Medicines & Healthcare products Regulatory Agency

Business Plan 2024/25

Keeping patients safe and enabling access to high quality, safe and effective medical products

Published October 2024

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Introduction

Welcome to the Medicines and Healthcare products Regulatory Agency's (MHRA) ambitious Business Plan for 2024/25.

Our mission is to protect and promote public health by ensuring that healthcare products, used every day by millions of people in the UK, work and are acceptably safe. We watch tirelessly over safety and put patients at the heart of everything we do. We facilitate prompt access to innovation for the transformative benefits it can bring, while balancing this work against the needs of patients for swift access to the well-established healthcare products that are the backbone of healthcare in UK.

Our Business Plan for 2024/25 is built around four strategic priorities:

1	**Maintain public trust through transparency and proactive communication**
2	**Enable healthcare access to safe and effective medical products**
3	**Deliver scientific and regulatory excellence through strategic partnership**
4	**Become an agency where people flourish alongside a responsive customer service culture**

These strategic priorities aim to set the conditions for our agile, enabling agency to deliver the best experiences and outcomes for all who use our services. We will harness digital technology to support and revolutionise the ways we work while we create a UK regulatory system that will meet the diverse challenges of a rapidly advancing global healthcare system. We will be introducing new risk proportionate regulatory approaches to ensure that the UK remains at the forefront of medical and scientific discovery and is an attractive environment in which to develop novel and innovative medical products. We will continue to involve patients in our benefit risk decisions and in communicating the best advice on how to use medical products safely and effectively.

A key focus this year will be the optimisation of our service delivery for customers. This will involve optimising our performance and eliminating any outstanding backlogs which persist after the diversion of resource to our world-leading response to the Covid pandemic. We will enhance the transparency of our performance data to aid predictability for those who use our services and to ensure greater accountability.

Underpinning service optimisation will be our two new regulatory IT systems, SafetyConnect and RegulatoryConnect. SafetyConnect will ensure we continue to respond effectively to new safety signals throughout the product life-cycle. RegulatoryConnect will modernise our existing management systems, and ensure more timely and efficient services. It is at the heart of our vision to make the UK a leader in risk proportionate regulation. In order to operate sustainably and in line with the principles of HM Treasury's Managing Public Money, we will progress our next fees review.

There are exciting developments in regulatory science, and we will be establishing new and stronger partnerships with academic and industry research bodies, forming a network of scientific excellence and driving collaborative innovation.

We are an Executive Agency of the Department of Health and Social Care and we work to serve ministers and Parliament. We have an important role in the delivery of the new Government's priorities, including its mission to build an NHS fit for the future, driving innovation in the life sciences, and ensuring faster regulatory approval. We will also continue to work closely with our parent Department on a number of other priorities, for example in supporting work to prevent, mitigate and manage medicines shortages.

Finally, to ensure we fulfil the commitments above, we will invest in our talented people and create satisfying roles and careers, implement an exciting and robust talent management program, promote diversity and inclusivity, and continue to grow as an organisation where every individual can reach their full potential and deliver excellent performance.

Our priorities for 2024/25

1 Maintain public trust through transparency and proactive communication

1.1 Embed our patient involvement strategy and begin implementation of our strategy for strengthened safety communications.

1.2 Increase accountability and predictability by improving transparency of key information, including providing a more comprehensive overview of our core services.

1.3 Strengthen regulatory approaches to tackling health inequity across the product lifecycle.

1.4 Pilot the introduction of a single unified agency gateway for customers to accelerate enquiry responses and enhance customer satisfaction.

2 Enable healthcare access to safe and effective medical products

2.1 Improve and optimise regulatory services via development of new risk-proportionate regulatory pathways including international recognition of other stringent regulators' decisions.

2.2 Deliver innovative pathways for access to transformative medicines and medical devices in co-ordination with health technology assessment and health service bodies.

2.3 Launch a range of new digital tools that improve delivery of regulatory services for all who use them.

2.4 Improve our biotherapeutics laboratory capability and services, especially for new cell and gene therapies and immunotherapies.

3 Deliver scientific and regulatory excellence through strategic partnership

3.1 Implement our regulatory science and data strategies, establishing a network of Centres of Excellence in Regulatory Science and Innovation.

