

# Meeting our objectives

## Objective 1

**Authorise veterinary medicines efficiently, using good science, thus ensuring their safety, quality and efficacy, and in accordance with legislative requirements.**

**For new UK Marketing Authorisations, performance against legislative and internal targets for the assessment process**

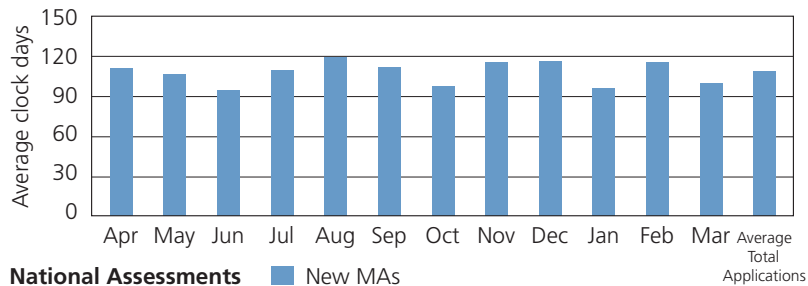
### Expected Outcome

To sign off<sup>A</sup> or refer to the VPC new applications for Marketing Authorisations within 120 clock days, and determine<sup>B</sup> all applications within 210 clock days<sup>C</sup>.

### Outcome

#### TARGETS (average clock days)

Signed off or referred to VPC within 120 days



**National Assessments** ■ New MAs

A total of 58 applications were signed-off or referred to the VPC during the year. Fifty seven of these were within the 120 day target timeframe, giving a 98.28% success rate.

During the year a total of 87 applications for new national Marketing Authorisations were determined, all within the 210 day statutory target.

### Evaluated by

For the 120 day measure, we assessed our performance as follows:

>90% completed	Excellent
80-90% completed	Effective
<80% completed	Unacceptable

For the 210 day measure, we will meet our statutory obligations to determine all these applications within 210 clock days.

- Monthly performance reports to Director and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Peer review of the quality of scientific assessment by the VPC and other Government Departments.
- Management Board review of performance each quarter.

A 'Sign off' is the time taken to complete scientific assessment.

B 'Determine' is the time taken to 'sign off' and issue authorisation documentation.

C 'Clock days' is that time when the application is under assessment by the VMD and excludes that time when further information is awaited from applicants in response to VMD questions.

# For applications for variations to UK Marketing Authorisations, performance against internal targets for the assessment process

## Expected Outcome

For Type I variations, complete our initial assessment within 30 clock days, and sign off applications within 60 clock days. For Type II variations, complete our initial assessment within 60 clock days and sign off, or refer to the VPC, applications within 120 clock days.

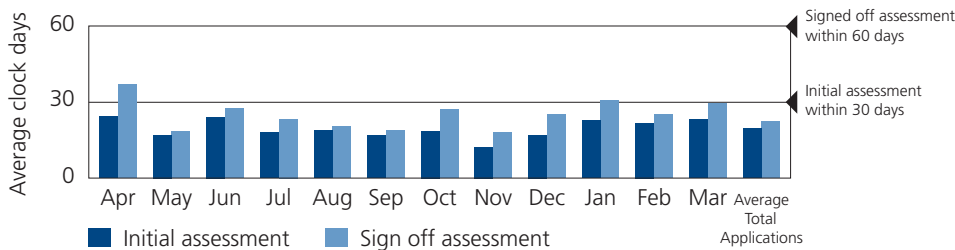
## Outcome

A total of 335 Type I national variations had an initial assessment completed within 30 days. Four missed the target resulting in a performance of 98.80%.

A total of 356 Type I national variations were signed off within the 60 days. One missed the target resulting in a performance of 99.72%.

### National Type I Variations

#### Type I

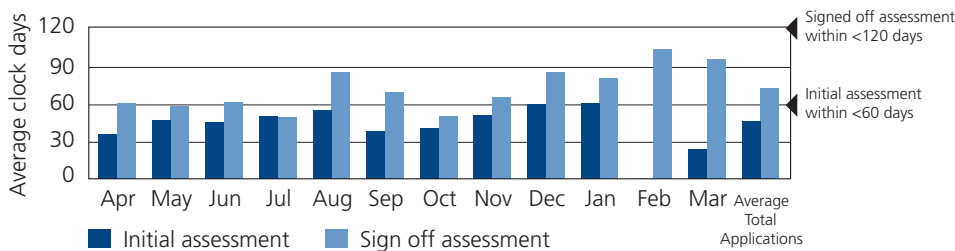


### National Type II Variations

A total of 233 Type II national variations had an initial assessment completed within 60 days. None missed the target resulting in a performance of 100%.

