HEART FAILURE HUB SCOTLAND

NHS Scotland Heart Failure Transition and Recovery Plan in response to COVID-19 (25th May 2020)

The COVID-19 pandemic has placed enormous pressure on NHS Scotland and the impact on heart failure (HF) care has been devastating. Many HF staff have been redeployed and non-urgent HF care has been put on-hold, with patients placed in a 'virtual waiting room'. This has resulted in a large backlog of people awaiting tests (NTproBNP, ECG and Echocardiography) to confirm the diagnosis of HF and commence disease-modifying treatment, proven to reduce the risk of hospitalisation and prolong life. For others, optimisation of treatment and management of their long-term condition has been interrupted. Additionally, the emergency response to the acute phase of COVID-19 prioritised discharge of patients from acute care and did not sufficiently consider the impact on Community and Primary care services.

Specific challenges have also evolved for HF services due to the cardiac manifestations of SarsCoV2, which include HF, in addition to the well documented delayed presentation of people with acute cardiac events i.e. heart attack, who are therefore sustaining more cardiac damage than usual and thus more frequently developing HF. These factors may consequently increase the incidence and prevalence of heart failure in Scotland. It will be vital that Boards ensure their HF teams are appropriately resourced to manage the backlog that has accumulated in addition to simultaneously accommodating a potential increase in HF patient numbers across Primary and Secondary care, as a result of COVID-19.

Public Health measures will further impact upon HF services. In order to facilitate safe physical distancing for patients and for staff and to minimise hospital attendances for patients, appointment times will require major revision and provision of community point-of-care diagnostics (NTproBNP, ECG +/- echocardiography) will be necessary. Where community point of care diagnostics is not possible, NHS Scotland Boards should give priority to developing hospital-based point of care diagnostic clinics (i.e all investigations and clinical review undertaken during one hospital visit) with a commitment to progressing to community delivered services at the earliest opportunity.

As we now attempt to transition from the emergency response to a recovery phase, whilst at the same time ensuring that we are prepared for future COVID-19 waves, a well-planned, responsive, and sustainable model of HF care is required. NHS Boards are therefore recommended to adopt a tiered approach to HF care, as described below, and Health care professionals across the whole system should be familiar with the model.

Emergency phase: Severe pandemic related system pressure
Priority to highest-risk patients

Transition/planned recovery phase: Moderate pandemic related system pressure
Priority to intermediate and highest-risk patients

Reinstatement phase: Little or no pandemic related system pressure
Full service

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Emergency phase: Severe pandemic related system pressure
Priority to highest-risk patients

The Scottish Heart Failure Hub has already produced National recommendations and guidance for the delivery of essential HF services, to those at **highest risk** of deterioration, hospitalisation or death, during the emergency response to a health pandemic. However, this is not a sustainable strategy that can be continued over a prolonged period of time.
http://www.heartfailurehubscotland.co.uk/wp-content/uploads/2020/03/Provision-of-Essential-Heart-Failure-Services-in-Scotland-during-COVID19-1.pdf

Key recommendations

1. NHS Scotland Boards advised to **retain key specialist HF staff** in order to continue to deliver essential HF services across Scotland to those at highest risk.
2. Recommended and nationally agreed **'minimum criteria' for essential HF service provision** in Scotland during the emergency phase of COVID-19.
3. Guidance for Scottish HF teams regarding **risk stratification** and delivery of care to patients at highest risk.
4. Identification of a **lead HF clinician** within each NHS Scotland Board

Successes to date

The response from Scottish HF teams during the emergency phase of COVID-19 has been outstanding. Delivery of care to those at highest risk has been provided across Scotland. Rapid transformation of services has taken place and new adaptive ways of working have been quickly developed and implemented. Key priorities have focused on patient safety, multi-disciplinary team (MDT) working and the delivery of remote and ambulatory care pathways, in order to avoid hospital attendance or admission wherever possible.
See appendix 1 below for best practice examples in Scotland

Transition/Planned Recovery phase
Moderate pandemic related system pressure
Priority to intermediate and highest-risk patients

We have now moved into a transition/planned recovery phase. i.e the period between an emergency response and re-instatement of full services, or vice-versa. Significant local planning will be required to work towards and deliver this phase. HF specialist staff should not be redeployed during this phase, in order to ensure sufficient resource to manage the backlog that has accumulated during the emergency phase and to provide pro-active care to a larger patient group i.e. patients at **intermediate and highest risk**.