3.2 Improve and update our UK regulatory frameworks in line with evolving science and technology, to streamline our processes and remove unnecessary burdens.

3.3 Strengthen our pandemic and escalating infectious disease programme, contributing to the UK's pandemic preparedness.

3.4. Strengthen our strategic partnerships, in the UK and internationally, to help us deliver our priorities.

4 Become an agency where people flourish alongside a responsive customer service culture

4.1 Ensure that we recruit and develop people with the right skills and capability to deliver our current and future plans.

4.2 Promote staff wellbeing and help staff manage their workloads effectively, including through clarity on targets and with right-sized teams.

4.3 Deliver a responsive service culture, with robust and risk-proportionate decision-making, and achieve an improved internal control environment.

4..4 Review and update our service and product fees, informed by activity recording data, so that the agency continues to be financially sustainable.

Objectives for 2024/25

This section shows more detailed objectives under each of our 4 priorities.

1. Maintain public trust through transparency and proactive communication

1.1 Embed our patient involvement strategy and begin implementation of our strategy for strengthened safety communications.

1.1.1 Refresh existing patient networks to improve our communications to them by end Q3.

1.1.2 Ensure that patients who contribute to regulatory and safety reviews receive feedback, including regarding the impact of their contribution, by end Q4.

1.1.3 Embed greater patient involvement across regulatory pathways by developing patient involvement in pre-authorisation work by end Q4.

1.1.4 Establish new systems to better engage with healthcare professionals by end Q4.

1.1.5 Launch a new design for our risk and safety communication products, including a newly designed monthly bulletin, by end Q4.

1.2 Increase accountability and predictability by improving transparency of key information, including providing a more comprehensive overview of our core services.

1.2.1 Consolidate and publish key performance data by end Q4 to provide better transparency and predictability of performance.

1.2.2 Publish accessible minutes of all independent advisory bodies and their supporting expert groups within one month of adoption by those committees, from end Q3.

1.2.3 Publish Freedom of Information responses within one month of replying to the original request from end Q3.

1.2.4 Provide more comprehensive information about how we regulate and our decision-making processes by end Q3.

Objectives for 2024/25

1.3 Strengthen regulatory approaches to tackling health inequity across the product lifecycle.

1.3.1 Work with the Health Research Authority to develop guidance to encourage clinical trialists to consider equality, diversity, and inclusion in their clinical trials and clinical investigations by end Q3.

