New restrictions introduced on sales of stimulant laxatives to counter risks from overuse

The Medicines and Healthcare products Regulatory Agency (MHRA) has taken action to reduce abuse and overuse of these products, and new packs will begin to appear in stores over the summer. Additional label warnings make clear that stimulant laxatives do not help with weight loss.

Anyone with regular bouts of constipation is advised against the long overuse of stimulant laxatives (including products containing bisacodyl, senna or sodium picosulfate) which can result in damage to the digestive system, including chronic constipation and damage to the nerves and muscles of the colon.

Instead, they should talk to a healthcare professional, who will provide advice, first on trying alternatives, such as diet and lifestyle changes, but also on switching to other products such as bulk laxatives, which work in the same way as fibre to increase the bulk of stools.

Parents and carers can talk to a pharmacist about treatment of short-term constipation in children over 12. However, they should seek advice from a prescriber such as their GP if the child is younger than 12 years or they are worried about their child's health.

Dr Sarah Branch, Director of MHRA's Vigilance and Risk Management of Medicines Division, said:

Stimulant laxatives can provide short-term relief to some people with occasional constipation, and most people use these medicines safely. However, there is evidence of misuse by people with eating disorders, and of long-term use by the elderly, as well as inappropriate use in children.

Patient safety is our highest priority. We believe these new measures are necessary to address the risks associated with misuse, while continuing to allow safe and appropriate access to these medicines without prescription to treat short-term constipation.

Sandra Gidley, President of Royal Pharmaceutical Society, said:

Misusing laxatives can have a serious impact on the health of patients and the new risk minimisation measures will improve patient safety. We're pleased to have worked with the MHRA on new

guidance for community pharmacists and their teams so they can give patients the best advice.

As experts in medicines, pharmacists are well placed to help ensure patients do not overuse stimulant laxatives. If a patient has a question about different laxative products or are unsure about what they are currently taking, the pharmacy team will be able to help and signpost on if necessary.

Rebecca Willgress, Beat Eating Disorders Charity Head of Communications, said:

We welcome the news that the sale of laxatives will be more tightly controlled, and will come with increased warnings against overuse.

Laxatives can prove attractive for people affected by eating disorders, but also have the potential to cause serious health problems. Our own 2014 survey on sufferers who abused laxatives found that nearly all had bought laxatives over the counter, and 66.7% said they had developed a dependency on them.

We hope that these new regulations will make it more difficult for people who are unwell to obtain laxatives, as well as help to educate the wider public on the dangers of abusing them.

The new guidelines have been introduced following a review into the safety of these medicines. The review, by the Commission on Human Medicines (CHM), was prompted by concerns regarding the overuse and misuse of stimulant laxatives by patients with eating disorders, overuse in the elderly and use in children without medical supervision.

Additional warnings regarding the risk of overuse and making clear that these products do not help in weight loss are being added to packs.

The new guidelines restrict the use of stimulant laxatives sold in retail outlets to patients over the age of 18. Pharmacists will be able to sell stimulant laxatives for use in children aged 12 and over.

Anyone experiencing a side effect through use of a stimulant laxative, or any other medical product, should report this to the MHRA through the <u>Yellow Card</u> scheme

Ends

Notes to Editor

- 1. Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. Underpinning all our work lies robust and fact-based judgements to ensure that the benefits justify any risks. The MHRA is a centre of the Medicines and Healthcare Products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health
- 2. Stimulant laxatives work by stimulating the muscles that line your gut, helping them to move stools along the back passage. 13.9 million packs were sold in the UK in 2016 and approximately 1 million of these were prescribed.
- 3. Stimulant laxative medicines available in the UK over-the-counter are bisacodyl (such as Dulcolax), senna and sennosides (such as Senokot), and sodium picosulfate (such as Dulcolax Pico).

GCSE and A level students to receive centre assessment grades

Students in England will receive centre assessment grades for this week's GCSE results and last week's A and AS level results, the Government and Ofqual have confirmed today (17 August).

Ofqual had consulted on and implemented a standardisation process for exam results this summer, but the system has resulted in too many inconsistent and unfair outcomes for A and AS level students. Over the last few days, it has become clear that the algorithm has revealed a number of anomalies that had not been anticipated by Ofqual and which severely undermined confidence in the system.

Subsequently, the Government and Ofqual have jointly agreed to revert to centre assessment grades, which are the grades which schools and colleges assessed students were most likely to have achieved, had exams gone ahead. This was deemed to be the fairest approach to avoid some students receiving grades that did not reflect their prior performance.

