

Scottish Government Health Directorates

UK GOVERNMENT WHITE PAPER – TRUST, ASSURANCE AND SAFETY – THE REGULATION OF HEALTH PROFESSIONALS IN THE 21ST CENTURY

IMPLEMENTATION IN SCOTLAND - UPDATE

PROGRAMME OF WORK	OVERALL OBJECTIVE / S	SUMMARY OF UK PROGRESS AND INTERVENTIONS REQUIRED ON BEHALF OF SGHD	RAG STATUS [with explanatory comment as necessary]
<p>1. Assuring independence: the governance and accountability of the professional regulators</p>	<p>To establish and sustain confidence in the independence of the Professional Regulatory Bodies.</p>	<ul style="list-style-type: none"> • Scotland was represented on the DH Working Group. Its Chair's final report in November 2007 made 32 recommendations, most of them accepted by Ministers. • Each regulatory body is to be run by a small Board-like council (9-15 members). Councils will no longer be representative, and will not have a professional majority. Members will be appointed for their personal skills and attributes. • Section 60 Orders are paving the way for Constitution Orders aimed at smaller, more Board-like Councils. They will also provide for the regulators to submit their annual reports, accounts and strategic plans to the Privy 	<p>GREEN</p>

		<p>Council for laying before Parliament; and, for those regulators operating in devolved areas, also the Scottish Parliament. In addition they are making further provisions aimed at rationalisation and harmonisation between regulators.</p> <ul style="list-style-type: none"> • Two such Orders have already been made - the NMC Order and the 1A Order, which between them cover all the regulators operating in reserved areas only. A further Order (the 1B Order) will follow shortly for those regulators working in devolved areas. • Following consultations, Constitution Orders have been made, providing for new Councils for the GMC, NMC, GOC, GCC and GOsC, who all operate in reserved areas only. An Order has also been made for the CHRE, which operates across the UK. • Their Council members are being/will be selected by the Appointments Commission for a maximum of two 4-year terms. Legislation is ensuring that each Council has at least one member who lives or works wholly or mainly in Scotland. The Scottish appointment to the CHRE has been made by the Scottish Ministers, as provided for in the Health and Social Care Act 2008. • The appointments process is well underway for all these (reserved) regulators, and 	
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		<p>appointments are being confirmed once the required legislation is all in place.</p> <ul style="list-style-type: none"> • SGHD has negotiated the process of appointment and there has been/ will be a Scottish representative on each of the panels interviewing potential Scottish members. • The 1B Order, which will make similar changes for those regulators operating in devolved areas, is expected to be ready for laying in March 2009. Related Constitution Orders for the GDC and the HPC are out for consultation but final versions can only be made once the 1B Order is in place. That Order also includes a number of other provisions, including the extension of regulation to pharmacy technicians in Scotland (legislation is already in place for PTs in England and Wales but has not yet been commenced) and the introduction of regulation for practitioner psychologists across the UK. • Revised Committee rules for the HPC and GDC will follow and must be laid 28 days before each Council is established. • Each Council will be required to produce a set of key performance indicators. • An annual assessment of each regulator's performance will be produced by CHRE to the relevant Parliament. In the case of 	
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		<p>Regulatory Bodies operating in devolved areas, this will include the Scottish Parliament.</p> <ul style="list-style-type: none"> • Regulators have a responsibility to ensure that all employers understand when it is appropriate for complaints to be referred to the Professional Regulator. CHRE was charged with coordinating this work and has now published its report. Scotland may consider that further work is required. • A 3- month consultation was launched in December 2008 by DH, including on behalf of the Scottish Ministers, on the draft General Pharmacy Order 2009. This Order will set up a new General Pharmacy Council to take on the regulatory body role of the Royal Pharmaceutical Society of Great Britain, which will continue in a professional role analogous to a Royal College. SGHD (CPO) is involved in the set up of the new body and CHRE requested input from SGHD to ensure that best regulatory practice is applied to the new body and that the needs of a devolved Scotland are met. Responses to the consultation are being considered by Scotland, England and Wales for the final version. This will have to be laid before the Scottish Parliament as well as Westminster. Once the Order has been made, a series of 	
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		associated statutory instruments will follow to put in place associated rules and regulations.	
2. Medical Education and Revalidation	<p>To implement objective and periodic reaffirmation of continuing fitness to practise – for doctors in first instance.</p> <p>Professional Regulatory Bodies to continue to be responsible for the assurance of standards (including educational) for the professions.</p>	<ul style="list-style-type: none"> • The DH working group has published its final report on revalidation. SGHD was represented on this group. • Revalidation for doctors will be a five year continuous process rather than an event. • It is likely to be informed by locally-based annual appraisal, periodic multisource feedback (MSF) and documentation of outcomes of any complaints. Information from clinical audit data could also be included but this is not yet certain. • Implementation will be carefully piloted and iterative. Licensing will commence in Scotland in Autumn 2009, and, in preparation, the GMC wrote to all doctors in early December 2008. Licensing will be the first step towards implementation of revalidation, which is expected to commence in 2010 -11 [NB This is the timetable for England. The CMO (England) report states that the GMC will discuss with the Devolved Administrations how the timetable may need to differ]. • MSF tools will need to meet the principles set by the GMC; the actual process is yet to be 	<p>AMBER -> GREEN [Revalidation not yet implemented but excellent progress being made by GMC]</p>

