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NHS Business Services Authority
Drug Tariff Part IX Annual Review
2022-2023

1. Summary

During the period 1st April 2022 and 31st March 2023, 235 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in the NHS England Wales Drug Tariff (the 'Drug Tariff') of which 158 were eventually approved for listing; 19 were withdrawn by the applicant; one was rejected; 38 were referred to the applicants for further information; one is currently on hold at the applicant's request; and 18 are currently being processed internally. There was an average time to listing of 43 days, representing the time period between NHS Prescription Services sending the proposed Drug Tariff PDF entry to the applicant for approval and final publication in the Drug Tariff.

The number of annual price increase requests reduced slightly from 55,153 in 2021-2022 to 55,132 in 2022-2023.

The number of exceptional price increase requests rose from 12 in 2021-2022 to 36 in 2022-2023 which accounted for 22,303 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), energy, transport, and manufacturing costs. As requests for energy, 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 continues to 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, the NHS Business Services Authority (NHSBSA) 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. 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.

In December 2022, responsibility for Part IX work was passed from the Prescribing Policy and Charges Team (Medicines Directorate, DHSC) to the newly formed MedTech Directorate in DHSC.

This paper reviews the activity of NHS Prescription Services between 1st April 2022 and 31st March 2023 with regards to the administration of the application process for listing in Part IX, the Part IX price increase mechanism, applications for exceptional price increases 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 and these are:

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

During 1st April 2022 – 31st March 2023, the total number of applications handled by the Part IX support team was 476 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. The average time for NHS Prescription Services to receive the information requested from applicants was 27 days.

Between 1st April 2022 and 31st March 2023, a total of 235 new applications were passed through for professional assessment. This represents a 5% increase in the number of applications made compared with 2021-22 when 227 were received. Figure 1. illustrates the total number of applications which completed full assessment over the previous four financial years The average number of applications assessed over the four-year period is 224.

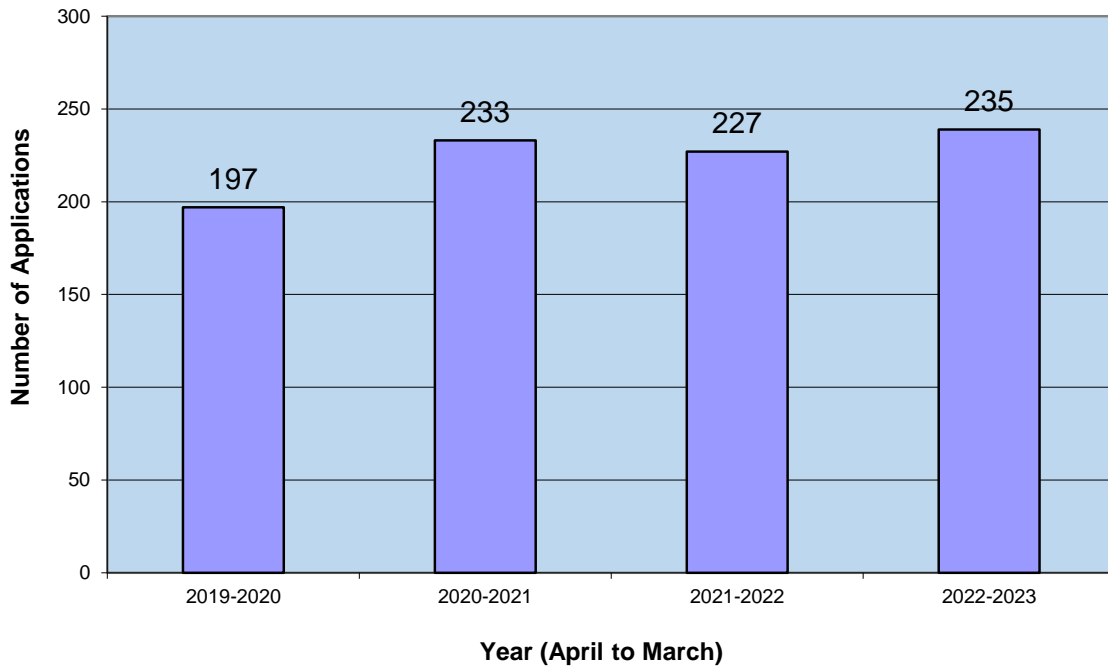


Figure 1. Number of Part IX applications assessed over the previous four financial years.

