Business Services Authority

NHS Business Services Authority

Drug Tariff Part IX Annual Review

2020-2021

1. Summary

Between 1st April 2020 and 27thJuly 2020 the Part IX process was suspended temporarily by the Department of Health and Social Care, and NHS Prescription services (part of the NHS Business Services Authority). This was considered necessary to allow staff to respond to urgent Covid-19 related work and establish an effective home-working environment. On 27th July 2020 the application and assessment process restarted as a digital submission process only.

During the period 27th July 2020 to 31st March 2021, 233 new Part IX applications for products to be considered for inclusion in Part IX of the NHS England and Wales Drug Tariff were received. This represented an increase of 18% compared with 2019-2020. The percentage of applications for unique products was 8% of all applications received; for 'me-too' type products was 86%; and the percentage of line extensions was 6% of all applications. A significant proportion of the 'me-too'/ 'line extensions' involved requests for listings with higher prices compared with similar products already in the Drug Tariff. Applications of this type require applicants to provide more information to meet the cost-effectiveness criterion.

The majority of applications received are subsequently approved. The main reasons for a delay in the process are:

- CE documents are either missing or incorrect
- Digital photographs (or samples) not showing the information requested
- Insufficient information for cost-effectiveness assessment

The most common reason for applications remaining in the pending state for an extended time is due to applicants requiring extra time to compile additional information to support the cost effectiveness of their product.

During 2020-21, there was an 11% increase in the number of price increases requested through the price increase mechanism compared with 2019-20. The price increases implemented for July accounted for 37% of the total in the period 2020-21. Four requests for exceptional price increases were received, but none were awarded.

2. Introduction

The legislative basis for Part IX of 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, to determine the prices on the basis of which the payment for such appliances and chemical reagents is to be calculated and to remove products from Part IX when NHS Prescription Services is notified that they are no longer available.

Between 1st April 2020 to 27th July 2020 the Part IX application process was temporarily suspended by the DHSC, and NHS Prescription Services due to the challenges presented by the COVID-19 pandemic on the workforce. During the suspension a digital submission process was agreed, and the application process restarted on July 27th 2020.

This paper reviews the activity of NHS Prescription Services between 27th July 2020 and 31st March 2021 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 the Drug Tariff Guidance Notes 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.

Between 27th July 2020 and March 2021, a total of 233 new applications were received. This represents a 18% increase in the number of applications made compared with 2019-20 when 197 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 was 264.

