Conditions for which over the counter items should not routinely be prescribed – Guidance for NHS Wales
Consultation Responses

Respondent	Sub-section (if specified)	Comment
Anonymous 1		The bulk of the recommendations that you make are in line with guidance, but if the guidance is to be followed to the letter, it would preferable that many of the items were removed from being permitted to be prescribed at all. The guidance assumes that a patient would not being seeing a GP with any of the listed conditions, but this clearly will never be the case as a GP will continue to see undifferentiated presentations. E.g. a patient attends with hand dermatitis and requires treatment with emollient and a moderate to potent topical steroid. Firstly there is a differential diagnosis that is not always obvious, secondly, whilst the minor ailments scheme might be available I have seen cases of clear mis diagnosis of dermatological conditions and thirdly I feel it perfectly reasonable to prescribe if treatment is indicated. 2. I note the advice about dry eyes- there are no exceptions-how about a patient with Sjogren's. 3. Conjunctivitis- no exceptions given at all? I could list many other examples. I agree fully with the rationale behind the guidance, but it is much easier to issue than be the clinician implementing it, unless you remove some of the medications from prescription altogether.
Anonymous 2		The respondent considers that decisions as to whether patients presenting with these conditions require a prescription need to be co-produced by clinicians and their patients on an individual basis, taking into account the clinician's judgement regarding concurrent clinical factors as well as other issues such as health literacy, vulnerability and the ability of the patient to afford to purchase a Pharmacy Only and General sales List (P/GSL) products.
		We would urge AWPAG and the Pharmacy Directors Peer Group to include recommendations on **how** to communicate information about these prescribing restrictions to members of the public in the guidance.
Anonymous 3		I welcome limits placed on the prescribing of ineffective treatments. My comments relate to the equity and cost implications. The consultation document: "Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for NHS Wales" is largely based on the NHS England document; but in contrast to NHS England, the NHS in Wales has implemented a policy of universal free prescriptions, and consequently there may be an equity implication which conflicts with this policy. The consultation document proposes that patients access medicines for common, self-limiting ailments by means other than via their general practitioners. This will principally mean a purchase of a GSL or P medicine from a pharmacy or another outlet. There are equity considerations that appear not to have been considered. Patients who are least likely to pay /afford self-

		treatment are those who are most economically disadvantaged, who are elderly or vulnerable. These are (and always have been) protected from prescription charges (which were abolished in 2007 "to ensure people are not put off getting medication they need due to cost").
Anonymous 4		I can see that this consultation closely mirrors the consultation in England earlier this year, although the consultation time is much shorter. Much valid feedback was ignored in that consultation and the changes were introduced regardless. I hope that the feedback given to the English proposal will be fully considered as part of the process in Wales. The BMA conclusion there was... (the bolding is the BMA's not mine) 1. For OTC medicines, we believe that it is already an intrinsic part of a GP's job to help patients to care for their own minor illnesses, and to explain the availability and proper use of over-the-counter preparations. The NHS England guidance for CCGs, is useful for those situations where advice about self-care may be all that a patient needs. However, as there has been no change to the regulations that govern GP prescribing this guidance cannot be used by Clinical Commissioning Groups to ban all such treatments. 2. GPs must continue to treat patients according to their individual circumstances and needs, and that includes issuing prescriptions where ***there are reasons why self-care is inappropriate.*** This guidance does make it clear that such requirements continue to apply in individual situations. We welcome the recognition of the need for flexibility within the guidance but it is vital that these are preserved in local implementation of this policy by CCGs. ***The NHS England commissioning guidance does not alter the contractual obligations for GPs – they remain obliged to prescribe what they believe their patients require, and CCGs are not able to introduce local prescribing bans***. This is because any prescribing policy must fall within the GMS contract, according to paragraph 14.2.2: ***14.2.2.*** *Subject to clause 14.2.4 and 14.2.5 and to clauses 14.6 to 14.7 a prescriber shall order any drugs, medicines or appliances which are needed for the treatment of any patient who is receiving treatment under the Contract by— (a) issuing to that patient a non-electronic prescription form or nonelectronic repeatable prescription completed in accordance with clause 14.2.8; or (b) where clause 14.3 applies, creating and transmitting an electronic prescription.* Prescribers in general practice can advise patients that treatments are available without prescription, but were they to then refuse to issue an FP10 for treatment that they had recommended they would be in breach of paragraph 14.2.2 and open to complaint and possible financial redress. Has there been any assessment in England since to review the impact of the changes. I suspect that for many of the reasons above and below the impact has been small as most GPs will continue to do what they think is right for their patients and in accordance with their contractual obligations. In Wales we have the Choose Pharmacy Scheme and Common Ailments Service. The consultation refers to these schemes but does not recognise the conflicts in advice and limitations of the CAS. There needs to be more cross referencing between the AWMSG Common Ailments formulary and the proposal. Then the holes in the approach soon become apparent. Firstly I am all in favour of "ask your pharmacist" and patient self-care empowerment. I truly believe that patient education is the key and that pharmacists have a key role to play in this respect. However we must also recognise that these common ailments can be worrying and troublesome and that patients have concerns

