Institution: University of Hertfordshire

Unit of Assessment: Panel A (3A): Pharmacy and Pharmacology

a. Context

The unit approaches impact by integrating basic science and clinical practice to meet the needs of modern healthcare, and the crucial roles of pharmacy, pharmacology and clinical medicine in drug design, medicine development, disease management and enhanced public health. We have developed a research framework that builds on the principles of collaboration and partnership with end-users that include the pharmacy profession, pharmaceutical industry, regulatory bodies, clinicians and health professionals, policy makers, and health service commissioners/ providers.

The **Centre for Research in Topical Drug Delivery and Toxicology (TDDT)** aims at the cost-effective development of medicines to achieve optimal efficacy whilst mitigating toxicological risk, forging links with industry and the NHS. The research has helped improve drug delivery systems (see the Topical Formulation case study) and develop new *in silico, in vitro/ex vivo* and analytical methods that have been used to improve on existing products (e.g. Zyclara) and in developing generics (e.g. amorolfine nail laquer equivalent of Loceryl), both described in case study. This benefits patient groups through enhanced effectiveness, quality and safety of the medicines developed, and reduced pharmaceutical development process costs and, subsequently, in goods.

The **Centre for Clinical Practice, Safe Medicines and Drug Misuse Research** (**CPSMDM**) contributes directly to improving the impact of pharmacists in clinical practice, patient safety in General Practice and hospitals, reducing medication errors, and informing policy formulation on drugs of misuse and licit/illicit psychoactive agents. It also provides key data for evidence-based interventions to reduce morbidity and mortality in the general population and special 'at risk' groups, such as drug users. The general public and clients of health practitioners, including pharmacists, benefit from evidence-based training given to practitioners to reduce medicines errors. Our collaborative research on prescribing errors in general practice has led to a Royal College of General Practitioners curriculum update. Provision of information to (inter)national policy advisors and professionals on the nature and potential adverse effects of prescribed and illicit drugs (see 'Legal Highs' case study) helps to support the development of evidence-based policies and practices, service commissioning and treatment provision, informing public health, and potentially reducing morbidity and mortality while promoting wellbeing and enhancing quality of life.

Research in the **Pharmacology and Clinical Sciences Group** on the discovery of basic mechanisms that can aid identification of novel therapeutic targets and agents meets the needs of the pharmaceutical industry and the health service. The research on management of chronic kidney disease has led to the establishment of conservative management programmes (see 'End Stage Kidney Disease' case study) in many Renal Units in the UK and internationally as a potential alternative to dialysis for some older, frailer patients.

b. Approach to impact

Our approach to impact is:

i. Regular horizon-scanning to identify gaps in target areas, then creating and developing distinct research developments in our areas of strength.
ii. Impact analysis for each research proposal, considering the potential to contribute to advancing knowledge, informing clinical practice, making policy recommendations, and/or developing new platform technologies, analytical techniques, models or medicines; and exploiting translational research, intellectual property, follow-on grants and commercialisation with industry.
iii. For each research grouping, developing a research impact plan alongside the required research delivery plan which identifies both the areas and future lines of enquiry. The research impact plan therefore indicates the likely future impacts associated with research delivery.
iv. Engagement with a wide network of non-academic users and beneficiaries of the research, achieving impact through several different mechanisms.

TDDT engages with the Pharmaceutical Industry (inter)nationally to exploit performance-testing models and the group's formulation expertise for pharmaceutical product development. This is

exemplified by collaborations with MedPharm Ltd (developing and optimising MedSpray and MedTherm); Chanelle Medical (*in vitro* and *ex vivo* equivalence testing of a generic nail lacquer); Peplin/Leo Australia (development to market of Picato); Medicis and Graceway (development to market of various packaging forms of Zyclara).

In **CPSMDM**, impact is achieved largely through engagement with government agencies/departments, regulatory bodies, policy makers and health service commissioners/providers to influence policy and decision making. **Schifano** advises the Italian government's Anti-Drug Policies Department; **Corazza** is advisor to the Global Public Health Intelligence Network (GPHIN), a Canadian public health early warning system for drug misuse; and **Corkery** collaborates with both the UK and European Early Warning Systems on Novel Psychoactive Substances (NPS) and the Scottish Crime and Drug Enforcement Agency. **Schifano** and **Corkery** are both active members of the Advisory Council on the Misuse of Drugs (ACMD) and its sub-group on novel substances, and the European monitoring Centre for Drugs and Drug Addiction (EMCDDA). **Schifano** has also served as member of other bodies influencing government policy, including the Executive Board of the Royal College of Psychiatrists, Faculty of Substance Misuse. **Dhillon** is member of: General Pharmaceutical Council; Department of Health Medical Education England (Modernising Pharmacy Careers Programme Board); and board member and patient safety lead of the Eastern Academic Health Science Network (EAHSN). To reach its diverse potential beneficiaries, **CPSMDM** engages with a wide range of platforms including: establishing databases and websites for disseminating research findings, such as the Recreational Drugs European Network's (ReDNet) NPS technical folders, available via secure online subscription to clinicians and other healthcare professionals; presentations to data providers and users, making the programme's work more visible and creating opportunities to inform public debate around substance misuse; annual reports (available online) to UK stakeholders including the ACMD, Department of Health, National Treatment Agency (NTA), data providers (coroners, General Mortality Registers, Drug & Alcohol Action Teams), and international bodies (e.g. EMCDDA, UN); using websites to monitor data provision trends, supply movements, collect research data and disseminate results; organising events such as the ReDNet–EMCDDA conferences on novel psychoactive substances (Budapest, March 2012; Swansea, September 2013, also streamed online for greater audience reach); and developing novel technological tools such as SMAIL [text removed for publication] for health professionals to download information on 'legal highs' to smartphones, in keeping with changing communication trends and ensuring that the targeted audience is reached.

