

Guidance on the Disclosure of Types of Human and Veterinary Medicines Information Held by the Human and Veterinary Regulatory Authorities

Prepared by:

Medicines and Healthcare Products Regulatory Agency (MHRA)

http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=5

Veterinary Medicines Directorate (VMD) <http://www.vmd.gov.uk/>

In discussion with:

Association of the British Pharmaceutical Industry (ABPI) <http://www.abpi.org.uk/>

Proprietary Association of Great Britain (PAGB) <http://www.pagb.co.uk/>

National Office of Animal Health (NOAH) <http://www.noah.co.uk/>

Food Ethics Council (FEC) <http://www.foodethicscouncil.org/>

NOTE: These notes are a general guide only and must not be treated as a complete or authoritative statement of the law on any particular case

Table of contents

1. Who is this guidance for?
2. Who wrote this guidance?
3. What overriding principle does this guidance apply to the disclosure of types of human and veterinary medicines information?
4. What information can someone ask for?
5. Will someone be able to get any information they want?
6. Why might information be withheld?
7. How does the Access to Information (ATI) legislation take account of the legitimate interests of third parties who have supplied information to the regulatory bodies?
8. What is the public interest test?
9. Do third parties (e.g. the pharmaceutical companies) have a say in whether the information is released?
10. What will it cost to get the information?
11. How does the fees limit affect requests for information held by the Human and Veterinary Regulatory bodies?
12. What human and veterinary medicines information has the MHRA and the VMD released already?
13. How does someone make a request?

This guidance is for information only: the regulatory bodies treat each request on its own merits in accordance with the ATI legislation and the accompanying legislative guidance.

1. Who is this guidance for?

This guidance is for those involved in making and receiving requests to release information relating to human and veterinary medicines authorised for use in the UK by the MHRA or the VMD.

2. Who wrote this guidance?

This guidance was prepared by the two regulatory bodies with responsibility for human and veterinary medicines: the MHRA and the VMD, in discussion with a working group consisting of the organisations listed above. It replaces the guidance in the memorandum of understanding (MOU) between the ABPI, PAGB, and MHRA, and NOAH and VMD, in place since late 2004, which used a 'traffic light' coding system to differentiate between types of information.

3. What overriding principle does this guidance apply to the disclosure of types of human and veterinary medicines information?

All parties to this guidance agree that the Freedom of Information Act (FOIA) and the Environmental Information Regulations 2004 (EIR) presuppose that information will be disclosed on request. They want to be as open as possible. They believe that transparency is good for the regulatory process as even the best regulatory processes can benefit from broader input and scrutiny.

In December 2006, the ABPI, PAGB, MHRA, NOAH and VMD embarked on a review of the MOU and consulted other interested parties including the FEC. Their review concluded that the guidance in the MOU had not adequately reflected the greater spirit of openness and commitment to disclosure that the ATI legislation was designed to foster in public bodies.

In practice this has not affected what the regulatory bodies disclosed as they treat each request on its own merits in accordance with the ATI legislation and the accompanying legislative guidance. You can find out more about the ATI legislation, which includes the EIRS, the FOIA and the Data Protection Act 1998, at:

<http://www.defra.gov.uk/corporate/opengov/accessinfo.htm>

4. What information can someone ask for?

Any information that the regulatory bodies hold is potentially disclosable (but see also Question 6 below on why information might be withheld). Below is a tabulated breakdown of the main types of human and veterinary medicines information held by the regulatory bodies.

Table 1 indicates documents the regulatory bodies will routinely publish on their websites or in print.

Table 2 indicates documents/information the regulatory bodies will disclose on request (and in some cases may inform interested third parties as they do so). Tables 1 and 2 do not include any information that may be exempt from disclosure by the ATI Legislation.

Table 3 indicates the kind of information the regulatory bodies may be able to disclose from documents on request, but will need to check whether disclosure is in the public interest. This table includes examples of some of the most common reasons why a check is appropriate.