Re-organisation of HF services, including managing the backlog and recovering access to consultations, echocardiography (the key test to diagnose HF), cardiac device implantation and long-term condition management will be required.

Novel and innovative care models and pathways, including cessation of some historical practices, should be evaluated, embedded where successful and comply with Public Health and infection control guidance.

The following patients should be considered to be at **intermediate or highest risk** and be provided with appropriate Telephone consultation (TC), Video consultation (VC) or Face to Face (FtF) consultation:

1. People referred with new HF symptoms from A&E or Primary Care.
2. All patients who were placed in a virtual waiting room when services were operating in the emergency phase should be re-triaged and a decision made regarding whether they require TC/VC specialist consultation +/- their referral upgraded to urgent.
3. People known to have HF who have unstable or deteriorating symptoms.
4. People who have recently been discharged from hospital following an admission due to acute HF (review within 2 weeks of discharge).
5. People who have recently been discharged from hospital following an admission with acute myocardial infarction and whose left ventricular ejection fraction (LVEF) is <35% (review within 2 weeks of discharge).
6. People living with HF who have advanced care plans in place and require supportive/palliative HF care in the community.
7. People with ongoing symptoms who are eligible for optimisation of guideline directed pharmacotherapy.
8. People with ongoing symptoms who are eligible for cardiac device therapy [Cardiac Resynchronisation Therapy (CRT) and Internal Cardiac Defibrillator (ICD)].
9. People who missed a review appointment due to services operating in the emergency phase (TC/VC consultation may be safest for these people if there has been no deterioration of symptoms, their HF therapy has not been changed and they are on optimal medical therapy).

Timelines for assessment of people with suspected 'new' heart failure should align with SIGN147 guidance
Within 2 weeks if NTproBNP > 2000pg/ml (BNP > 400pg/ml)
Within 6 weeks if NTproBNP 400 - 2000pg/ml (BNP 100 – 400pg/ml)

Key recommendations for Transition/Planned Recovery phase

1. Service planning should comply with Public Health and Health Protection Scotland guidance.
2. Active clinical triage should be undertaken by specialist clinicians.
3. Pro-active inpatient and outpatient HF care should be provided to all patients at intermediate and highest risk.
4. Consultations should be undertaken using TC, VC or FtF methods as appropriate and specific provision should be made for shielded patients.
5. Heart Failure teams should be appropriately resourced to manage the backlog in addition to the potential increase in patient numbers as a result of COVID-19.
6. Recovering access to echocardiography, cardiac device implantation and long-term condition management will be crucial for the delivery of safe HF care.
7. Community point of care diagnostics, ambulatory/remote monitoring and patient self-management strategies should be prioritised for implementation where not currently available.

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Reinstatement phase: Little or no pandemic related system pressure
Full service

A re-instatement phase will take place when there is little or no additional pressure on the health care system as a result of the pandemic and a full service can be reinstated. All patients should be reviewed as per normal service criteria.

New and innovative models and pathways of care, including cessation of some historical practices, should be evaluated and embedded where successful. A full complement of services should be reinstated with a focus on person-centred TC, VC and FtF consultation options in addition to ambulatory care services delivered closer to people's homes.

Appendices

Appendix 1: Examples of successfully implemented 'best practice' models of care, applicable to all pandemic operation levels

Appendix 2: Ensuring patient and staff safety within heart failure services during all pandemic operation levels

Appendix 3: Optimisation of Heart Failure Therapy During a Pandemic

Appendix 4: A pragmatic approach to optimisation of heart failure therapy during a pandemic

Appendix 5: Routine heart failure blood monitoring in Primary Care during a pandemic

Thank you

The Scottish Heart Failure Hub would like to take this opportunity to thank:

- Every person in Scotland living with heart failure who has displayed **patience** about the impact on their service, **kindness** towards each other and towards healthcare staff and **engagement** with heart failure self-management and public health advice.

