

# Sapphire Clinics (London) Limited

## Inspection report

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This report describes our judgement of the quality of care at this service. It is based on a combination of what we found when we inspected, information from our ongoing monitoring of data about services and information given to us from the provider, patients, the public and other organisations.

## Ratings

### Overall rating for this location

Good 

Are services safe?

Good 

Are services effective?

Good 

Are services caring?

Good 

Are services responsive to people's needs?

Good 

Are services well-led?

Outstanding 

# Overall summary

## **We carried out an announced comprehensive inspection at Sapphire Clinics (London) Limited as part of our inspection programme.**

The key questions are rated as:

Are services safe? – Good

Are services effective? – Good

Are services caring? – Good

Are services responsive? – Good

Are services well-led? – Outstanding

We carried out this announced comprehensive inspection of Sapphire Clinics (London) Limited under Section 60 of the Health and Social Care Act 2008 as part of our regulatory functions. This inspection was planned to check whether the service was meeting the legal requirements and regulations associated with the Health and Social Care Act 2008.

Sapphire Clinics (London) Limited provides medical treatment for patients focused around the use of Cannabis-based products for medicinal use (CBPMs) by experienced medical staff working within the latest Governmental guidelines.

The Managing Director is the registered manager. A registered manager is a person who is registered with the Care Quality Commission to manage the service. Like registered providers, they are 'registered persons'. Registered persons have legal responsibility for meeting the requirements in the Health and Social Care Act 2008 and associated Regulations about how the service is run.

We did not speak directly with patients during the inspection.

### **Our key findings were:**

- The service routinely reviewed the effectiveness and appropriateness of the care it provided. It ensured that care and treatment was delivered according to evidence-based guidelines.
- The provider had systems in place to protect people from avoidable harm and abuse.
- There was a clear vision to provide a safe, personalised, high quality service.
- All staff we spoke with felt valued by the leaders and said there was a high level of staff support and engagement.
- Patients could access care and treatment from the service within an appropriate timescale for their needs.
- The service had comprehensive business development strategy that effectively monitored the service provided to assure safety and patient satisfaction.
- The provider was involved in a variety of cross collaborative working projects and were engaged with policy makers in relation to furthering the understanding of CBPMs and developing this area of medicine.
- Feedback about the practice was extremely positive from patients and peers. The clinic had received two awards for best medical cannabis clinic from service users and the industry.
- There was a strong focus on continuous learning and improvement. The provider had set up the Sapphire Institute for staff training. The educational programme was open to any interested clinician.

### **We saw the following areas of outstanding practice:**

# Overall summary

- The leadership, governance and culture was used to drive and improve the delivery of high-quality person-centred care. The provider had set up The UK Medical Cannabis Registry, which is a bespoke real-world data collection platform to systematically monitor patient outcomes
- The leadership drove continuous improvement. The custom-built IT system was designed and developed by patients and staff to improve patient care.
- There was a clear proactive approach to seeking out and embedding new ways of providing care and treatment. The clinic took part in 'Grand Rounds' with an international clinic where both clinics presented interesting and complex cases for MDT teaching and learning.

**Dr Rosie Benneyworth BM BS BMedSci MRCGP**

Chief Inspector of Primary Medical Services and Integrated Care

## Our inspection team

Our inspection team was led by a CQC lead inspector. The team included a CQC specialist adviser and a member of the CQC medicines team.

## Background to Sapphire Clinics (London) Limited

Sapphire Clinic London Ltd provides medical treatment for patients focused around the use of Cannabis-based products for medicinal use (CBPMs) by experienced medical staff working within the latest Governmental guidelines. The service is located at 10 Harley Street, London W1G 9PF. The building entrance lobby is accessed via steps from the pavement. Wheelchair access is via a ramp at the front of the building. The service has access to consultation rooms and a waiting area for patients. However, at the time our inspection most consultations were taking place online due to Covid – 19.

The opening hours are 9am to 5pm Monday to Friday. Patients can also book appointments for evenings and weekends. The medical team comprises of eight consultants who specialise in Psychiatry, Pain and Neurology. There is also a managing director, operations director, a medical director, chief financial officer, chief pharmacist and five administration and support staff.

The service treats a range of conditions including pain, psychiatric conditions, neurological conditions, gastroenterological and palliative care.

