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**NHS Business Services Authority**  
**Drug Tariff Part IX Annual Review**  
**2021-2022**

## 1. Summary

During the period 1<sup>st</sup> April 2021 and 31<sup>st</sup> March 2022, 227 applications were assessed by NHS Prescription Services (NHS Business Services Authority) for listing in the NHS England Wales Drug Tariff (the 'Drug Tariff') of which 166 were eventually approved for listing; 13 were withdrawn by the applicant; one was rejected; 39 were referred to the applicants for further information; and eight are currently being processed internally. There was an average time to listing of 46 days, representing the time from NHS Prescription Services sending the proposed Drug Tariff PDF entry to the applicant for approval to final publication.

The number of annual price increase requests reduced slightly by 10%. Due to the volatility of the forecast gross domestic product deflator (GDP) the Department of Health and Social Care (DHSC) and Part IX Industry Forum agreed to apply a maximum price increase of 1.25% in place of the usual formula of forecast (GDP-0.75)% for the period 6<sup>th</sup> May 2021 - 5<sup>th</sup> May 2022.

The number of exceptional price increase requests rose from four in 2020-2021 to 12 in 2021-2022 which accounted for 246 individual lines. The reasons commonly cited by manufacturers were the increase in cost of raw materials especially oil-based products (such as plastics and paraffin-based substances), transport, and manufacturing costs. As requests for transport and manufacturing costs are outside the remit on which NHS Prescription Services can award an exceptional price increase, these required referral to the DHSC for case-by-case consideration. The time spent processing these requests is currently having a significant impact on NHS Prescription Services' workload.

## **2. Introduction**

The legislative basis for Part IX of the NHS England Wales Drug Tariff (the 'Drug Tariff') is sections 126 and 164 of the National Health Service Act 2006 and regulation 89 of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) regulations 2013. The Drug Tariff is compiled and published monthly by NHS Prescription Services on behalf of the Secretary of State for Health and Social Care, as provided for by these legislative provisions. Part IX of the Drug Tariff is the list of appliances and chemical reagents approved on behalf of the Secretary of State and which may be prescribed at NHS expense by an appropriate prescriber.

Responsibility for administration of Part IX of the Drug Tariff is shared between the Department of Health and Social Care (DHSC) and NHS Prescription Services of the NHS Business Services Authority (NHSBSA). The DHSC has responsibility on all aspects of policy. NHS Prescription Services has responsibility for approval of the lists of appliances and chemical reagents on behalf of the Secretary of State for the purposes of the 2006 Act; for the determination of the prices based on which the payment for such appliances and chemical reagents is to be calculated, and for removal of products from Part IX when NHS Prescription Services is notified that they are no longer available.

During 2021-2022 NHS Prescription Services proposed to report the statistics in a timelier manner which was more representative of the process; this was subsequently agreed with the Drug Tariff Part IX Forum members. Statistics are now reported every month and show the 'journey' of the applications from their entry into NHS Prescription Services to their status after first professional assessment.

This paper reviews the activity of NHS Prescription Services between 1<sup>st</sup> April 2021 and 31<sup>st</sup> March 2022 with regards to the administration of the application process for listing in Part IX, the Part IX price increase mechanism, any applications for an exceptional price increase and the Part IX Appeal process.