It is important to note, however, that the ATI legislation provides a right to information, not to actual documents. In the tables below we give some examples of the kinds of information contained in the different documents that we hold. This is intended to be helpful to those making and receiving requests for information but it is not a complete list.

5. Will someone be able to get any information they want?

Not necessarily. Depending what information is requested, the regulatory body may be able to point to existing publications containing the information, to disclose unpublished documents containing the information, or to extract the information from documents containing some information that cannot be disclosed (this is known as redaction). In some instances, however, the regulatory body may be obliged to withhold information under the ATI legislation. When information is withheld, the regulatory body will tell the requestor that it has withheld information and why.

6. Why might information be withheld?

The ATI legislation states that it is sometimes in the public interest not to disclose information. It recognises that bodies which provide information to public authorities have legitimate interests and sensitivities. In relation to human and veterinary medicines, the pharmaceutical industry has particular legitimate interests and sensitivities about the disclosure of information which is related to their commercial interests, information provided in confidence, and personal information. Another example might be people who report human suspected adverse reactions to veterinary medicines to the VMD - they would have legitimate concerns about the VMD disclosing their personal information (see Table 3 below).

The parties to this guidance have set out in Table 3 below what the legitimate interests and sensitivities are in relation to specific information, based on their experience with requests. However, the MHRA and the VMD treat each request on a case by case basis in accordance with the ATI legislation.

It is also important to note that the commercial sensitivity (particularly the market sensitivity) of information may decrease with time. The question to be considered is whether the 'sensitivity' applies at the time the request is received.

The Information Commissioner and the Information Tribunal have ruled on these matters. You can find out more about their decisions at: <http://www.ico.gov.uk/> and <http://www.informationtribunal.gov.uk/>

7. How does the access to information legislation take account of the legitimate interests of third parties who have supplied information to the regulatory bodies?

The ATI legislation created exemptions from the duty to disclose information (known as 'exceptions' in the EIR). The FOIA draws a distinction between 'absolute exemptions' and 'qualified exemptions'. If information falls within the terms of a provision conferring an 'absolute exemption' then there is no automatic right of access. If information falls within the terms of a provision conferring a 'qualified exemption' then it is necessary for the public authority to apply a public interest test. You can find out more about FOIA exemptions including those related to commercial interests or information provided in confidence, at: <http://www.foi.gov.uk/yourRights/exemptions.htm> and EIR exceptions at: <http://www.defra.gov.uk/corporate/opengov/eir/guidance/exceptions.htm>

8. What is the public interest test?

The starting point whenever considering the balance of the public interest is that there is a general public interest in disclosure. In contrast, there is no general public interest in public authorities withholding information. But the right to know must be balanced against the need to facilitate effective government. Therefore, for each qualified exemption, and the disclosure of any particular piece of information falling within it, there may be particular public interest considerations in favour of refusing the request. If this applies, the regulatory body will

explain why and the requestor can appeal. You can find out more about the EIR exceptions at: <http://www.defra.gov.uk/corporate/opengov/eir/guidance/exceptions.htm> and FOI Act and the public interest at: <http://www.foi.gov.uk/guidance/exintro/chap07.htm>

9. Do third parties (e.g. pharmaceutical companies) have a say in whether the information is released?

When considering the information to be released the regulatory bodies would check whether any third party may have sent or supplied the information or have a close and direct interest in it. Timely consultation with third parties may play an important part in considering whether exemptions apply, particularly those relating to confidence or commercial sensitivity. However, any views expressed by third parties concerning release of information are NOT binding on the regulatory bodies. The regulatory bodies hold the information, and are under the statutory duty to provide access to the information, not the third party. The regulatory body has to take the final view as to whether information should be released and a refusal by a third party to consent to the release of information is not binding on it. If the third party considers that the release of the information would be an actionable breach of confidence, then the MHRA or VMD would take legal advice.