Students awaiting their GCSE grades on Thursday will receive their centre assessment grade from their school or college, and students who received their A or AS level results last Thursday (13 August) will be reissued their centre assessment grade. If students' calculated grades were higher than the

centre assessment grade, their calculated grade will stand.

To ensure students can progress to higher education, the Government intends to remove temporary student number controls which had been introduced for the coming academic year

Education Secretary Gavin Williamson said:

This has been an extraordinarily difficult year for young people who were unable to take their exams.

We worked with Ofqual to construct the fairest possible model, but it is clear that the process of allocating grades has resulted in more inconsistency and unfairness than can be reasonably resolved through an appeals process.

We now believe it is better to offer young people and parents certainty by moving to teacher assessed grades for both A and AS level and GCSE results.

I am sorry for the distress this has caused young people and their parents but hope this announcement will now provide the certainty and reassurance they deserve.

Schools and colleges will receive students' final GCSE grades on Wednesday, meaning they will be available to young people on Thursday as planned.

Earlier this year the Government announced that assessments and exams would not take place in schools and colleges this summer, following the closure of schools and colleges as a response to the public health crisis.

On 3 April, Ofqual announced a system based on teachers submitting grades and rankings for students and then launched a consultation on the approach. This consultation included the statistical standardisation of centre assessment grades in order to ensure that overall grades were broadly in line with previous years.

The Government recognises the move to centre assessment grades will have implications for universities and students, and therefore intends to remove student number controls. The move will help to prioritise students' interests and ensure that there are no barriers to students being able to progress.

The Government is working closely with the sector to create additional capacity and ensure they are as flexible as possible, and are setting a clear expectation that they honour all offers made and met. The Universities Minister Michelle Donelan will lead a new taskforce, working with sector groups, to ensure students can progress to the next stage of their education.

Students who previously missed their offer and will now meet it on the basis of their centre assessment grade should get in contact with the university. Those who have accepted an offer will be able to release themselves if they

<u>Grading of vocational and technical</u> <u>qualifications</u>

News story

Limited statistical standardisation used in grading these qualifications.



The statistical standardisation approach that was used for A levels was not generally used for vocational and technical qualifications (VTQs), many of which took into account work that learners had already completed in the course of their study. A separate regulatory framework, designed to provide the flexibility needed to cater for the diversity of the landscape of vocational and technical qualifications, covered other qualifications including BTEC, International Baccalaureate and many thousands of others.

Under the framework for VTQs, each awarding organisation has been responsible for developing its own model for issuing results in line with a set of principles. The framework allows awarding organisations, where necessary, to prioritise the issue of sufficiently valid and reliable results over the maintenance of standards. Ofqual developed and implemented this framework in close collaboration with awarding organisations and the wider sector. Although calculated results have been issued for many VTQs, in only a very few cases has the same kind of statistical standardisation process of Centre Assessment Grades (CAGs) been used — in other words, we think there are few qualifications where the cohort has received entirely algorithmically determined grades. Instead, awarding organisations have devised approaches which maximised the use of the most trusted evidence and applied a robust form of quality assurance (often involving collection of additional evidence to support teacher judgements).

In many cases where CAGs formed part of the awarding approach, they were issued at unit level (and not at qualification level) and this was generally

not the only piece of evidence used — many VTQs are modular in nature and so students will have "banked" results from units they had already taken. The use of banked results helps deliver results that best reflect each learner's level of knowledge, skills and understanding. So CAGs have not, in most cases, weighed so heavily in VTQ qualification-level results. Feedback from the sector so far is that VTQ results have been largely stable and consistent with centres' expectations. A move away from a statistical standardisation approach towards using CAGs alone would have limited impact as it would not change the results for the vast majority of VTQ learners.

For the small number of qualifications that have used a statistical standardisation approach similar to the Ofqual model for A levels and GCSEs, we have asked awarding organisations to review their approach. This is likely to mean a small proportion of VTQ results will be reissued.

Published 17 August 2020

Statement from Roger Taylor, Chair, Ofqual

News story

A statement from the Chair of Ofqual on how GCSE, AS and A level grades will be awarded this summer.



We understand this has been a distressing time for students, who were awarded exam results last week for exams they never took. The pandemic has created circumstances no one could have ever imagined or wished for. We want to now take steps to remove as much stress and uncertainty for young people as possible — and to free up heads and teachers to work towards the important task of getting all schools open in two weeks.

After reflection, we have decided that the best way to do this is to award

grades on the basis of what teachers submitted. The switch to centre assessment grades will apply to both AS and A levels and to the GCSE results which students will receive later this week.