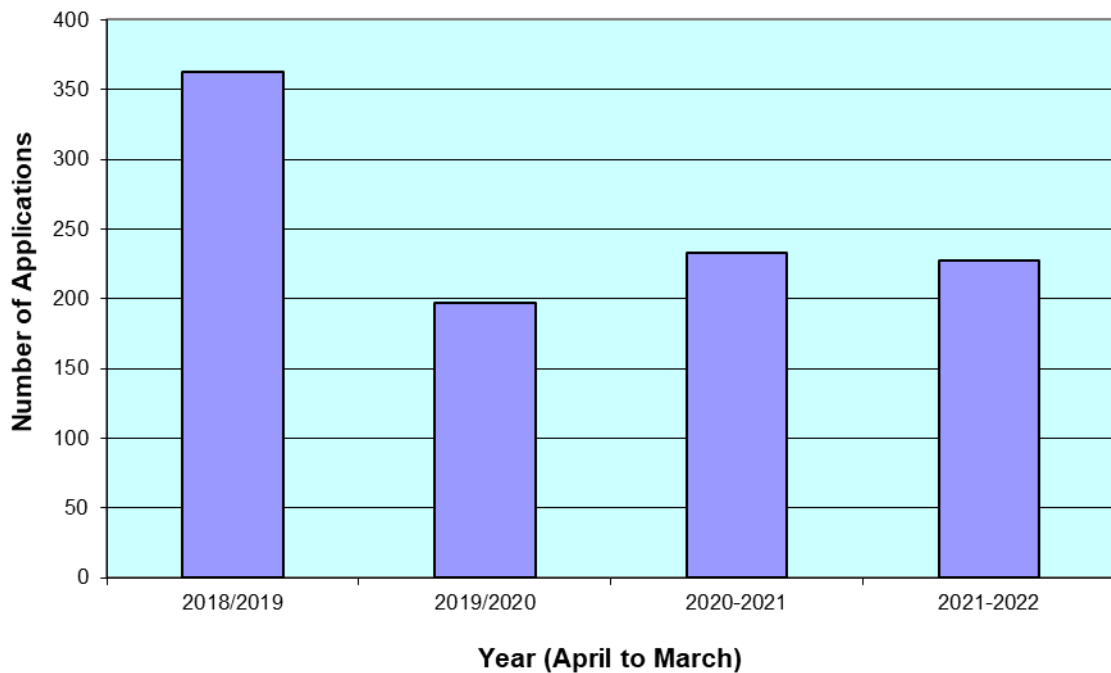
## **3. Applications for inclusion in Part IX**

The application procedure for products to be listed in Drug Tariff Part IX is set out in [An Introduction to Part IX of the Drug Tariff](#) on the NHSBSA website. There are three criteria that an application must satisfy to be approved for listing in Part IX which are:

- i. The products are safe and of good quality;
- ii. They are appropriate for prescribing in primary care;
- iii. They are cost effective.

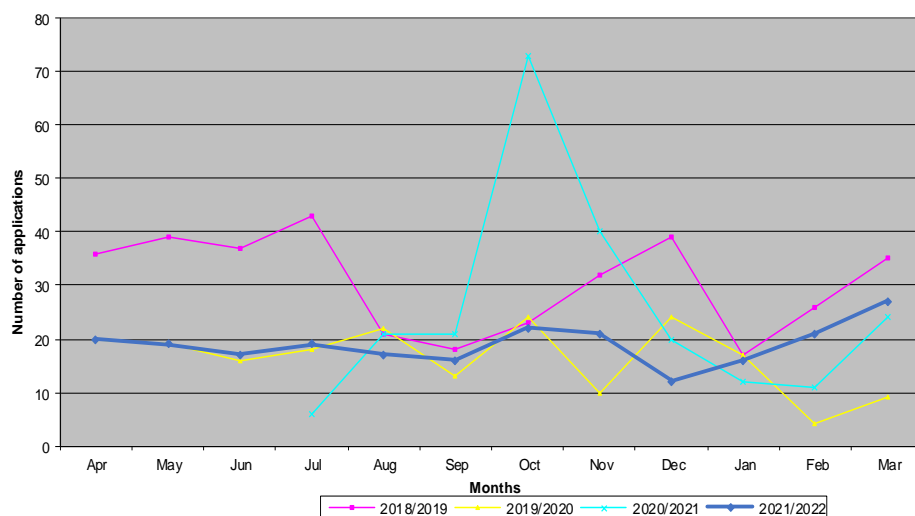
The number of applications handled by the support team was 467 which includes repeated handling of the same applications due to incomplete/wrong information. The average time to assess the completeness of the basic information (i.e., that the form had been completed correctly and the certificates were correct) was two days. The average time to check the quality of the photographs, packaging and signed forms was seven days.

Between 1<sup>st</sup> April 2021 and 31<sup>st</sup> March 2022, a total of 227 new applications were passed through for professional assessment. This represents a 2% decrease in the number of applications made compared with 2020-2021 when 233 were received. Figure 1 illustrates the total number of applications received over the previous four financial years. The average number of applications received per year over the four-year period is 264.



**Figure 1.** Number of Part IX applications received over the previous four financial years.

Figure 2 shows the numbers of applications received month-by-month and makes comparison with the data from previous financial years.



