Guide to the New Structure

Licensing (LD), Vigilance Risk Management of Medicines (VRMM) and Information Management (IMD) Divisions

March 2006
Introduction

On 27\textsuperscript{th} March 2006, the MHRA implements the new structure created by the Business Realignment project. This launches the new:

- Licensing Division
- Vigilance Risk Management of Medicines Division
- Information Processing Unit (within Information Management Division)

Enclosed within this document you will find information about each of the new teams in the realigned organisation, as well as the principles followed to design the new ways of working.

The next few pages outline the principles of the new organisational design, highlighting the new teams created by the Business Realignment project and their areas of responsibility.

Design Principles

Three Key Attributes

1. A Service Culture, that focuses on serving internal and external customers
2. One Team, committed to a common purpose
3. Accountable Authority, with clear roles and responsibilities that achieve strategic goals

Drivers for Change

- Expectations on regulatory bodies have changed from a number of key stakeholders, including the public and ministers; looking for improved choice and access to medicines
- The Agency has taken on increasingly new tasks and responsibilities; with new legislation influencing proactive pharmacovigilance, better safety updating and better patient information
- There is a clear desire to retain international standing at the leading edge of public health
- New opportunities are offered by both Sentinel and Lincoln signal detection
- There is a desire to adapt actively, rather than passively, to challenges faced by the Agency
- This is an opportunity to fully explore the freedoms of an Executive Agency and Trading Fund
- The influence of the European Risk Management Strategy and the need to move to proactive pharmacovigilance

Managing the Change

- A dedicated project was initiated in January 2005 to define a detailed organisation design, characterised by the three key attributes above
- Data-gathering to understand the existing flow and management of Agency activity involved over 60 individual discussions
- Following that, over 40 organisation design sessions were held, involving a cross-section of staff from the Agency, defining the detail of each organisation change
- Over thirty workshops were held throughout the project with the Licensing and Post-Licensing management groups, as well as Executive Board members
- A series of group communications events ran from March to September 2005, enabling staff to gain an opportunity to understand and input into the design process and outcomes
- From October 2005, individual consultation began on the impact of the realignment process
- From November 2005, managers and HR have worked to manage a transparent recruitment process, populating the final organisation
• From December 2005, managers within the realigned structure have worked to define and complete activities required to make the changes in March 2006
• March 2006 has seen a number of events with staff to communicate progress and prepare everyone for Go-Live on 27th March

The New Teams

• **Product Lifecycle Assessment Teams (PLATs):** Multi-disciplinary assessment teams aligned by therapeutic area to assess product licence applications over a product’s lifecycle
• **Service Management Team:** Designed to manage industry enquiries and expectations, working closely with the PLAT management teams to resolve complex issues and assist workload management. In addition, this team will monitor all European applications against relevant targets and timescales and support European committee delegates
• **Centralised Expert Committee Support:** Accountable for the provision of dedicated service to expert advisory bodies, as well as to internal operating divisions
• **Information Processing:** Processing all submissions to the Agency, operating as a central service provider to the operating divisions
• **Vigilance Risk Management of Medicines:** Providing increased pro-active monitoring of public health issues, in the areas of:
  - Pharmacovigilance Risk Management (including Pharmacoepidemiology research and intelligence)
  - Therapeutic Review (renewals, reclassifications, Periodic Safety Update Reports (PSURs), safety-related Variations and proactive class reviews)
  - Pharmacovigilance Signal Management (Adverse Drug Reactions (ADRs), Safety Signals and Quality Research & Standards)
  - Information for Public Health (Freedom of Information (FOI), patient information, advertising)
  - Special Populations – pro-active reviews focussed on specific patient groups, (in the first instance, paediatrics)

Design Implementation

The significant majority of the new structure will become operational on 27th March 2006 (Go-Live). From Go-Live, recruitment will be ongoing and operational readiness preparation underway to enable the phased introduction of the Service Desk, full Signal Management capability and proactive Class Reviews, by July 2006. In addition to this, a focused plan will be in place to further develop the capability and potential of the Information Processing function.