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

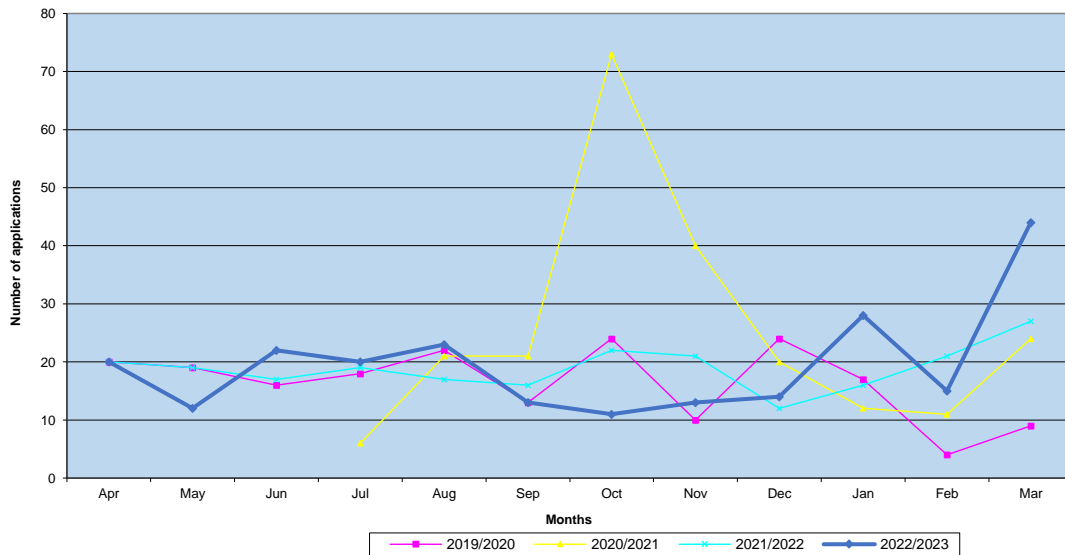


Figure 2. Number of Part IX applications assessed each month over the previous four financial years.

A summary of the status of all applications received and processed April 2022-March 2023 is provided in Table 1. Full detail of the status of all applications processed between April 2022 and March 2023 is given in Appendix 1.

Waiting for first professional assessment	0
Approved	158
Withdrawn by applicant	19
Ready to be submitted to Part IX meeting	8
Awaiting additional information from applicant	38
Awaiting assessment of additional information received	10
Rejected	1
On hold at applicant's request	1
Total	235

Table 1. Status on 31st March 2023 of applications assessed April 2022-March 2023

The number of applications withdrawn by the applicant during 2022-2023 increased compared with last year (13 withdrawn). One application was rejected during 2022-2023 because one or more of the three criteria for listing were not met. There were no appeals made against decisions.

On 31st March 2023, 158 applications had been approved, with an average time to listing of 43 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 14 applicants were still to confirm that they were ready to progress. Figure 3 shows the number of applications received each month during the past year. Received applications refers to complete (2nd 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.

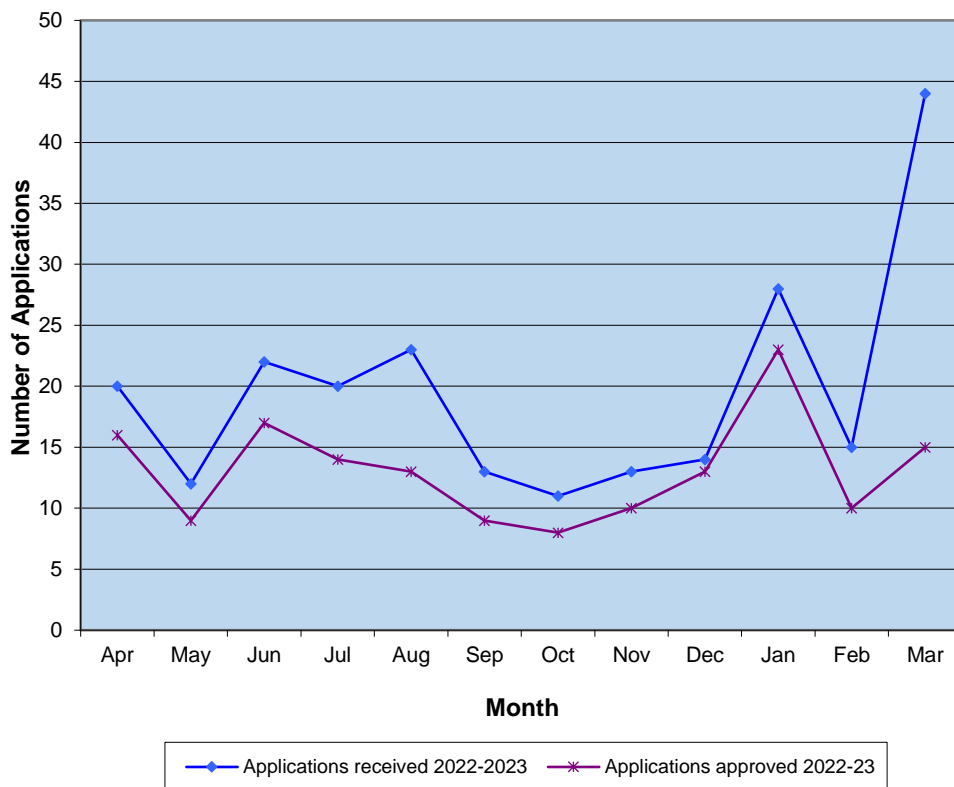


Figure 3. Number of Part IX applications received during 2022-2023 vs. those that have subsequently been approved.