		<p>confirmed. The GMC will develop and consult on principles for MSF in 2009 and is continuing to commission research into its own MSF tool.</p> <ul style="list-style-type: none"> • Annual appraisal for doctors will be standardised and be more rigorous and challenging than current versions. "Good Medical Practice" has been categorised into 4 domains and 12 attributes. Work is underway to map the attributes to required evidence. • In Scotland, we will pilot the type of information to be gathered for both primary and secondary care in NHS Highland in close collaboration with the GMC, to commence early 2009. The UK Academy of Medical Royal Colleges will also be consulted. SGHD is leading on the pilot in collaboration with the GMC. A further pilot has commenced within NHS Lothian on tackling concerns locally. The pilot is being carried out in collaboration with the GMC and NCAS and aims to develop general guidance for local systems about the processes that should be in place to deal with poor performance. • The CMO requested that all NHS Boards in Scotland produce a report on the performance of appraisal of doctors in Spring 2008. These reports have now been collated and a summary report is being prepared. As 	
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		<p>expected, there is some variation between Boards' performances. The summary report will provide NHS Boards with a clear view of their relative performance, highlighting action for each to take in specific areas. Additionally the reports have highlighted issues best pursued at a national level. Contact has already been established with NES with regards to training of appraisers, and with NHS QIS with regards to External Quality Assurance. A Scottish Appraisal Leads Group is being established under the chairmanship of Professor Paul Padfield of NHS Lothian, which will have representatives from primary and secondary care from each NHS Board, and will be tasked with continuous improvement and harmonisation of appraisal across Scotland.</p> <ul style="list-style-type: none">• Revalidation (both re-licensure and recertification) will consist of a <u>single</u> process with dual outcomes. Progress with recertification is, however, at different stages across the different Royal Colleges. Academy of Medical Royal Colleges (AoMRC) has asked each College and Faculty to map the GMC framework to the required evidence for each specialty and for each grade of doctor. AoMRC also has workstreams addressing CPD, specialty-specific MSF, ePortfolios for	
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		<p>revalidation, evidence required for non-clinical work and remediation.</p> <ul style="list-style-type: none"> • A UK Revalidation Programme Board has been set up by the GMC and met for the first time in February 2009. A representative of CMO Scotland was involved in the selection of its Chair, Sir Michael Pitt. The Programme Board will report directly to the GMC and oversee the delivery of revalidation by the four UK countries. The Scottish Government Health Directorates are represented on the Board by Dr Frances Elliot. A parallel Scottish Revalidation Delivery Board will be set up to take forward Scottish implementation. • A Responsible Officer Network is also in development and the first meeting will be held in February 2009. • It is clear that successful revalidation needs to be underpinned by high quality systems of clinical governance. This will be key to success. • An Order (reserved) has been made which paves the way for relicensing and recertification. It will be followed by rules relating to the issuing of licences. Consultation is currently underway on the draft rules. The consultation closes on 21 April 2009. 	
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		properly debated, but “registration only” is provided for in the Medical Act, although this has not yet been enacted through the 2002 Section 60 Order, but will become available to coincide with the introduction of licensing in Autumn 2009.	
3. Non-Medical Revalidation	To implement objective and periodic reaffirmation of continuing fitness to practise – for all non-medical healthcare professional in due course [starting with nurses in 2010 – 11].	<ul style="list-style-type: none"> The group met for the fifth time on Thursday 10 July 2008 – and for the last time face to face. The 5th meeting was given over to agreeing the <i>high level principles</i> for revalidation, which had been the subject of two previous rounds of comments from members since May 2008. The final document is now available on the DH website - www.dh.gov.uk. The Regulatory Bodies will now progress work on models of revalidation that are fit for purpose for their respective registrants. It is unlikely that approaches will be harmonised. The group previously received a report from the “Standards Sub-Group” which is a group that was looking at the feasibility of using a framework, such as the KSF, to provide evidence that would be needed for revalidation. As a result of the group’s work, DH has commissioned a piece of formalised work to explore this in more depth for both NHS and non-NHS sectors 	<p>AMBER -> GREEN</p> <p>Work has progressed with each RB having commenced initial work on a profession-specific plan for revalidation. Not all plans have yet been shared publicly.</p>