This phased approach to Go-Live will enable the Agency to focus on delivering core activities from 27th March, and introduce those more pro-active and elective activities as additional necessary staff are recruited.
Organisation Designs

*Licensing Division*

- **Director**
  - Ian Hudson

- **Deputy Director**
  - Siu Ping Lam

- **Group Manager**
  - Liz Baker
    - **PLAT 1**
      - Cardiovascular, Diabetes
    - **PLAT 2**
      - Respiratory, ENT; Endocrine; Dermatology
    - **PLAT 3**
      - CNS, Anaesthetics

- **Group Manager**
  - David Hook
    - **Statistics Unit**
      - **PLAT 4**
        - GI & Nutrition; Blood
      - **PLAT 5**
        - Anti-infective; Obs & Gynae; Genito-Urinary Tract
      - **PLAT 6**
        - Musculoskeletal; Malignant Disease

- **Group Manager**
  - Andy French
    - **PLPI 1**
    - **PLPI 2**
    - **Clinical Trials Unit**
    - **Biologics / Biotechnology Unit**

- **Unit Manager**
  - Leslie Whitbread
    - **Expert Committee Support Unit**
      - Service Management Unit
      - Service Desk Team, European Procedures Team
Licensing

Product Lifecycle Assessment Teams (PLATs)

The PLAT teams will comprise the following roles:
- PLAT Managers
- Medical Assessors
- Pharmaceutical Assessors
- Pre-Clinical Assessors
- Scientific Assessors
- Scientific Specialists
- Medical Writers
- Service Coordinators
- Executive Assistants

**PLAT Therapeutic Groupings:**
- PLAT 1: Cardiovascular; Diabetes
- PLAT 2: Respiratory; Ear Nose & Throat; Endocrine; Dermatology
- PLAT 3: Central Nervous System (CNS); Anaesthetics
- PLAT 4: Gastro Intestinal & Nutrition; Blood
- PLAT 5: Anti-infective; Obstetrics & Gynaecology; Genito-Urinary Tract
- PLAT 6: Musculoskeletal; Malignant Disease

**What does this team do?**

Each PLAT will be responsible for the following activities within a specified therapeutic area:
- Safety Specification of the Risk Management Plan (in conjunction with VRMM)
- Scientific/pre-submission advice (National and European Medicines Agency (EMEA))
- Assessment of:
  - New Active Substance marketing authorisations (National, Mutual Recognition (MR), Decentralised Procedures (DCP) and Centralised)
  - Abridged marketing authorisations (National, MR, DCP and Centralised - Complex, Standard, Simple)
  - Non vigilance-related Type IB Variations where UK is Reference Member State (RMS)
  - Certain non vigilance-related Type IB Variations where the UK is Concerned Member State (CMS) where assessors’ input is required
  - Non vigilance-related Type II Variations
- Quality audit of Type 1A Variations (following scientific validation within Information Processing)

**What are the new ways of working within this team?**

PLATs are grouped in specialist therapeutic areas (see chart above). Full marketing authorisation applications for Herbal products will be assessed by a PLAT team, based upon the therapeutic area. Herbal registration products will be managed by PLAT 5.

Assessment of a product throughout its lifecycle will be undertaken by the following teams:
- New marketing authorisations, abridged marketing authorisations and non safety-related Variations requiring assessment will usually be completed by assessors within the same PLAT (special arrangements will be made, when required, depending upon PLAT workloads)
- Safety-related assessment of Variations will be completed by VRMM
Dedicated Service Coordinators will perform a dual role of:

- Responding to industry queries and escalating those that are complex, where appropriate
- Monitoring progress of assessment work against forecasts and targets

**What are the aims for the team?**

**To improve assessment quality by:**

- Continuing to develop specialist product knowledge within assessment teams
- Increasing consistency of decision making and collaboration of assessors within therapeutic areas
- Developing the Agency’s ability to look across concurrent events or applications within therapeutic areas

**To improve assessment efficiency by:**

- Reducing duplication of effort
- Focusing assessors on assessment activity by providing appropriate service management and administrative support

**To improve the service provided to industry by:**

- Channelling industry enquiries through a dedicated Service Desk
- Using Service Coordinators to answer industry enquiries within a PLAT where possible

**Point of contact for further information**

**Group Manager:** Liz Baker, David Hook  
**Unit Managers:** Keith McDonald, Geoff Houghton, Tim Berridge, Simon Day, Sue Harris, Maureen Riach
What does this team do?