### **How we inspected this service**

We reviewed information sent to us by the provider remotely prior to attending the site to reduce the time spent on site in line with our Covid- 19 inspecting guidance. We spoke with the managing director, clinical director, registered manager, two consultants and administrative staff. We looked at records related to patient assessments and the provision of care and treatment. We also reviewed documentation related to the management of the service. We reviewed patient feedback provided to a third party.

To get to the heart of patients' experiences of care and treatment, we always ask the following five questions:

- Is it safe?
- Is it effective?
- Is it caring?
- Is it responsive to people's needs?
- Is it well-led?

These questions therefore formed the framework for the areas we looked at during the inspection

# Are services safe?

## **We rated safe as Good because:**

### **Safety systems and processes**

#### **The service had clear systems to keep people safe and safeguarded from abuse.**

- The landlord for the building conducted safety risk assessments. They had appropriate safety policies, which were regularly reviewed and communicated to staff. They outlined clearly who to go to for further guidance. Staff received safety information from the service as part of their induction and refresher training. The service had systems to safeguard children and vulnerable adults from abuse.
- The provider had systems in place to assure themselves that an adult accompanying a child had parental authority.
- The service worked with other agencies to support patients and protect them from neglect and abuse. Staff took steps to protect patients from abuse, neglect, harassment, discrimination and breaches of their dignity and respect.
- The provider carried out staff checks at the time of recruitment and on an ongoing basis where appropriate. Disclosure and Barring Service (DBS) checks were undertaken where required. (DBS checks identify whether a person has a criminal record or is on an official list of people barred from working in roles where they may have contact with children or adults who may be vulnerable).
- Staff received up-to-date safeguarding and safety training appropriate to their role. All staff were trained to level 2. They knew how to identify and report concerns. Staff who acted as chaperones were trained for the role and had received appropriate DBS check.
- The landlord for the building had an effective system to manage infection prevention and control, which had been updated to reflect the changes needed following the Covid-19 pandemic. The landlords had carried out Legionella testing and were following the identified actions.

### **Risks to patients**

#### **There were systems to assess, monitor and manage risks to patient safety.**

- At the time of our inspection, due to the pandemic, consultations were being carried out online. The doctors told us they conducted consultations in private in order to maintain patient confidentiality. All consultants used an encrypted, password secure laptop to log into the operating system, which was a secure programme.
- There were arrangements for planning and monitoring the number and mix of staff needed.
- There was an effective induction system for all staff tailored to their role. This included all clinicians having to complete a number of Continuing Professional Development (CPD) modules about CBPMs and attending two Multi-disciplinary (MDT) meetings before providing consultations.
- Staff understood their responsibilities to manage emergencies and to recognise those in need of urgent medical attention. For example, we saw there were occasions where consultants had stopped the consultations due to concern about the symptoms patients were describing, and asked them to contact their own GPs as a matter of urgency or advised them to go to the hospital.
- When there were changes to services or staff the service assessed and monitored the impact on safety.
- There were appropriate indemnity arrangements in place.

### **Information to deliver safe care and treatment**

#### **Staff had the information they needed to deliver safe care and treatment to patients.**

- Individual care records were written and managed in a way that kept patients safe. The care records we saw showed that information needed to deliver safe care and treatment was available to relevant staff in an accessible way.

# Are services safe?

- The service had systems for sharing information with staff and other agencies to enable them to deliver safe care and treatment.
- The service had a system in place to retain medical records in line with Department of Health and Social Care (DHSC) guidance in the event that they cease trading.
- Clinicians made appropriate and timely referrals in line with protocols and up to date evidence-based guidance.

## **Safe and appropriate use of medicines**

### **The service had reliable systems for appropriate and safe handling of medicines.**

- The service kept prescription stationery securely and monitored its use.
- The service carried out monthly controlled drugs and prescribing audits to ensure safe prescribing was taking place.
- The service only prescribed Cannabis-based products for medicinal use (CBPMs) which are Schedule 2 controlled drugs (medicines that have the highest level of control due to their risk of misuse and dependence). Clinicians prescribed CBPMs to patients and gave advice on how to administer them in line with legal requirements and current national guidance. Where there was a different approach taken from national guidance there was a clear rationale for this that protected patient safety, which was recorded in the patient's records.
- CBPMs are currently unlicensed medicines. Treating patients with unlicensed medicines is higher risk than treating patients with licensed medicines, because unlicensed medicines may not have been assessed for safety, quality and efficacy. Therefore, they must be prescribed and supplied in line with the Medicines and Healthcare products Regulatory Agency (MHRA) guidance for the prescribing and supply of unlicensed medicines.
- They had effective protocols for verifying the identity of patients including children.