		and may prefer to have the advice of a trained diagnostician. Patients often see GPs for confirmation of the diagnosis as much as they do for medicines. Very few people would give up lots of time to see a GP purely to avoid paying a few pounds for a treatment for an acute condition. Many of those that do are often truly living on the breadline. The message that may come out of this approach is *"don't visit your GP"* if you have these conditions. The risks are, inappropriate self-management, failure to warn about risks (e.g. Lyme disease after Tick bites), and failure to spot more serious conditions through differential diagnosis (e.g. myocardial infarction in over 55y.o. masquerading as heartburn). If the message is "*its OK to visit your GP, but you will have to buy the treatment over the counter"* then this should be clear and unambiguous. However it does place the GP in an invidious position- see "NHS principles" below. Pharmacist do not always the training to diagnose and certainly diagnosing did not form part of my undergraduate training. I have confidence that, given a diagnosis, I can provide treatment recommendations that are as good as or better than most medics, but I don't always have the same confidence (or indeed appropriate medical equipment) in confirming the diagnosis. There are contradictions all over the place between the Consultation Document and the AWMSG formulary. I have highlighted some of these below. It is critical that advice is consistent and properly evidence based. The credibility of the scheme and of the community pharmacist depends on this. My concerns about Choose Pharmacy are highlighted in the attached e-mail recently sent to the Chief Pharmaceutical Officer. [Attachment removed to maintain anonymity of the respondent]. I am not convinced that this guidance will have any significant impact on cost in our local surgery. I see relatively little prescribing for these types of products. I remain uneasy about the conflict with the political message "free at point of delivery" for those who rarely consult with a GP with a self-limiting but definitely troublesome condition. But I can acknowledge that the guidance may help empower the prescribers to say "no" if faced with an unreasonable request for treatment. Here are my comments; some more pedantic than others.. but the Oral thrush one is especially pertinent. No action was taken with respect to my feedback on the consultation of the Common Ailments Scheme, and I suspect this will be the same: too many political reputations involved; but I can but try!! Please consider.
Anonymous 5		• If we are advising pts to self-care then will the CAS scheme have capacity to deal with so many patients? • Very difficult to limit variation as interpretation will be subjective and down to clinical discretion • Previous attempts at implementing this strategy have been of limited success and generated many pt complaints • A lot of inconsistencies between messages in OTC document and CAS providing treatment

Anonymous 6		**INTRODUCTION** **The Respondent** is pleased to provide a response to the consultation by the All Wales Therapeutics and Toxicology Centre on Conditions for which over the counter items should not routinely be prescribed in primary care. The Respondent is a professional association and trade union representing and negotiating on behalf of all doctors and medical students in the UK. It is a leading voice advocating for outstanding health care and a healthy population. It is an association providing members with excellent individual services and support throughout their lives **RESPONSE** The Respondent responded to the NHS England consultation on guidance for CCGs regarding over the counter items on 19 February 2018. This is attached as Annex A. [Attachment removed to maintain anonymity of the respondent]. Given that the AWTTC consultation is based entirely on this guidance, our previous response remains a valid representation of our position. As such, we will not be providing an extensive response to this consultation and would draw your attention to specific thoughts on each recommendation made within this previous submission (Annex A page 4-11). [Attachment removed to maintain anonymity of the respondent]. However, we feel that it is important that we reiterate some of the key conclusions made in our previous response. GPs must retain professional autonomy to do what they determine is clinically most appropriate for patients (which may include a prescription for these items). Page 2 of 2 For medicines available over-the-counter, we believe that it is already an intrinsic part of a GP's job to help patients to care for their own minor illnesses, and to explain the availability and proper use of over-the-counter preparations (which can be available through the Common Ailments Scheme). The proposed guidance is useful for those situations where advice about self-care may be all that a patient needs. However, as there has been no change to the regulations that govern GP prescribing, this guidance cannot be used by NHS Wales to ban prescription of all such treatments. GPs must continue to treat patients according to their individual circumstances and needs, and that includes issuing prescriptions where there are reasons why self-care is inappropriate Subsequent to NHS England's publication of their revised guidance, the Respondent also issued guidance for GPs which built on the response to the consultation. While it is primarily focused at GPs in England, the advice within is largely applicable on a UK-wide basis. The guidance can be found at: www.bma.org.uk/advice/employment/gp-practices/serviceprovision/prescribing/over-the-counter-medicines-guidance
Anonymous 7		The document as a whole seems to us to underestimate the impact on individuals of skin disease. Given the current difficulties in accessing dermatology services in Wales, these proposals may have the effect of discouraging individuals from seeking the appropriate level and form of specialist health. The possibility of epidemics of certain conditions in institutions such as schools also seems to have been given little or no consideration.
Anonymous 8		It is a shame and missed opportunity to not have included a dermatologist on the group reviewing the skin products. Although there are practitioners in the community with expertise and experience of treating skin problems, input from secondary care would have improved this document and helped with respect to patient safety issues that could arise where errors or omissions have occurred. It is clear that the current level of spend is unsustainable and we should be diverting resources to areas of