10. What will it cost to get the information?

Most requests are free. If the regulatory bodies calculate that it will cost more than £600 to find the information and prepare it for release, they can turn down a request under the FOI Act. In such cases they will ask the requestor to narrow down their request by being more specific in the information they are looking for. You can find out about EIR fees at <http://www.defra.gov.uk/corporate/opengov/eir/guidance/eir-feeguidance.htm>

11. How does the fees limit affect requests for information held by the Human and Veterinary Regulatory bodies?

A wide ranging or very general request, or a request covering large amounts of data, is likely to exceed the cost threshold. If a requestor thinks that their request might be affected in this way they might want to use the following contact links to get advice and assistance from VMD or MHRA staff before they make a request <http://www.vmd.gov.uk/Contacts.htm> and http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=546.

12. What human and veterinary medicines information has the MHRA and the VMD released already?

Information released by the MHRA in relation to particular requests is available at http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=862
The VMD aim to make information released by the VMD available in 2008.

If the information requested is about a product authorised by the MHRA or VMD on or after 30 October 2005, it might be found in the MHRA's Public Assessment Report (PAR) or the VMD's United Kingdom Public Assessment Report (UKPAR), albeit with commercially or personally confidential information removed. PARs can be found at http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=857
UKPARs can be found at <http://www.vmd.gov.uk/ukpars/default.aspx>

13. How does someone make a request?

By writing to or emailing the regulatory bodies using the contacts at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=546 for MHRA, or by completing the MHRA request form at: http://www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=557; and VMD at <http://www.vmd.gov.uk/Contacts.htm>.

Table 1: The regulatory bodies will routinely publish the documents in the following table on our websites or in print. They do not include exempt information.

<p>1</p>	<p>MHRA/VMD - Common general information: Consultative letters covering proposals to amend the Orders and Regulations made under the Medicines Act 1968 Guidance notes and application forms Definitions of the legal status of medicines The principles of the Adverse Drug Reaction reporting schemes Summaries of prosecutions Annual report of the Medicines Act Advisory Bodies (The Stationery Office), and the Veterinary Products Committee (VPC) Code of Conduct for members of the Medicines Act Advisory Bodies, and the VPC Declarations of interest of members of the Medicines Act Advisory Bodies, and the VPC Summaries of the meetings of the Medicines Act Advisory Bodies, and the VPC - including those of their sub-committees Register of licensed manufacturing sites Register of licensed wholesale dealers sites MHRA and VMD publication schemes Papers cleared for publication by the Medicines Act Advisory Bodies, and the VPC</p>
<p>1a</p>	<p>MHRA general information: MHRA Annual Report and Accounts (The Stationery Office). MHRA Annual Business Plan and Corporate Plan MHRA Framework Document (revised at 3-5 yearly intervals) The Medicines Control Agency Trading Fund Order 1973 (The Stationery Office). MHRA's Customer Service Charter Guidance leaflets on the law and procedures applicable under the Medicines Act (formerly known as Medicines Act Leaflets - MALs) Levels of fees charged by the MHRA The "Black triangle" list of new medicines under intensive surveillance "Important Safety Messages" and the MHRA/Committee on Safety of Medicines editions of Current Problems in Pharmacovigilance Drug Alerts, including reasons for alert and action to be taken (these appear since 29 October 2001) Guidelines for Company-Sponsored Safety Assessment of Marketed Medicines (SAMM guidelines) Information about the medicines testing scheme Final determinations of the Independent Review Panel for Borderline products Consultative letters on applications to re-classify the legal status of medicinal products The Agency's bi-monthly updating service (MAIL)</p>