## **Track record on safety and incidents**

### **The service had a good safety record.**

- There were comprehensive risk assessments in relation to safety issues. They had a custom-built IT system that met the requirement of NHS data security and protection Toolkit (GCP). The system also enabled auditing of prescriptions and had an integrated patient interface which allowed patients to sign documentation, book appointments and request more medication. It also gave patients access to guides for taking medication.
- The service monitored and reviewed activity. This helped it to understand risks and gave a clear, accurate and current picture that led to safety improvements.

## **Lessons learned and improvements made**

### **The service learned and made improvements when things went wrong.**

- There was a system for recording and acting on significant events. Staff understood their duty to raise concerns and report incidents and near misses. Leaders and managers supported them when they did so.
- There were adequate systems for reviewing and investigating when things went wrong. The service learned and shared lessons identified themes and took action to improve safety in the service. For example, we saw that where a processing error had occurred in relation to obtaining patient information the provider informed all affected people and provided additional training to its staff.
- The provider was aware of and complied with the requirements of the Duty of Candour. The provider encouraged a culture of openness and honesty. The service had systems in place for knowing about notifiable safety incidents.

When there were unexpected or unintended safety incidents:

# Are services safe?

- The service gave affected people reasonable support, truthful information and a verbal and written apology.
- They kept written records of verbal interactions as well as written correspondence.
- The service acted on and learned from external safety events as well as patient and medicine safety alerts. The service had an effective mechanism in place to disseminate alerts to all members of the team including sessional and agency staff.

# Are services effective?

**We rated effective as Good because:**

## **Effective needs assessment, care and treatment**

**The provider had systems to keep clinicians up to date with current evidence-based practice. We saw evidence that clinicians assessed needs and delivered care and treatment in line with current legislation, standards and guidance (relevant to their service)**

- Cannabis-based products for medicinal use (CBPMs) were legalised in the UK on 1 November 2018, but the regulations around its use and supply remain strict. We noted the provider assessed needs and delivered care in line with relevant and current evidence-based guidance and standards such as The Society for Cannabis Clinicians and National Institute for Health and Care Excellence (NICE) best practice guidelines.
- Patients' immediate and ongoing needs were fully assessed. This included their clinical needs and their mental and physical wellbeing. Clinicians obtained enough information from the patients and their NHS GP to confirm a diagnosis.
- We saw no evidence of discrimination when making care and treatment decisions.
- One month's supply of medication was prescribed and patients had to have follow up consultations to obtain repeat prescriptions.

## **Monitoring care and treatment**

**The service engaged in some quality improvement activity.**

- The service used information about care and treatment to make improvements. The service had carried out a clinical outcomes audit to not only improve their own practice, but also inform other clinicians in UK and globally. The audit assessed two outcomes, firstly whether there had been any changes in patients reported outcome measures (PROMs) over a three-month period whilst taking the prescribed medication, and frequency of adverse events. We saw that 129 patients were included in the audit. We noted the results demonstrated there was an overall improvement in health-related quality of life in patients on CBMPs, particularly in relation to anxiety, sleep and pain. The frequency of adverse events was low with the most common ones being constipation and sleepiness. The clinic would then discuss different options with individual patients where there had been no improvement or where they were concerned about adverse events.

## **Effective staffing**

**Staff had the skills, knowledge and experience to carry out their roles.**

- All staff were appropriately qualified. As this was a new and evolving area of medicine the Chief Pharmacist provided weekly training for all operations staff and circulated research updates to all staff.
- Relevant professionals (medical) were registered with the General Medical Council (GMC) and were up to date with revalidation.
- We saw that all staff had completed generic mandatory training such as Health and Safety, GDPR and Mental Capacity Act.

