Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA Post Transition Update

Craig Copland

MHRA Post Brexit Update

- MHRA Responsibilities under the Tobacco and Related Products Regulations 2016
- Product Notification Process
- Compliance Findings 2021
- Yellow Cards and ADR Reports
- Market Surveillance and Cross Agency Collaboration

Post-Brexit regulatory environment

- From Jan 1st, 2021, the MHRA has delivered a dedicated GB only submission portal – MHRA Submissions

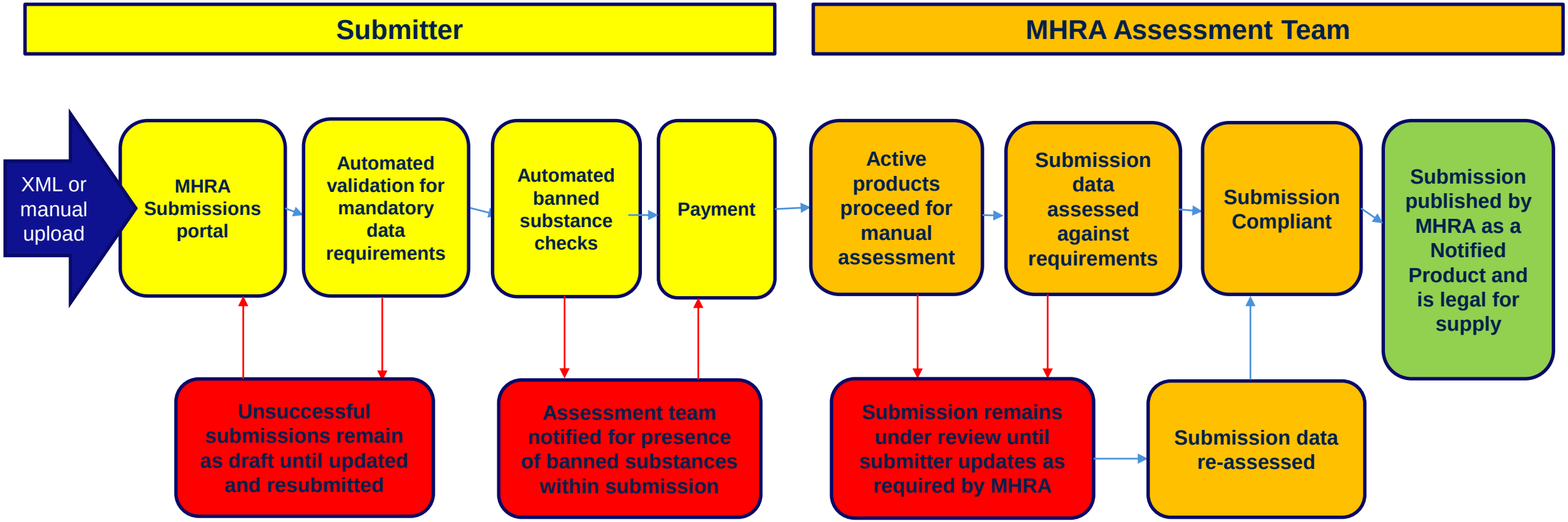
- Provide continuity for existing products by retaining current ECIDs and submitter IDs

GB Notification Process

When is a product Notified ?

- Product submission successfully validated by MHRA Submissions
- Fee Paid
- Completion of successful manual assessment
- Published on MHRA website