		greatest need. From a skin perspective more specific advice could have been included with respect to products with little evidence of effectiveness, for example, bath additives, topical nail treatments and expensive emollients compared to cheaper alternatives. These are far less controversial and, from the data we have reviewed at the Dermatology Board, the savings could be significant. I should point out that although I currently chair the Dermatology Board, these are my comments. This consultation document came through between meetings and we have not had the opportunity to discuss.
Anonymous 9		People on low incomes may not be able to afford to buy over-the-counter medicines and products. We fully appreciate that there are issues across the whole of NHS Wales, not just in prescription medicines, but imposing blanket policies on GPs that do not take into account demographic differences across the country, or allow for flexibility for individual patients, risk alienating the most vulnerable in society. There is evidence that self-restriction of medications due to cost is common in seniors who lack prescription coverage, particularly among certain vulnerable groups. Seniors in these high-risk groups who have prescription coverage are much less likely to restrict their use of medications[1]. There are also studies, where health care provision is not universally funded, that highlight the direct and indirect costs of dry eye treatment[2]. These costs are significant in the context of the poorest in society and could drive further health inequalities. 1. Steinman, M.A., Sands, L.P. & Covinsky, K.E. J GEN INTERN MED (2001) 16: 793. 2. J Yu, CV Asche and CJ Fairchild. (2011) The economic burden of dry eye disease in the USA: A decision tree analysis
Anonymous 10		This consultation document has been discussed at the Respondent's Medicines Management Programme Board and received support. For some time the Health Board has recognised the need for all Wales advice or a Welsh Government position on the use of over the counter medicines that should not routinely be prescribed. This document will enable a consistent approach to be delivered across Wales, allowing Health Boards to make better use of the limited resources available.
Anonymous 11		I am in general agreement with the proposal however, in Wales we should acknowledge that the Eye Health Examinations Wales (EHEW) service should be the main option to differentially diagnose the red flag conditions, triage urgent pathologies that present with similar symptoms to conjunctivitis and dry eye and see patients where self care measures or OTC medications have not helped. An acknowledgement of the role that optometrists play in self-care and management would also be advised.
Anonymous 12		To whomever this may concern, I am writing, in addition to submitting a formal response to the consultation, to outline our views on an area of considerable concern to the Respondent. Whilst we recognise and accept the pressures faced by the NHS and the need to spend public resources in the most cost-effective way possible, we are very worried that these proposals represent an erosion of the NHS constitution's principle that "access to NHS services is based on clinical need, not on an individual's ability to pay". Not only do these proposals represent an attack on the very principles of the NHS, they do not offer good value and, we believe, will increase costs, disempower prescribers, put patient outcomes at risk, create and worsen inequalities in healthcare and

		disadvantage the most vulnerable members of society. From the previous exercise in England, we know that this view is shared by a wide range of other stakeholders, including patient groups and clinical special interest groups. Therefore, we are alarmed that these concerns have not been accurately recognised in the proposals put out for consultation and that the All Wales Prescribing Advisory Group felt it appropriate that a four-week consultation scheduled over the Christmas period was the appropriate way to gather important feedback on the proposed changes. Ultimately, due to its timing, stakeholders may not have been in a position to submit a response before the 11th January deadline, an issue that has already been brought to our attention by other stakeholders. It is also not clear to the Respondent why the consultation had to be instigated immediately after the ratification of the proposals by the AWPAG in early December, without any apparent milestones in 2019, that would require these proposals to be rushed through in the current manner. Ultimately, this underpins the perception that this consultation is merely a formality rather than substantive opportunity for stakeholders to register their concerns or suggestions. Specifically, the inclusion of constipation alongside such other conditions as dandruff, as well as the assertion that "it can be effectively managed with a change in diet or lifestyle", trivialises what is potentially a very serious condition that if left untreated, can lead to fatal complications. Moreover, the consultation classifies constipation as "infrequent" or "minor." However, these are not medically recognised classifications and we consider that this lack of clarity will only serve to increase the variation that this consultation seeks to address. Constipation already represents a significant burden on NHS resources in terms of nursing time, investigation, intervention, medication and on-going management. If relying on patients to self-diagnose and self-treat, this will increase A&E admissions and subsequently GP visits, and the costs associated with resource use. As such, we have very little confidence that NHS Wales will actually gain a net benefit from restricting licensed and effective treatments, with primary care costs being displaced by interventions that are not only avoidable but much costlier to the patient and the health system. Considering the negative impact that these proposals will have on many patients, especially those in the most disadvantaged parts of our society, we have to question the merits of the proposals and whether they truly sit within the fundamental principles of our NHS.
Anonumous 13		We noted that the use of the word 'minor conditions' had been avoided in the NHS Wales document and we particularly welcomed that change from the England document.
Anonymous 14		Whilst we appreciate the need to curb inappropriate variation of services, we would like to highlight the point that people on low incomes may not be able to afford to buy over the counter medication and products. Imposing blanket policies that don't take into account geographic differences across the country or allow for flexibility for individual patient's risk alienating the most vulnerable of society
Anonymous 15		The Respondent is the body which represents the vast majority of independent community pharmacy owners in all four countries in the UK. We count amongst our members independent regional chains through to single-handed independent pharmacies. This spread of members, our UK-wide geographical coverage, and our remit for NHS and non-NHS affairs means that we are uniquely representative of the independent community pharmacy sector. In addition to being a representative voice, we provide members with a range of professional services to help them maintain and improve the health of the communities they serve.
		We welcome the opportunity to respond and provide comments to the All Wales Prescribing Advisory Group (AWPAG) consultation on Conditions for which over the counter items should not routinely be prescribed in primary care: Guidance for NHS