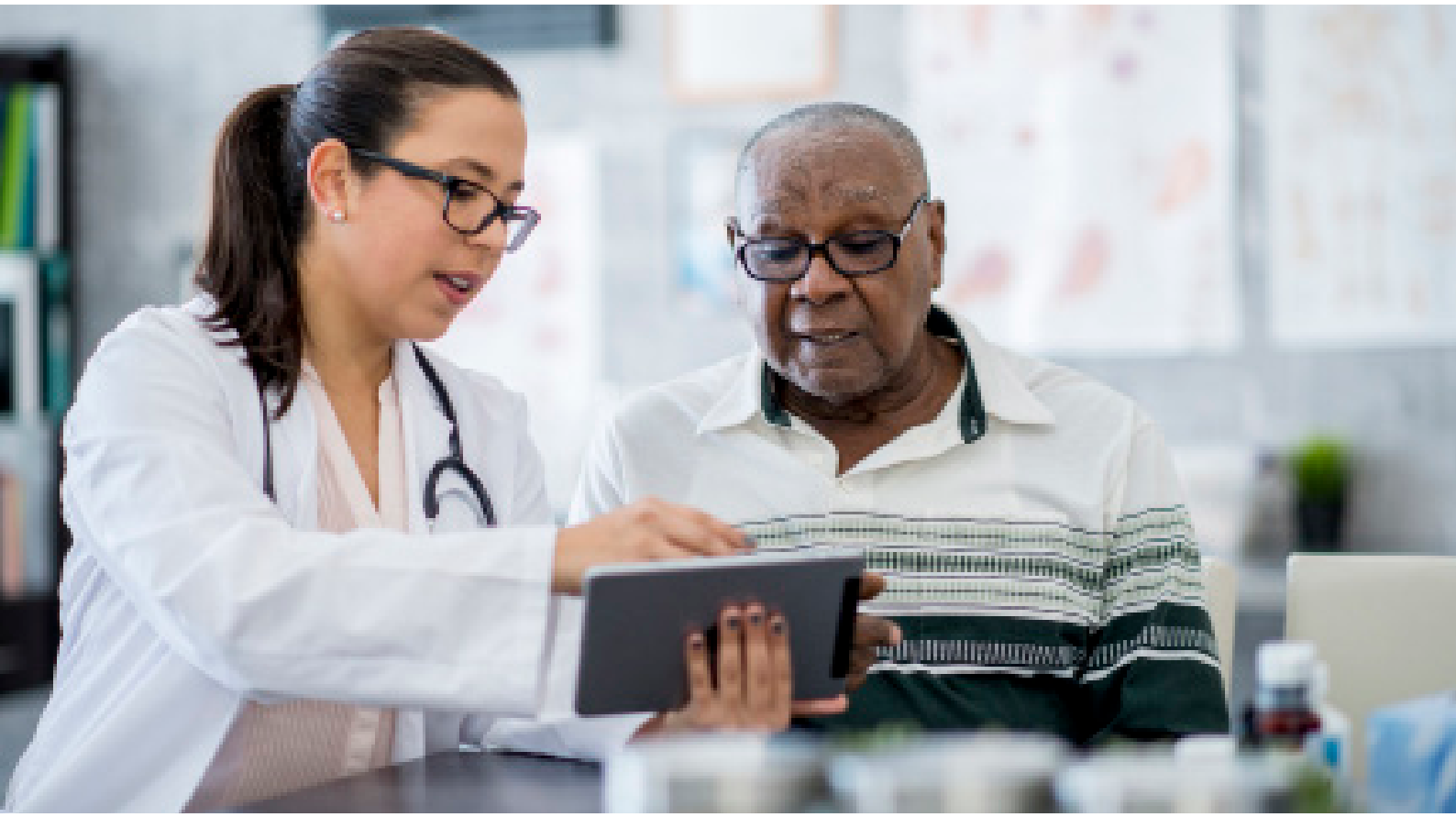
1.3.2 Publish a road map towards further strengthening of regulatory approaches to tackling health inequity by end Q4.

1.4. Pilot the introduction of a single unified agency gateway for customers to accelerate enquiry responses and enhance customer satisfaction.

1.4.1 Identify the types of automated solutions that meet our customer needs most effectively (e.g. webforms, self-service, a Customer Relationship Management system) by end of Q3.

1.4.2 Introduce improvements to our internal knowledge hub to improve how we handle enquiries and introduce consistent customer service standards by end Q3.

1.4.3 Pilot a single unified gateway for patient, public and industry enquiries by end Q4.



Objectives for 2024/25

2. Enable healthcare access to new, safe and effective medical products

2.1 Improve and optimise regulatory services via new risk-proportionate regulatory pathways including international recognition of other stringent regulators' decisions.

2.1.1 Optimise the performance of our regulatory services to operate reliable and predictable timelines, including eliminating any service backlogs by end Q4.

2.1.2 Review our medicines International Recognition Procedure to ensure the pathway is working as intended and there is ongoing adherence to statutory timelines by Q3.

2.1.3 Balance medicines National Assessment and International Recognition Procedures so that at least 50% of novel therapies are assessed via a National Assessment route.

2.1.4 Deliver the 2024/25 milestones for medical devices international recognition in our roadmap of activity, working in parallel on approaches to maintain the UKCA as an attractive route for innovators.

2.1.5 Provide individual timeframes for applicants, encompassing all pre-submission and licensing activities by Q3.

2.1.6 Improve our scientific advice service to ensure sustainable delivery and delivery by expected timelines, with associated fees, by end Q4.

2.2 Deliver innovative pathways for access to transformative medicines and medical devices in co-ordination with health technology and health service bodies.

2.2.1 Launch a refreshed Innovative Licensing and Access Pathway (ILAP) to accelerate access to innovative medicines by end Q3.

