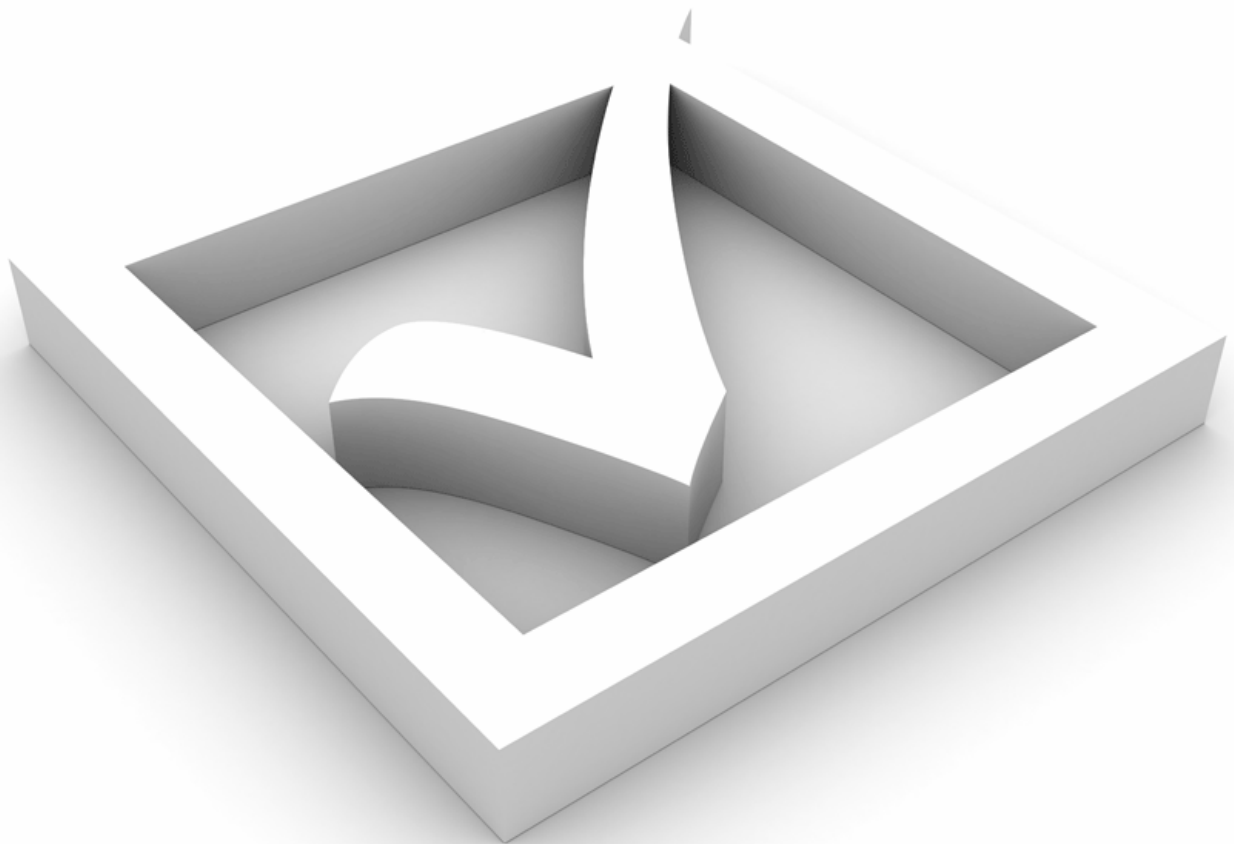


# Information Fair Trader Scheme Report

MHRA

July 2008



<b>PART ONE: INTRODUCTION</b>	<b>3</b>
<b>PART TWO: KEY CHANGES</b>	<b>5</b>
<b>PART THREE: HIGHLIGHTS AND AREAS FOR IMPROVEMENT</b>	<b>6</b>
<b>PART FOUR: PROGRESS</b>	<b>9</b>
<b>APPENDIX 1: SUMMARY OF RECOMMENDED ACTIONS</b>	<b>10</b>
<b>APPENDIX 2: LICENCE REVIEW</b>	<b>11</b>
<b>APPENDIX 3: IFTS WEBSITE ASSESSMENT</b>	<b>15</b>

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## PART ONE: INTRODUCTION

### **Information Fair Trader Scheme**

1. The Information Fair Trader Scheme (IFTS) is the best practice model for public sector bodies wishing to demonstrate compliance with the Re-use of Public Sector Information Regulations 2005. IFTS ensures that re-users of public sector information can be confident that they will be treated reasonably and fairly by public sector information providers.
2. IFTS is also the mechanism by which the Controller of HMSO regulates those Crown bodies with a delegation to administer their own licensing. All such bodies with a delegation must remain accredited to the Scheme. The Medicines and Healthcare products Regulatory Agency (MHRA) has a delegation.