The Statistics Unit is responsible for:

- Providing statistical assessment of applications (National and European)
- Providing input into the Committee for Medicinal Products for Human Use (CHMP) biostatistical and general guidelines
- Drafting scientific advice for the CHMP and MHRA

What are the new ways of working within this team?

The Statistics Unit will continue operating following unchanged procedures.

What are the aims for the team?

To provide high quality assessments by:

- Developing specialist therapeutic and statistical knowledge
- Providing scientific consistency across the PLATs

Point of contact for further information:

Unit Manager: Simon Day
Parallel Imports Units (PLPIs)

What does this team do?

PLPI Units 1 and 2 are responsible for assessment of:

- Parallel Import applications (Initial, Variations and Renewals)
- Homeopathic applications (Initial, Variations and Renewals)

What are the new ways of working within this team?

The assessment and determination of PLPI and homeopathic products will continue following unchanged procedures as these units already deal with the lifecycle of the licenses concerned. A dedicated Service Coordinator will perform a combined role of:

- Responding to industry queries and escalating those that are complex, where appropriate
- Monitoring progress of assessment work against forecasts and targets
- Managing the administrative team involved in the maintenance of European Community Marketing Authorisation (ECMA) reference data and other administrative support tasks

The data entry processing of all PLPI and homeopathic products will be undertaken within the new Information Processing Unit. Applications will be passed to the PLPI Units once the cases have been validated within the Sentinel Product Licensing Case Folder.
What are the aims for the team?

To improve assessment quality by:

- Increasing the focus of the PLPI Units on assessment activities

To improve assessment efficiency by:

- Increasing the focus of assessors on assessment activity by providing appropriate service management and administrative support
- Reducing duplication of effort

To improve the service provided to industry by:

- Channelling industry enquiries through a dedicated Service Desk
- Using the Service Coordinator to answer industry enquiries within the PLPIs, where possible

Point of contact for further information:

Group Manager: Andy French
Unit Managers: Mark Ellison, Uche Abass
**Biologica ls and Biotechnology Unit**

- **Group Manager**
- **Biologicals / Biotechnology Unit Manager**
- **Medical Assessors**
- **Pharmaceutical Assessors**
- **Pre-Clinical Assessor**
- **Medical Writer**
- **Service Coordinator**
- **Executive Assistants**

**What does this team do?**

The **Biologica ls and Biotechnology Unit** is responsible for:

- The assessment of New Active, Abridged and Variation applications for biological/biotechnology medicinal products including vaccines
- Provision of scientific and regulatory advice on biological/biotechnology medicinal products to biopharmaceutical companies
- Contribution to guidance notes published by European Medicines Agency (EMEA)
- Advice through participating membership of various committees on Advanced Therapies such as Tissue Engineering, Gene Therapy, Cell Therapy, Transgenics etc.
- Policy lead on matters relating to biological/biotechnology in emerging matters of public health importance such as Transmissible Spongiform Encephalopathies (TSE)

**What are the new ways of working within this team?**

Working practice within the Biologicals and Biotechnology Unit will be substantially the same. The dedicated Service Coordinator will perform a dual role of:

- Responding to industry queries and escalating those that are complex, where appropriate
- Monitoring progress of assessment work against forecasts and targets

The data entry processing of all Biologicals/Biotechnology applications will be undertaken within the new Information Processing Unit. Applications will enter the Biologicals/Biotechnology Unit once the cases have been validated within the Sentinel Product Licensing Case Folder.
What are the aims for the team?