**Figure 2.** Number of Part IX applications received each month over the previous four financial years.

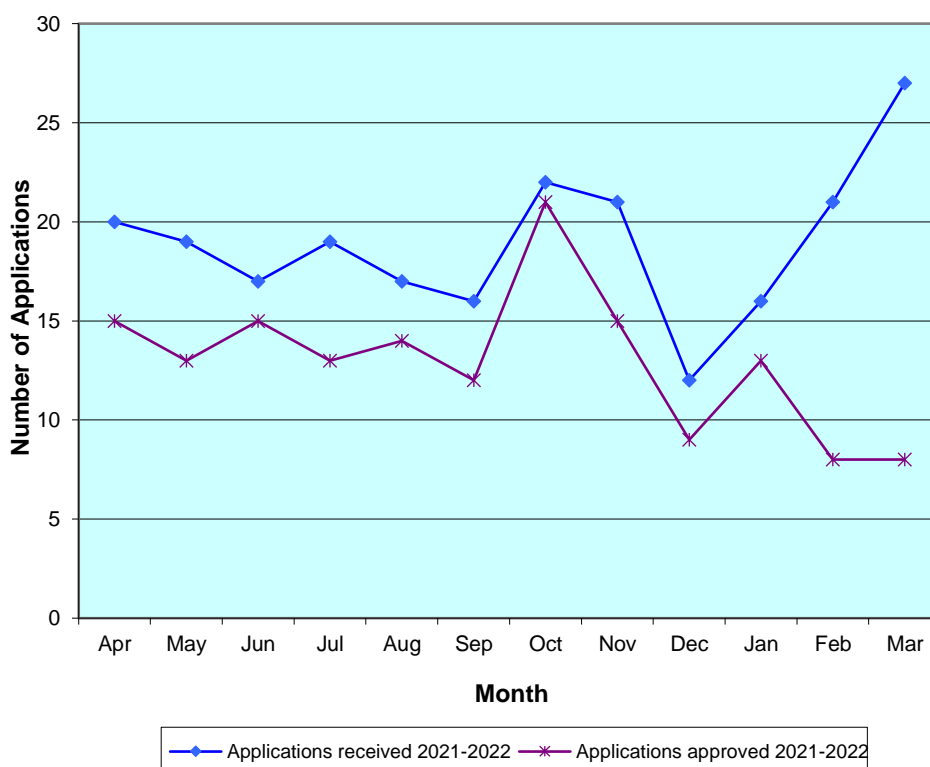
A summary of the status of applications received April 2021-March 2022 is provided in Table 1. Full detail of the status of all applications processed between April 2021 and March 2022 is given in Appendix 1.

<b>Waiting for first professional assessment</b>	<b>0</b>
<b>Approved</b>	<b>166</b>
<b>Withdrawn by applicant</b>	<b>13</b>
<b>Ready to be submitted to Part IX meeting</b>	<b>2</b>
<b>Awaiting additional information from applicant</b>	<b>39</b>
<b>Awaiting assessment of additional information received</b>	<b>6</b>
<b>Rejected</b>	<b>1</b>
<b>Total</b>	<b>227</b>

**Table 1.** Status of applications received April 2021-March 2022 on 31<sup>st</sup> March 2022

On 31<sup>st</sup> March 2022, 166 applications had been approved, with an average time to listing of 46 days (between sending the proposed Drug Tariff PDF entry and acceptance letter to confirm the listing with the applicant, and the product being

listed in the Drug Tariff), and twenty-two applicants were still to confirm that they were ready to go progress. Figure 3 shows the number of applications received each month during the past year. Received applications refers to complete (2<sup>nd</sup> stage applications) that have been submitted to NHS Prescription Services. The gap between the lines represents those that have been withdrawn or that are pending or on-hold.