1b	<p>Guide to UK Good Laboratory Practice (GLP) Regulations List of licences granted to wholesale dealers (updated bi-monthly) List of licences granted to manufacturers (updated bi-monthly) <u>After</u> Suspension of a Marketing Authorisation/Licence: Annual disclosure of statistical list of suspensions and outcomes <u>After</u> Revocation of a Marketing Authorisation/Licence: Annual disclosure of list of revocations Complaints about advertising of Products: Annual publication of reports of investigations of complaints</p> <p>VMD general information: VMD Annual report VMD Corporate and Business Plans VMD Service Charter VMD quarterly bulletin (MAVIS) Consultation letters covering proposals to amend legislation or procedures (current and previous). Information on Research and Development projects. VMD series of guidance documents (VMGN) VPC / VRC News Releases, Agendas and Reports, and, from January 2000, Summary Minutes List of homeopathics under the Grandfather Clause List of substances permitted under the Small Animal Exemption Scheme VMD general guidance documents.</p>
2 2a	<p>Product licence and Marketing Authorisation documents: Updated list of granted Marketing Authorisations Updated list of granted Parallel Import licences</p> <p>MHRA Only: Remote access to third party non-confidential information about marketing authorisation (part of Remote Access to Marketing Authorisations (RAMA) subscription service) Remote access for companies to view confidential information about their own marketing authorisations (part of RAMA subscription service)</p>
3	<p>Decisions about designation of Borderline Products/Unauthorised Products: Disclosure of reports of review panel</p>

Table 2: The regulatory bodies will disclose the documents/information in the following table on request (and in some cases may inform interested third parties as they do so). They do not include exempt information.

1	<p>MHRA/VMD – Common general information: [None at time of publication]</p>
2	<p>Product licence and Marketing Authorisation documents: Dates of when licences were first granted Aggregated (i.e. not company specific) statistical information on the number, type and outcomes of applications List of licences granted to manufacturers (VMD only - Schedule 6 and vaccine sites in the UK) List of holders of Marketing Authorisations Dates of when licences were renewed or cancelled</p>
3	<p>Quality, Safety and Efficacy documentation: Quantitative composition when a legal requirement (e.g. parenterals for human use)</p>
4	<p>Marketing Authorisation / Licence / Variation / Renewal Applications:</p> <p>4.1 After grant: Decisions taken by the Medicines Advisory Bodies or the VPC Release of information about source country for Parallel Import licence Summary of Product Characteristics Patient Information Leaflet (PIL) (MHRA)/ Package Leaflet (VMD) (PIL will be accompanied by a statement saying that copyright remains with the MA Holder. And that the document(s) is not to be used for commercial purposes)</p> <p>4.2 Decisions taken by the Medicines Advisory Bodies or VPC relating to refusal of application and reason(s) for that refusal</p> <p>4.3 After Suspension of a Marketing Authorisation/Licence: Reasons leading to decision to suspend Decision to suspend</p> <p>4.4 After Revocation of a Marketing Authorisation/Licence: Reasons leading to decision to revoke Decision to revoke</p>
5	<p>Pharmacovigilance - MHRA Only (for VMD see Table 3 below): Drug Analysis Printouts (DAPs) detailing top level information on the adverse events reported for a particular drug substance Reaction Analysis Printouts (RAPs) providing information on reports of a particular reaction by drug substance</p>

6	Inspection reports
6.1	<p>Publication of Inspection Reports of Manufacturers: Guidance to manufacturers re: inspections Annual programme for inspections Number and reasons for inspections extra to programme (anonymised)</p>
6.2	<p>Publication of Inspection Reports of Wholesale Dealers: Guidance to wholesale dealers re: inspections Annual programme for inspections Number and reasons for inspections extra to programme (anonymised)</p>
6.3	<p>Publication of Inspection Reports of Laboratories: MHRA guidance to Laboratories re inspections MHRA guidance to inspectors Annual programme for inspections Number and reasons for inspections extra to programme (anonymised)</p>
6.4	<p>Publication of Good Clinical Practice (GCP) Information and Inspection Reports (human medicines only): MHRA's guidance re: GCP inspections Annual programme for inspections Number and reasons for inspections extra to programme (anonymised)</p>
6.5	<p>Pharmacovigilance Inspections: Guidance to manufacturers re inspections Annual programme for inspections Number and reasons for inspections extra to programme (anonymised)</p>
7	<p>Decisions about designation of Borderline Products/Unauthorised Products: Disclosure of pre-decision correspondence between company and MHRA /VMD about borderline products Disclosure of substance of complaints made about Borderline Products Disclosure of MHRA/VMD's review of complaint, action taken and outcome Annual publication of selected reports of investigations of complaints</p>

Table 3: The regulatory bodies may be able to disclose information from the documents in the following table on request, but will need to check whether disclosure is in the public interest.