		Wales. The proposals outlined in this consultation have been set up with the main aim of reducing NHS spending. The Respondent recognises the current financial pressures of the NHS. However, it is concerned with the broad brush methodology being considered, as well as the problems for the health and wellbeing of people who cannot access full treatment as a direct result of this policy. It is recognised that NHS England has already begun implementing some of the policies mentioned in the AWPAG's consultation and initial indications show that this is already beginning to have a negative impact on patients.
		Broadly the Respondent is supportive of the recommendations outlined in this consultation, and also suggests: 1. Any recommendations that will be applied to the GP prescribers be also applied to recommendations to all prescribers including community pharmacists who prescribe via the common ailments service 2. Patients must not be withheld prescriptions if the healthcare professional feel that one is needed
Anonymous 16		We welcome the initiative to encourage the efficient use of NHS resources. Self care must be the key message. England have progressed a robust approach of a black list which is appealing but this needs to be balanced by the care of vulnerable patients. The final guidance will need a equality impact assessment. We believe that those who can afford to should self care and those with limited resources should access the Community Pharmacy Common Ailment Service – limiting access to the vulnerable people in Wales would make the best use of NHS resources both drug costs and clinician and community pharmacy capacity. In reality having a "softer" self care approach makes it challenging to front line clinicians when faced with patient's expectations and that given the demands from WG on delivering cash releasing savings we need to be cautious in our approach. We recommend that the financial drug savings should not be a focus of the guidance, but ensuring the patient is seen by the right healthcare professional, at the time and receive gold standard care. The financial figures in the paper are not reflective of self limiting conditions and include chronic management of patients, so there is a need to either refine the data or remove the figures completely as they are being misinterpreted and seen as potential savings. If financial details are retained in full then we need to include and monitor the cost of the clinical time saved of staff within a GP practice, MIU, ED, for the consultations. Costs will be incurred by the CAS scheme which needs to be evaluated to ensure cost effective. There is a minimal risk that the costs of "self care" will transfer into community pharmacy. This cost also needs to be monitored.
		We have concerns around the capacity within community pharmacies to deliver a robust service that would be needed to deliver for this range of conditions. There is a need to engage at the coal face to see if this can be delivered for patients. Should CAS become and advanced service for community pharmacy? Should the reimbursement be per consultation?
		The formulary is evidence based and provides best practice around the management of self care. This guidance needs to be utilised by all prescribers /services delivered by NHS Wales , including : GP Practice –GPs and other prescribers, Out of hours and extended hours, Outpatient clinics, Acute hospitals, Opticians, Dentists, Community providers i.e. midwives, DNs, Community Pharmacies etc. for consultations of self limiting conditions. The risk is that patients may be referred to the community pharmacist who provides the evidence based advice and then a dissatisfied patient obtain treatment from the GP

		practice, MIU, or ED undermining the CAS service. i.e. a whole system approach
		State the guideline applies to adults and children
		The guidance needs to include a statement providing clarity around GMC view whereby a patient attends with a condition (although minor) and seen by a GP and sign posted instead of receiving a prescription. Will this be seen as poor practice?
		The guidance needs to include a statement providing clarity around GSM contract that covers if a patient attends with a condition (although minor) is there an obligation to provide a prescription if patient insists?
		Was AWMSG's Patient Group consulted? What is the recommended method of getting this advice to the public BEFORE they book appointments? Also communication to other health care professionals such as opticians who often tell patients to go to the GP to get eye drops for dry eyes.
		Would we recommend a "homely remedy list" be created for care homes to avoid residents each having their own common ailment remedies.
		• Not every item allowed to be prescribed is within the CAS formulary and this can be confusing – we have had instances where GPs have "stopped prescribing for hay fever" – but the items that the patient uses are not in the formulary (and they had tried all the items that were included) • Painkillers – clarity on when should/ shouldn't be prescribed – 32 pack size of paracetamol = 4 days supply from a pharmacy. Anyone being advised to take painkillers for longer than 5 days potentially should be prescribed? (again this issue happened in North Wales where patients were directed to a pharmacy to buy) • Significant issues with the CAS service software – repeat functionality to "speed up" the process rather than requiring a new consultation for each supply of items that can be repeated. • Sore Throat – where does the new Sore Throat Test & Treat service sit alongside this? • Dry eye – this is often a long-term condition but CAS will only allow one episode in 12 months (optometrists do not recommend hypromellose – Regional Optical Committee) We would suggest that all conditions not included in CAS but included in the consultation are considered to be included in CAS going forward. Eg migraine/ insect bites and stings
Anonymous 17		The Respondent is fully supportive of the principles behind the AWTTC proposal to ensure that any expenditure by NHS Wales on medicines, either OTC or otherwise, is based on the best available evidence and expenditure is cost effective. The Respondent has however some reservations about the blanket approach being taken, in that, evidence may well indicate that treatment may not reduce the duration of the condition, however many OTC medicines are used for relief of the symptoms associated with the condition e.g. hayfever and failure to manage the symptoms effectively may make the difference between a patient needing to take time off work or being able to continue working. The Respondent would also wish to recommend that rather than advising a patient that they can purchase OTC treatments it should be clearly stated in the guidance that the patient is referred to a community pharmacy for appropriate advice on self care. AWTTC will, we are sure, be aware that OTC medicines can be purchased from outlets other than community pharmacies, such as corner shops and local garages, where the quality of advice provided will often fall far short of that provided in a community pharmacy.