- All NHS Scotland heart failure staff for their unwavering commitment to delivering both emergency and heart failure care during COVID-19.

- The UK heart failure charities - British Heart Foundation, Chest Heart Stroke Scotland, Pumping Marvellous and Cardiomyopathy UK, for the phenomenal support they have provided to Scottish heart failure patients and teams.

- NHS Scotland Health Boards in anticipation of their commitment to fully supporting and prioritising the urgent recovery of heart failure care.

- The National Advisory Committee for Heart Disease and the Scottish Government Heart Disease Team in anticipation of their continued support and guidance.

Appendix 1

Examples of successfully implemented 'best practice' models of care applicable to all pandemic operation phases:

1. Use of NTproBNP in the community for the diagnosis of HF

2. Active Clinical Triage by senior clinicians (HF specialist nurses and consultants) to risk stratify existing patient caseloads and new referrals

3. GP access to specialist staff Monday-Friday eg. 'Consultant Connect'

4. Remote patient consultations - telephone consultation (TC) and video consultation (VC) eg. 'Near Me' and 'Attend Anywhere' platforms

5. Urgent face-to-face (FtF) clinic consultations and domicillary visits where deemed necessary following specialist triage

6. One-stop clinics delivering same day diagnostics (echocardiogram, ECG +/- NTproBNP) plus FtF consultation, for urgent new referrals

7. Development of inpatient HF teams to deliver specialist HF care, anticipatory care planning, early supported discharge and links to local palliative care services as required. Inpatient review of these patients has been proven to reduce readmission rates and has facilitated TC/VC remote consultations

8. Provision of 'rescue packs' to specialist HF nurses (short courses of oral diuretics provided to patients to improve deteriorating symptoms without the need for GP or Pharmacist prescribing & dispensing)

9. Provision of 'diuretic lounges' and 'hospital at home' services: intravenous diuretics delivered in day units or at home in order to ameliorate the symptoms of HF without hospital admission

10. MDT working with primary care, medicine for the elderly and allied healthcare professionals

11. Access to community phlebotomy, to minimise hospital attendance and facilitate symptom monitoring and safe optimisation of HF therapy

12. Provision of remote monitoring technology to patients, including blood pressure (BP) i.e. FLORENCE, heart rate (HR) and oxygen (O2) monitors and weighing scales, in order to facilitate patient self-management, ambulatory monitoring and remote care

13. Provision of home-based cardiac rehabilitation programmes

14. Provision of remote cardiac device monitoring including novel mobile/drive-through services

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Appendix 2: Ensuring patient and staff safety within heart failure services during all pandemic operation levels

- Up to date Public Health advice should be adhered to, local infection control measures should be in place and appropriate Personal Protective Equipment (PPE) should be provided to all staff in line with Health Protection Scotland guidance.

- All services should have a COVID-19 checklist in place and face-to-face consultations should be undertaken in a protected environment.

- Appropriate provision should be made for patients who are shielding. Use of new technology such as 'Near Me' and 'Attend Anywhere' will be suitable for some but not all patients. Many shielded patients will still require clinical examination and access to technology will be a barrier for some.

- The clinical notes of all patients placed in a virtual waiting room (new and return patients awaiting clinic consultation or diagnostic investigations) should be reviewed on a regular basis and their risk status updated, recorded and acted upon in order to ensure patient safety.

- Any interim hospitalisation or death of a person whilst they remain in a virtual waiting room should be recorded.

- Data should be submitted monthly to a heart failure risk register.

- In order to comply with Public Health Scotland guidance around safe physical distancing measures, face-to-face appointments for consultation or investigations will require to be appropriately timed. Full waiting rooms will no longer be possible. This will have enormous impact on service capacity. Review of real estate and consideration of 7 - day working models is likely to be required to deliver future services that meet demand.

- To facilitate safe physical distancing and to minimise hospital attendances for patients, provision of community point-of-care diagnostics (NTproBNP, ECG +/- echocardiography) will be necessary. Where this is currently impossible, Boards are requested to prioritise the development of hospital-based point of care diagnostic clinics, with a commitment to progressing to community delivered diagnostic services at the earliest opportunity.