## **Coordinating patient care and information sharing**

**Staff worked together, and worked well with other organisations, to deliver effective care and treatment.**



# Are services effective?

- Patients received coordinated and person-centred care. Staff referred to and communicated effectively with patients NHS GPs. For example, patients could not undertake a consultation until the provider had received the patients 'summary of care' report from GPs.
- Before providing treatment, doctors at the service ensured they had adequate knowledge of the patient's health, any relevant test results and their medication history. We saw examples of patients being signposted to more suitable sources of treatment where this information was not available to ensure safe care and treatment.
- All patients were asked for consent to share details of their consultation and any medicines prescribed with their registered GP on each occasion they used the service. We saw evidence of letters sent to their registered GP in line with GMC guidance.
- Care and treatment for patients in vulnerable circumstances was coordinated with other services. For example, mental health services.
- The service monitored the process for seeking consent appropriately. All patients had to give consent for the service to contact their NHS GP, to obtain their medical history and diagnosis and share with them information about their prescription before they were given a consultation. If this consent was not given or was withdrawn at any time the patient would not be eligible to be treated with CBPMs. All potential patients were made aware of this when they first contacted the clinic.

## **Supporting patients to live healthier lives**

### **Staff were consistent and proactive in empowering patients and supporting them to manage their own health and maximise their independence.**

- Where appropriate, staff gave people advice so they could self-care.
- Risk factors were identified, highlighted to patients and where appropriate highlighted to their normal care provider for additional support. For example, patients and their GPs were made aware of the dangers of not using the CBPMs in the manner prescribed and the legal consequences.
- Where patient needs could not be met by the service, staff redirected them to the appropriate service for their needs.

## **Consent to care and treatment**

### **The service obtained consent to care and treatment in line with legislation and guidance.**

- Staff understood the requirements of legislation and guidance when considering consent and decision making.
- Staff supported patients to make decisions. Where appropriate, they assessed and recorded a patient's mental capacity to make a decision.

# Are services caring?

## **We rated caring as Good because:**

### **Kindness, respect and compassion**

#### **Staff treated patients with kindness, respect and compassion.**

- The service sought feedback on the quality of clinical care patients received. All patients were sent feedback questionnaires after all consultations. Feedback from patients was positive about the way staff treat people.
- Staff understood patients' personal, cultural, social and religious needs. They displayed an understanding and non-judgmental attitude to all patients. All staff had completed Equality and Diversity training.
- The service gave patients timely support and information.

### **Involvement in decisions about care and treatment**

#### **Staff helped patients to be involved in decisions about care and treatment.**

- Interpretation services were available for patients who did not have English as a first language. Patients were also told about multi-lingual staff who might be able to support them. Information leaflets were available in easy read formats, to help patients be involved in decisions about their care.
- For patients with learning disabilities or complex social needs family, carers or social workers were appropriately involved.
- Staff communicated with people in a way that they could understand, for example, communication aids and easy read materials were available.

### **Privacy and Dignity**

#### **The service respected patients' privacy and dignity.**

- Staff recognised the importance of people's dignity and respect. All consultants followed guidelines about how consultation should be conducted when they were not onsite.

# Are services responsive to people's needs?

**We rated responsive as Good because:**

## **Responding to and meeting people's needs**

**The service organised and delivered services to meet patients' needs. It took account of patient needs and preferences.**

- The provider understood the needs of their patients and improved services in response to those needs. For example, they reviewed their processes for providing information and guidance to patients about how to use the different medications following patient feedback.
- The facilities and premises were appropriate for the services delivered.

## **Timely access to the service**

**Patients were able to access care and treatment from the service within an appropriate timescale for their needs.**

- Patients had timely access to initial assessment and treatment. We noted that where there was a delay to a patient being given initial consultation appointments this was due to the provider not receiving medical information in a timely manner from the patients GP.
- Waiting times, delays and cancellations were minimal and managed appropriately.
- Patients reported that the appointment system was easy to use.
- Referrals and transfers to other services were undertaken in a timely way. For example, where the provider had identified safeguarding concerns, they had made immediate appropriate referrals to other support services.

## **Listening and learning from concerns and complaints**

**The service took complaints and concerns seriously and responded to them appropriately to improve the quality of care.**

- Information about how to make a complaint or raise concerns was available. We noted the provider took all complaints, including informal feedback, extremely seriously. Staff treated patients who made complaints compassionately.
- The service informed patients of any further action that may be available to them should they not be satisfied with the response to their complaint.
- The service had a complaint policy and procedures in place. The service learned lessons from individual concerns, complaints and from analysis of trends. It acted as a result to improve the quality of care. For example, they had reviewed and changed the way patients could request medication following a number of complaints that patients were struggling to request medication in a clear and timely fashion.