To improve the service provided to customers and stakeholders including industry by:

- Providing timely, high-quality reports and assessment decisions
- Continuing to play a lead role in matters relating to European Medicines Agency (EMEA)
- Keeping abreast of the latest scientific developments in relation to biological/biotechnology medicinal products

Point of contact for further information

**Group Manager:** Andy French  
**Unit Manager:** Narayanan
What does this team do?

The Clinical Trials Unit is responsible for:

- The assessment of all Clinical Trial Authorisation (CTA) applications from industry and academic sponsors to conduct clinical trials with both licensed and unlicensed medicines in the UK. This also includes the assessment of any proposed changes to previously approved CTAs
- The assessment of the safety of clinical trials (pharmacovigilance)
- The maintenance of the UK sections of the European Clinical Trials database (EudraCT) and the Clinical Trials safety database (Eudravigilance)
- The provision of scientific and procedural pre-submission advice to sponsors
- The provision of advice and support regarding the legislation that applies to clinical trials

What are the new ways of working within this team?

The processing of all new CTA applications will be undertaken within the new Information Processing team. Applications will enter the Clinical Trials Unit once the cases have been validated and the structured data entry has been completed within the Sentinel Case Folder.

The assessment of Clinical Trial applications will continue following unchanged procedures.

What are the aims for the team?

- To continue to provide a timely and efficient CTA assessment service to applicants using the new ways of processing applications
- To continue to develop Pharmacovigilance capability using cross Agency and European Medicines Agency (EMEA) links
• To provide a high quality and timely scientific and regulatory advice service to the UK clinical trials community
• To improve the service provided to industry by:
  o Channelling industry enquiries through a dedicated Service Desk
  o Using the Service Coordinator to answer industry enquiries within the Clinical Trials Unit, where possible

Point of contact for further information:

**Group Manager:** Andy French  
**Unit Manager:** Martyn Ward
Service Management

What does this team do?

The Service Management function will be responsible for:

- Handling enquiries received from industry, relating to Marketing Authorisations. This includes all enquiries relating to New Market Applications, Licence Variations, Drug Master Files, PLPIs, Notified Bodies Consultation, Clinical Trials, and Herbals and Homeopathic products. These enquiries will be initially handled by the Service Desk and routed appropriately when necessary
- Handling enquiries received from the European Medicines Agency (EMEA) and other Member States concerning applications in the Centralised, Mutual Recognition (MR) and Decentralised Procedures (DCP). These will be directed to the European Procedures team who will coordinate the completion of these applications
- Monitoring assessment activities against targets across the assessment teams for the different work types and procedures (focusing on national applications). The activity will be managed by the Service Manager

What are the new ways of working within this team?

The Service Desk is the Agency’s central point of contact with industry and will receive enquiries via telephone, email, dedicated mailboxes, fax and letter. The Centralised, MR and Decentralised Procedure applications will be coordinated and monitored by the European Procedures team.

- Coordinating and monitoring responsibilities will involve tracking Centralised, Mutual Recognition (MR) and Decentralised applications to completion across the assessment teams and evaluating these against Agency and European targets
- This structure will provide clear accountability and proactive tracking, through the Service Coordinator role, to ensure European Procedures are completed within the specified and required timeframes
What are the aims for the team?

To improve the service provided to industry by:

- Developing and managing relationships with industry stakeholders
- Achieving a structured and effective process by which industry stakeholders are able to communicate with the Agency
- Improving the quality, accuracy and uniformity of communication with industry

To improve assessment quality and efficiency by:

- Reducing disruption caused to Assessors by handling non-scientific industry enquiries
- Monitoring assessment activities against targets
- Providing overall project management for National, Centralised, MR and Decentralised Procedures to ensure adherence to the defined timetables

Point of contact for further information:

Unit Manager: Leslie Whitbread
Service Manager: Robin Fraser
Service Desk Team Lead: Paul Cottingham
Centralised Coordinator: Katherine Haros
MR/Decentralised Coordinator: Alan Thompson
**Centralised Expert Committee Support function**

What does this team do?