GB notification process



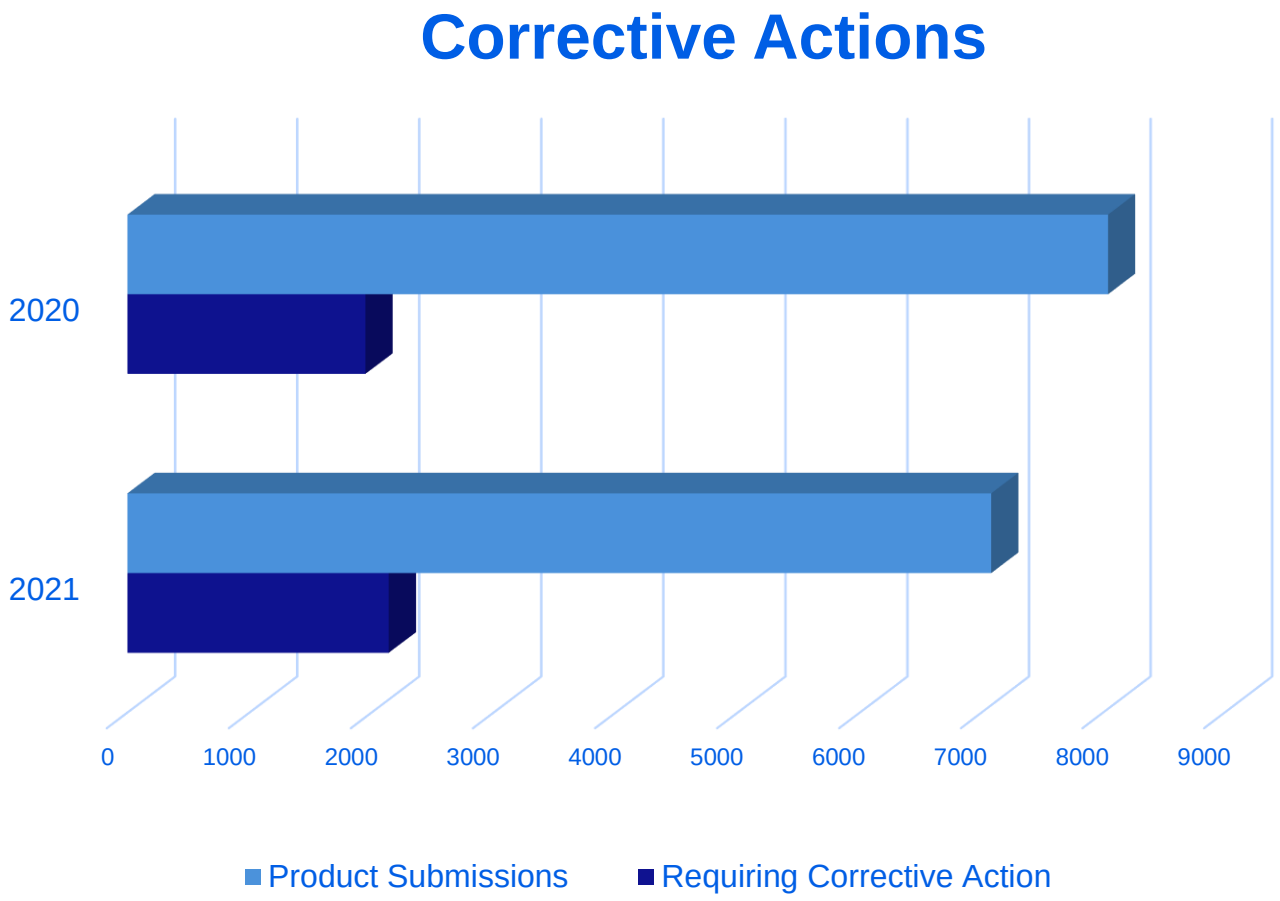
Compliance issues in notifications

- Submission data missing mandatory requirements for system validation
- Fee payment unsuccessful
- Non- compliant Toxicology / Emissions / Ingredients
- Responsible Persons information incomplete
- Required corrective action incomplete