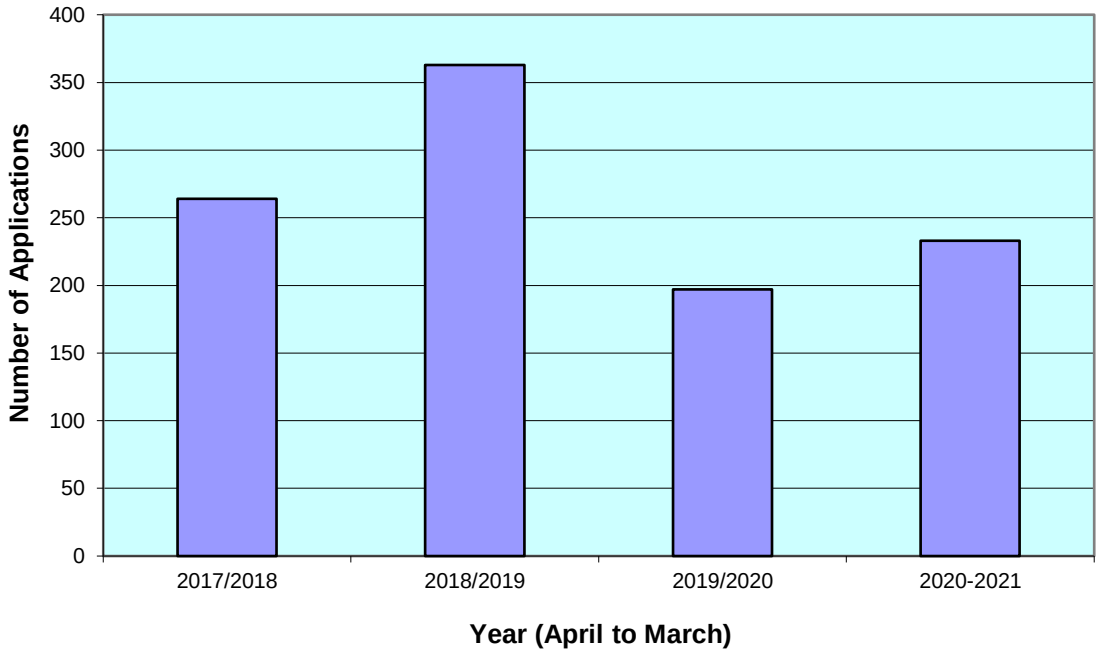

Figure 1. Number of Part IX applications received over the previous four financial years.

Figure 2 shows the numbers of applications received month-by-month and makes comparison with the data from previous financial years. The Part IX process was suspended between 1st April and 27th July 2020 and so the average number of 29 applications per month is calculated over an 8-month period. During 2019-2020, an average of 16 applications were received per month.

Despite the process being suspended for four months and clearly communicated, 65 applications were received during the suspension. These were put on hold and only confirmed as still valid to process once the recommencement was announced. This accounted for the large peak in applications during the period of September and December 2020 as they filtered back into NHS Prescription Services.

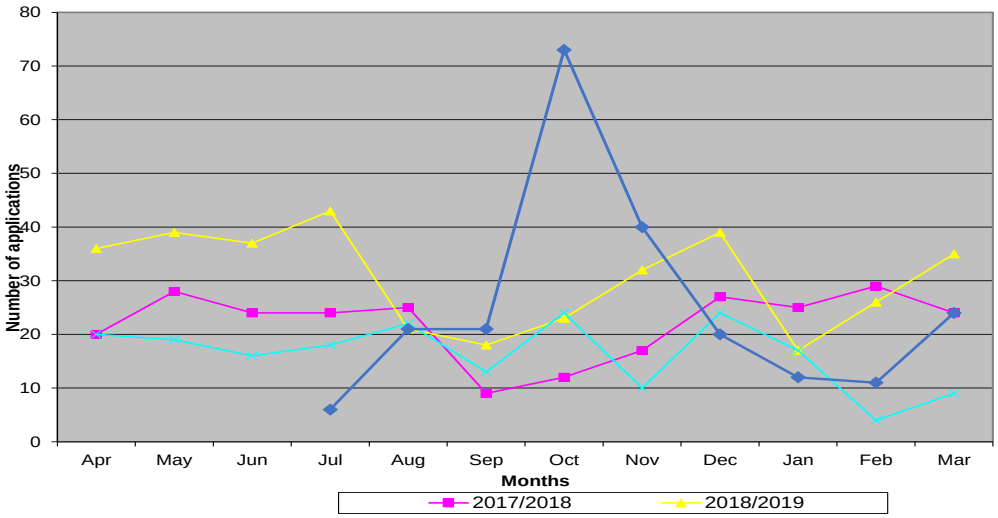

Figure 2. Number of Part IX applications received each month over the previous four financial years.

Table 1 shows a breakdown of the types of applications received during 2020-2021 compared to the previous year. The percentage of the total applications for 'new' products decreased to from 11% last year to 8%. The percentage of 'me-too' products increased from 75% to 86%, and the percentage of 'line extension' products decreased from 14% to 6%. The evaluation of 'new' products is often more complex and time consuming than applications for line extensions or products where similar products are already listed ('me-too' products). These can require prolonged correspondence with the applicant as the necessary information is collated. Increased workload is also associated with a 'me-too' product where the applicant requests a higher price for similar items currently listed in Part IX. The request for an increased price needs to be justified by the applicant often

resulting in a more complex and time-consuming application process with more correspondence and negotiation. These factors need to be considered alongside the total number of applications received to fully consider the workload associated with the application process.