The centralised Expert Committee Support (ECS) function will undertake Committee secretariat responsibilities and Committee administration responsibilities to provide the highest level of service to the Expert Committee Members to include the delivery of papers to members of advisory bodies two weekends before the meeting.

The Expert Committee Support function will provide administration support for the following advisory bodies:

- Commission on Human Medicines (CHM)
- CHM Expert Advisory Groups (EAGs)
- Committee for Medicinal Products for Human Use (CHMP) briefing
- Mutual Recognition Facilitation Group (MRFG) briefing
- Committee on the Safety of Devices
- Independent Review Panel for Advertising
- Independent Review Panel for Borderline

The Expert Committee Support function will also be responsible for:

- Coordinating the Commission/Committee appointment process
- Coordinating the Commission/Committee annual reporting process

What are the new ways of working within this team?

The work undertaken within the Expert Committee Support Unit will be based upon the support currently provided by the Committee Support Unit. New ways of working will focus upon:

- Improving the consistency and quality of papers submitted to advisory groups (new SOP published)
- Developing the link between the Expert Committee Support function and Scientific EAGs supported from assessment teams
- Maintaining accurate and up to date advisory body information is published
- Ensuring European Committee delegates receive accurate and timely briefings
What are the aims for the team?

The centralised Expert Committee Support function will aim to:

- Increase the efficiency of Committee support activities
- Provide a consistent, high standard of support to the Expert Committee Members
- Increase the transparency and perceived independence of Expert Committees to the external stakeholder environment
- Improve the governance of Expert Committees in terms of consistency of responses to requests for information, and the implementation of robust internal audit trails
- Increase expertise and flexibility of resources to manage Committee support activities

Point of contact for further information:

Unit Manager: Leslie Whitbread
Section Supervisor: Leonard Williams
Vigilance Risk Management of Medicines (VRMM)

Pharmacovigilance Risk Management

The Therapeutic Teams are:

- **Therapeutic Team 1**: Cardiovascular; respiratory; endocrine; hormonal; steroids; paediatrics; infections; NSAIDS; vaccines; obs & gynae
- **Therapeutic Team 2**: Neuro-psychiatric; psychosis; depression; epilepsy; Parkinson’s; dementia; sleep disorders; drugs and driving; analgesia; MS; antihistamines; benzodiazepines; HIV; diabetes.
- **Therapeutic Team 3**: Oncology, GI, diagnostics, ophthalmology, dermatology, Genito-Urinary, anti-obesity, rheumatoid arthritis, contrast media, blood products, immunosuppressants, Total Parenteral Nutrition (TPN), enzyme replacement

What does this team do?

The Pharmacovigilance Risk Management Group is responsible for:

- Undertaking regulatory actions or implementing appropriate risk minimisation tools
- Undertaking risk benefit assessment of marketed medicines
- Completing proactive class reviews on new drugs or high profile safety issues
- Assessing PSURs for all black triangle drugs and those with specific safety concerns
- Assessing applications to vary the licence of Black Triangle drugs, and Urgent Safety Restriction (USR) and safety call-in Variations.
- Creating and updating Public Assessment Reports (PARs) on safety issues
- Working with the Communications Division to manage the communication of safety concerns
- Monitoring the progress of drug safety issues
- Supporting the work of the Pharmacovigilance Working Party delegate
- Providing epidemiology data to Agency teams
- Undertaking epidemiological studies according to the requirements of key stakeholders as well as providing reports and studies for Expert Committees
What are the new ways of working within this team?

Pharmacovigilance Risk Management will work with the Licensing division to undertake the assessment and monitoring of Risk Management Plans which accompany all new products from November 2005.

Pharmacovigilance Risk Management will be working with the new technology and the Pharmacovigilance Signal Management Group to detect, manage and track all signals.

There will be a greater emphasis on proactive pharmacoepidemiological research.