Anonymous 7	section 2.2	We believe that patient groups/charities like us should be included as stakeholders.
Anonymous 18	section 2.2 Stakeholders	Patient groups should be added to the Stakeholder's list
Anonymous 12	2.0 Purpose	Whilst we recognise and accept the pressures faced by the NHS and the need to spend public resources in the most cost-effective way possible, we are very worried that these proposals represent an erosion of the NHS constitution's principle that "access to NHS services is based on clinical need, not on an individual's ability to pay". We feel strongly that the consultation is in breach of the NHS's own legal framework as it is stated in Principle 2 of the NHS Constitution that 'Access to NHS services is based on clinical need, not an individual's ability to pay. NHS services are free of charge, except in limited circumstances sanctioned by Parliament and should therefore be determined by Government, rather than being a decision made by the NHS. Not only do these proposals represent an attack on the very principles of the NHS, they do not offer good value. We believe they will increase costs, disempower prescribers while placing increasing burden on them, put patient outcomes at risk, create and worsen inequalities in healthcare and disadvantage the most vulnerable members of society. Restricting prescribing will exacerbate health inequalities, entrenching a two-tier health system where patient outcomes are dependent on the ability to pay for the most effective treatment available. From the previous consultation in England, we know that this view is shared by a wide range of other stakeholders including patient groups and clinical special interest groups. Likewise, serious concerns have been raised by those who would be tasked with implementing the guidance, namely CCGs, GPs and pharmacists; many of whom consider these proposals to be completely unworkable.1 As such, the Respondentis alarmed by the timing of the consultation and questions whether stakeholders have been given sufficient time and opportunity to input in a meaningful and effective manner.
Anonymous 19	2.0 Purpose	Whilst I recognise and accept the pressures faced by NHS Wales and the need to spend public resources in the most cost-effective way possible, I am very worried that these proposals represent an erosion of the NHS constitution's principle that "access to NHS services is based on clinical need, not on an individual's ability to pay". I feel strongly that the consultation is in breach of the National Health Service's own legal framework as it is stated in Principle 2 of the NHS Constitution that 'Access to NHS services is based on clinical need, not an individual's ability to pay. NHS services are free of charge, except in limited circumstances sanctioned by Parliament and should therefore be determined by Government, rather than being a decision made by the NHS.' Not only do these proposals represent an attack on the very principles of NHS Wales, they do not offer good value. I believe they

[1] https://www.chemistanddruggist.co.uk/opinion/nhs-englands-plans-ration-otc-prescriptions-wont-work-pharmacy?cid=ENL-CDNEW-SATREV-LN-TOPSTORY-2018-0310