		<ul style="list-style-type: none"> • Sue Hill, the Chief Scientific Officer at DH, previously gave a presentation on the career framework for healthcare scientists and what she perceived as the regulatory implications. This covered off different levels of practice from entry level to advanced practice. It is unclear at this stage whether the HPC will be implicated in all levels or whether there will be a Professional Body that takes responsibility for, for example, “advanced” [yet to be clearly defined] levels of practice. The new model is causing some anxieties in terms of its implications for existing groups and those already regulated. Public consultation is in progress. • The need for recognition of a level of “Advanced Practice” is currently being debated. CHRE is to be commissioned by DH England to lead agreement on a way forward for advanced practice across the professions, with clear differentiation between what is required for public protection and what focuses on professional standing alone. • A pilot in Scotland to be progressed by NES and testing out part of a three-layer risk based model of revalidation for dentists will start late spring 2009. Approximately 100 dentists from general practice and salaried dental services will take part. Details are at: 	
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		www.nes.scot.nhs.uk/dentistry/revalidation/ and the consultation document can be found at www.gdc-uk.org/Our+current+reforms/Revalidation/Open+consultation+on+revalidation/	
4. Tackling concerns: the local role	<p>The overarching working group is coordinating a series of reforms which will strengthen local arrangements for identifying poor practice among healthcare workers and taking effective action where poor practice is suspected. The main working group is coordinating the work of six sub-groups. The Scottish Government has membership on all six – as an observer on those where policy is being made for England only.</p> <p><u>GMC affiliates subgroup</u> Develop and pilot a new system of GMC affiliates at local level. These bodies will provide the General Medical Council with a regional presence in order to support</p>	<ul style="list-style-type: none"> • The overarching group has drafted its final report and publication is awaited. Aspects covered in the Health & Social Care Act 2008, which received Royal Assent in July, are being progressed. • <u>Responsible officers (ROs)</u>: A DH 3 month consultation on the proposed contents of regulations relating to these officers was published on 23 July 2008 following the enactment of the Health and Social Care Act 2008. It is anticipated that in NHS Scotland ROs will be the Board Medical Directors. All doctors will have to relate to a RO, and independent healthcare services will also be required to have access to a RO. In Scotland, Medical Directors may also take on that role for a small number of doctors not employed or contracted with their Boards. The key roles of the RO will be oversight of the revalidation process, and proactive liaison with the GMC. DH is considering the responses to the consultation for the drafting of the instructions to their solicitors for the RO regulations. 	<p>AMBER [not all aspects relate to reserved areas. Scotland not implicated in all aspects of the RO role and will observe the outcomes of GMC Affiliate pilots in England].</p>