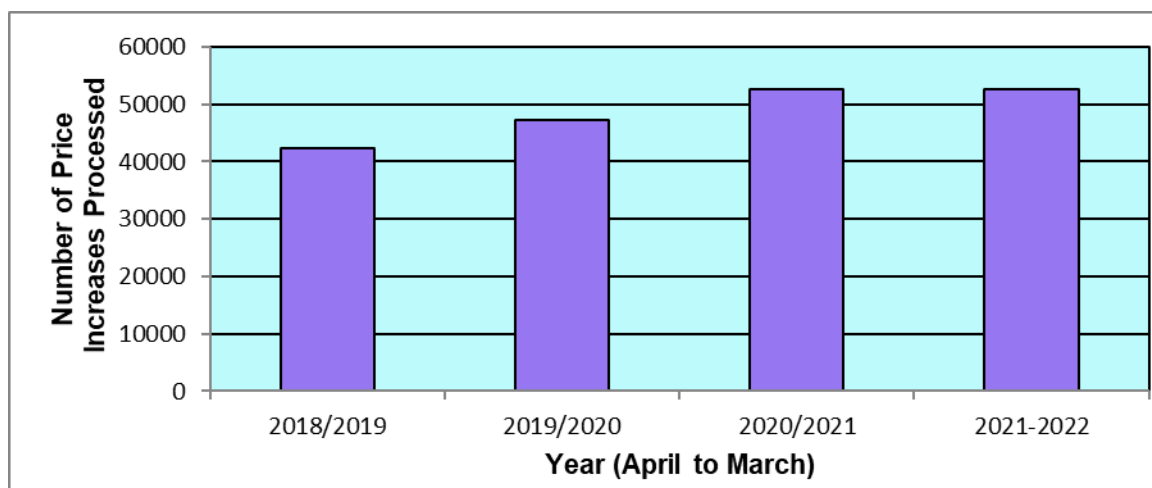
**Figure 3.** Number of Part IX applications received during 2021-2022 vs. those that have subsequently been approved.

#### 4. Part IX Prices

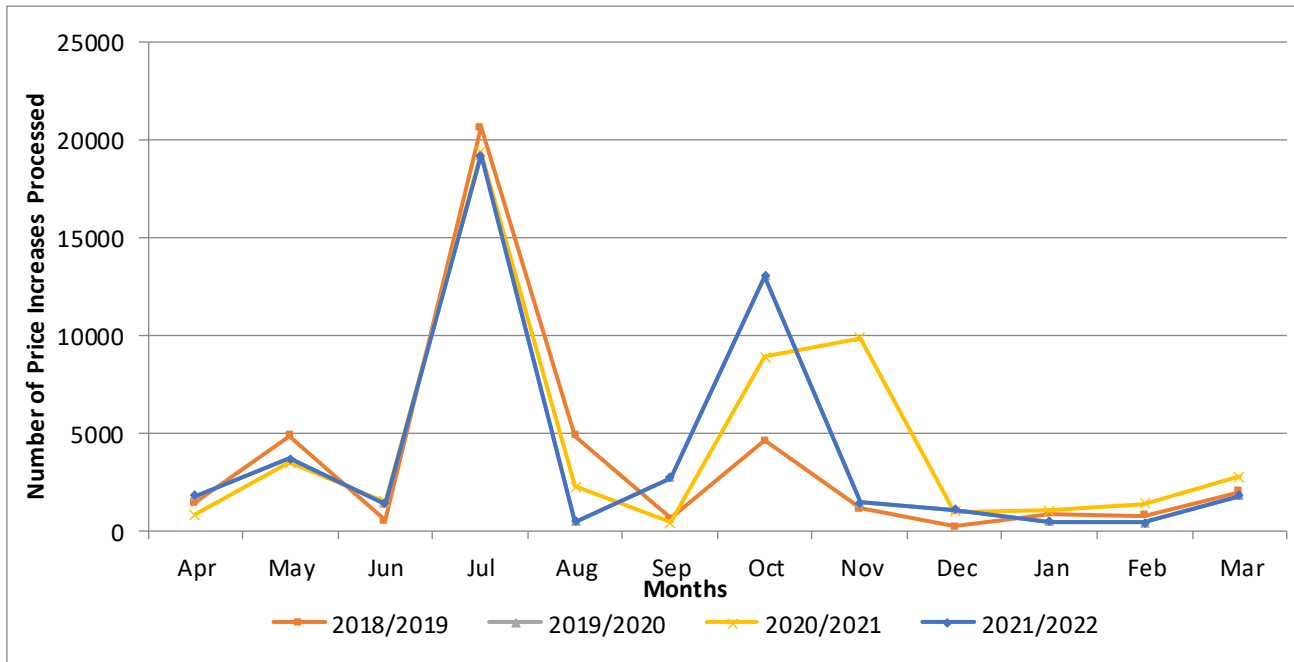
The mechanism to allow annual price rises to products listed in Part IX is set out in Annex D to the [An Introduction to Part IX](#) and has been agreed between the DHSC and the Drug Tariff Part IX Forum. Manufacturers are required to give two months’ notice before the publication deadline of the Drug Tariff in which the price rise will take effect, and a formula using the Gross Domestic Product deflator (GDP) forecast is applied to all requests.