		will increase costs, disempower prescribers while placing increasing burden on them, put patient outcomes at risk, create and worsen inequalities in healthcare and disadvantage the most vulnerable members of society. Restricting prescribing will exacerbate health inequalities, entrenching a two-tier health system where patient outcomes are dependent on the ability to pay for the most effective treatment available. From the previous consultation in England, I have been made aware that this view is shared by a wide range of other stakeholders including patient groups and clinical special interest groups. Likewise, serious concerns have been raised by those who would be tasked with implementing the guidance, namely local health boards (LHBs), GPs and pharmacists; many of whom consider these proposals to be completely unworkable. As such, I am alarmed by the timing of the consultation and question whether stakeholders have been given sufficient time and opportunity to input in a meaningful and effective manner.
Anonymous 4		NHS principles - *Meets the needs of everyone, free at point of delivery and based on clinical need not ability to pay*. - Not being respected?
Anonymous 20	2nd paragraph	Allowing Health Boards to interpret the advice and determine how it is best implemented is likely to lead to postcode prescribing/availability.
Anonymous 5		Interpretation should be national not at HB level, to minimise variation and to be able to give a standard response to pt complaints.
Anonymous 21		"…the guidance contained herein does not remove the clinical discretion of the prescriber in accordance with their professional duties. " We are reassured by this statement and wonder if it should be highlighted and given more prominence.
Anonymous 16	To be actioned in section 1.0 or 6.0	Include a bullet point list of conditions covered for easy reference.
Anonymous 3		The consultation document indicates that during the financial year April 2017 to March 2018, NHS Wales spent approximately £27 million in primary care on 6.8m prescriptions for items which are available over the counter. Assuming conservatively that these were based on 3.4m GP consultations, then the GP costs (which might still be incurred with patients seeking advice/treatment) might dwarf the benefits of reduced medication costs - £95m (based on £28 cost of GP consultation) vs £27m. It would appear that a broader impact assessment has not been conducted, either of the impact on GP consultations, or the expected increased use (and associated costs) of the community pharmacy Common Ailment Service.
Anonymous 20	1st paragraph, 2nd sentence	Suggest rewording as 'Welsh Government and NHS Wales Chairs, Chief Executives and Medical Directors …
	sentence starting 'By reducing…'	Suggest rewording to 'By reducing spend on the types of treatments listed above, resources can be allocated to other higher priority areas that are likely to have a greater impact on patients, or be used to support improvements in services and/or deliver transformation that will ensure the long-term sustainability of the NHS.

	bullet points indicating how money saved could be used	Suggest removing 'more' from each example. Costs of drug treatment for breast cancer and Alzheimer's are likely t vary considerably between patients and so I'm not sure that they are good examples to use.
Anonymous 12		The Respondent agrees that it is "vital that a prudent approach is taken to reviewing the prescribing of over the counter items." However, it has to be questioned whether this is adequately reflected in the proposals. Importantly: • Where patients are not able to get access to licensed treatments in primary care, there is evidence to show that this places increased pressures on A&E services, increasing downstream costs for the NHS and impacting patients' outcomes and quality of life. • It has been recognised that GPs will be placed under pressure to step up treatment inappropriately where they are aware that patients will not be able to afford to buy OTC medicines they would have otherwise been able to prescribe. • This can lead to prescribing medicines which can be more expensive and sub-optimal in treating the patient's condition.
		The Respondent agrees that it is of paramount importance to ensure these proposals take sufficient account of the NHS' legal duties to advance equality and reduce health inequalities. A number of conditions listed in Section 6 of the consultation document are suffered disproportionately by some groups protected by the Equality Act 2010. For example, constipation is disproportionately and severely suffered by older people, the very young and by pregnant women. Constipation is also an associated condition of a number of physical and learning disabilities, as well long-term and chronic illnesses such as Parkinson's disease. Blanket restrictions to medicines such as laxatives that are safe, effective and essential to the treatment of constipation will only worsen patient outcomes and will further increase existing health inequalities for those patients. If left untreated, or if treated inappropriately, constipation for example can lead to, or exacerbate, the symptoms of other conditions and can have a significant impact on the quality of life of patients and their carers. Therefore, in these circumstances constipation cannot be classified as "minor" and "suitable for self-care" and it is dangerous to apply a blanket classification in this way.
		The principles of the consultations fundamentally undermine the principles of the NHS that treatment should be free at the point of care and not determined by the patient's ability to pay. It is clear that these proposals will disproportionately affect those on low incomes and the most vulnerable in our society. Poorer patients, who are less able to pay for their medicines, will suffer disproportionately from these restrictions, creating and exacerbating health inequalities. In the period 2012-2014, in the UK 89.9% of all prescriptions were free of charge. These proposals targeting prescriptions in primary care for OTC items will pass the burden of payment to patients who are least able to afford it. These proposed changes therefore penalise those who can least afford it. It has been recognised that GPs may feel under pressure to step up treatment inappropriately to Prescription Only Medicines

		(POM), where they are aware that patients will not be able to afford to buy medicines over the counter that they would have otherwise been able to prescribe. This can lead to prescribing medicines which are more expensive but also sub-optimal in treating the patient's condition. This again, leads to an inequity of treatment and worsened patient outcomes, determined by the patient's ability to pay. Further to this, where patients are expected to pay for their own medication and are unable to do so, they may not take any treatment for their condition.
		It is misleading and dangerous to class some of the conditions listed as "self-limiting" or "lend[ing] themselves to self-care" as many are symptoms of very serious and life-threatening conditions or in themselves are on a continuum which at the chronic or moderate to severe end can be serious and debilitating and significantly impact quality of life. As stated above, in certain circumstances constipation cannot be classified as "minor" and it is dangerous to apply a blanket classification in this way.