	<p>arrangements for joint working between local employers and the GMC.</p> <p><u>Responsible officer subgroup</u> Develop a new role of Responsible Officer so that in future all practising doctors in England will relate to a Responsible Officer who will be a senior doctor with local responsibility for overseeing the revalidation process and handling complaints against doctors.</p> <p><u>Information subgroup</u> Design and implement systems for sharing information that could lead to early identification of poor practice in order to better protect the public.</p> <p><u>Clinical governance subgroup</u> Improve systems for local investigation and local decision making to ensure patient safety and quality assurance through revitalisation of clinical</p>	<p>Scotland will be involved throughout that process. Although RO responsibilities relating to regulation by the GMC are reserved, clinical governance functions are devolved.</p> <ul style="list-style-type: none"> • <u>GMC affiliates</u>: Two GMC pilot studies were launched in England in autumn 2008, and are expected to run for one year. Their aim is to establish whether the appointment of medical and paired lay GMC affiliates will help bridge the gap between national and local regulation, and provide more appropriate resolution of complaints and concerns about doctors in England. The lay affiliate is envisaged as a senior GMC employee. The affiliates' key roles will include supporting the Responsible Officers, ensuring consistency of approach and providing advice on individual cases. <i>Scotland will await the result of the pilot/s before considering whether there is a need for GMC affiliates / similar in Scotland. A mapping exercise, of structures and processes in place in Scotland, has been completed against White Paper requirements.</i> • <u>Regional Medical Regulation Support Team in England</u>: These regional groups (at SHA level in England), will include all the relevant stakeholders such as Responsible Officers, 	
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	<p>governance processes.</p> <p><u>Death certification subgroup</u> Develop an improved system for death certification to ensure greater scrutiny of the medical certification of cause of death process.</p> <p><u>Performers list subgroup</u> Review the current Performers List arrangements (under which GPs and other primary care contractors must be registered with a Primary Care Trust in order to practice locally), with a view to ensuring that they continue to provide necessary and appropriate safeguards.</p>	<p>GMC affiliate, Postgraduate Deans and an NCAS representative. They will meet regularly to gain an oversight of regulatory activity in that region, to maintain consistency and to learn from each other. There is no perceived need for these teams in Scotland. The GMC is considering holding a biannual one day meeting in Scotland for Responsible Officers, which would fulfil the networking, educational and information sharing aspects of these teams. A Responsible Officer Network is currently being established in Scotland and the GMC is working with Scottish Medical Directors on a proposed model for closer working.</p> <ul style="list-style-type: none"> • <u>Recorded concerns:</u> This concept remains troublesome and has little support from stakeholders. It remains unclear who would store such recorded concerns. However, current thinking seems to limit recorded concerns to matters which have been formally investigated. Some of these issues will, hopefully, be explored through the piloting of GMC Affiliates. The related provisions in the Bill do not extend to Scotland and this was carefully negotiated. • <u>Information Handling:</u> This group is working on the English agenda largely with observers from Scotland. It is anticipated that the 	
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		<p>outputs will be useful to England, and Scotland will observe with interest. There has been a call for a single point of entry for patient complaints and support.</p> <ul style="list-style-type: none"> • The discussions and outputs from groups relating to devolved areas, such as <u>Clinical Governance</u> and <u>Performers' lists</u>, are being observed with advice and information shared on Scottish systems as required. • All sub-groups from the Tackling Concerns Locally Group have drafted their reports and publication is awaited. 	
<p>5. Tackling concerns: the national role</p>	<p>To improve the investigation of concerns about health professionals at a local level, and to assure confidence in medical practice in particular, including improving the way concerns about health professionals are managed nationally.</p>	<ul style="list-style-type: none"> • The Health and Social Care Act 2008, made in July, provided for the civil standard of proof to be used by all the healthcare regulators. Some of them – the GMC, NMC and GOC have historically used the criminal standard, although the GMC adopted the civil standard for new hearings on 31 May 2008. The requirement to use the civil standard commenced on 3 November 2008. • The CHRE has taken forward work on both the threshold for investigation, and on the establishment of common protocols for investigation. • NCAS is now formally operating in Scotland, as of 1 April 2008, and has an office in Edinburgh. A stakeholder event was held on 22nd April 2008. A Scottish handbook and the 	<p>GREEN</p>

		<p>SLA is in development. NCAS's activities in Scotland are limited to doctors and dentists.</p> <ul style="list-style-type: none"> The Health and Social Care Act 2008 provided for the Office of the Health Professions Regulators Adjudicator (OHPA) to be set up to adjudicate in the GMC's and General Optical Council's fitness to practise cases. Meantime, other regulatory bodies will continue to perform both the adjudication and investigation roles. Subordinate legislation to put OHPA in place is currently being drafted by DH in this reserved area, and will be sent to SGHD for comments. 	
<p>6. Information about health professionals</p>	<p>To ensure that information on the professional credentials of health professionals are more easily accessible to patients, the public, professionals and employers.</p> <p>To ensure that entry to the register is managed appropriately for patient safety and that the registers themselves provide information, with appropriate safeguards, to enhance patient safety.</p>	<ul style="list-style-type: none"> There is ongoing discussion about what information should be held, by regulators and others, about individual registrants. 	<p>AMBER [satisfactory progress being made but much work still to be done].</p>