2.2.2 Finalise the Innovative Devices Access Pathway (IDAP) pilot, completing evaluation to determine next steps to be implemented in 25/26 by end Q4.

2.3 Launch new digital tools to improve delivery of regulatory services for all who use them.

2.3.1 Deliver second release of RegulatoryConnect, maximising the use of self service and notification to support optimal performance of licensing procedures for new and established medicines by end Q4.

2.3.2 Improve reporting systems including delivery of the SafetyConnect programme to improve our ability to detect and act on safety issues for all regulated health products by end Q4.

2.3.3 Deliver new digital services to support clinical trials to make processes more streamlined and efficient by end Q3.

2.3.4 Secure Police National Database accreditation to optimise intelligence sharing with law enforcement and regulatory partners across the UK in support of our mission to protect public health by the end of Q4.

Objectives for 2024/25

2.4 Improve our regulatory laboratory capability and services, especially for new vaccines, cell and gene therapies and immunotherapies.

2.4.1 Improve our laboratory capability in the assessment of safety and effectiveness of biologicals, including immunotherapies for conditions such as cancer and inflammatory diseases by end Q4.

2.4.2 Evaluate novel reference materials for establishment as International Standards designed to underpin diagnostic assays, with a particular emphasis on cancer genomics by end Q4.

2.4.3 Facilitate an international workshop of antimicrobial resistance (AMR) innovators and stakeholders to identify approaches to accelerate patient access to novel anti-microbial products by end Q4.

2.4.4 Consult on regulatory best practice for microbiome and phage derived medicinal products designed as novel anti-microbials by end Q3.

Objectives for 2024/25

3. Deliver scientific and regulatory excellence through strategic partnerships

3.1 Implement our regulatory science and data strategies, establishing a network of Centres of Excellence in Regulatory Science and Innovation.

3.1.1 Ensure the agency uses data optimally to support decision making, publishing our data strategy by end Q3 and implement 2024/25 recommendations by end Q4.

3.1.2 Grow the agency's reputation for scientific excellence by publishing our science strategy by end Q4 and implement 2024/25 recommendations by end Q4.

3.1.3 To help ensure our regulatory decisions reflect the best possible science create a UK network of Centres of Excellence of Regulatory Science and Innovation across all priority areas by end Q4.

3.2 Improve and update our UK regulatory frameworks in line with evolving science and technology, to streamline our processes and remove unnecessary burdens.

3.2.1 Prepare legislation to deliver a new and risk-proportionate UK clinical trials regulatory framework, lay legislation in Q4. And publish updated guidance from October 2024.

3.2.2 Deliver a regulatory framework for point-of-care manufacture of personalised medicines, supporting the introduction of these new therapies, by end Q4.

3.2.3 Progress delivery of an overhauled regulatory framework for medical devices in line with the 2024/25 milestones in our roadmap.

3.2.4 Supporting access to medicines in Northern Ireland on the same basis as the rest of the UK by implementing the medicines elements of the Windsor Framework, by 1 January 2025.

3.2.5 Develop and consult on proposals for a new regulatory framework for innovative biotherapeutics and personalised immunotherapies by end Q4.

Objectives for 2024/25

3.3 Strengthen our pandemic and escalating infectious disease programme, contributing to the UK's pandemic preparedness.

3.3.1 To underpin vaccine development for priority pathogens and assure the performance of diagnostic tests, develop and distribute novel reference materials in collaboration with our partners by end Q4.

3.3.2 Develop, calibrate and distribute critical biological materials through our World Health Organisation (WHO) Essential Regulatory Laboratory for Influenza to support influenza pandemic readiness by end Q4.

3.3.3 Conduct regulatory research to establish immune correlates of protection for, or markers associated with, 4 escalating diseases that support priority pathogen vaccine development and are calibrated WHO International Standards by end Q4.

3.4 Strengthen our strategic partnerships, in the UK and internationally, to help us deliver our priorities.

3.4.1 Progress system alignment with our partners across the UK health family to enable technical information to be more routinely shared by end Q4.

3.4.2 Develop operations and a new strategic plan with the Access Consortium by end Q4 to maximise international co-operation and make consortium members regulators of choice.