Application type	Applications 2017-2018	Applications 2018-2019	Applications 2019-2020	Applications 2020-2021
'New' products	15(6%)	30(8%)	22(11%)	18(8%)
Line extensions	71(27%)	64(18%)	28(14%)	14(6%)
'Me-too' products	178(67%)	269(74%)	147(75%)	201(86%)

Table 1. Summary of the types of applications received during 2020-2021 compared with the previous three years. ("New" products are those where no similar products have been listed in the Drug Tariff before; Line extensions are extensions to existing ranges in the Drug Tariff; "Me-too" products are products where similar products are already listed in the Drug Tariff)

A summary of the status of all applications received and processed in 2020-2021 is provided in Table 2.

APPLICATIONS RECEIVED 2020-2021	**233***
Approved	122**
Rejected	3**
Withdrawn by company	13**
Pending / On Hold	119***

Table 2. Summary of applications received approved, pending and rejected in 2020-21

(* the applications received refer to those logged between 27th July 2020 and 31st March 2021; ** the figures for approved, rejected and withdrawn refer to all applications processed between 27th July 2020 and 31st March 2021 which includes some carried over from the previous financial year. Therefore, the sum of the approved, rejected, withdrawn and pending does not equal the total applications received in 2020-2021; *** the number of pending/on-hold applications is correct as of the 31st of March 2021)

The number of applications withdrawn by the applicant during 2020-2021 increased compared with last year. NHS Prescription Services continues to review applications where the applicant has not responded to requests for 3 to 6 months to ensure all applications are current. Three applications were rejected during 2020-2021 because one or more of the three criteria for listing were not met. There were no appeals made against decisions.

There were 119 applications pending or on hold as of 31st March 2021. On average 53% of ‘me-too’/line extensions could be processed first time, without requesting further information from the applicant. This has decreased from 66% last year. Of the applications that could not be assessed first time insufficient information to support cost effectiveness was the main reason for contacting the applicant and accounted for 42% of requests. Incorrect or incomplete digital photographs accounted for 35% of referrals back to the applicant and incorrect certificates accounted for 23%.

Of the total number of referrals back to the applicants:

- 36% related to the ‘declaration of conformity’ certificate not being provided
- 21% were due to applicants not providing confirmation as to which member state of Europe the product is registered in
- 43% were due to no or incorrect notified body certificates
- 53% of ‘me-too’/ line extensions required additional information to support a premium price. This is also the main reason that applications remain pending for a long period of time
- 35% related to problems with the digital photographs of the products. Most commonly applicants do not provide clear photographs of the CE mark and notified body number, or a photograph of the sample removed from the packaging. Other reasons include incorrect packaging/ label of each of the variants applied for (e.g., each different size of dressing)

NHS Prescription Services approved 122 applications for products to be listed in Drug Tariff Part IX during 2020-2021. Figure 3 shows the number of applications received in each month and those which were subsequently approved. The gap between the lines represents those that have been withdrawn or that are pending or on-hold.