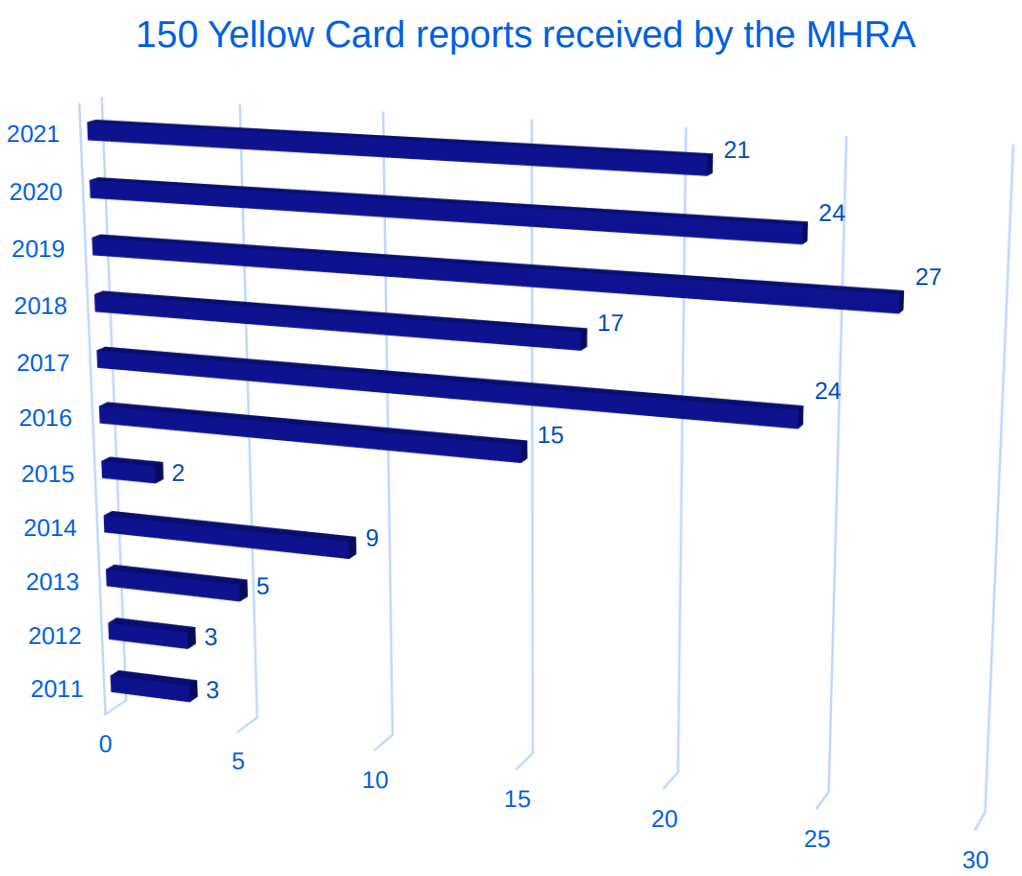
Compliance – Corrective Actions

Increase in required corrective actions between 2020 and 2021:

- Automated validation is assisting targeted manual reviews
- Publication rates higher than 2020
- Increase in new submitters due to disposable products



Yellow Card – A Decade of Reporting



EVALI - MHRA response

- Review of FDA Data
- Guidance for medical professionals – Drug Safety Update
- CHM review of Data
- ADR reports requested from E-Cigarette Submitters for review (125)