### **First verification**

3. MHRA was first verified in August 2005. It was not accredited to the Scheme at this stage, gaining accreditation following a re-verification in July 2006.

### **Re-verification**

4. Re-verification is important as organisations change and staff move on. It is also an opportunity for OPSI to ensure that the recommendations of the last verification have been fully implemented. The recommendations made after the July 2006 visit and MHRA's progress in meeting them can be found in Part Four of this report.
5. The frequency of re-verification is based on several risk factors. These include the complexity of the system that is in place to licence public sector information, how critical the information is to the body in question, the standard of compliance with recommendations from the previous verification, and the degree of policy change that is envisaged. MHRA is assessed as being low risk.

### **Licensing Activity at MHRA**

6. MHRA is an agency of the Department of Health (DoH) and is a Trading Fund. Its role involves ensuring that medicines, healthcare products and equipment meet standards of safety and quality.
7. Most of the information featured on the MHRA website is available for re-use free of charge. However, some material is chargeable. This includes:
  - General Practice Research Database (GPRD)
  - British Pharmacopoeia (BP)
  - Remote Access to Marketing Authorisations (RAMA)

## **Overall Assessment**

8. As detailed in Part Four of this report, MHRA has made progress against the recommendations that were made at the last verification. It should also be recognised that the original verification, in July 2005, was extremely comprehensive and the small number of recommendations in the most recent report is indicative of the significant amount of work that MHRA undertook to gain accreditation. It has produced a Crown copyright Action Plan, setting out its intentions of expanding the take-up of extracts from its product licensing database that it has recently begun to licence.
9. MHRA has a well-established process for licensing the use of GPRD and the publication and use of BP. Its recent licensing of extracts from its product licensing database has been evaluated and set up in a professional manner. Interviews that we conducted while on site and the material that we reviewed indicates a well-run licensing process for which requests are transacted without undue delay. Pricing is transparent and based on an analysis of costs incurred.
10. In conclusion, MHRA has consolidated the extensive work that it undertook to gain accreditation to IFTS and its plans to expand its activities, subject to the constraints of the Medicines Act, data protection and commercial confidentiality, are sound. We have made a small number of recommendations aimed at strengthening its approach.
11. Based on the team's assessment, MHRA is re-accredited to IFTS and should be re-verified in 3-4 years.

## PART TWO: KEY CHANGES

12. MHRA's exploitation of its key information resources has not changed markedly since our last visit. However, it has recently begun to licence the re-use of its product licensing data.
13. In its response to the Office of Fair Trading's CUPI (Commercial Use of Public Information) report, published in December 2006, the Government referred to the Cross-cutting Review of the Knowledge Economy of 2000 and the Chief Secretary to the Treasury asked Trading Funds to submit Crown copyright action plans for opening access to information further. MHRA completed its action plan in March of this year, setting out plans to expand the re-use of its information.
14. Questions of relating to copyright and re-use have been overseen by the Head of External Relations, Information Management, for some years, ensuring continuity. This person has now been joined by an assistant working on a part-time basis.
15. The Chief Executive of the organisation was in post at the time of the last verification and has recently renewed his commitment to IFTS. He has been briefed on the recently-announced review of Trading Funds led by the Shareholder Executive within which MHRA will be in the "follow up" group.