There was no easy solution to the problem of awarding exam results when no exams have taken place. Ofqual was asked by the Secretary of State to develop a system for awarding calculated grades, which maintained standards and ensured that grades were awarded broadly in line with previous years. Our goal has always been to protect the trust that the public rightly has in educational qualifications.

But we recognise that while the approach we adopted attempted to achieve these goals we also appreciate that it has also caused real anguish and damaged public confidence. Expecting schools to submit appeals where grades were incorrect placed a burden on teachers when they need to be preparing for the new term and has created uncertainty and anxiety for students. For all of that, we are extremely sorry.

We have therefore decided that students be awarded their centre assessment for this summer — that is, the grade their school or college estimated was the grade they would most likely have achieved in their exam — or the moderated grade, whichever is higher.

The path forward we now plan to implement will provide urgent clarity. We are already working with the Department for Education, universities and everyone else affected by this issue.

Published 17 August 2020

Improving Student Loans Company service for customers in repayment

Improving Student Loans Company service for customers in repayment.

Over the last 18 months, we have made significant improvements to the student loan repayment process. More frequent data sharing (MFDS), a joint programme of work with HMRC and our Government shareholders, has helped us to reduce the amount customers are over-repaying on their student loan and provides upto-date balances for those who repay through PAYE.

MFDS and refunding customers

Previously, repayment information was only shared between HMRC and SLC following the end of the tax year. This meant that our customers were not

able to see up-to-date balance information and it caused some customers to over-repay their loans. From April 2019, SLC and HMRC began sharing repayment information on a weekly basis.

Over-repayments occur when a customer does not switch to direct debit in the final stages of their repayment term and are entirely avoidable. We have been working hard to ensure that every customer knows when to switch to direct debit, and for those who don't, we have been speeding up and improving our refund process. As a result, during 2019-2020, we refunded £60 million to customers who had made recent and historic over-repayments on their student loans. We are only able to do this when we have up-to-date customer information.

A further positive outcome of MFDS is that we are reducing the gap between over-repayments and refunds significantly. In the last financial year, we received just over £19 million in over-repayments and have been able to refund almost £16 million back to those customers within the same period.

In March 2020, we went one step further and established automatic refunds to customers who we hold up-to-date information for, making it easier to return funds to customers who have failed to join the direct debit scheme and have not yet claimed a refund. Since its introduction, we have automatically refunded over £4 million.

We also appreciate there will be other circumstances where customers may be entitled to a refund. Our most recent improvements have focused on helping people who have over-repaid at the end of their loan; however, we are committed to improving the experience of all our customers.

We want to go further to help customers who begin repaying through their salary before they need to. Customers are eligible for a refund when their employer mistakenly commences deductions before the Statutory Repayment Due Date is reached. Our new <u>online repayment service</u> makes it much easier for customers to identify this and we are looking at ways to enhance our guidance and communications to make it even easier for eligible customers to request a refund.

Viewing up to date balances online

A key benefit of MFDS is that it has enabled SLC to significantly upgrade our digital service with the introduction of a new online repayment service (ORS).

Last month (July 2020), we launched <u>ORS</u> to make it easier for our customers to view their balance.

ORS is based on extensive feedback from customers who want to be able to access their balance in this way. We receive around 200,000 calls annually from customers asking for up-to-date balance information and, prior to the introduction of ORS, customers received an annual statement by post containing information which, depending on their circumstances, may not be up to date.

With the introduction of ORS, customers can quickly check their online account for an up-to-date balance and will have much greater visibility of the final stages of repayment and when to join the direct debit scheme. ORS also removes the need for paper statements. Customers can still request a paper statement but we expect this to be a small minority thanks to the online service.

The launch of ORS has also given us the opportunity to redesign our guidance for customers and to better explain how student loans are different to other types of borrowing, including a recent article on <u>8 things you should know about your student loan</u>, available on our new GOV.UK website.

Ensuring customers avoid over-repayment

By switching to direct debit in the final stages of their repayment term, customers can avoid over-repayment altogether. We've made it even easier for customers to get in touch, particularly those that have moved overseas, with a dedicated social media team to answer any queries on repayments.

We are now in the process of contacting all customers to invite them to access their account via ORS so that when they log-on they can see their current balance. We also explain what makes student loans different to other types of borrowing in clear information and guidance. If customers are in credit they can contact us to receive a refund.

Customers can check their balance by logging into their account via www.gov.uk/sign-in-to-manage-your-student-loan-balance.

For more information, visit www.gov.uk/repaying-your-student-loan.