4. Part IX Annual Price Increase Requests

The mechanism to allow annual price rises to products listed in Part IX is set out in Annex C to the document [An Introduction to Part IX](#) 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. During 2022-23 the forecast GDP deflator varied between 2.00 – 3.23.

Figure 4 illustrates the change in the number of price increase requests that have been processed for Part IX products over the last four years, and Figure 5 shows how this varies month-on-month, with peaks in July, October, and January. In total 107 manufacturers submitted 222 price change requests resulting in a total of 55,132 individual price changes in the period April 2022 to March 2023. This is similar to the previous year (55,153). The figure for August was the highest at 17,612 price increases, then January at 14,941 and December the third highest at 6,363. The price rises for August accounted for 32% of those price increases implemented in the

whole period of 2022-23; and were predominantly for ranges of lymphoedema garments.

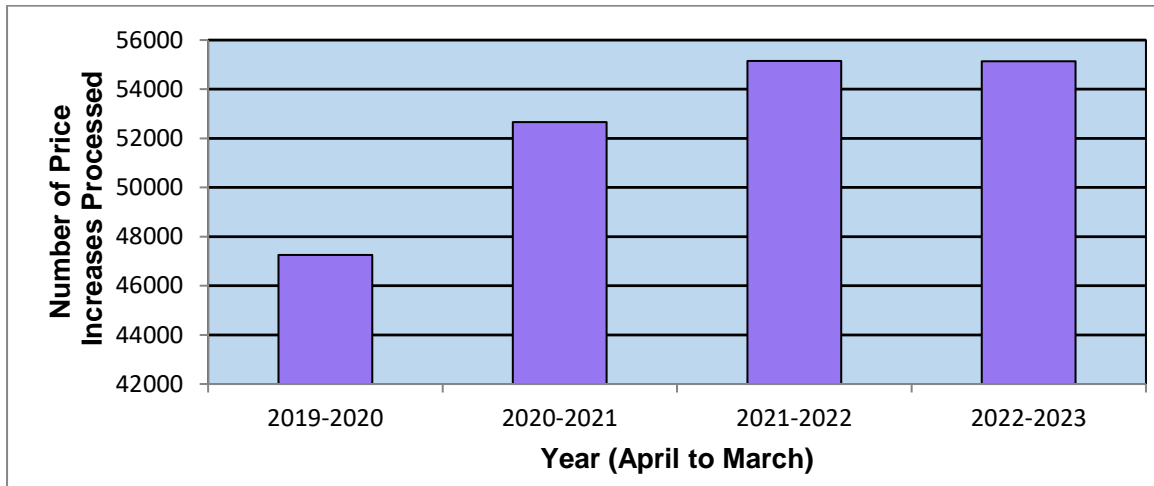


Figure 4. Number of price increases processed for Part IX appliances and chemical reagents for the previous four financial years.