- Community care, ambulatory care and patient self-management strategies should be prioritised within NHS Scotland Boards to minimise hospital attendance.

- Boards should ensure their heart failure teams are appropriately resourced to manage the backlog that has accumulated and the potential increase in patient numbers as a result of (1) the cardiac manifestations of SarsCoV2, which includes heart failure, and (2) the well-documented issue of people presenting late to hospital during COVID-19, with serious cardiac conditions. These factors may result in a sharp rise in heart failure patient numbers across Scotland.

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This guideline was created independently by the Heart Failure Hub Scotland with no input from Novartis.

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Appendix 3: Optimisation of Heart Failure Therapy During a Pandemic

Optimum disease modifying pharmacotherapy for people diagnosed with HF reduces cardiovascular death and hospitalisation and prolongs life. (Vaduganathan M et al. Lancet 2020. https://doi.org/10.1016/S0140-6736(20)30748-0).

There are 4 important classes of HF disease modifying pharmacotherapy – Beta-Blocker (BB), Renin-Angiotensin-Aldosterone System inhibitor (RAASi), Mineralocorticoid Receptor Antagonist (MRA) and Sodium-Glucose-CoTransporter 2 inhibitor (SGLT2i).

In order to achieve greatest benefit from HF therapies, early initiation and multiple drug titrations are required. However, initiation and titrations are guided by heart rate, blood pressure and kidney function and these measurements cannot be undertaken without access to appropriate technology and phlebotomy services.

Despite the obvious challenges of obtaining these measurements during a pandemic, failure to initiate and/or optimise disease-modifying therapy for people with HF will result in a higher rate of hospitalisation and premature death. Every effort should be made to avoid this.

Appendix 4: A pragmatic approach to optimisation of heart failure therapy during a pandemic

A pragmatic approach to optimisation of heart failure therapy during a pandemic

1. Select, where possible and where appropriate, therapies that require the fewest titration steps eg. Bisoprolol as BB of choice and Sacubitril Valsartan as RAASi of choice when left ventricular ejection fraction (EF) is less than 40%.

2. Ensure, where possible and where appropriate, that all patients hospitalised with new HF and EF <40%, are commenced on triple therapy including BB, RAASi and MRA prior to discharge.

3. Ensure that all patients with HF and Type 2 Diabetes are considered for SGLT2i therapy.

4. Ensure, where possible and where appropriate, that all hospitalised patients with known HF are reviewed by the HF team during admission, pharmacotherapy is optimised and cardiac device therapy is considered.

5. Ensure, where possible and where appropriate, that all patients have BP, HR and oxygen monitors and weighing scales in their homes.

6. Provide access to community phlebotomy for HF services. Novel evolving service models including drive-through and mobile services should be considered.

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Appendix 5: Routine heart failure blood monitoring in Primary and Secondary Care during a pandemic

Routine heart failure blood monitoring in Primary Care during a pandemic

- National and local guidelines recommend interval measurement of kidney function for patients being treated with the following heart failure therapies: RAASi, MRA and SGLT2i.
- In order to minimise the requirement for patients to attend healthcare facilities during a pandemic, it is recommended that if 2 previous blood tests of kidney function within the preceeding 12 months were stable and there has been no interim change in symptoms or medication, routine measurement of kidney function can be postponed until the next planned date.
- Further work should be undertaken by heart failure services to address the requirement for heart failure blood monitoring as this may be an area where activity could be safely reduced.

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Prescribing Information:

ENTRESTO® (sacubitril/valsartan)

Important note: Before prescribing, consult Summary of Product Characteristics (SmPC).

Presentation: Film-coated tablets of 24 mg/26 mg, 49 mg/51 mg and 97 mg/103 mg of sacubitril and valsartan respectively (as sacubitril valsartan sodium salt complex).

