

**NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA157; Dabigatran etexilate for the prevention of venous thromboembolism after hip or knee replacement surgery in adults**

This guidance was issued September 2008 with a review date of June 2011.

**Background**

At the GE meeting of 7 June 2011 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<b>Proposal put to consultees:</b>	A review of the guidance should be transferred to the static guidance list.
<b>Rationale for selecting this proposal</b>	<p>Since TA157 was issued, NICE has published a clinical guideline CG92 'Venous thromboembolism: reducing the risk of venous thromboembolism (deep vein thrombosis and pulmonary embolism) in inpatients undergoing surgery'. Although the clinical guideline does not reproduce the wording of TA157 verbatim, the recommendation has been effectively incorporated in that dabigatran is included in the list of options for pharmacological VTE prophylaxis after surgery in both elective hip and elective knee replacement. There is no new evidence to suggest that this recommendation should change.</p> <p>Moving TA157 to the static list means that the Technology Appraisal guidance will remain extant alongside the clinical guideline. This has the effect of preserving the funding direction. The review decision date for the clinical guideline is January 2013. If it is decided that the clinical guideline should be reviewed, then a new proposal for TA157 can be developed during the pre-scoping stages of that guideline.</p>

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

<b>Recommendation post consultation:</b>	Following consultation it is recommended that this guidance is transferred to the static guidance list
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<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
Royal College of Pathologists / British Society for Haematology	No comment	Please note that the Royal College of Pathologists and the BSH have no comments to make on the review for the above appraisal.	Following consultation it has been recommended that TA 157 be transferred to the static guidance list
Healthcare Improvement Scotland	No comment	Healthcare Improvement Scotland has no comment to make on the proposal to move this guidance to the static list and we have noted this proposal.	Following consultation it has been recommended that TA 157 be transferred to the static guidance list
Department of Health	No comment	We have no comments to make regarding NICE's proposal	Following consultation it has been recommended that TA 157 be transferred to the static guidance list
Sanofi	No comment	Please note that Sanofi have no comments at this time.	Following consultation it has been recommended that TA 157 be transferred to the static guidance list

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
Boehringer-Ingelheim	Agree	I'd like to confirm that Boehringer Ingelheim Ltd is in favour of the proposal to move the guidance for TA157 to the static list, therefore we have no further comments to make.	Following consultation it has been recommended that TA 157 be transferred to the static guidance list
Royal College of Nursing	No comment	Nurses caring for and treating people with hip and knee surgery were invited to comment on the proposals regarding the review of the above health technology appraisal.  There are no comments to make on this proposal at this stage on behalf of the Royal College of Nursing	Following consultation it has been recommended that TA 157 be transferred to the static guidance list

**No response received from:**

<u>Patient/carer groups</u>	<u>General</u>
<ul style="list-style-type: none"> <li>• Afiya Trust</li> <li>• AntiCoagulation Europe (ACE)</li> <li>• Black Health Agency</li> <li>• British Lung Foundation</li> <li>• Chinese National Healthy Living Centre</li> <li>• Counsel and Care</li> <li>• DVT Awareness Campaign</li> <li>• Equalities National Council</li> <li>• Lifeblood: The Thrombosis Charity</li> <li>• Muslim Council of Britain</li> <li>• Muslim Health Network</li> </ul>	<ul style="list-style-type: none"> <li>• Board of Community Health Councils in Wales</li> <li>• British Cardiovascular Industry Association</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• Medicines and Healthcare products Regulatory Agency</li> <li>• National Association of Primary Care</li> <li>• National Pharmacy Association</li> <li>• NHS Alliance</li> </ul>

- South Asian Health Foundation
- Specialised Healthcare Alliance

#### Professional groups

- Anticoagulation Specialist Association
- Association of Surgeons of Great Britain and Ireland
- British Association for Service to the Elderly
- British Association for Surgery of the Knee
- British Cardiovascular Society
- British Geriatrics Society
- British Orthopaedic Association
- British Society for Haemostasis and Thrombosis
- British Thoracic Society
- British Vein Institute
- Clinical Leaders of Thrombosis (CLOT)
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Physicians
- Royal College of Surgeons
- Royal Society of Medicine
- Society for Vascular Technology
- Society of Vascular Nurses
- United Kingdom Clinical Pharmacy Association
- Vascular Society of Great Britain and Ireland

#### Others

- NHS Manchester
- NHS North Lancashire
- Welsh Government

- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

#### Possible comparator manufacturers

- Amdipharm (bemiparin sodium)
- Bayer healthcare (rivaroxiban)
- GlaxoSmithKline (fondaparinux sodium)
- Leo Laboratories (tinzaparin sodium)
- Pfizer (dalteparin sodium)
- Valeant Pharmaceuticals (reviparin sodium)

#### Relevant research groups

- Antithrombotic Trialists' (ATT) Collaboration
- Cochrane Peripheral Vascular Disease Group
- MRC Clinical Trials Unit
- National Institute for Health Research
- Research Institute for the Care of Older People
- Thrombosis Research Institute

#### Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

#### Associated Guideline Groups

- National Clinical Guideline Centre

	<u>Associated Public Health Groups</u> <ul style="list-style-type: none"><li>• none</li></ul>
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**GE paper sign-off:** Janet Robertson, Associate Director – Technology Appraisals Programme

**Contributors to this paper:**

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Date: 02 August 2011