Medicines & Healthcare products Regulatory Agency

# Submitting via MHRA Submissions portal

This publication was withdrawn on 31 January 2020

**22nd October 2019**



CPRD NIBSC MHRA

# Agenda

| Item |
| --- |
| Intro |
| The MHRA Submissions homepage |
| Submitting e-cigarettes |
| Submitting via Human Medicines |
| Submitting PSURS |
| Submitting PIPs |
| Next Steps |

# Introductions

# This webinar

- The requirements and proposals we are presenting are drafts, and do not at this stage represent Government policy.

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- The recording of the webinar will be published on the gov.uk site.

- This session is to provide information and can be shared with colleagues.

- Everything discussed would only be in the event of a no-deal scenario.

# The story so far

- We held a general overview webinar in late November 2018 which covered all aspects of the MHRA IT Contingency programme.

- A second webinar on the topic of gaining access to the MHRA Submissions portal was recorded in mid Feb. The ability to gain access has been live since 4th March and you are encouraged to register to use MHRA Submissions prior to Day 1



- At the start of March, there was a third webinar focussed on the pharmacovigilance solutions and how to register for either the MHRA Gateway or ICSR Submissions. Those wishing to submit and receive ICSRs/SUSARs from Day 1 have been able to register from Monday 11th March.

- On March 25th we did a fourth webinar which focused on the MHRA Submission portal and demonstrated the Human Medicine, e-cigarette, PSUR and PIP portals.

- Webinars are available to view on the gov.uk website

# Webinar purpose

This webinar will focus on MHRA Submissions

- Providing an overview of MHRA Submissions Homepage
- How to raise a query from the MHRA Submissions Homepage and find support documents
- Submitting marketing authorisation and Clinical trial applications via the Human Medicines tile
- Submitting PSURs
- Submitting PIPs
- Submitting e-cigarette notifications
- Next steps

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# 1. MHRA Submissions Homepage

# MHRA Submission Homepage

Video demo

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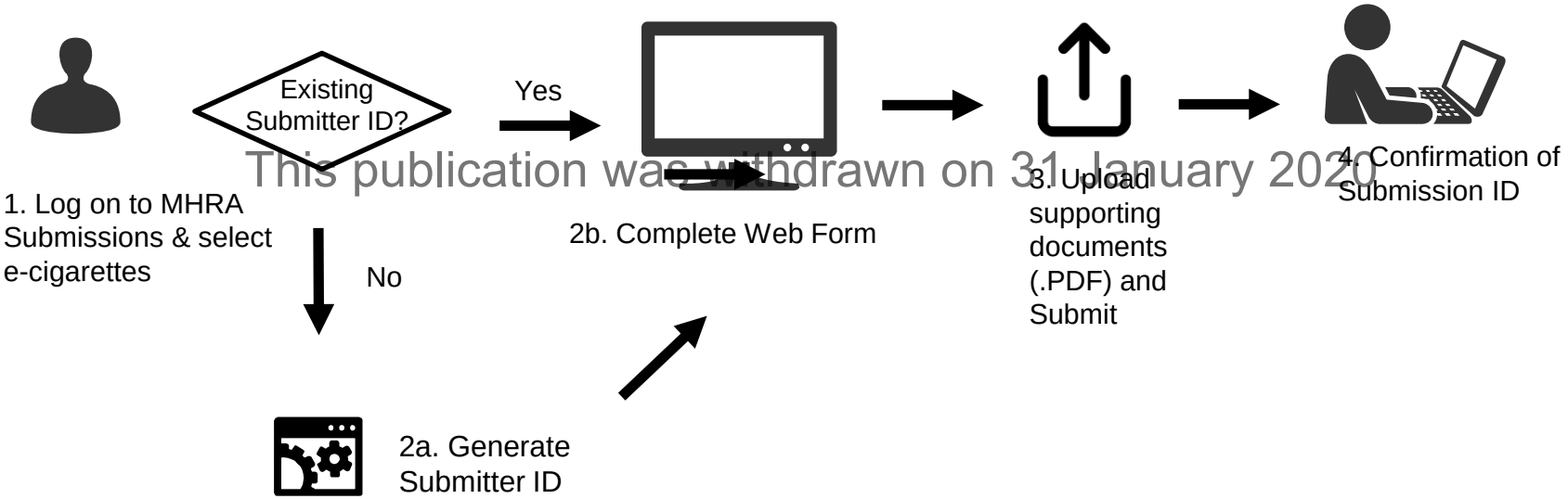
MHRA Submission Homepage

# 2. e-cigarette notifications

# E-cigarette Submission– Industry User Journey






| Submission Type | Route into MHRA | Submission Format | Associated File upload | XML Creation? |
|---|---|---|---|---|
| E-cigarette | MHRA Submissions | Webform, edit previously submitted data | attachments | No |

# E-cigarette Bulk Submissions– Industry User Journey




1. Log on to MHRA Submissions and select e-cigarettes
2. Complete Web Form
3. Upload XML files
4. Upload supporting documents (.PDF) and Submit
5. Confirmation of submitter ID

| Submission Type | Route into MHRA | Submission Format | Associated File upload | XML Creation? |
|---|---|---|---|---|
| E-cigarettes – Bulk | MHRA Submissions | Webform related to submitter details | attachments | No |

# E-cigarette notifications

Video demo

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Making an e-cigarette submission

Making a Bulk Submission

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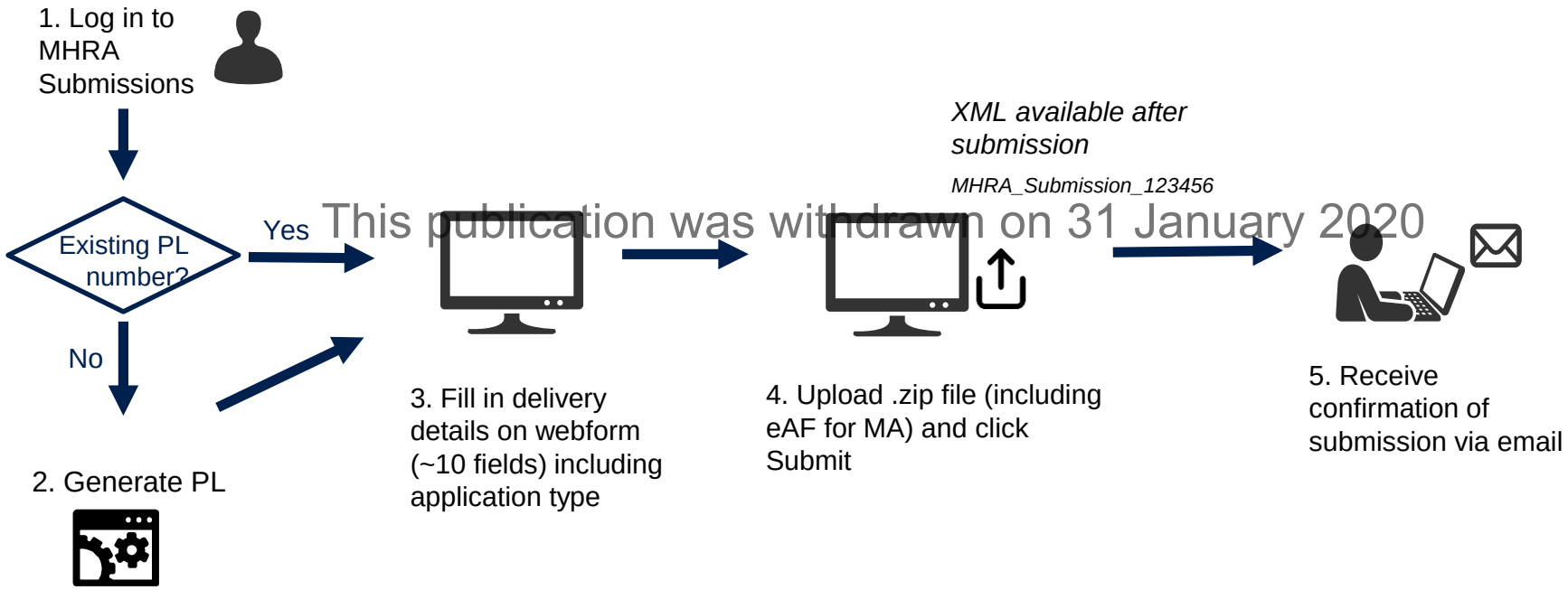
# 3. Human Medicines

# What applications will be sent via Human Medicines?

| Regulatory Activity |
|---|
| Initial Marketing Authorisation Application |
| CAP Grandfathering Full Initiating Sequence |
| CAP Grandfathering Full Initiating Sequence Incorporating Change of Ownership (COA) |
| CAP Grandfathering Minimal Initiating Sequence |
| CAP Grandfathering Minimal Initiating Sequence Incorporating Change of Ownership (COA) |
| Variation Type IA |
| Variation Type IA - Establishing UK QPPV-PSMF |
| Variation Type IB |
| Variation Type II |
| Renewal (yearly or 5-yearly) |
| Information Update |
| Active Substance Master File |
| Plasma Master File |
| Paediatric submission, Article 29 |
| Paediatric submission, Article 46 |
| Full PIQ assessment - Notification 61(3) |
| Change of Ownership Application (COA) |

| |
|---|
| Ownership Application (COA) - EU to UK MAH |
| Article 23a/24 Sunset Clause Notification |
| Withdrawal during assessment or withdrawal of a marketing authorisation |
| Clinical Trial |
| Parallel Import (PLPI) Variation |
| Parallel Import (PLPI) Initial |
| Parallel Import (PLPI) Renewal |
| Targeted Assessment |
| Baseline Submission |
| Development Safety Update Reports |
| BROMI Self Certification - Notification 61(3) |
| Notified Body Designation |
| Homeopathic National Rules (NR) |
| Homeopathic MP application (HR) |
| Herbal MP application (THR) |
| Article 45 - Paediatric submission |
| Early Access to Medicines UK |
| Export Certificates |
| CCC Procedure UK |

# Human Medicines– Industry User Journey

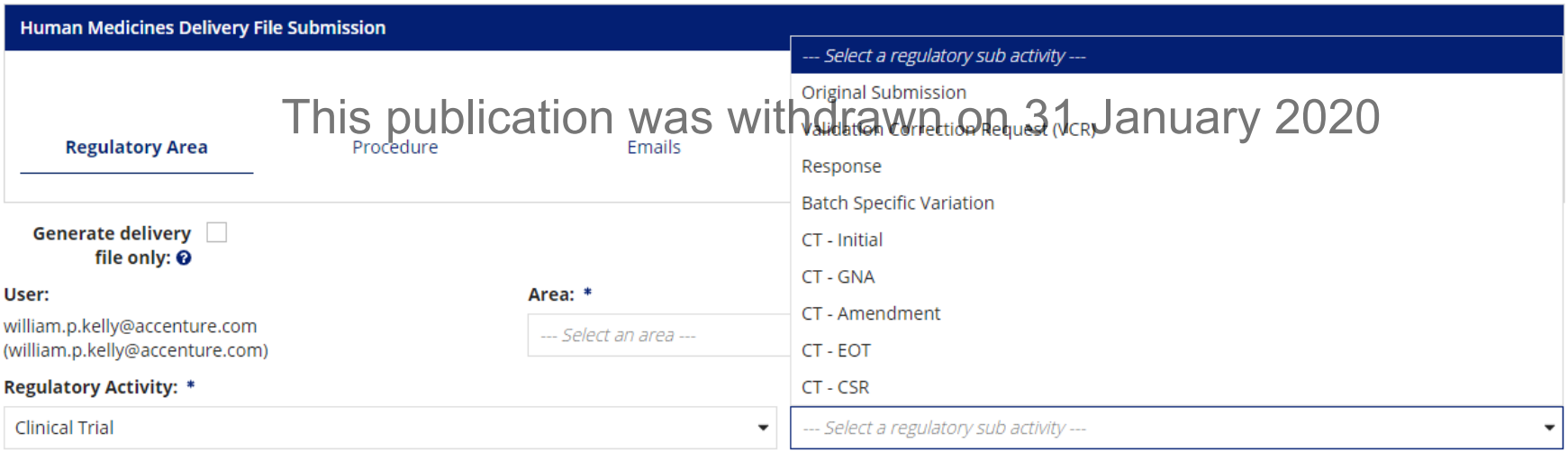





| Submission Type | Route into MHRA | Submission Format | Associated File upload | XML Creation? | Comments |
|---|---|---|---|---|---|
| All types outlined in previous slide | MHRA Submissions | • 1 webform, ~10 fields | .zip file (e.g. MA - eCTD format) | Yes | Note – Uploading large files as outlined here is the preferred method. Please inform us if you have a requirement to submit via SFTP from Day 1. |

# Clinical Trial applications

All clinical trial applications types will be submitted via this Human Medicines tile.

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You will still be required to obtain and use a EudraCT number as your reference number: you will continue to get this number from the EudraCT website.

# Human Medicines submissions

Video demos

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Generating a PL Number

Making a human medicines application

# 4. PSUR

# PSUR Submissions – Industry User Journey



1. Log on to MHRA Submissions. Go to PSUR tile

2. Complete Web Form (<10 fields)

3. Upload PSUR . Click submit

4. Receive email confirmation of submission

| Submission Type | Route into MHRA | Submission Format | Associated File upload | XML Creation? | Download copy of Application Required? |
|---|---|---|---|---|---|
| PSUR | MHRA Submissions | 1 webform, <10 fields | Zip/pdf or word | No | No |

# PSUR submissions

Video demo



Making a PSUR submission

# 5. PIPs

# PIPs Submissions – Industry User Journey



1. Log on to MHRA Submissions and select PIPs

2. Complete relevant Web Forms

3. Upload supporting documents (.PDF, .zip, unstructured documents). Click submit

4. Receive email confirmation of submission and notification of UK-PIP number

| Submission Type | Route into MHRA | Submission Format | Associated File upload | XML Creation? | Download copy of Application Required? |
|---|---|---|---|---|---|
| PIPs | MHRA Submissions | 5 webforms available | .PDF file, .zip file, unstructured documents | No | No |

# PIPs submissions

Video demo



Making a PiP Submission

# Next Steps and Timelines

- Ensure that your organisation completes the user access steps for MHRA Submissions prior to Day 1 in a no deal scenario.

- These steps and guidance are found here:
- https://www.gov.uk/guidance/making-submissions-to-the-mhra-in-a-no-deal-scenario



- Guides and videos will be published on Day 1

- The relevant tiles in MHRA Submissions will be launched for Day 1.