Yellow Card and Industry ADR Reports

99 (36%) were reported by members of the public

51 (19%) were reported by healthcare professionals

125 (45%) were reported by industry

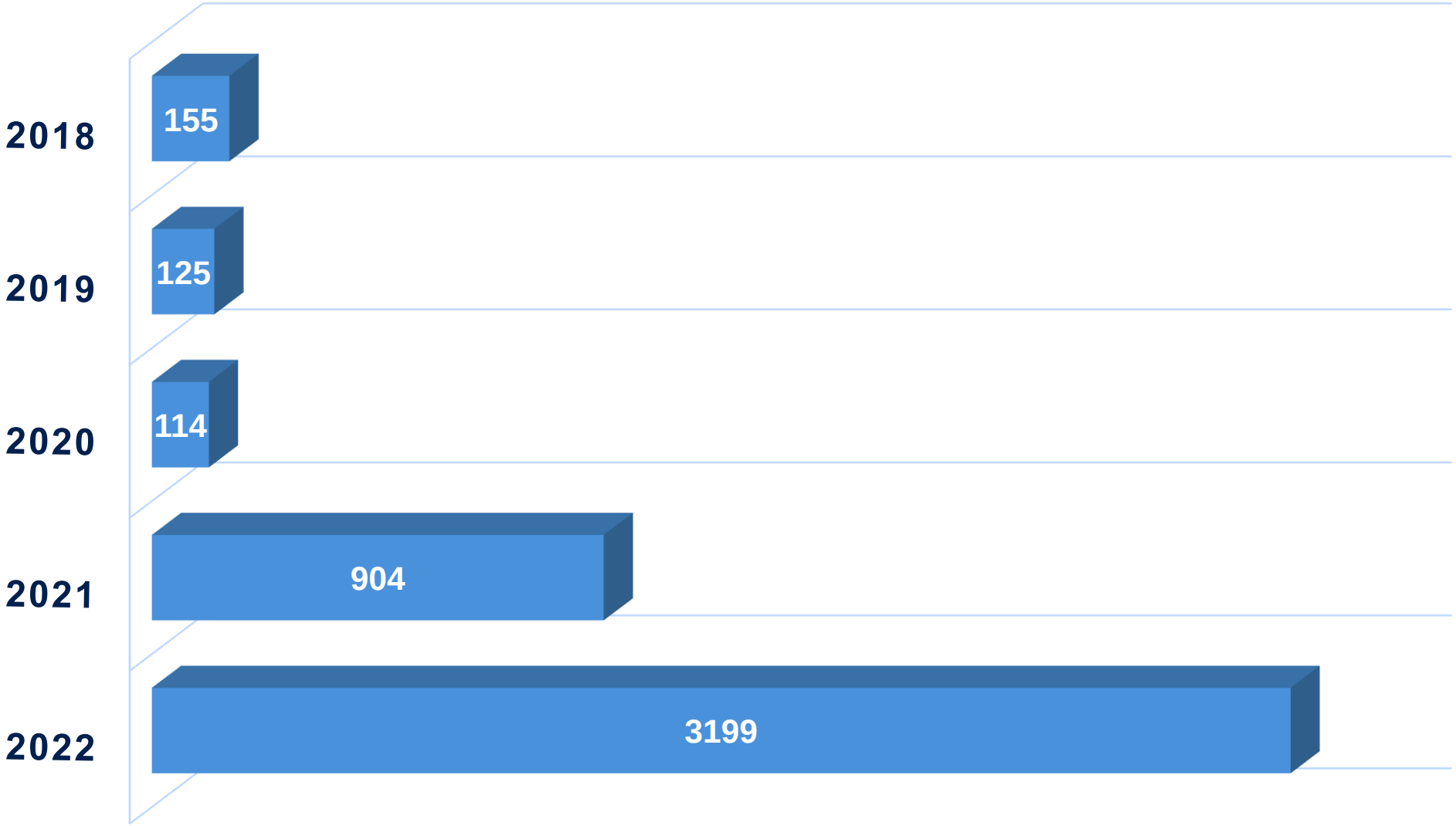
768 symptoms recorded across the 275 reports

Market Surveillance Activities

In 2021/22 the MHRA has received more than a 100% increase in intelligence referrals. These predominantly relate to:

- The notification status of products
- Provision of product notification data to support ongoing investigations
- Provision of evidence packages to support legal action
- Disposable Products

Market Surveillance – Disposable Publications



Market Surveillance Activities

In 2021/22 the MHRA has disseminated over 200 intelligence referrals to external agencies. A significant increase from 2020, 2019 and 2018. These predominantly relate to disposable products:

- Non compliant products notified for/or supplied to the UK market
- Takedown referrals via TS Primary Authority Partnerships

Market Surveillance Activities - Partnership

- Trading Standards – Collaboration on projects assessing retail and supply compliance, increased data sharing between agencies, increased MHRA staffing to support enforcement referrals and related work in 2022.

- Regular updates to the CTSI Tobacco Focus Group

- Collaborative working group with Trading Standards, Health and Safety Executive, HMRC, OPSS and Ports and Borders to provide updates on E-cigarette issues