## PART THREE: HIGHLIGHTS AND AREAS FOR IMPROVEMENT

### Openness

16. MHRA takes a positive approach to re-use. However, it is constrained by considerations of data protection and commercial confidentiality, with much of the material that it holds being the copyright of third parties.
17. Within these constraints, it has explored how its material might be more widely used, recently agreeing a contract for the commercial re-use of some of its product licensing data. This is currently licensed to one organisation, but it plans to approach other potential customers in the coming months.
18. Its existing information resources are well-advertised. Both the GPRD and the BP have dedicated websites.
19. MHRA has established a log of requests for re-use with comprehensive links to correspondence. We regard this as an example of good practice as it enables those responsible for licensing to gauge demand for information and track responses. On the rare occasion that requests have been declined, we found these to be for legitimate reasons, like not being prepared to grant an exclusive contract. We also found that such requests were processed within reasonable timescales.
20. After some internal debate, MHRA decided some time ago to contribute to the Department of Health's entries on "Inforoute", the Government's Information Asset Register (IAR). However, its entries have not been updated recently. As the Register is a good resource for interested parties to establish what is available for re-use, **we recommend that MHRA updates its Information Asset Register entries.**
21. MHRA has set out a timetable for contacting various parts of the healthcare sector with a view to promoting the re-use of its material. **MHRA should report progress on this initiative to OPSI by the end of the year.**

### Fairness

22. The contract to publish the BP on a non-exclusive basis was tendered according to European guidelines. MHRA is not aware of requests to re-publish significant extracts of the publication, as it is more commonly sourced as an academic work of reference in accordance with the normal citation rules, but we are satisfied that it would consider such requests fairly.
23. GPRD is subject to limitations on re-use as the deed of transfer by which it was given to the Department of Health, requires that it be used for public health research purposes and administered on a non-profit

basis. MHRA fairly adheres to these conditions and the various levels of use that are available to those who wish to access the database are very well documented. The costs that it incurs in collecting, processing and distributing the data are subject to periodic analysis and the organisation is currently looking at its database structure and server usage with a view to lowering costs. The operation of GPRD is ring-fenced from the rest of the organisation so that requests for access from elsewhere within MHRA are charged for on the same basis as an external request.

24. MHRA's recent venture to license the re-use of its product licensing data has been fairly priced according to the initial costs of analyst time to set up and then maintain a fixed query on the database. MHRA will review these costs over time. It currently has one licensee, but should any other companies approach MHRA for a licence to re-use the same data, we are confident that MHRA would issue it to them on the same terms.

### **Transparency**

25. MHRA's approach to licensing is thoroughly documented on its website along with the basis for charging for much of its material. The charges for GPRD are clearly set out on the GPRD website, as is an example contract.

### **Compliance**

26. OPSI has carried out a review of two of MHRA's standard licences as detailed in appendix 2. **MHRA should consider the points raised in the review when the licences are renewed.**
27. OPSI has conducted a website review, the results of which are appended to this report. MHRA has scored well on this, indicating the work that has gone in to providing comprehensive information about copyright, IFTS and re-use since the original verification.
28. The MHRA's Enquiry Point staff are well acquainted with who should receive queries relating to copyright, GPRD and BP. They also have comprehensive notes to hand, incorporated into their customer service manual which enables them to deal with straightforward queries at the first point of contact.
29. Some licensing activity has been in place for some years, taking place within given departments to the extent that some queries are routed directly to those departments, rather than via the copyright team. Although the person who is corporately responsible for licensing is consulted on key questions, **it would be beneficial for the copyright team, BP and GPRD to meet periodically to exchange information.**

### **Challenge**

30. Complaints on the basis of the PSI Regulations or MHRA's membership of IFTS are handled according to the organisation's standard complaints procedure. This process is well documented and

those we spoke to within the organisation were aware of how a complaint should be handled. All complaints are referred to a named individual who, working with an assistant, assesses what action is required. There is also scope for referral to an independent assessor.

31. No complaints under PSI or IFTS are recorded as having been received and none have been raised with OPSI. In this context, the fact that the lead complaints officer was unaware of OPSI's complaint-handling role is not entirely surprising. However, it is clearly explained on the copyright section of the MHRA website that complainants have the option of approaching OPSI should they be dissatisfied with MHRA's complaint investigation.

## PART FOUR: PROGRESS

Recommendations of previous verification and if they have been met.