		The consultation document references that "more cost-effective use of limited resources allows money to be spent where it is most needed," which could be spent on a certain number of additional nurses, procedures, or treatments. The Respondent welcomes this evidence-based approach, however is concerned that the conclusions in the consultation document may not be a true reflection of the unintended consequences that would result from the recommendations. For example
		
		• Constipation is a common problem, with an estimated 1 in 7 adults and 1 in 3 children affected at any given time. [2]
		• Despite an estimated 2 million sufferers of chronic constipation in the UK[3], it is often under-recognised as an important health issue.
		• Constipation already represents a significant burden on NHS resources in terms of nursing time, investigation, intervention, medication and on-going management.
		• Research has shown that where constipation is not managed effectively through appropriate treatment, this leads to thousands of hospital admissions each year, often through A&E:
		  ○ 66,287 people in the UK were admitted to hospital with constipation as the main condition in 2014/15, equivalent to 182 people a day.
		  ○ Of those, 48,409 were unplanned emergency admissions (this is equivalent to 133 per day).
		  ○ The total cost to hospitals for treating unplanned admissions due to constipation was £145 million in 2014/15.
		  ○ Studies show that up to 50% of older patients in geriatric hospital wards or care homes are affected by faecal impaction.[4]
		
		Although the above figures relate to the UK, it is clear that the opportunity cost of approximately £1.6 million per annum (as outlined in the consultation document) for prescribing treatments for constipation in primary care could well be an effective use of NHS resources. It also must be questioned whether NHS Wales will actually gain a net benefit from restricting licensed and

[2] https://www.coloplast.co.uk/Global/UK/Continence/Cost_of_Constipation_Report_FINAL.pdf
[3] https://www.coloplast.co.uk/Global/UK/Continence/Cost_of_Constipation_Report_FINAL.pdf
[4] http://www.burdenofconstipation.com

		effective treatments earlier in the patient pathway. Without a full impact assessment it is not possible to guarantee that these recommendations will not just lead to increased pressures on A&E services, thereby increasing downstream costs for the NHS on interventions that are not only avoidable but also much costlier to the patient and the health system.
Anonymous 19		I agree that it is "vital that a prudent approach is taken to reviewing the prescribing of over the counter items." However, it has to be questioned whether this is adequately reflected in the proposals. Importantly: • Where patients are not able to get access to licensed treatments in primary care, there is evidence to show that this places increased pressures on A&E services, increasing downstream costs for NHS Wales and impacting patients' outcomes and quality of life. • It has been recognised that GPs will be placed under pressure to step up treatment inappropriately where they are aware that patients will not be able to afford to buy OTC medicines they would have otherwise been able to prescribe. This can lead to prescribing medicines which can be more expensive and sub-optimal in treating the patient's condition.
		I agree that it is of paramount importance to ensure these proposals take sufficient account of NHS Wales' legal duties to advance equality and reduce health inequalities. A number of conditions listed in Section 6 of the consultation document are suffered disproportionately by some groups protected by the Equality Act 2010. For example, constipation is disproportionately and severely suffered by older people, the very young and by pregnant women. Constipation is also an associated condition of a number of physical and learning disabilities, as well long-term and chronic illnesses such as Parkinson's disease. Blanket restrictions to medicines such as laxatives that are safe, effective and essential to the treatment of constipation will only worsen patient outcomes and will further increase existing health inequalities for those patients. If left untreated, or if treated inappropriately, constipation for example can lead to, or exacerbate, the symptoms of other conditions and can have a significant impact on the quality of life of patients and their carers. Therefore, in these circumstances constipation cannot be classified as "minor" and "suitable for self-care" and it is dangerous to apply a blanket classification in this way.
		The principles of the consultations fundamentally undermine the principles of NHS Wales that treatment should be free at the point of care and not determined by the patient's ability to pay. It is clear that these proposals will disproportionately affect those on low incomes and the most vulnerable in our society. Poorer patients, who are less able to pay for their medicines, will suffer disproportionately from these restrictions, creating and exacerbating health inequalities. These proposals targeting prescriptions in primary care for OTC items will pass the burden of payment - estimated at £27 million, as outlined in the document - to patients who are least able to afford it. These proposed changes therefore penalise those who can least afford it. It has been recognised that GPs may feel under pressure to step up treatment inappropriately to Prescription Only Medicines (POM), where they are aware that patients will not be able to afford to buy medicines over the counter that they would have