Indications: In adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction. **Dosage & administration:** The recommended starting dose of sacubitril/valsartan is one tablet of 49 mg/51 mg twice daily, doubled at 2-4 weeks to the target dose of one tablet of 97 mg/103 mg twice daily, as tolerated by the patient. In patients not currently taking an ACE inhibitor or an ARB, or taking low doses of these medicinal products, a starting dose of 24 mg/26 mg twice daily and slow dose titration (doubling every 3 - 4 weeks) are recommended. A starting dose of 24 mg/26 mg twice daily should be considered for patients with SBP ≥100 to 110 mmHg, moderate or severe renal impairment (use with caution in severe renal impairment) and moderate hepatic impairment. Do not co-administer with an ACE inhibitor or an ARB. Do not start treatment for at least 36 hours after discontinuing ACE inhibitor therapy. Sacubitril/valsartan may be administered with or without food. The tablets must be swallowed with a glass of water. Splitting or crushing of the tablets is not recommended. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients. Concomitant use with ACE inhibitors. Do not administer until 36 hours after discontinuing ACE inhibitor therapy. Known history of angioedema related to previous ACE inhibitor or ARB therapy. Hereditary or idiopathic angioedema. Concomitant use with aliskiren-containing medicinal products in patients with diabetes mellitus or in patients with renal impairment (eGFR <60 ml/min/1.73 m^2). Severe hepatic impairment, biliary cirrhosis and cholestasis. Second and third trimester of pregnancy. **Warnings/ Precautions:** Dual blockade of the renin angiotensin-aldosterone system (RAAS): Combination with an ACE inhibitor is contraindicated due to the increased risk of angioedema. Sacubitril/valsartan must not be initiated until 36 hours after taking the last dose of ACE inhibitor therapy. If treatment with sacubitril/valsartan is stopped, ACE inhibitor therapy must not be initiated until 36 hours after the last dose of sacubitril/valsartan. Combination of sacubitril/valsartan with direct renin inhibitors such as aliskiren is not recommended. Sacubitril/valsartan should not be co-administered with another ARB containing medicinal product. Hypotension: Treatment should not be initiated unless SBP is ≥100 mmHg. Patients with SBP <100 mmHg were not studied. Cases of symptomatic hypotension have been reported in patients treated with sacubitril/valsartan during clinical studies, especially in patients ≥65 years old, patients with renal disease and patients with low SBP (<112 mmHg). Blood pressure should be monitored routinely when initiating or during dose titration with sacubitril/valsartan. If hypotension occurs, temporary down-titration or discontinuation of sacubitril/valsartan is recommended. Impaired or worsening renal function: Limited clinical experience in patients with severe renal impairment (estimated GFR <30 ml/min/1.73m^2). There is no experience in patients with end-stage renal disease and use of sacubitril/valsartan is not recommended. Use of sacubitril/valsartan may be associated with decreased renal function, and down-titration should be considered in these patients. Hyperkalaemia: sacubitril/valsartan should not be initiated if the serum potassium level is >5.4 mmol/l. Monitoring of serum potassium is recommended, especially in patients who have risk factors such as renal impairment, diabetes mellitus or hypoaldosteronism or who are on a high potassium diet or on mineralocorticoid antagonists. If clinically significant hyperkalaemia occurs, consider adjustment of concomitant medicinal products or temporary down-titration or discontinuation of sacubitril/valsartan. If serum potassium level is >5.4 mmol/l discontinuation should be considered. Angioedema: Angioedema has been reported with sacubitril/valsartan. If angioedema occurs, discontinue sacubitril/valsartan immediately and provide appropriate therapy and monitoring until complete and sustained resolution of signs and symptoms has occurred. sacubitril/valsartan must not be re administered. Patients with a prior history of angioedema were not studied. As they may be at higher risk for angioedema, caution is recommended if sacubitril/valsartan is used in these patients. Black patients have an increased susceptibility to develop angioedema. Patients with renal artery stenosis: Caution is required and monitoring of renal function is recommended. Patients with NYHA functional classification IV: Caution should be exercised due to limited clinical experience in this population. Patients with hepatic impairment: There is limited clinical experience in patients with moderate hepatic impairment (Child Pugh B