Principle	Recommendation	Priority	Action Taken	Status
Openness	The MHRA should undertake a full information audit to ensure that it fully recognises what information assets it holds.	High	The MHRA has yet to conduct a full information audit, but it has fully assessed the characteristics of information that has been the source of key IT projects. It prefers to prioritise raising awareness of its key information resources. It will review lower-profile information holdings as they come to the attention of the copyright team and will consider them for inclusion within the IAR which it is tasked with updating.	Ongoing
Transparency	OPSI recommends that the MHRA publishes on its website as much information about what is available for access and re-use as possible.	High	MHRA has considered this recommendation seriously, but should re-visit this requirement once it has considered the latest website review and has implemented its plans to broaden the take-up of its product licensing data.	Complete
Fairness	It is recommended that the MHRA ensures that all staff that deal with licensing queries are aware of the need to treat customers fairly and equally for the same types of re-use.	Medium	Key personnel have now been thoroughly briefed on the requirements of fair licensing.	Complete

## APPENDIX 1: SUMMARY OF RECOMMENDED ACTIONS

This is a summary of the recommended actions to:

- remedy the weakness identified; and,
- strengthen the commitment to Information Fair Trading.

Principle	Ref	Recommendation	Priority
Openness	20	We recommend that MHRA updates its Information Asset Register entries.	H
	21	MHRA should report progress on this initiative to OPSI by the end of the year.	H
Compliance	26	MHRA should consider the points raised in the review when the licences are renewed.	M
	29	It would be beneficial for the copyright team, BP and GPRD to meet periodically to exchange information.	M

## APPENDIX 2: LICENCE REVIEW

<b>Licence Review 1: Full Feature General Practice Research Database, Level 3</b>
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### Evaluation Criteria

#### **1. Clarity of licence terms**

*Check for clarity of language, jargon, legalistic language, plain English*

We found this to be an effective document that is, on the whole, clearly drafted.

#### **2. Comprehensiveness of licence terms**

*Are there any significant omissions? Does the licence contain terms that you would not expect to find in a licence?*

Clause 11.2: If any research is produced based on the data there should be a specific acknowledgment of any Crown copyright content directly used/quoted.

#### **3. Fairness**

*Does the licence contain terms that are unfair or unnecessarily discriminate between different user groups?*

Clause 8.3: Given the amount of money being paid, it could be seen as unfair that the Licensor is under no obligation to add new data to the database. However, it is acknowledged that the database supports longitudinal research and that benefit remains in the data as originally supplied up to the point of renewal of the licence.

Clause 8.5: Interrupting the service outside of normal downtime without compensation could be seen as draconian. MHRA should consider redrafting this clause to emphasise that withdrawal of service during contracted hours is an extremely rare occurrence and that every effort will be made to restore the service as soon as possible. Compensation claims could be considered if the interruption lasts more than a given number of hours.

#### **4. Consistency**

*Does the licence contain any terms which are inconsistent and contradictory?*

Clause 31.2: To be consistent with the previous sub-clause, a reference should be made to the Welsh courts.

## **5. Practical Arrangements**

*Is it clear what the process is for making payments, amending terms for example?*

Clause 4.1: We are puzzled as to why the initial payment of £50,000 would not follow the process of an invoice being raised and the licensee paying within the 30 days, as would be the case with subsequent transactions as covered in clause 4.2.

## **6. Restrictiveness of terms**

*Are any of the terms unnecessarily restrictive?*

Clause 12: The Licensee is required to warrant and indemnify. Surely, the Licensor should reciprocate, particularly in terms of warranting that the Data and the Database do not infringe any third party IPRs and that the Licensor has the right to grant the rights contained in the agreement.

Clause 20.1: It is customary in licensing agreements to establish a process under which the party that commits an alleged breach is notified of the breach and is given a period of time in which to respond and/or remedy the breach. In this agreement, however, the Licensor has the unilateral right, following suspension of the licensee, to terminate with immediate effect for unauthorised use. We recognise that GPRD is subject to a Deed of Transfer and that MHRA is required to license, including as set out in the Restrictions On Use, in accordance with the deed. We do, however, feel it would be beneficial to set out in greater detail what form the investigation would take to establish unauthorised use while the licensee is suspended and that the licensee will be given an opportunity to explain the circumstances of the alleged unauthorised use.

## **7. Additional Comments**

None.

## Licence Review 2: Data Licence Agreement

### Evaluation Criteria

#### 1. Clarity of licence terms

*Check for clarity of language, jargon, legalistic language, plain English*

Clause 2.1: The second half of this clause deals with termination arrangements. We think it would be more logical to cover these aspects either at clause 8 (termination) or better still include a new clause after clause 8 that would deal with the consequences of termination. It may be clearer if the clause was broken down so that termination for breach is distinguished from termination by giving one month's notice.