Pharmacoepidemiology will be embedded within the therapeutic teams to provide therapeutic epidemiology research and analysis with regards to Risk Management Plans. The Pharmacoepidmiologists within the therapeutic teams will have strong links to Pharmacoepidemiology Research and Intelligence function, which is part of this group.

The new Medical Writer resource will help with greater transparency by routinely publishing the basis for safety decisions.

What are the aims of this team?

- To evaluate signals of new drug safety hazards
- To undertake risk/benefit assessment of marketed medicines and take appropriate regulatory action
- To undertake the assessment of black triangle safety Variations
- To undertake and manage high quality epidemiological studies and research
- To provide research and intelligence to aid risk/benefit and decision making to protect public health

Point of contact for further information:

Group Manager: Sarah Wark
Unit Managers: Morell David, Rafe Suvarna, Julie Williams, Lesley Wise
Pharmacovigilance Signal Management

What does this team do?
The Pharmacovigilance Signal Management Group will:

Manage signals, quality standards and research

- Classify and commit all Adverse Drug Reaction (ADR) reports
- Ensure that potential drug safety signals from whatever source are detected and recorded in Sentinel in a consistent and high quality manner (examples of possible source of signals are ADR reports, Periodic Safety Update Reports, Clinical Trials and Literature Reviews)
- The team will use the Lincoln Technology system to generate the signals from the Yellow Card information and regularly review signal detection methodologies and outputs to ensure best methods are being deployed
- Manage the publication (as appropriate) of identified signals and MHRA action to ensure transparency (e.g. on MHRA website)
- Prioritise, report on and take forward detected safety signals from whatever source and maintain an audit of actions taken
- Ensure high quality ADR and Signals are captured by providing quality specific pharmacovigilance and signal detection training to all pharmacovigilance staff and introducing regular auditing of pharmacovigilance processes and decisions
- Work with IMD to ensure the correct operation of electronic reporting systems supporting communication with Market Authorisation Holders (MAHs) and the European Medicines Agency (EMA)
- Undertake regular quality audits of drug safety (including ADR report) and signal information capture

Provide high quality data and information

- Provide raw ADR data to external researchers for applications approved by Independent Scientific Advisory Committee (ISAC) and work with those researchers to assist with interpretation of the information and ensure the data is used to best effect
• Provide high quality information to stakeholders on drug safety issues both proactively (e.g. on MHRA website) and in response to queries
• Work with the Communications Division to promote the Yellow Card scheme for patients and healthcare professionals and to investigate and develop new methods of gathering ADR reports and data
• Provide information and policy on regulatory standards with regard to Pharmacovigilance; monitoring internal and external compliance
• Provide a range of management reports to the Pharmacovigilance Group and wider VRMM Division

What are the new ways of working within this team?

An important new way of working is the further collation of all VRMM drug safety signals from all data sources. The signal management review meeting will provide this focus; where representatives from Signal Management, Risk Management and Therapeutic Review Groups will assign priorities, deadlines and reviewers to each new signal. The outcome of signals will also be looked at. The new Signal Management team will organise these functions.

The Group will provide the Commission on Human Medicines (CHM) and its expert advisory groups with signal statistics on a regular basis, aiming for increased transparency with publication of identified signals.

Other new functions include developing and implementing better methods for literature scanning for signals, undertaking routine and regular audits to monitor the effect of regulatory actions, reviewing signal detection methodologies, providing quality specific pharmacovigilance and signal detection training to all pharmacovigilance staff and introducing auditing of pharmacovigilance processes. There will be new workflow rules surrounding the prioritisation, classification and committal of ADR reports to facilitate signal evaluation.

The new Group structure will support these new ways of working with a new Signal Management and Quality Standards & Research Unit, working along side the Pharmacovigilance Information Unit.

The Pharmacovigilance Information Unit will be responsible for the classification and committal of ADRs reports, responding to queries and on a therapeutic basis, conducting signal impact analysis and evaluation.

The Quality and Research Standards team will be responsible for audit, compliance, ADR raw data provision and management reports.

What are the aims of this team?