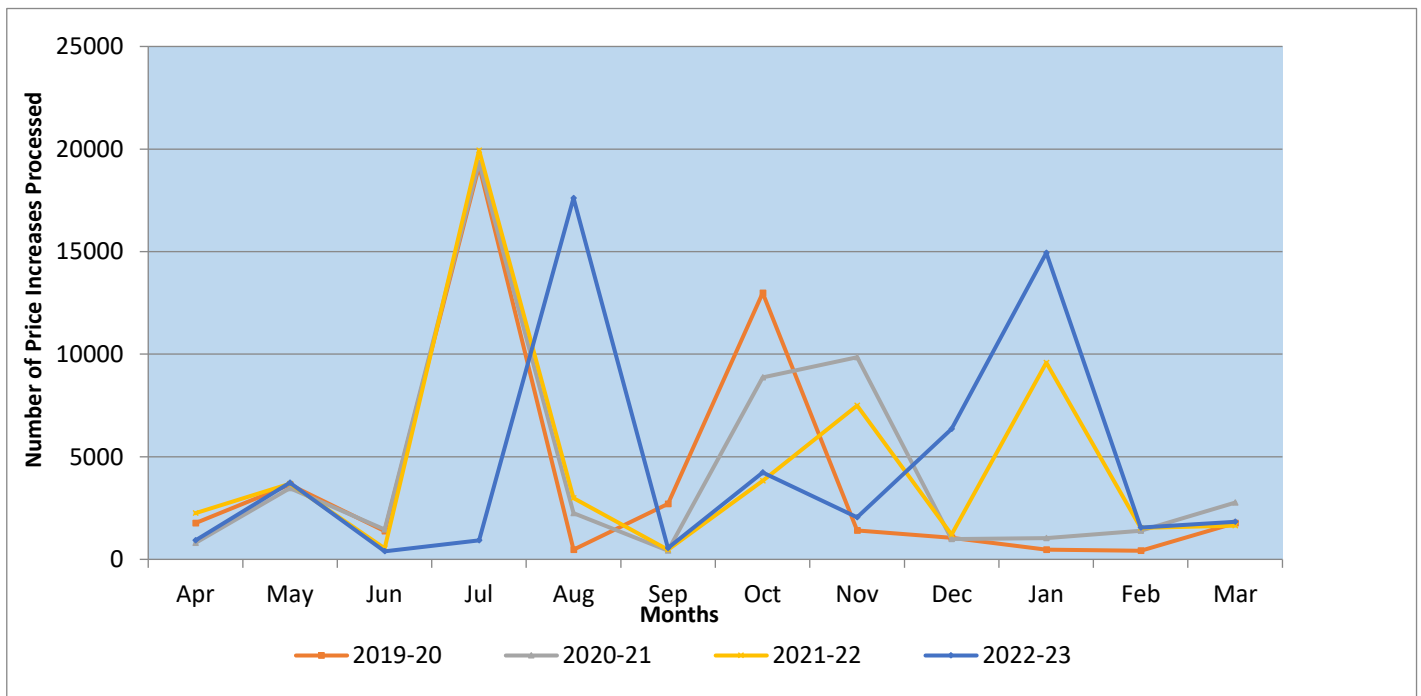


Figure 5. Number of Part IX price increases processed for each Drug Tariff edition over the previous four financial years.

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' (EPI) request.

NHS Prescription Services are directed by DHSC to consider applications for additional price rises for products where cost pressures are being incurred due to two factors only: raw material shortages where suitable alternatives are not available, or the imposition of statutory duties with a recognised cost impact. NHS Prescription Services will refer any requests due to other circumstances to DHSC who will consider each on a case-by-case basis.

Reasons commonly cited for submitting EPI requests include the increased costs of raw materials especially oil-based products (such as plastics and paraffin-based substances), energy, transport and manufacturing costs, and high rates of inflation. As a result, NHS Prescription Services has experienced an unprecedented number of exceptional price increase requests. There were 36 submissions for exceptional price increases for the period April 2022 to March 2023 which impacted 22,303 individual products. Eighteen submissions received an increase (either backdated pay award¹ or an EPI was granted) which applied to 214 individual products. Table 2 summarises the status of these applications on 31st March 2023.

Number of requests	36
Number accepted backdated prices in lieu of EPI award	11
Number awarded an EPI	7
Number refused an EPI	14
Number still waiting for resolution	3
Number closed by applicant	1

Table 2. Status of requests from manufacturers for exception price increases on 31st March 2023.

¹ In the event of any missed annual price increase requests, the applicant will be offered a price based on what this would be had they applied for the increase(s)

Appendix 1

Drug Tariff Part IX Statistics: April 2022–March 2023

Below is a breakdown of the status of applications processed from April 2022 - March 2023.

1st Stage (initial) Applications received April 2022 – March 2023

1 st stage (initial) applications received	476
Average days taken to log initial application and reply to applicant	2 days
Percentage of 1 st stage applications that have been logged	100%

2nd Stage Applications received April 2022 – March 2023

2 nd stage applications received	235
Average days taken for acknowledgement letter to be sent	7 days
Percentage of 2 nd stage applications that have been acknowledged	100%

Of the applications received April 2022 – March 2023 how many have received their first assessment.

Number of applications	235
Percentage of applications received that have been assessed	100%

Status of Applications received April 2022 – March 2023

Waiting for first professional assessment	0
Approved	158
Withdrawn by applicant	19
Ready to be submitted to Part IX meeting	8
Awaiting additional information from applicant	38
Awaiting assessment of additional information received	10
On hold at applicant's request	1
Rejected	1
Total	235

Status of Approved Applications received April 2022 – March 2023

Total number of applications approved	158
Average days between acceptance letter and entry date offered (time to listing)	43 days
Listing date confirmed by applicant	144
Awaiting confirmation from applicant of entry date	14