Due to the volatility of the forecast GDP deflator - where some negative figures were forecast - during the period 6<sup>th</sup> May 2021 to 5<sup>th</sup> May 2022, agreement was reached between the DHSC and the Part IX Industry Forum that the forecast GDP deflator would be replaced by the figure of 2.0%. The maximum price rise which could be applied during the period was 1.25 (2.0 - 0.75)%. After this period, the maximum price which could be applied returned to the (forecast GDP – 0.75)%.

Figure 4 illustrates the number of price increase requests that have been processed for Part IX products over the previous four years, and Figure 5 shows how this varies month-on-month, with peaks in July and October. In total 91 manufacturers submitted 187 price change requests resulting in a total of 47,256 price changes in the period April 2021 to March 2022. This is a 10% decrease on the previous year. The figure for July was the highest at 19,177 price increases, then October at 12,983 and May the third highest at 3,645. The price rises for July accounted for 41% of those price increases implemented in the whole period of 2021-2022; and were predominantly for ranges of lymphoedema garments.



**Figure 4.** Number of price increases processed for Part IX appliances and chemical reagents for the previous four financial years.



**Figure 5.** Number of Part IX price increases processed for each Drug Tariff edition over the previous four financial years.

## 5. Exceptional Price Increases

Requests for a price increase greater than that permitted by the pricing mechanism can only be approved if special circumstances prevail and is called an 'Exceptional Price Increase' request.

NHS Prescription Services will consider applications for additional price rises for products where cost pressures are being incurred in exceptional circumstances. The only two factors on which NHS Prescription Services can award an exceptional price increase are raw material shortages where suitable alternatives are not available or the imposition of statutory duties with a recognised cost impact. NHS Prescription Services will consider whether to refer any requests to DHSC because of other circumstances on a case-by-case basis.

The financial year 2021-2022 has been particularly challenging for manufacturers due to several compounding global factors including the increase costs of raw materials especially oil-based products (such as plastics and paraffin-based substances), transport and manufacturing costs. As a result, NHS Prescription Services has experienced an unprecedented number of exceptional price increase requests and each of these has been considered on its own merit because of the unique set of circumstances each one has presented. There were 12 submissions



for exceptional price increases for the period April 2021 to March 2022 which impacted 246-individual lines. Three of these were awarded and they applied to 215 individual products.

There is also evidence emerging that some applicants do not fully understand the obligations they have in terms of managing a listing and its price in the Drug Tariff. NHS Prescriptions Services are increasingly being 'instructed' to increase the price in the Tariff which is contrary to our directed process. The time spent dealing with the issues this creates continues to have a significant impact on NHS Prescription Services' workload.

## **Appendix 1: Drug Tariff Part IX Statistics – April 2021– March 2022**

Below is a breakdown of the status of applications processed from April 2021 - March 2022.

### **1<sup>st</sup> Stage (initial) Applications received April 2021 – March 2022**

<b>1<sup>st</sup> stage (initial) applications received</b>	<b>467</b>
<b>Average days taken to log initial application and reply to applicant</b>	<b>2 days</b>
<b>Percentage of 1<sup>st</sup> stage applications that have been logged</b>	<b>100%</b>

### **2<sup>nd</sup> Stage Applications received April 2021 – March 2022**

<b>2<sup>nd</sup> stage applications received</b>	<b>227</b>
<b>Average days taken for acknowledgement letter to be sent</b>	<b>7 days</b>
<b>Percentage of 2<sup>nd</sup> stage applications that have been acknowledged</b>	<b>100%</b>

Of the applications received April 2021 – March 2022 how many have received their first assessment

<b>Number of applications</b>	<b>227</b>
<b>Percentage of applications received that have been assessed</b>	<b>100%</b>