To manage drug safety signals, information provision and compliance in an excellent, timely, scientific, systematic and transparent way that best protects public health.

Point of contact for further information:

Group Manager: Jane Moseley
Unit Manager: Kavita Chadda
The Therapeutic Review Group is responsible for:

- Assessment of vigilance-related applications to vary a marketing authorisation
- Assessment of Periodic Safety Update Reports (PSURs) and marketing authorisation renewals
- Assessment of applications to reclassify a marketing authorisation
- Undertaking therapeutic reviews
- Compiling European Harmonisation reports
- Working with I&S Division on Borderline and Defective Medicines

What are the new ways of working within this team?

The organisation will be split into three therapeutic teams of medical, pharmaceutical and scientific assessors with a shared Toxicologist and Service Coordinator, supported by Executive Assistants. Each therapeutic team will be responsible for managing the assessment of Periodic Safety Update Reports (PSURs), Renewals, vigilance-related Variations, and Reclassifications according to their therapeutic grouping. Each team will be responsible for the completion of a defined number of prioritised class reviews, according to the strategic objectives of the VRMM organisation.
Assessment of Variations:

- Therapeutic Review Teams will manage non black triangle safety Variations
- Pharmacovigilance Risk Management will manage black triangle Variations
- The PLAT function within Licensing will manage all other Variations

As well as routine safety Variations received from companies, the teams will actively seek to update product information when identified as being necessary following submission of renewals and PSURs or therapeutic reviews. This co-ordinated approach will be more readily achievable in the context of dedicated therapeutic teams.

Assessment of Renewals and PSURs:

Due to a change in legislation, the number of renewals submitted will reduce. However, the group will be responsible for assessing a greater number of PSURs in more depth. New procedures are being developed to reflect the new European procedures.

Assessment of Reclassifications:

Reclassifications will benefit from assessment within therapeutic areas. A more co-ordinated, proactive approach will be developed involving consultation and communication with stakeholders. Where appropriate, teams will liaise with Policy Division on wider prescribing.

Therapeutic Reviews:

Products or classes of products with changed risk/benefit ratios will be proactively reviewed to ensure consistency with best therapeutic practice. Targeted reviews will be prioritised according to clear criteria, using information gathered from a variety of internal and external sources, including signals generated within Pharmacovigilance Signal Management and Risk Assessment.

All of the above will require liaison with Information for Public Health to ensure best practice is adopted for updating patient information.

Service Co-ordination:

The Service Coordinator is a new role and will be responsible for working with the Therapeutic Review Group Unit Managers to ensure work is prioritised and workflow is maintained.

**What are the aims for this team?**

The Therapeutic Review Group will promote safe and effective use of medicinal products consistent with best clinical practice by updating marketing authorisations and product information for patients and healthcare professionals through Renewal, PSUR, Variation or Reclassification procedures or following therapeutic review.

The Therapeutic Review Group aims are:

- To manage therapeutic reviews according to the strategic objectives of the VRMM organisation
- To utilise the regulatory tools available to the Agency in order to take decisive action to safeguard public health
- To manage the reclassification process to widen availability of medicines, where it is safe to do so

**Point of contact for further information:**

**Group Manager:** Sarah Branch
**Unit Managers:** Anne Ambrose (TG1), Martin Hurst (TG2), Ruth Hargreaves (TG3)
Information for Public Health (IPH)

What does this team do?

The Information for Public Health Group is responsible for championing high quality patient information, advertising standards, Freedom of Information (FOI) requests as they relate to VRMM and leading key VRMM projects.

The Patient Information Quality & Advertising Standards Units are responsible for:

- Leading the development of cutting-edge patient information within the Agency
- Leading policy development with regards to leaflets, labels and advertising within Europe
- Undertaking a strategic approach to raising the standards of public information through liaison with the industry and the public
- Managing the resolution of complaints about leaflet, labels and medicines advertising

The FOI team are responsible for receiving all VRMM FOI requests and coordinating answers in a timely manner as well as taking the lead on FOI issues as they impact on VRMM.