<p>7. Council for Healthcare Regulatory Excellence – White Paper commissions</p>	<p>CHRE is charged with taking forward a number of commissions as a result of White Paper policy intentions.</p> <ul style="list-style-type: none"> • CHRE is to advise on development of common standards and systems across professional groups where this would benefit patient safety. • CHRE is to advise on how Advanced Practice should be addressed, if at all, from a regulatory perspective. • CHRE is to work with stakeholders to develop common protocols for investigation and referral to Regulatory Bodies. • CHRE to investigate the feasibility of closer cooperation between regulators and employers when a health professional enters employment for the first time. • CHRE to provide advice on systems and processes for 	<ul style="list-style-type: none"> • The civil standard of proof now applies across all regulated healthcare professional groups. CHRE is also discussing with key players the potential for a shared Code of Conduct across the professions and also the potential for sharing certain functions. The Regulatory Bodies have already agreed on a set of shared values. The Office of the Health Professions Adjudicator will also be implicated in this policy intention in the future. • DH has commissioned work on Advanced Practice with input from the Devolved Administrations. An interim report is expected in Spring 2009. • CHRE has drafted a report on common protocols for investigation which has been put to the Tackling Concerns Locally Clinical Governance sub-group. In summary, CHRE has concluded that improving communications and improving access to existing advice from Regulatory Bodies is more proportionate and practical than producing common protocols. • CHRE has consulted on the need for adequate information and close co-operation between regulators and employers when a health professional enters employment for the first time. CHRE has concluded that 	<p>AMBER – GREEN [satisfactory progress being made but some work still to be done].</p>
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	<p>ensuring that students are fit to undertake education and training as health professionals; and whether students and trainees should have closer relationships with their future regulators prior to qualification and how this might be achieved.</p> <ul style="list-style-type: none"> • CHRE to recommend a single standard definition of good character. 	<p>there is no need for extra regulatory burden.</p> <ul style="list-style-type: none"> • CHRE has also consulted on how to ensure students are made aware of their responsibilities as health professionals at an early stage. CHRE has concluded that a stronger relationship is needed between the education provider, Regulatory Body and student through Codes of Conduct and guidelines for fitness to practise.. • CHRE has consulted in relation to its work on a definition of good character. It is clear that this is an area hampered by complexity. 	
<p>8. New roles and emerging professions</p>	<p>To consider the scope of statutory regulation and other models.</p> <p>To ensure that any future system of regulation is proportionate to the risks and benefits entailed.</p>	<ul style="list-style-type: none"> • This whole area is one that is devolved to the Scottish Parliament. • The interim report, written by the Chair of the DH Extending Professional Regulation (EPR) group, was seen by DH and Scottish Ministers and the final draft report is expected shortly. SGHD fed in to all drafts via direct membership and through comments from its own EPR group. • Criteria for statutory regulation have been considered and further work will assist decisions on whether new groups of healthcare workers require statutory professional self-regulation or another form to protect the public. SGHD is working to influence decisions regarding both regulation 	<p>AMBER – GREEN</p>

		<p>of new groups and choice of Regulatory Body with a view to continued UK wide regulation, sensitive to Scottish needs.</p> <ul style="list-style-type: none"> • The DH group has commissioned work on exploring different models of regulation and on the levels of risk associated with different types and levels of practice. Work on the development of a risk assessment tool is also in progress. This work will provide a much needed evidence base for future regulatory decisions. • A model of employer-led regulation was piloted in Scotland as one of the alternative models to statutory regulation. The pilot (managed by NHS Quality Improvement Scotland on behalf of SGHD) took place in three NHSS Boards and one independent hospital on behalf of the 4 UK countries and completed at the end of December 2008. An independent evaluation ran concurrently with the pilot, and the report was received late February 2009. • The HCSW project is a high profile piece of work which is breaking new ground in the regulatory field. It illustrates well the regulatory move from Government to governance. It is as yet unclear however whether the model is workable across the rest of the UK, governance arrangements 	
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		<p>being different in each of the four countries.</p> <ul style="list-style-type: none"> • In the first half of 2009, Scottish Ministers will make a decision regarding future policy in this area. Outcomes from a national stakeholder event held in Edinburgh in October 2008 will also inform future policy decisions and soundings as to the practicalities are being taken from key stakeholder groups in NHS Scotland. • Regulation of Healthcare Scientists, of Psychotherapists and Counsellors, and of Herbalists, Acupuncturists and Traditional Chinese Medicine Practitioners are areas of current consideration. It is anticipated that Psychologists and also Pharmacy Technicians will be statutorily regulated in 2009. • The Health and Social Care Act 2008 made provision for the Hearing Aid Council to be dissolved. A section 60 Order regulating hearing aid dispensers in the private sector is to come into force at that point, so that the registration of this group continues. That Order is currently being drafted for consultation. The regulation of hearing aid dispensers in the public sector will follow later. 	
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11th March 2009