# Are services well-led?

## **We rated well-led as Outstanding because:**

The leadership, governance and culture was used to drive and improve the delivery of high-quality person-centred care. The provider had set up The UK Medical Cannabis Registry, which is a bespoke real-world data collection platform to systematically monitor patient outcomes

The leadership drove continuous improvement. The custom-built IT system was designed and developed by patients and staff to improve patient care.

There was a clear proactive approach to seeking out and embedding new ways of providing care and treatment. The clinic took part in 'Grand Rounds' with an international clinic where both clinics presented interesting and complex cases for MDT teaching and learning.

## **Leadership capacity and capability;**

### **Leaders had the capacity and skills to deliver high-quality, sustainable care.**

- The leadership drove continuous improvement and inspired and motivated staff to develop in their roles.
- Leaders were knowledgeable about issues and priorities relating to the quality and future of services. They understood the challenges and the risks associated with unlicensed medicines and the lack of controlled trial data were addressing this through carrying out research using data collected from their patients with the aim of evidencing the effectiveness and tolerability of medical cannabis and further identifying any potential risks.
- have created a methodology to systematically monitor patient outcomes.
- Leaders at all levels were visible and approachable. They worked closely with staff and others to make sure they prioritised compassionate and inclusive leadership.
- The provider had effective processes in place to assess the competencies of all staff they employed in order to plan appropriate training and development.

## **Vision and strategy**

### **The service had a vision and credible strategy to deliver high quality care and promote good outcomes for patients.**

- There was a clear vision and set of values. The service had a realistic strategy and supporting business plans to achieve priorities.
- The service developed its vision, values and strategy jointly with staff and external partners.
- Staff were aware of and understood the vision, values and strategy and their role in achieving them.
- The service monitored progress against delivery of the strategy.

## **Culture**

### **The service had a culture of high-quality sustainable care.**

- Staff felt respected, supported and valued. They were proud to work for the service.
- The service focused on the needs of patients.
- Openness, honesty and transparency were demonstrated when responding to incidents and complaints. The provider was aware of and had systems to ensure compliance with the requirements of the duty of candour.

# Are services well-led?

- Staff told us they could raise concerns and were encouraged to do so. They had confidence that these would be addressed.
- There were processes for providing all staff with appraisals and career development conversations. Staff were supported to meet the requirements of professional revalidation where necessary. The provider had implemented an internal annual doctors appraisal process.
- There was a strong emphasis on the safety and well-being of all staff.
- The service actively promoted equality and diversity. Staff had received equality and diversity training. Staff felt they were treated equally.
- There were positive relationships between staff and teams.

## **Governance arrangements**

### **There were some systems of accountability to support good governance and management.**

- Structures, processes and systems to support good governance and management were clearly set out, understood and effective. The governance and management of partnerships, joint working arrangements and shared services promoted interactive and co-ordinated person-centred care.
- Staff were clear on their roles and accountabilities.
- Leaders had established policies, procedures and activities to ensure safety and assured themselves that they were operating as intended.
- Clinical audit had a positive impact on quality of care and outcomes for patients. There was clear evidence of action to change services to improve quality.
- The service used performance information which was reported and monitored. They had daily reports showing operational performance.
- The information used to monitor performance and the delivery of quality care was accurate and useful. There were plans to address any identified weaknesses.
- Leaders and managers encouraged staff to take time out to review individual and team objectives, processes and performance.
- The service submitted data or notifications to external organisations as required.
- There were effective arrangements in line with data security standards for the availability, integrity and confidentiality of patient identifiable data, records and data management systems.

## **Managing risks, issues and performance**

### **There were clear and effective processes for managing risks, issues and performance.**

- There was an effective, process to identify, understand, monitor and address current and future risks including risks to patient safety.
- The service had processes to manage current and future performance. Performance of clinical staff could be demonstrated through audit of their consultations, prescribing and referral decisions. Leaders had oversight of safety alerts, incidents, and complaints.
- The provider had plans in place and had trained staff for major incidents.