It is not clear what action is required of the Licensee in the context of its relationship with its customers/end users. If, for example, the Licensee receives the data from MHRA and then provides it in an inaccurate form to its customers, we would assume that MHRA would wish the Licensee to notify the customer and delete the data.

The word *satisfaction* in line 7 of clause 8.1 is rather curious. Maybe it should read *satisfying the requirements of clause 8.3 below*. We assume that the obligations of clause 8.3 apply equally to termination by notice. If so, it may be better to add a sentence to clause 8.3 to the effect that this clause applies to termination under both clause 8.1 and 8.2.

#### 2. Comprehensiveness of licence terms

*Are there any significant omissions? Does the licence contain terms that you would not expect to find in a licence?*

In the preamble, we suggest that an additional recital is added to the effect that the Data, as defined below, is subject to Crown copyright protection and that MHRA licenses the re-use of the Data under a delegation of authority granted by the Controller of HMSO.

Clause 1.1, definition of Products: The licence should relate to specific products that are listed in an annex.

Clause 2.3: The IPR (assuming that we are just talking about copyright) rests with MHRA on behalf of the Crown and not the Licensor.

Clause 2.4: It may be better to reframe this clause to the effect that the Licensor only asserts IPR in the Data and makes no claim on any other IPR in the Products.

Clause 3.2: We suggest that MHRA says that if there is any doubt, the Licensee should consult MHRA immediately for its views.

Clause 7: It may not be advisable to provide an indemnity where there is no upper limit. Modifying or deleting such a clause would not prevent the Licensee from taking action against MHRA for a failure of the warranties.

### **3. Fairness**

*Does the licence contain terms that are unfair or unnecessarily discriminates between different user groups?*

The period of seven days for remedying a material breach is very short. Is this practicable? The usual period is about sixty days. Similarly, the period of notice is very short for termination under 8.2. Given that the Licensee's business could be dependent on receiving the data, is this realistic? Also, failure to provide possible reasons for termination could lead to the perception that this could be done arbitrarily.

### **4. Consistency**

*Does the licence contain any terms which are inconsistent and contradictory?*

No comments.

### **5. Practical Arrangements**

*Is it clear what the process is for making payments, amending terms for example?*

Clause 2.2: On condition that payment is made on time, it may be useful to spell out when the updates would be provided (for example, last working day of each quarter).

### **6. Restrictiveness of terms**

*Are any of the terms unnecessarily restrictive?*

No comments.

### **7. Additional Comments**

None.

## APPENDIX 3: IFTS WEBSITE ASSESSMENT

Organisation: Medicines and Healthcare products Regulatory Authority (MHRA)  
Site available at: [www.mhra.gov.uk](http://www.mhra.gov.uk)  
Date assessed: 24 July 2008

- 1.1 Does the website have an Information Asset Register? **Yes, via a link to the DoH IAR**  
<http://www.mhra.gov.uk/Aboutus/Freedomofinformationanddataprotection/Freedomofinformation/index.htm> **and then**  
<http://www.info.doh.gov.uk/doh/iar.nsf?open>
- 1.2 If yes, how many clicks is it from the homepage? **2**
- 1.3 How long did it take to find? **2 – 3 minutes**
- 1.4 If there is no IAR, is there other guidance on what information is available? **N/A**
  
- 2.1 Does the PSB use standard licences? **Yes**
- 2.2 Are these published in full on the website? **MHRA uses the OPSI value-added template** <http://www.opsi.gov.uk/click-use/value-added-licence-information/index.htm> **An example GPRD licence is published on its dedicated website**  
<http://www.gprd.com/docs/Sample%20Licence%202006.pdf>
- 2.3 If yes, how many clicks are they from the homepage? **3**
- 2.4 How long does it take to find? **2 – 3 minutes**
- 2.5 How many standard licences are there? **The majority of its material is governed by a single value added licence. In the case of GPRD, there are a number of different levels of access utilising a single licensing framework**
- 2.6 Is there an explanation of what different licences are for and is it clearly understood? **Yes**
  