The regulatory bodies treat each request on its own merits in accordance with the ATI legislation and the accompanying legislative guidance. The following are examples of some of the most common reasons why the regulatory bodies may need to check whether disclosure is in the public interest.

Any information prior to granting or refusing an application

Pharmaceutical Companies have a legitimate commercial interest in limiting knowledge of any information related to a product they plan to bring to market. In a highly competitive market the knowledge of the existence of work on a new product might offer commercial advantage to a competitor and adversely affect the originating company's return on investment, which in time might lead them to bring fewer products to market.

After grant: "Know-how" and trade secrets

Some of the information in this table may be "know-how" and trade secrets (including for example: formulas, programs, process or information contained or embodied in a product, unpublished aspects of intellectual property (IP), including but not limited to IP such as trade marks, patents etc.); and commercial confidences (for example: structures, pricing, client lists and development plans of a company). These examples are for illustrative purposes only and do not represent an exhaustive list.

This type of information represents a considerable investment by the company submitting the dossier. It could, if disclosed, harm their commercial interests and offer commercial advantage to competitors. For example, to disclose this information could weaken the position of the marketing authorisation holder in a competitive environment by revealing market-sensitive information or information of potential usefulness, enabling a competitor to submit an application for a competitor product or a generic marketing authorisation.

Release of such information could affect decisions by pharmaceutical companies to market medicines in the UK to the detriment of patient and animal welfare. Any request for information that we suspect may have commercial sensitivity would be tested for public interest with the third party before disclosure.

Information on adverse medicine reactions

Regulatory Agencies would not disclose the personal information contained in individual Adverse Drug Reaction (ADR) reports (MHRA) and individual Suspected Adverse Reaction (SAR) reports (VMD), as this would be in breach of the provisions of the FOIA section 40, and the EIR regulation 13. Any adverse medicine reaction or adverse event information released would normally be accompanied with a guidance note to its interpretation. The VMD would discuss requests for the release of adverse reaction information with companies, because the small size of the veterinary medicines market means that information on a particular medicinal substance could lead to the identification of a particular product and affect that companies commercial interests.

Disclosure of personal data

The disclosure of personal data is covered by Section 40 of the FOIA and Regulation 13 of the EIR. Disclosure of personal information in contravention of these provisions would be unfair and, therefore, breach the first principle of the Data Protection Act 1998. Specifically, the individuals involved will not have been made aware that their details might be released and, therefore, have no expectation that this may occur. More generally such disclosures might (for example) act as a disincentive to companies to use the UK as the route by which they obtain MAs for their products, if they judge that their specialists are at risk of being lobbied or otherwise influenced by disclosure of personal information.

Additionally, Section 38 of the FOI Act (Health and Safety) may apply to (for example) some Agency assessors, and external authors of expert reports working for companies that have been subject to attacks or intimidation by animal rights activists or other groups with vested interests. There are therefore, legitimate concerns that such information could be used to target named individuals (particularly where the information alludes to, or contains references to animal testing). This risk may also make it more difficult for Regulatory Agencies to recruit suitably qualified staff, thus hindering their ability to carry out their statutory duties with regard to human and animal, safety, health and welfare, and undermining the regulatory process.

Therefore, in all relevant cases, Regulatory Agencies will redact the names and other identifying information relating to such individuals.

