) Clinical Research Group have published performance criteria for implementing the Directive in their Clinical Research Report. The group consists of representatives from the pharmaceutical industry, the Medical Research Council and the Bioindustry Association as well as officials from DH RDD, NHS and MHRA. They meet regularly to assess information on Government performance in a number of

aspects of conducting clinical trials in the UK including ability of investigators to complete trials compared to other countries. This Government-industry group will monitor the impact of the amendment to the UK Regulations on the commercial clinical trials environment in the UK.

- (c) Second, the Biosciences Leadership Council, which has been formed following the Bioindustries Innovation Growth Team – BIG-T can be expected to take an interest in the impact of any amendments to the Regulations on the development of medicines from the biosciences.
- (d) Third, the UK Clinical Research Collaboration, established in 2004, brings together most of the key stakeholders that shape the clinical research environment in the UK. One of its objectives is to streamline the regulatory and research governance processes. As part of this it is monitoring the impact of the Clinical Trials Regulations on non-commercial research. It can be expected to monitor the impact of amendments to the Regulations

11. SUMMARY AND RECOMMENDATIONS

- (a) The proposed amendments to the Regulations to allow conduct of clinical trials of emergency care medicines in the UK will impact on the pharmaceutical industry and those sponsoring publicly-funded clinical trials of medicines in the following ways:

Additional Regulatory Burden

- (b) The proposed changes would not increase the regulatory burden because the proposals are in line with the ICH GCP guidance, which is the accepted standard for conducting clinical trials in Europe, United States and Japan and other countries throughout the world.

Additional Costs

- (c) The amendment to allow deferral of informed consent to allow trial of urgent treatment for incapacitated adults was proposed by those conducting this type of clinical trial. Its implementation will be welcomed and is not expected to increase the burden or costs of this type of research.

RECOMMENDATION

This impact assessment considers two options for implementing an emergency care research amendment:

Option 1 – Continue to rely on existing arrangements which would prevent incapacitated adults from participating in clinical trials of emergency care.

Option 2 – Implement the emergency care research amendment of the Clinical Trials Regulations which would not increase the regulatory burden but benefit:

- **incapacitated adults who require emergency care by allowing them to participate in clinical trials of new treatments that might improve their prospects of recovery and survival;**

- future incapacitated adults by improving treatments for conditions that require emergency care;
- UK researchers by allowing them to participate in multinational trials of emergency care treatments;
- Public health by providing the opportunity to reduce mortality and morbidity of conditions requiring urgent treatment; and
- The pharmaceutical industry by allowing them to develop new essential medicines for emergency care as part of their business.

After careful consideration I recommend that the Government adopts the option to amend the Clinical Trials Regulations to implement the emergency care research amendment.

I have read this document and am satisfied that the benefits justify the costs.

Signature (Minister responsible) Andy Burnham

Date 15th November 2006

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