3.4.3 Make a leading contribution to global regulatory best practice and harmonisation through the International Coalition of Medicines Regulatory Authorities (ICMRA), the International Medical Devices Regulators Forum (IMDRF), and the International Council for Harmonisation (ICH), by end Q4.

Objectives for 2024/25

4. Become an agency where people flourish alongside a responsive customer service culture

4.1 Ensure that we recruit and develop people with the right skills and capability to deliver our current and future plans.

4.1.1 Review our external recruitment and internal promotions processes to ensure that we develop the workforce needed to deliver current and future business plans by end Q3.

4.1.2 Implement a new talent management plan, ensuring staff understand the support available to enable them to achieve their career goals, by end Q4.

4.1.3 Develop our managers to support staff development through, setting challenging objectives, giving effective feedback, coaching, mentoring and identifying development opportunities by end Q4.

4.1.4 Embed our commitment to diversity and inclusion in talent acquisition and staff development by end Q4.

4.2 Promote staff wellbeing and help staff manage their workloads effectively, including through clarity on targets and with right-sized teams.

4.2.1 Launch an annual recognition scheme to celebrate outstanding achievements by end Q3.

4.2.2 Launch a new wellbeing survey to better monitor wellbeing concerns and implement new wellbeing tools in response to feedback by end Q3.

4.2.3 Focus on process efficiency and productivity improvements in the context of agreed workload predictions, prior to decision-making about rightsizing teams (ongoing and likely to last into 25/6).

4.2.4 Promote open dialogue about productivity, work processes and priorities to enable managers to make improvements in work life balance for all colleagues by end Q4.

4.3 Deliver a responsive service culture, with robust and risk-proportionate decision-making, and achieve an improved internal control environment.

4.3.1 Develop an agency wide view of culture that combines a high performance and a focus on wellbeing by end Q2, and pilot use of a culture barometer by Q3.

4.3.2 Ensure all our managers are promoting and supporting risk-proportionate decision-making in all areas of activity (ongoing and likely to last into 25/6).

4.3.3. Ensure all staff have meaningful objectives that focus on productivity and wellbeing by end Q4.

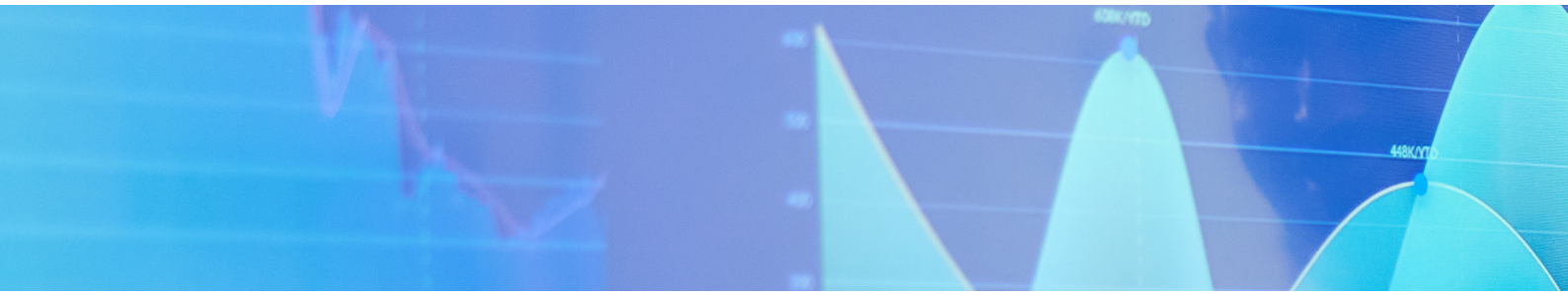
4.3.4 Deliver an improved control environment to safeguard our critical public health outcomes by end Q4.

Objectives for 2024/25

4.4 Review and update our service and product fees, informed by activity recording data, so that the agency continues to be financially sustainable.

4.4.1 To ensure our costs continue to be covered, launch public consultation on our fees in Q2 and deliver a fees adjustment by the first quarter of 2025/26.