	Type of document or database	Examples of information within these documents where we need to test disclosure is in the public interest	Information within these documents that we believe we can disclose (but will consult third party in advance)
1	<p><u>After grant or refusal of application and reason(s) for that refusal: Quality, Safety and Efficacy documentation including:</u></p> <ul style="list-style-type: none"> • All Chemistry Manufacturing and Control (CMC)/quality documentation – Part I/II or Modules 2 and 3 • Pre-clinical/safety data – Part III or Module 4 • Clinical/efficacy data – Part IV or Module 5 • Company expert reports/Common Technical Document (CTD) overall summary – safety, quality and efficacy • Assessment reports produced by the MHRA/VMD – safety, quality and efficacy • Correspondence between MHRA/VMD, advisory body and company • Papers submitted to the Medicines Advisory Bodies • Reasons for the decisions taken by the Medicines Advisory Bodies 	<p>Composition and product Development: in general, pharmaceutical development information. This includes detailed data concerning active substance, formulation and manufacturing and test procedures and validation. This also includes scientific advice meetings.</p> <p>The names of manufacturers or suppliers of the active substance or the excipients unless disclosure is necessary for public health reasons (e.g. for some biological products).</p> <p>Active Substance: Detailed information on the synthesis or manufacture of the active substance, including details on the by-products and degradation products of active ingredients and validation of the manufacturing/synthesis process.</p> <p>Detailed information concerning the particulars of studies regarding polymorphism and particle size.</p> <p>Concerning impurities and degradation products, qualitative and quantitative information unless disclosure is necessary for public health reasons.</p> <p>Detailed information on the test methods used and the specification and quantitative acceptance criteria established for the active substance, unless the tests meet specific monographs in the European Pharmacopoeia.</p>	<p>Composition and product Development: The final qualitative formulation (composition) of the authorised product.</p> <p>Active Substance: General, non-detailed information on the structure of the active substance. Including rDNA products e.g. protein sequence, glycosylation.</p> <p>General, non-detailed information on the results of studies regarding polymorphism and particle size.</p> <p>A general, non-detailed description of the types of test methods used and the appropriateness of the specification.</p>

	Type of document or database	Examples of information within these documents where we need to test disclosure is in the public interest	Information within these documents that we believe we can disclose (but will consult third party in advance)
	<p>After grant or refusal of application and reason(s) for that refusal: Quality, Safety and Efficacy documentation including: (continued)</p>	<p>Finished product: The detailed descriptions of the manufacturing and control processes for the product.</p> <p>Details of the validation of the manufacturing process</p> <p>Detailed information on the test methods included in the specification of the finished product and the quantitative acceptance criteria, unless the tests are of Pharmacopoeial standard.</p> <p>Novel packaging or medical device aspects.</p> <p>Non-Clinical and Clinical Information: Specific details on a method used in a study. Specific data generated by the applicant using another marketing authorisation holder's product, e.g. comparative studies against the reference medicinal product.</p> <p>Specific information related to environmental risk assessments and risk management plans.</p> <p>A development plan from the company, e.g. in a different indication.</p>	<p>Finished product: A general, non-detailed description of the types of test methods used and the appropriateness of the specification.</p> <p>Information on the outcome of stability studies (e.g. carried out in real time conditions or accelerated conditions).</p> <p>Non-Clinical and Clinical Information: any general, non-specific information encompassing non-clinical and clinical development of the medicinal product.</p> <p>General, non-specific information related to environmental risk assessments and risk management plans.</p>

	Type of document or database	Examples of information within these documents where we need to test disclosure is in the public interest	Information within these documents that we believe we can disclose (but will consult third party in advance)
2.	Clinical Trials Authorisation (CTA) and Animal Test Certificate (ATC)	<ul style="list-style-type: none"> • existence of application for CTA/ATC • the totality of data provide by company requesting CTA/ATC • confirmation that CTA/ATC has been granted • confirmation that CTA/ATC has been refused • disclosure of MHRA/VMD assessment of CTA/ATC application after related Marketing Authorisation granted. • disclosure of any advice given by MHRA/VMD during trial • disclosure of Adverse Drug Reactions (ADRs) from clinical trials • disclosure of clinical trials data after grant of marketing authorisation to the product to which trial relates (unless already published by company in the public domain). 	None relating to specific CTAs/ATCs. (Unless the existence of the study has already been published e.g. on clintrials.gov – a public website).
3.	Marketing Authorisation / Licence / Variation / Renewal Applications		
3.1a	MHRA Only <ul style="list-style-type: none"> • Drug-Device combination • Non orthodox practitioner licence 	All Information.	No Information.
3.1b	VMD Only <ul style="list-style-type: none"> • Provisional Marketing Authorisations • Emergency vaccines 	All Information.	No Information.
3.2	<u>After</u> Suspension of a Marketing Authorisation/Licence	Any information relating to conditions attached by MHRA/VMD to reintroduction.	General information that a product had been suspended but not why it had been suspended.