classification) or with AST/ALT values more than twice the upper limit of the normal range. Caution is therefore recommended in these patients. B-type natriuretic peptide (BNP): BNP is not a suitable biomarker of heart failure in patients treated with sacubitril/valsartan because it is a neprilysin substrate. Psychiatric disorders: Hallucinations, paranoia and sleep disorders, in the context of psychotic events, have been associated with sacubitril/valsartan use. If a patient experiences such events, discontinuation of sacubitril/valsartan treatment should be considered. **Interactions:** Contraindicated with ACE inhibitors, 36 hours washout is required. Use with aliskiren contraindicated in patients with diabetes mellitus or in patients with renal impairment (eGFR <60 ml/min/1.73 m^2). Should not be co-administered with another ARB. Use with caution when co-administering sacubitril/valsartan with statins or PDE5 inhibitors. Monitoring serum potassium is recommended if sacubitril/valsartan is co-administered with potassium-sparing diuretics or substances containing potassium (such as heparin). Monitoring renal function is recommended when initiating or modifying treatment in patients on sacubitril/valsartan who are taking NSAIDs concomitantly. Reversible increases in serum lithium concentrations and toxicity have been reported during concomitant administration of lithium with ACE inhibitors or angiotensin II receptor antagonists including sacubitril/valsartan. Therefore, this combination is not recommended. If the combination proves necessary, careful monitoring of serum lithium levels is recommended. If a diuretic is also used, the risk of lithium toxicity may be increased further. Co-administration of sacubitril/valsartan and furosemide reduced Cmax and AUC of furosemide by 50% and 28%, respectively, with reduced urinary excretion of sodium. Co-administration of nitroglycerin and sacubitril/valsartan was associated with a treatment difference of 5 bpm in heart rate compared to the administration of nitroglycerine alone, no dose adjustment is required. Co-administration of sacubitril/valsartan with inhibitors of OATP1B1, OATP1B3, OAT3 (e.g. rifampicin, ciclosporin), OAT1 (e.g. tenofovir, cidofovir) or MRP2 (e.g. ritonavir) may increase the systemic exposure of LBQ657 or valsartan. Appropriate care should be exercised. Co-administration of sacubitril/valsartan with metformin reduced both Cmax and AUC of metformin by 23%. When initiating therapy with sacubitril/valsartan in patients receiving metformin, the clinical status of the patient should be evaluated. **Fertility, pregnancy and lactation:** The use of sacubitril/valsartan is not recommended during the first trimester of pregnancy and is contraindicated during the second and third trimesters of pregnancy. It is not known whether sacubitril/valsartan is excreted in human milk, but components were excreted in the milk of rats. Sacubitril/valsartan is not recommended during breastfeeding. A decision should be made whether to abstain from breast feeding or to discontinue sacubitril/valsartan while breast feeding, taking into account the importance of sacubitril/valsartan to the mother. **Undesirable effects:** *Very common (≥1/10):* Hyperkalaemia, hypotension, renal impairment. *Common (≥1/100 to <1/10):* Anaemia, hypokalaemia, hypoglycaemia, dizziness, headache, syncope, vertigo, orthostatic hypotension, cough, diarrhoea, nausea, gastritis, renal failure, acute renal failure, fatigue, asthenia. *Uncommon (≥1/1,000 to <1/100):* Hypersensitivity, postural dizziness, pruritis, rash, angioedema. *Rare (≥1/10,000 to < 1/1,000)*: Hallucinations (including auditory and visual hallucinations), sleep disorders. *Very rare (<1/10,000):* Paranoia.

Legal classification: POM. **Marketing Authorisation Numbers, quantities and price**: Entresto 24 mg/26 mg film-coated tablets £45.78 per 28 tablet pack (EU/1/15/1058/001); Entresto 49 mg/51 mg film-coated tablets £45.78 per 28 tablet pack, £91.56 per 56 tablet pack (EU/1/15/1058/002-003); Entresto 97 mg/103 mg film-coated tablets £91.56 per 56 tablet pack (EU/1/15/1058/006). **Date of last revision of prescribing information: May 2021**. MLR ID: 129646. **Full prescribing information (SmPC) is available from:** Novartis Pharmaceuticals UK Ltd, 2nd Floor, The WestWorks Building, White City Place, 195 Wood Lane, London, W12 7FQ. Tel: 01276 692255.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard Adverse events should also be reported to Novartis via uk.patientsafety@novartis.com or online through the pharmacovigilance intake tool at www.report.novartis.com. If you have a question about the product, please contact Medical Information on 01276 698370 or by email at medinfo.uk@novartis.com