A total of 224 Type II national variations were signed off within the 120 days. Two missed the target resulting in a performance of 99.12%.

#### Type II



## Evaluated by

We will assess our performance as follows:

>95% completed	Excellent
90-95% completed	Effective
<90% completed	Unacceptable

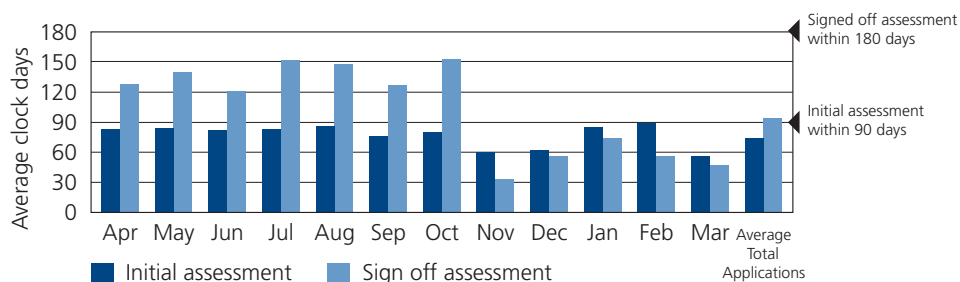
- Monthly performance reports to Director and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Peer review of the quality of scientific assessment by the VPC and other Government Departments.
- Management Board review of performance each quarter.

## For applications for renewals of UK Marketing Authorisations, performance against internal targets for the assessment process

### Expected Outcome

To complete our initial assessment within 90 clock days and sign off applications within 180 clock days.

### Outcome



A total of 235 national renewals had an initial assessment completed within 90 days. Five missed the target resulting in a performance of 97.92%.

A total of 227 national renewals were signed off within 180 days. Four missed the target resulting in a performance of 98.58%.

### Evaluated by

We will assess our performance as follows:

>95% completed	Excellent
90-95% completed	Effective
<90% completed	Unacceptable

- Monthly performance reports to Director and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Peer review of the quality of scientific assessment by the VPC and other Government Departments.
- Management Board review of performance each quarter.

## For applications for Animal Test Certificates (ATCs) in the UK, performance against internal targets for the assessment process

### Expected Outcome

To validate applications for ATCs within five calendar days of receipt, and to determine Type A applications within 30 days of receipt of a valid application. Determine Type B applications within 50 calendar days of receipt of a valid application.

### Outcome

Twelve Type IA ATCs were validated within five days and five were signed off within the 30 day target. For both targets 100% compliance was achieved.

Twenty eight Type IB ATCs were validated within five days. Two were validated outside this target resulting in a performance of 93.33%. Ten applications were signed off within the 50 day target. Two were signed off outside the target resulting in a performance of 83.33%.

## Evaluated by

We will assess our performance as follows:

>95% completed	Excellent
90-95% completed	Effective
<90% completed	Unacceptable

- Monthly performance reports to Director and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Peer review of the quality of scientific assessment by the VPC and other Government Departments.
- Management Board review of performance each quarter.

## ATC

Number received	36
Number issued	39

## Time taken for assessment of issued ATCs

Days	0-15	16-31	32-60	61-90
No. Applications	15	13	9	2

## Total time from Validation to Determination

Days	0-15	16-31	32-60	61-90
No. Applications	16	9	12	2

## For all UK applications, other than ATCs, performance against internal targets for the start and end of the authorisation process

### Expected Outcome

To validate within ten calendar days of receipt, and issue relevant documentation within ten calendar days of sign off.