Our key performance indicators



In the financial year 2024/25, we aim to:

1. **Complete 95% of all initial Clinical Trial Authorisations and Clinical Investigation applications within their category's statutory timeframe (30 days and 60 days, respectively).**

2. **Certify 95% of vaccine batches within 43 days and 95% of blood product batches within 15 days of submission.**

3. **Determine 95% of medicines licence applications within 210 days via the national route.**

4. **Determine 95% of medicines licence applications through the International Recognition Procedure within 60 days via recognition Route A and within 110 days via Route B.**

5. **Determine 95% of all variations within their category's statutory timeline (Type 1b: 30 days and Type 2: 90 days or 120 days).**

6. **Grant, vary or refuse 95% of applications for manufacturing and distribution authorisations within their category's statutory timeline (90 days and 30 days, respectively).**

7. **Process 90% of Fatal Adverse Drug Reaction reports for medicines within 24 hours and 100% within 72 hours; and process 95% of serious Adverse Drug Reaction reports for medicines within 72 hours and 100% within 5 days.**

8. **Deliver scientific advice to 95% of requests within 70 days of the request being made.**

The MHRA is committed to delivering its services by, and where possible ahead of, statutory timelines and to being transparent about our service performance levels. We have refreshed our key performance indicators (KPIs) as part of work to improve performance and to make the agency's performance much more transparent. Our performance against our KPIs will be reported annually in our Annual Report and Accounts.

Budget 2024/25

Our ambition is to remain financially sustainable and recover the costs for our day-to-day operational responsibilities through this Corporate Plan period. However, the MHRA is not able to use income for capital investment, so will continue to rely on the Department of Health and Social Care (DHSC) to provide the capital budget.

The table below shows our budget for this year's Business Plan:

	£m
Operational Income	151.4
DHSC resource DEL Funding	34.6
Total Funding	**186**
Staff	103.5
Operating	72.1
Projects	10.4
Total Costs	**186**
Surplus/Deficit	0
DHSC Capital Funding	**25.5**

Corporate governance

We are governed by a unitary agency board that is responsible for advising on the strategic direction of the MHRA, ensuring that objectives in the Business Plan are met.The board supports the Chief Executive in the delivery of services and overall performance by providing leadership, developing strategy, advising on the delivery of policies, maintaining high standards of corporate governance, scrutinising performance and ensuring controls are in place to manage risk.

Our Chief Executive, as the Accounting Officer for the MHRA, is responsible to ministers, the Permanent Secretary of the DHSC and Parliament directly for the use of public funds and for the day-to-day management of the agency.

As a public body, we take our responsibilities to ensure optimal governance seriously. In 2023/24 the Government Internal Audit Agency rated the MHRA as Limited assurance for the third consecutive year, indicating that some areas of our control environment need strengthening. Although the auditor has recognised that we are on a positive trajectory, decisive action must now be taken to strengthen our control environment through an Executive owned Route to Moderate plan focussed on the core themes identified and driven through the timely closure of management actions, through maturing of the assurance and controls mapping activities already underway and through ensuring that we are meeting the Government Functional Standards. Ensuring our agency is well run, with appropriate controls to ensure we can meet our objectives consistently, is the responsibility of all staff. In addition to the objectives above over 2024/25, our staff will be:

- Fulfilling their commitments to remain vigilant to any health and safety risks that may impact them or others and report these proactively. Staff are responsible for ensuring they follow existing guidance and best practice procedures to maintain their own wellbeing and promote the positive wellbeing of their colleagues.

- Working closely with Government's Internal Audit Agency to facilitate any audit engagements and deliver actions agreed in response to audit recommendations to address any weaknesses in our operations and or control environment, according to agreed deadlines.

- Supporting our Quality Management System through working with colleagues to provide challenge and review of our current systems, addressing areas for improvement and developing our approach to quality in support of our service redevelopment.

- Constantly managing operational risks at all levels in the organisation, in line with our risk management framework, to best enable delivery against our objectives in our challenging and complex delivery environment.

This is in addition to the duty on all staff to ensure value for money in our use of public funds, including where such funds are created through our fees for services.

We apply the Public Sector Equality Duty requirement to new or changing policies, projects and services impacting patients, the public and our staff.

Contact us

If you are a patient, member of the public, healthcare professional, or work in the sectors we regulate and would like more information on our work, please contact us.

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Published: