Making a submission to the Medicines and Healthcare products Regulatory Agency on CD or DVD

The MHRA will not accept submissions sent on disk that do not comply with the standards and conventions detailed in this section.

Companies are encouraged to send submissions via the MHRA Portal. If this is not possible, or an applications is too large (> 100 MB zipped) to be submitted via the Portal, the MHRA will accept submissions on disk. The following disk formats are acceptable:

- CD-ROM
- CD-R
- CD-RW
- DVD-R
- DVD-RW

The following formats are not acceptable:

- DVD-ROM
- DVD-RAM

File formats

All files submitted on disk must be in Adobe Acrobat PDF format with the sole exception of the MHRA Word template for the Summary of Product Characteristics (SmPCs). **No other file formats should be used**.

Guidance on preparing PDF documents

As far as possible all data should originate from electronic files rather than from scanned data. There may be circumstances where the data is only available in paper format, please advise us in advance if this is the case.

In order to process PDF documents efficiently MHRA assessors need to be able to easily navigate and manipulate the document (eg copy and pasting sections of the document or splitting a large document into multiple smaller documents). To facilitate this process the following points should be noted when creating PDF documents.

- All PDF documents should be created directly from Word or undergo Adobe Acrobat optical character recognition (OCR) at the time of creation. PDF document scanned images should not be provided as it is not possible to cut-and-paste data in this format.
- PDF documents should not be file protected as this prevents the printing and manipulation of the document.
- Fonts that are not supported by Microsoft Word should not be used on PDF documents.

- All PDF documents should be appropriately bookmarked to ensure that assessors can jump directly to the sections of interest. Only the simplest of PDF documents (eg a simple letter responding to an RFI) should be submitted without bookmarks.

Labelling disks

Each disk should be labelled in the following manner:

- PL number (and case number * for RFIs) or EudraCT number or NB number or Mutual Recognition Procedure(MRP) number
- For ASMFs, MHRA national reference number and/or EU/ASMF reference number (when available) and the holder's ASMF version number
- For portal applications only (see section 3.2) the portal ticket number should be quoted.
- Description of contents (eg. variation, MA application, PSUR, response to RFI, new ASMF, etc)
- Company name
- Date sent.

* The case number is quoted in RFI letters and is a four digit number appended to the MA number (0007 in the example above).

PL 99000/1234-0007
Variation – response to RFI
AnyCompany plc
11 July 2006

MFD-99999-1-22222 - EU/ASMF/99999
New ASMF
Applicant's Part Version number / Restricted Part version number
AnyCompany plc
11 July 2006

A disk should only contain data relating to one type of submission.

The disk may be printed or labelled with an adhesive paper label or a permanent marker pen.

The MHRA will not accept submissions sent on disk that do not comply with the standards and conventions listed in this section of the website.

Posting disks

The address to be used for sending disks to the MHRA will depend on the type of submission. All disks should be sent to the address below ensuring the area number that relates to the submission type is quoted.

Information Processing Unit
[Please see list below **]
Medicines & Healthcare products Regulatory Agency
151 Buckingham Palace Road
London
SW1W 9SZ

**Address to the following area code depending on the type of submission included in the disk.
Area 1 New National Market Authorisation Application and response to related RFIs
Area 2 MR and Decentralised Procedures Applications and responses to related RFIs
Area 3 Variation Applications and responses to related RFIs
Area 4 MA renewals, PSURs and response to related RFIs
Area 5 PLPI, Homeopathic and Notified Body Applications

Area 6 Clinical trial applications and related responses to RFIs
Area 7 Active Substance (Drug) Master Files