### Outcome

The validation and sign off performance for the various application types is detailed in the following table:

Application Type	Validation (No. Applications)	Performance
Type I Scientific Variations	330	98.8%
Type I Administrative Variations	286	97.9%
Type IB Variations	40	100%
Type II Variations	251	99.60%
Renewals	281	100%
New Marketing Authorisations	53	100%

Application Type	Issued (No. Applications)	Performance
Type I Variations Scientific and Administrative	652	100%
Type IB Variations	75	100%
Type II Variations	204	99.51%
Renewals	341	100%
New Marketing Authorisations	54	100%

## Evaluated by

We will assess our performance as follows:

>95% completed	Excellent
90-95% completed	Effective
<90% completed	Unacceptable

The following table shows the comparison of applications received and determined for each category for both 2004/2005 and 2005/2006. The table also shows the number of applications which were in progress at the end of 2005/2006.

	Received & validated in year 2004/05 & 2005/06		Determined in year 2004/05 & 2005/06		Work in progress 2005/06
<b>National:</b>					
New Marketing Authorisations	78	46	83	89	118
New Emergency Product Licences	38	32	37	38	0
New AVA	–	3	–	0	3
Type I Admin	278	286	277	327	2
Type I Scientific	500	330	529	325	9
Type II	185	251	187	227	88
Renewal	300	189	288	341	316
Type IA Admin	–	2	0	2	3
Type IA Scientific	–	128	0	130	0
Type IB Admin	–	42	0	24	20
Type IB Scientific	–	103	0	79	32
<b>ATC:</b>					
Type A	14	11	13	11	2
Type B	20	27	19	28	5
Var & Ren	18	17	24	18	7
<b>Centralised:</b>					
New Rapp/Co-Rapp	0	1	3	2	5
Type I	38	12	37	11	1
Type II	14	7	12	7	3
Others	49	28	30	43	11
MRL	3	4	3	3	5
Zootechnical FA	4	1	6	6	6
<b>Mutual Recognition:</b>					
UK CMS	29	22	29	20	15
UK RMS	9	24	13	22	10
<b>Variations:</b>					
UK CMS	137	86	128	94	34
UK RMS	64	61	61	63	26
<b>Renewals:</b>					
UK CMS	25	13	15	1	3
UK as RMS	15	7	11	9	6

In addition we also:

- issued 61 EU Batch Release Certificates, 98.36% of which were within the 10 working days deadline;

- issued 62 UK Batch Release Certificates, 99.80% of which were within the 10 working days deadline;
- issued 2,912 Special Treatment Authorisations, 99.09% within the 10 working days deadline;
- issued 432 Special Treatment Certificates, 100% within the 10 working days deadline;
- issued 876 Special Import Certificates, 100% within the 10 working days deadline;
- issued 1,324 Export Certificates 99.77% within the 4 working days deadline.

### Evaluated by

>95% completed	Excellent
90-95% completed	Effective
<90% completed	Unacceptable

## Comply with timetables agreed with the EMEA for new European procedures (centralised and MRLs) and legislative timetables for all decentralised and mutual recognition procedures

### Expected Outcome

To achieve 100% performance against agreed timetables thus achieving predictability for industry in the regulatory process and to maintain the VMD's position as a leading regulatory authority in the EU.

### Outcome

The UK undertook work in each of the different types of European Procedures. All targets required 100% compliance and the VMD achieved this demanding standard for the majority of the procedures. On three occasions assessment reports were not completed within the 90-day target, however this did not have any detrimental affect on the applicants because the procedures ran to the expected timetables. The following table details the numbers and types of procedure undertaken within the UK:

	No. Applications
UK as RMS producing assessment report within 90 days	23 out of 25
UK as RMS during the 90 day Mutual Recognition phase	22
UK as the CMS	20
UK as the RMS for Mutual Recognition variations	63
UK as the CMS for Mutual Recognition variations	94
UK as RMS for renewals: assessment report within 90 days	10 out of 11
UK as CMS for renewals	12
Centralised procedure with UK as Rapporteur	2
MRL assessments submitted to CVMP	2
Centralised variations	18
Centralised applications with UK comment only	17
Centralised variations with UK comment only	37

During the year a process was introduced before the November deadline at both European and national level for managing applications received under the new Decentralised Procedure.

### Evaluated by

- Monthly performance reports to Directors and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Peer review of the quality of scientific assessment by the VPC and other Government Departments.
- Management Board review of performance each quarter.
- EU meetings (CVMP and the VMRFG – now the Veterinary Co-ordination Group for Mutual Recognition and Decentralised Procedures).
- Project team review.
- Industry liaison meetings.