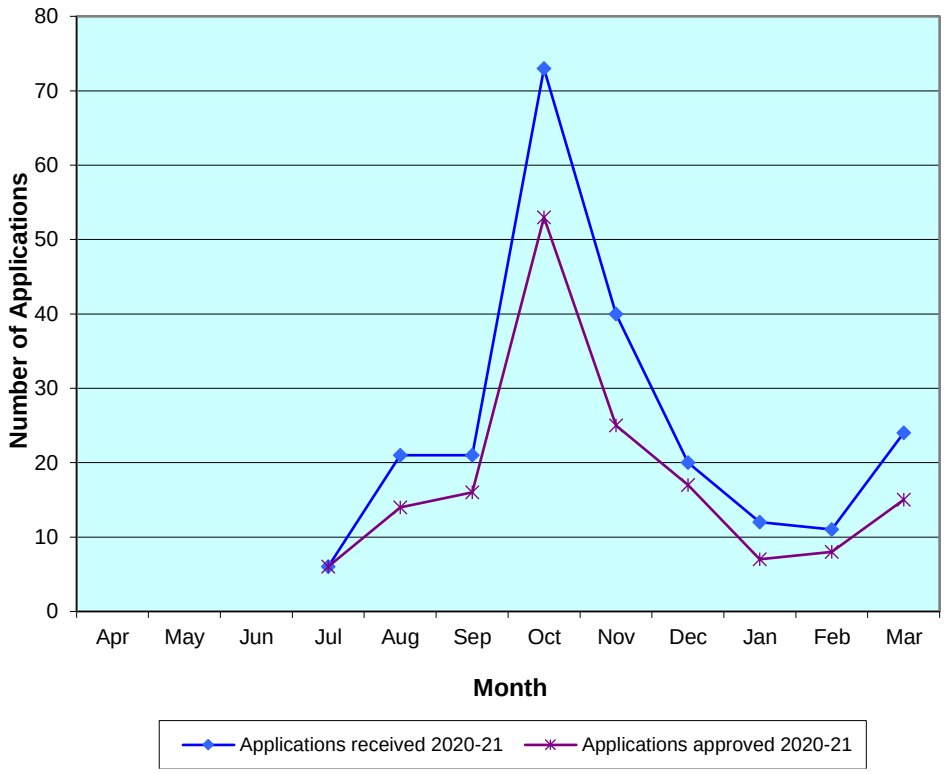

Figure 3. Number of Part IX applications received during 2020-2021 *vs.* those that have subsequently been approved.

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 Drug Tariff Part IX Guidance Notes and is an agreement 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 related to the Gross Domestic Product (GDP) forecast is applied to all requests. Requests for a price increase greater than that permitted by the pricing mechanism can only be approved if special circumstances prevail (and this follows a separate procedure for exceptional price increase requests). There were 4 enquiries regarding exceptional price increases for the period April 2020 to March 2021 but none of these were awarded as they did not meet the criteria.

Figure 4 illustrates the change in the number of price increase requests that have been processed for Part IX products. In total 79 manufacturers submitted 181 price change requests resulting in a total of 52,656 price changes in the period April 2020 to March 2021. This is an 11% increase on the previous year. Figure 5 shows the number of price increases processed for each edition of the Drug Tariff. The figure for July was the highest at 19,346 price increases, then November at 9,851 and October the third highest at 8,864. The price rises for July accounted for 37% of those price increases implemented in the whole period of 2020-21; and were predominantly for ranges of lymphoedema garments.

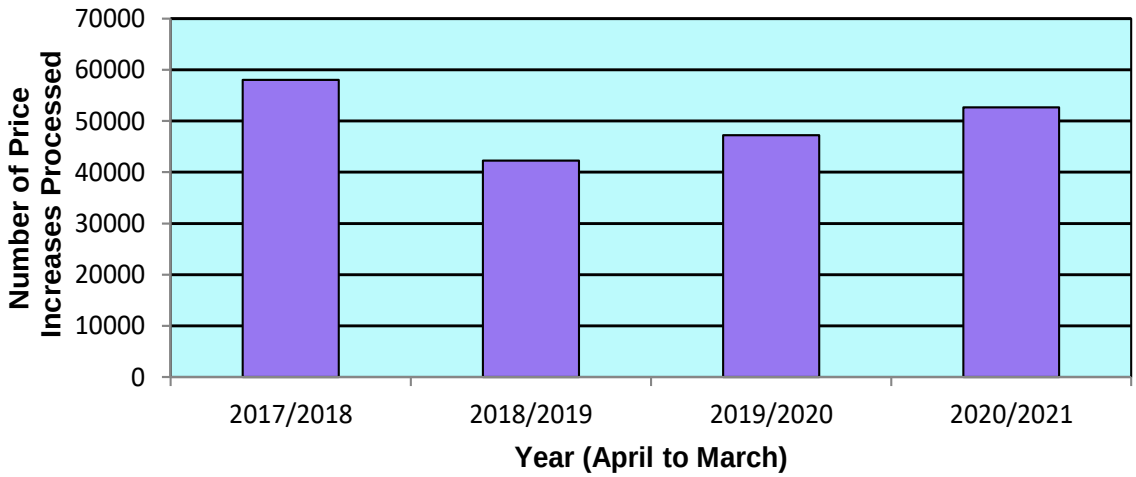

Figure 4. Number of price increases processed for Part IX appliances and chemical reagents for the previous four financial years.