## **Appropriate and accurate information**

### **The service acted on appropriate and accurate information.**

- Quality and operational information was used to ensure and improve performance. Performance information was combined with the views of patients.

# Are services well-led?

- Quality and sustainability were discussed in relevant meetings where all staff had sufficient access to information.

## **Engagement with patients, the public, staff and external partners**

### **The service involved patients, the public, staff and external partners to support high-quality sustainable services.**

- The service encouraged and heard views and concerns from the public, patients, staff and external partners and acted on them to shape services and culture. They had co-produced patient information leaflets and videos with their patients based on feedback. They also facilitated quarterly Patient Group Webinars to provide information to patients about different products and how to use them safely and appropriately.
- Staff could describe to us the systems in place to give feedback. They told us they had weekly meetings where they were invited to give feedback and could also provide feedback anonymously.
- The service was transparent, collaborative and open with stakeholders about performance.

## **Continuous improvement and innovation**

### **There was evidence of systems and processes for learning, continuous improvement and innovation.**

- There was a clear proactive approach to seeking out and embedding new ways of providing care and treatment and the leadership drove continuous improvement. The custom-built IT was designed and developed by patients and staff to improve patient care. The automatic clinic letters have led to a decrease in patient complaints regarding time to receive letters. The six-month audit carried out in June 2020 showed 20 informal complaints with regards to 'Patient communication – clinic letter delay'. However, the audit carried out in January 2021 showed complaints had reduced to 1, despite appointments increasing by 395%. They had also reduced the time for GP and patients to receive correspondence from 7-10 days to an average of 4 days from appointment when they implemented automatic letter generation. Additionally, the system has also reduced the frequency of prescription errors from 20 to 1 during the auditing period and improved prescription turnaround time from 10-14 days to 1-2 days.
- There was a focus on continuous learning and improvement. The provider had set up Sapphire Institute for staff training and had developed a CPD accredited course for clinicians, a medical consultant appraisal framework and an induction checklist. All the training on offer was part of an educational programme that was open to any interested clinician.
- The leadership, governance and culture was used to drive and improve the delivery of high-quality person-centred care. The provider had set up The UK Medical Cannabis Registry, which is a bespoke real-world data collection platform to systematically monitor patient outcomes with the aim of providing data relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine related problem. The data presented in the initial audit, utilising NICE index value methodology for technology appraisals showed improvements in anxiety and sleep specific outcomes at 1, 3 and 6 months in patients treated at Sapphire. The data had undergone peer-review and been published in Neuropsychopharmacology Reports and is accessible to any interested clinician.
- A systematic approach was taken to working with other organisations to improve care outcomes. There was also a strong record of sharing work internationally and supporting the UK medical profession with medicinal cannabis education. The provider had organised and facilitated an international conference where they shared the latest evidence base for medicinal cannabis and explained what access meant for patients and how clinics could support them through their care pathway.
- There was a clear proactive approach to seeking out and embedding new ways of providing care and treatment. The clinic took part in 'Grand Rounds' with an international clinic where both clinics presented interesting and complex cases for MDT teaching and learning. This provided the opportunity to benchmark clinical care at Sapphire against leading organisations and clinicians in countries with greater experience of medical cannabis treatments. Sapphire's

# Are services well-led?

MDT has used these forums to raise concerns about the potential of positive clinical impact in treating certain conditions, where there was lack of evidence in the UK. Patients were discussed with multiple international clinicians who had experience with similar cases. As a result of these discussions the MDT were supported to prescribe CBMP's for the patients and we saw evidence that showed improvements in patients' appetite and symptom control for certain patients.

- They had also established monthly meetings with the Society of Cannabis Clinicians in the UK to discuss complex cases and the latest research and international developments in the science of CBMP.
- The provider promoted and enabled equality of access to treatment as they had partnered with an independent charity to provide financial assistance to aid access to medical cannabis treatments for people where the costs would be beyond the financial means of the individual.
- The provider was involved in a variety of cross collaborative working projects and were engaged with policy makers in relation to furthering the understanding and developing this area of medicine. For example, we saw evidence of their engagement with the government health department, NHS England, NHS Digital, Royal Pharmaceutical Society and The Medicines and Healthcare products Regulatory Agency (MHRA).