	Type of document or database	Examples of information within these documents where we need to test disclosure is in the public interest	Information within these documents that we believe we can disclose (but will consult third party in advance)
4	<p>Pharmacovigilance</p> <ul style="list-style-type: none"> Individual Adverse Drug Reaction (ADR) reports (MHRA) and individual Suspected Adverse Reaction (SAR) reports (VMD) Periodic Safety Update Reports (PSURs) <p>MHRA Only</p> <ul style="list-style-type: none"> Product Analysis Printouts (PAPs) Anonymised Single Patient Printouts (ASPPs) 	<p>Personal data relating to patients or owners of animals.</p> <p>Specific product information.</p> <p>Sales data from PSURs.</p> <p>VMD Only</p> <ul style="list-style-type: none"> information on adverse events reports for a particular medicine. information on reports of a particular reaction by medicine substance. information on the adverse events reported for a particular product. <p>MHRA Only</p> <ul style="list-style-type: none"> PAPs detailing top level information on the adverse events reported for a particular product . ASPPs individual adverse event reports received by the MHRA and sent to the MA Holder to add to their safety database. 	Summary of non-specific information.
5 5.1	<p>Inspection Reports</p> <p>Publication of Inspection Reports of Manufacturers</p> <ul style="list-style-type: none"> MHRA/VMD inspection reports – Good Manufacturing Practice (GMP) (using disclosure template) MHRA/VMD inspection reports – GMP (full report) 	Information on Inspections: specific details e.g. information regarding facilities and equipment.	Information on Inspections: General, non-specific information on the outcome of inspections (e.g. compliance/non-compliance/outstanding issues to be addressed), we will also include the company's response to findings, where appropriate.

	Type of document or database	Examples of information within these documents where we need to test disclosure is in the public interest	Information within these documents that we believe we can disclose (but will consult third party in advance)
5.2	<p>Publication of Inspection Reports of Wholesale Dealers – MHRA/VMD inspection report</p> <p>Pharmacovigilance inspections – MHRA/VMD inspection reports</p>	<p>Personal details relating to company officials</p> <p>Product related information.</p>	<p>General non-specific information on the outcome of inspections (e.g. compliance/non-compliance/ outstanding issues to be addressed).</p>
6	<p>MHRA/VMD – Common general information</p> <ul style="list-style-type: none"> Minutes of the meetings of the Medicines Act Advisory Bodies (pre 1998) and VPC, including those of the Sub-Committees Papers considered by the Medicines Act Advisory Bodies and VPC 	<p>The minutes may record committee discussions about examples of information covered in section 1 above.</p> <p>The papers may include examples of information covered in section 1 above.</p>	<p>Information related to general discussions.</p>
7	<p>Product licence and Marketing Authorisation documents</p>	<ul style="list-style-type: none"> Histories of licensing of products (top line summary list of events) Histories of licensing of products (full details) Full UK product licences/Marketing Authorisations 	<p>Summary of Product Characteristics (SPC) (SPC will be accompanied by a statement saying that copyright remains with the MA Holder. And that the document(s) is not to be used for commercial purposes).</p>
8	<p>Complaints about advertising of products</p>	<p>Pre-decision correspondence between company and MHRA/VMD about advertising where complaint is upheld.</p>	<p>Pre-decision correspondence between company and MHRA/VMD about advertising where complaint is not upheld.</p>
9	<p>Personal Data</p>	<p>Name, title, address, location or other personal identifier of any official/employee/agent whose name appears on any documentation held by the MHRA/VMD unless the individual consents.</p>	