## Replace national Type I and II variations procedures with national Type IA, IB and II procedures in line with European procedures by November 2005

### Expected Outcome

To reduce the burden to industry by bringing the UK variation procedures in line with those used for European Procedures, thus introducing greater predictability for major variations and a more rapid turnaround for minor variations.

### Outcome

The new procedures were in operation by the November deadline. The following details the numbers and types of variations received under these new procedures:

- 130 Type IA variations have been completed within 14 days (100%).
- 86 Type IB variations have had an initial assessment completed within 30 days (98.9%).
- 76 Type IB variations have had further assessment completed to the sign off stage within 60 days (100%).
- 233 Type II variations have had an initial assessment completed within 60 days (100%).
- 224 Type II variations have had further assessment completed to the sign off stage within 120 days (99.12%).

### Evaluated by

- Monthly performance reports to Directors and CEO.
- Monthly Licensing Business senior managers performance review meetings.

We also assess our performance as follows\*:

>95% completed	Excellent
90-95% completed	Effective
<90% completed	Unacceptable

\*The overall performance for the year for variations can be found on page 23.

## Introduce new procedures to deal with renewals under the new legislation from November 2005

### Expected Outcome

To reduce the burden to industry by introducing revised procedures to manage renewals under the new legislation.

## Outcome

By the November deadline revised procedures were introduced in accordance with the new legislation. For products which have already been renewed and for which there are no outstanding conditions an administrative renewal has been introduced. The resulting documentation allows an unlimited life. A conditional renewal has also been introduced which provides for a targeted assessment of conditions set at a previous renewal. A full renewal process continues to operate for products which have not previously been renewed.

## Evaluated by

- Monthly performance reports to Directors and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Management Board review of performance each quarter.
- EU meetings (CVMP and the Veterinary Mutual Recognition Facilitation group – now the Veterinary Co-ordination Group for Mutual Recognition and Decentralised Procedures).
- Industry liaison meetings.

## Introduce legislation to implement Phase 2 of the revised Fee Structure in November 2005

### Expected Outcome

To introduce revised fees within the body of the new Veterinary Medicines Regulations 2005.

## Outcome

A fees section has been included within the body of the Veterinary Medicines Regulations. In addition to the inflationary uplift adjustments were made to the national and European variations in order to reflect more appropriately the work involved with these applications. There were also a number of other changes introduced in order to harmonise the fees with the Regulations.

## Evaluated by

- Monthly financial reports to Directors and CEO.
- Management Board review of performance each quarter.
- Project team review.
- Industry liaison meetings.
- Public consultation exercise.

## Introduce changes to the scheme for Marketing Authorisations for Parallel Imports (MAPIs) from November 2005

### Expected Outcome

Implement an accelerated process for Parallel Import applications for Mutually Recognised Products.

## Outcome

An accelerated process was introduced by the November deadline as part of a package of changes required to implement the new legislation. A shortened assessment time is now in place for Parallel Import applications received in respect of Mutually Recognised Products.

### Evaluated by

- Monthly performance reports to Directors and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Project team review.
- Industry liaison meetings.

We also assess our performance as follows:

>90% completed	Excellent
85-90% completed	Effective
<85% completed	Unacceptable

### From November 2005 publish Marketing Authorisations on our website (within 30 days of the issue of the authorisation) and the UK Public Assessment Reports (UKPARs) within the following 3 months

#### Expected Outcome

In order to provide greater transparency with the evaluation and subsequent authorisation of products information would be published, including the Public Assessment Reports, within a maximum of 120 days following authorisation.

#### Outcome

Two VMD websites were designed to provide a means to publish product information. By the beginning of November a Summary of Product Characteristics (SPC) website had been developed with the capability of storing alphabetically, by trade name, all authorised SPCs. Also in line with the requirements of the new legislation a website was developed by November for recording and storing Public Assessment Reports. This website contains a profile for each authorised product, a link to the SPC, a scientific discussion for those new products authorised after 30 October 2005 and details of post authorisation activity.

### Evaluated by

- Monthly performance reports to Directors and CEO.
- Monthly Licensing Business senior managers performance review meetings.
- Management Board review of performance each quarter.
- EU meetings (CVMP and the Veterinary Mutual Recognition Facilitation group – now the Veterinary Co-ordination Group for Mutual Recognition and Decentralised Procedures).
- Industry liaison meetings.
- Full internal SPC audit.