The Special Projects team will work on projects which cut across the whole of VRMM.

What are the new ways of working within this team?

To drive forward the Government’s focus on increasing transparency and openness towards release of all appropriate information, the group will be making available the decision-making process for adverts, patient leaflet and labels as well as providing detailed FOI responses.

The Patient Information Quality team will lead the development of cutting-edge patient information and carry out audits, identifying best practice and lessons learnt, as well as acting as a consultancy to the Agency and industry.
What are the aims of this team?

To champion the need for high quality information, in order to enable people to make well-informed decisions about, and to support the safe use of, medicines.

- To be a centre of excellence for patient information
- To deliver high standards in medicines advertising
- To be a focus for VRMM on freedom of information
- To deliver change so stakeholders feel the difference

Point of contact for further information:

**Group Manager:** Jeremy Mean  
**Unit Managers:** Beryl Keeley (Advertising Standards) and Jan MacDonald (Patient Information Quality)
What does this team do?

The Special Populations Unit ensures that special populations are considered by the Agency and Pharmaceutical Companies.

- Offering scientific advice to industry and Health Care Professionals on Special Populations
- Liaising with pharmaceutical companies to ensure that the most beneficial medicines are available to special populations; e.g. if a medicine is being discontinued, working with industry to understand the impact, or suggesting that a drug is reclassified
- Identifying medicines which are produced outside of the UK, and working with professional bodies and the pharmaceutical company to influence them to apply for a licence, allowing the medicine to be sold in the UK
- Monitoring clinical trials on special populations and requesting further information if required
- Liaising with pharmaceutical companies to influence the research and development of medicines which are suitable for special populations
- Assisting in the implementation of any legislation or Government strategy relating to a special population, e.g. Government Paediatric Strategy

What are the new ways of working within this team?

This team will continue to focus on the work is currently being undertaken in relation to the paediatrics population, however as this work is completed the team will focus on other special populations.

What are the aims of this team?

To make more safe medicines available to special populations.

Point of contact for further information:

Unit Manager: Julia Dunne
Information Processing

What does this team do?

The Information Processing Team is responsible for creating Sentinel case folders from scanned and electronic submissions. All information will initially be processed through the Submission Centre where case folders will be generated and simple case attributes for all scanned and electronic submissions entered. The submissions will then be distributed to the Regulatory and Scientific Submission Groups which are responsible for classifying and case validation.

Classifying and case validation will be completed by the following groups:

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<thead>
<tr>
<th>Regulatory Submission Group</th>
<th>Scientific Submission Group</th>
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<tbody>
<tr>
<td>PLPI</td>
<td>Type 1A;1B and II Variations</td>
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<tr>
<td>Clinical Trials</td>
<td>New Active Substances (National and MR)</td>
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<tr>
<td>PSURs/Renewals</td>
<td>Abridged (Complex, Standard, Simple)</td>
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<tr>
<td>Reclassification</td>
<td>Information Updates and cancellations</td>
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<tr>
<td>Patient Information</td>
<td>Herbals &amp; Homeopathics</td>
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<tr>
<td>Information Updates and cancellations</td>
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<tr>
<td>Notified Bodies</td>
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What are the new ways of working within this team?

Historically, submissions were completed in different teams across the Agency. The Information Processing unit centralises the creation of Product Licensing Sentinel case folders from scanned and electronic submissions.

By centralising the data input and case validation stage, it ensures the data entered in the system is of a consistent and quality standard and achieving greater flexibility to meet changing stakeholder need as electronic submissions are adopted.
Classifications and committal of all Adverse Drug Reaction Reports will be completed by Pharmacovigilance Signal Management.

What are the aims of this team?

- To ensure that submissions received by the Agency are handled proactively and effectively according to service level agreements and relevant business procedures
- Provide a customer-focused electronic submission receipt and handling function which satisfies the requirements of the Agency’s customers
- To provide a consistently high quality of data which is reliable and accurate

Point of contact for further information:

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