The **Pharmacology and Clinical Science Group**'s approach to impact is to work closely with NHS clinicians. Research user groups are engaged in the planning process and their requirements assessed to ensure that these are met. The impact of the work on the conservative management of advanced kidney failure has been amplified by national and international conference presentations, inclusion in national clinical guidelines, and co-authorship of Kidney Research UK patient information materials and a Department of Health (Kidney Care UK) document, 'End of Life Care in Advanced Kidney Disease'. In this context, **Farrington** also plays a national role in relation to kidney disease and renal care and sits on the British Renal Council.

The unit is supported by a number of institutional mechanisms such as the Research Institute's small grant scheme, which provides funding for staff to capture the impact of their work; a Business Development Coordinator based in the School of Life and Medical Sciences, who supports the development of external collaborations across commercial, educational and charitable sectors; and the Business Development Office and the Intellectual Property and Contracts office, which assist in developing potential spin-offs. A central team provides support for Knowledge Transfer Partnership Projects, and the Marketing and Communications Department organises publicity and PR for public events, as well as actively seeking opportunities for publicising and disseminating research.

Outreach and media exposure increase the visibility of our research and motivate potential partners to seek contact. Across the unit annual research showcase events and research open days are organised, to which all such parties and other collaborating institutions are invited. Staff use these and their own professional networks/contacts to help disseminate and their research.

c. Strategy and plans

The unit plans to build on the approach (discussed above) that it has developed to date by:

Enhancing the visibility of our research more widely by dissemination of findings in a user-friendly way through targeted communication to all user groups, including the development of websites with bespoke pages for academics, industrialists and the general public.

Strengthening links with regulatory authorities such as the ACMD, EMCDDA, NTA, MHRA and EMA through memberships and collaborations to guide and influence the policies and regulations around drug misuse, and also on the use of *in vitro/ex vivo* performance testing in topical and transdermal product approval.

Targeted communication to government agencies and departments of research outputs in our emerging priority area on reducing the health effects of exposure to an accidental or deliberate release of toxic substances. Communications will be provided as a series of recommendations, technical reports and guidance documents. In the UK, this will include providing training materials and operational guidance for all frontline personnel as part of the Home Office's 'initial operational response' programme. Public evidence for the impact of our work is envisaged to be available in the form of Home Office documentation by 2015. In the US, all federal and state emergency response agencies will be provided (scheduled by 2016) with guidance documentation (informed by our research) for responding to incidents involving the deliberate release of toxic materials.

Strategic development and exploitation of ReDNet to include novel psychoactive substance (NPS) misuse prevention and improvement of e-health; NPS related casualties, near misses and fatalities; and NPS chemical testing. We will increase the rapid dissemination of technical folders from the studies to professionals in over 40 countries (currently 30) via the latest advances in mobile phone technology (including the exploitation of SMAIL: see the 'Legal Highs' case study) and through interactive websites and social networking. Web monitoring activities in 8 languages will expand to include Farsi, Arabic and Chinese. The proposed strategy is multidisciplinary and its implementation will involve young people's participation: often the end-users and amongst those most at risk. This approach will also ensure a greater influence on policy making.

Engagement with the EAHSN, a new national initiative, with UH and the East & North Hertfordshire NHS Trust forming the southerly node. Staff from this unit of submission (**Dhillon**) lead the region on innovatory R&D in patient safety; others (**Farrington, Gorog**) are members of various clinical study groups. We will enhance our research and knowledge exchange through the EAHSN such that translation into effective and cost-effective treatment services for patients will occur, providing real benefits to the local and national economy. We will strengthen this with more strategic visiting and honorary NHS appointments to the university to support research in a Centre for Chronic Disease, proposed for 2014, linking directly to other EAHSN designated work streams and facilitating the opportunity to feed into the wider national and international health agenda.

d. Relationship to case studies

The three case studies demonstrate the unit's success in using an appropriate strategy in planning for impact. The first case study, **'Topical Formulation Development Using *in silico* and *in vivolex vivo* Models'** demonstrates how the development of novel research approaches and engagement with industry and government agencies have a huge impact on new medicines by reducing cost whilst enhancing product refinement and replacing animal use. The second case study, **'Mitigating the Harm of "Legal Highs"'**, results directly from identifying new drugs as an emerging issue for health professionals and their clients in the UK/Europe. The strategic decision to recruit a project manager (Corazza) for ReDNet with experience of working with international networks, together with the multi-disciplinary approach (including the unit's chemists analysing 'legal highs') strengthened the project's impact. The third case study, **'Effective Clinical Management of Highly Comorbid Patients with End Stage Kidney Disease'**, describes the impact of a stream of work continued over many years. It ranges from the identification of a group of patients with very poor prognosis on dialysis, through the description of alternative management options, through to their evaluation. It highlights the timescale often necessary to consolidate impact, the value of a sustained approach, and our emphasis on creating broad-ranging academic and clinical collaborations to study important clinical problems.