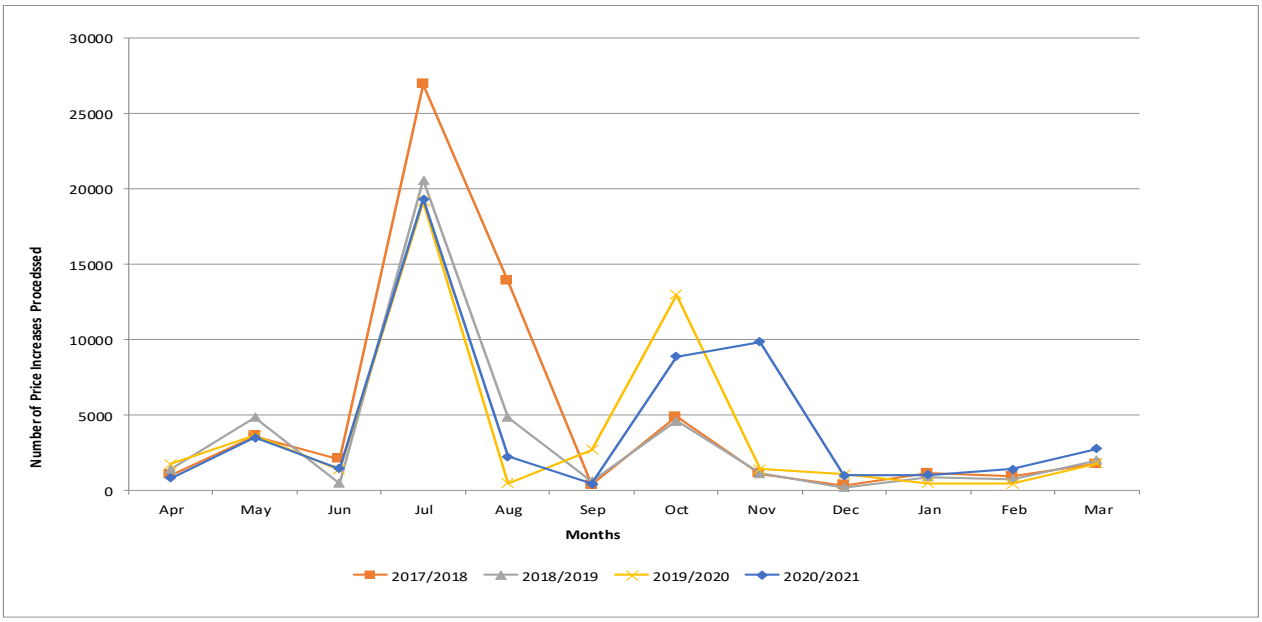

Figure 5. Number of Part IX price increases processed for each Drug Tariff edition over the previous four financial years.

5. Covid-19

Between 1st April 2020 and 27thJuly 2020 the Part IX process was temporarily suspended by the DHSC, and NHS Prescription services. This allowed staff to move to home working and work on urgent support for the Covid-19 pandemic. During this time the DHSC and NHS Prescription Services engaged with industry representatives and proposed an on-line digital submission process for applications. This adjustment allowed applications to be re-started in July 2020 and is still ongoing. With the backlogged cleared by January, this has proved to be an efficient way of working. There may be some additional changes once office-working resumes, but it is likely to continue going forward, as a hybrid office-home working culture is very likely to prevail. Processes are continually reviewed, and suggestions for improvement from all stakeholders are considered.