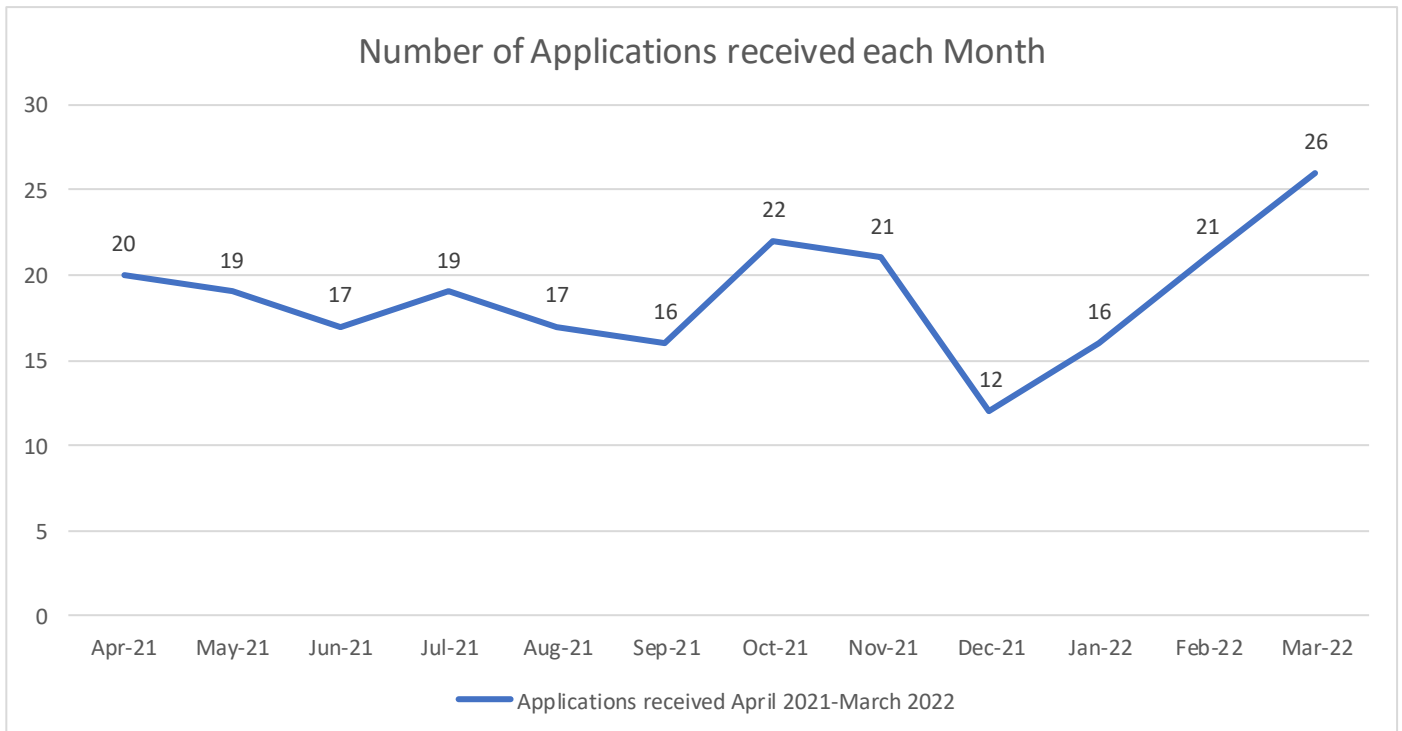
### **Status of Applications received April 2021 – March 2022**

<b>Waiting for first professional assessment</b>	<b>0</b>
<b>Approved</b>	<b>166</b>
<b>Withdrawn by applicant</b>	<b>13</b>
<b>Ready to be submitted to Part IX meeting</b>	<b>2</b>
<b>Awaiting additional information from applicant</b>	<b>39</b>

<b>Awaiting assessment of additional information received</b>	<b>6</b>
<b>Rejected</b>	<b>1</b>
<b>Total</b>	<b>227</b>

**Status of Approved Applications received April 2021 – March 2022**

<b>Total number of applications approved</b>	<b>166</b>
<b>Average days from NHS Prescription Services sending the proposed Drug Tariff PDF entry to the applicant for approval to final publication</b>	<b>46 days</b>
<b>Listing date confirmed by applicant</b>	<b>144</b>
<b>Awaiting confirmation from applicant of entry date</b>	<b>22</b>



The table above shows the number of applications received during the past year. Received applications refers to 2<sup>nd</sup> stage applications that have been submitted to NHS Prescription Services with all the mandatory information requested on the application forms and have subsequently received their acknowledgement letter.