- 3.1 Is there any charge made for licences? **Much of its material is free, but where there are charges it uses OPSI's scale for value-added material.**
- 3.2 Is there an explanation of the charges? **Yes**  
<http://www.opsi.gov.uk/click-use/value-added-licence-information/charging-value-added-material.pdf> **with added information on**  
[http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme\(IFTS\)/index.htm](http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme(IFTS)/index.htm) **and for GPRD**  
<http://www.gprd.com/serviceofferings/priceplan.asp>
- 3.3 Is there an explanation of how charges are drawn up? **Yes**
  
- 4.1 Is there an IFTS commitment on the website? **Yes**  
[http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme\(IFTS\)/index.htm](http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme(IFTS)/index.htm)
- 4.2 How many clicks is it from the homepage? **2**

- 4.3 How long does it take to find? > **1 minute**
- 5.1 Is there clear and precise information on how to apply for a re-use licence? **Yes**  
[http://www.mhra.gov.uk/home/idcplg?IdcService=GET\\_FILE&dID=24637&noSaveAs=1&Rendition=WEB](http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dID=24637&noSaveAs=1&Rendition=WEB)
- 5.2 Are there a variety of methods for applying for licences? **Yes**
- 5.3 Is it possible to apply online for a licence? **Yes**
- 5.4 Does it specify a timescale to grant licences? **Yes, 20 days**
- 6.1 Does the PSB have a procedure for complaints regarding licensing decisions? **Yes**  
[http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme\(IFTS\)/index.htm](http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme(IFTS)/index.htm)
- 6.2 How many clicks is it from the homepage? **2**
- 6.3 How long does it take to find? > **1 minute**
- 6.4 Does it mention that if the complainant is unhappy they can refer to OPSI or APPSI? **Yes**
- 7.1 Does the website explain what information is not available? **Yes**  
[http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme\(IFTS\)/index.htm](http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme(IFTS)/index.htm)
- 8.1 Does the website outline any exceptions to normal licensing policy? **Yes**  
[http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme\(IFTS\)/index.htm](http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme(IFTS)/index.htm)
- 8.2 If yes, does it explain why that exception has been made? **The list of exceptions is quite detailed and MHRA undertakes to give full reasons should a request be refused**
- 8.3 How many exceptions are there? **10**
- 9.1 Does the website have a Crown Copyright notice? **Yes**  
<http://www.mhra.gov.uk/CrownCopyright/index.htm>
- 9.2 Is it linked to from every page? **Yes**
- 9.3 How many clicks is it from the homepage? **1**
- 9.4 How long does it take to find?  
**Less than 1 minute**
- 9.5 Is OPSI/HMSO mentioned, with contact details? **Yes**
- 10.1 Does the website have an electronic search facility? **Yes**
- 10.2 If yes, how many clicks is it from the homepage? **0**
- 10.3 How long did it take to find? **Less than 1 minute**
- 11.1 Is the material available by electronic means? **Yes**  
<http://www.mhra.gov.uk/home/groups/es-foi/documents/websitesresources/con001896.pdf>
- 11.2 Is it possible to download direct from the website? **Yes**
- 12.1 Does the PSB outline its responsibilities under IFTS on their website?

**Yes**

[http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme\(IFTS\)/index.htm](http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme(IFTS)/index.htm)

- 12.2 Does the website explain what IFTS is aiming to achieve? **Yes**
- 12.3 Are the benefits of IFTS explained? **Yes**
- 12.4 Is the PSB using IFTS logos on their website and actively mentioning they are a member of the scheme? **Yes**
- 13.1 Does the PSB outline its policy towards its trading of PSI? **Yes**  
[http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme\(IFTS\)/index.htm](http://www.mhra.gov.uk/Aboutus/InformationFairTraderScheme(IFTS)/index.htm)
- 13.2 Does the PSB explain how it arrives at decisions? **Yes**
- 13.3 Does the website have an explanation of what re-use is? **Yes**
- 13.4 Does the website explain what Crown Copyright is? **Yes**  
<http://www.mhra.gov.uk/CrownCopyright/index.htm>
- 13.5 Does the website explain why licences are sometimes needed to re-use information? **Yes**
- 13.6 Does the website explain the difference between FOI and re-use? **Yes**
- 13.7 Does the website explain what a trading fund and delegated authority is? **Yes**

***This website contains the majority of the key information required by IFTS, is well set out and gives clear explanations.***

***The main website should have clearer links to two of its key products, British Pharmacopoeia <http://www.pharmacopoeia.co.uk/> and GPRD <http://www.gprd.com>***