		otherwise been able to prescribe. This can lead to prescribing medicines which are more expensive but also sub-optimal in treating the patient's condition. This again, leads to an inequity of treatment and worsened patient outcomes, determined by the patient's ability to pay. Further to this, where patients are expected to pay for their own medication and are unable to do so, they may not take any treatment for their condition.
		It is misleading and dangerous to class some of the conditions listed as "self-limiting" or "lend[ing] themselves to self-care" as many are symptoms of very serious and life-threatening conditions or in themselves are on a continuum which at the chronic or moderate to severe end can be serious and debilitating and significantly impact quality of life. As stated above, in certain circumstances constipation cannot be classified as "minor" and it is dangerous to apply a blanket classification in this way.
		The consultation document references that "more cost-effective use of limited resources allows money to be spent where it is most needed," which could be spent on a certain number of additional nurses, procedures, or treatments. I welcome this evidence-based approach, however I am concerned that the conclusions in the consultation document may not be a true reflection of the unintended consequences that would result from the recommendations. For example: • Constipation is a common problem, with an estimated 1 in 7 adults and 1 in 3 children affected at any given time. • Despite an estimated 2 million sufferers of chronic constipation in the UK , it is often under-recognised as an important health issue. • Constipation already represents a significant burden on NHS resources in terms of nursing time, investigation, intervention, medication and on-going management. • Research has shown that where constipation is not managed effectively through appropriate treatment, this leads to thousands of hospital admissions each year, often through A&E: • 66,287 people in the UK were admitted to hospital with constipation as the main condition in 2014/15, equivalent to 182 people a day. • Of those, 48,409 were unplanned emergency admissions (this is equivalent to 133 per day). • The total cost to hospitals for treating unplanned admissions due to constipation was £145 million in 2014/15. • Studies show that up to 50% of older patients in geriatric hospital wards or care homes are affected by faecal impaction. Although the above figures relate to the UK, it is clear that the opportunity cost of approximately £1.6 million per annum (as outlined in the consultation document) for prescribing treatments for constipation in primary care could well be an effective use of NHS Wales resources. It also must be questioned whether NHS Wales will actually gain a net benefit from restricting licensed and effective treatments earlier in the patient pathway. Without a full impact assessment it is not possible to guarantee that these recommendations will not just lead to increased pressures on A&E services, thereby increasing downstream costs for NHS Wales on interventions that are not only avoidable but also much costlier to the patient and the health system.
Anonymous 20	final sentence of 1st paragraph	Suggest rewording to 'Hence, further encouragement of self-care with required infrastructural support could impact significantly on workload[5].

	2nd paragraph	NHS Choices website is now just called NHS
	3rd paragraph	Don't like the phrase 'treat a range of self-treatable illnesses' – repetition of 'treat' – but not sure how to reword
Anonymous 7		We are concerned that patients will not be sufficiently aware of their own conditions to exercise proper self-help. The input of specialised dermatologists should not be substituted by those less qualified to diagnose.
Anonymous 18		The principle of self care is that the individual caring for themselves is able to recognise the ailment they have and how to proceed to manage it. In all cases, it should be made clear that should there be a concern or the patient is unsure of the diagnosis, help should be sought. It has been well established that Dermatology is poorly understood amongst doctors1. In this document you are expecting the general public, pharmacists and other health professionals to diagnose their own dermatological ailments in order to get treatment. The contrast with many of the other conditions listed is that they are actually symptoms such as cough, sore throat and colic. Throughout the document, there is no criteria for defining what constitutes "Mild", "Moderate" or "Severe". Many scoring systems exist and yet not a single one is alluded to. Where self care, or advice from a pharmacist has been given for a condition where previously a medical consultation was required, there seems to be no line of communication to the patient's doctor or hospital clinic to make them aware of this. Please find embedded a response from the Respondent on the principles of how this and other documents have possibly misunderstood the principles of mild disease and self care of dermatological conditions:[Attachment removed to maintain anonymity of the respondent]. 1. Hussain, W., Hafiji, J., Stanley, A. G. and Khan, K. M.(2008). Dermatology and junior doctors: an evaluation of education, perceptions and self-assessed competencies. British Journal of Dermatology; 195(2): 505-506.
Anonymous 4		Choose Pharmacy and the Common Ailment Service are having the impact of reducing access to all to non-commissioned over the counter advice - I have fed back on this previously (see attached). [Attachment removed to maintain anonymity of the respondent]. If the direction continues there will be no Community Pharmacy service left to support self-care. Bouncing a patient from the GP to the Common Ailments Scheme for conditions where no treatment can be offered, whilst considering that the Choose Pharmacy IT platform and consent process mean that a consultation takes typically over 15 minutes, is neither in the interest of the patient (wasted time and frustration), other patients and customers (restricted access to pharmacist for prescription issue and advice and OTC responding to symptoms advice), or to pharmacists (workplace pressures/targets/bureaucracy). There are loads of restrictions within the Common Ailments Service which are not being considered here, for example only 1 or 2 episodes per year of most conditions can be managed through the service; oral thrush can only be treated if patient has had recent antibiotics or inhaled steroids, etc etc.
Anonymous 20	2nd paragraph	Suggest rewording to 'The main objectives of the Common Ailments Service are to encourage patients who would otherwise have visited a GP for a common ailment to visit the community pharmacy instead; to provide advice and, where necessary, treatment; and promote self-care, thereby increasing resilience. Having the pharmacist provide advice about self-management of the presenting common ailment(s) encourages the patient to choose to self-care in the future'.

	3rd paragraph	Suggest rewording to 'This is particularly the case for patients who currently perceive a need to see a GP to manage any of the ailments covered by the service.
	5th paragraph	Is it accurate to say that the Common Ailments Formulary was 'developed by the AWMSG'? The preface to the document itself says 'This document has been prepared by a multiprofessional collaborative group, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC), and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG)'.
Anonymous 5		CAS scheme needs to be promoted to patients and the OTC message combined with this.
		There needs to be a national promotion of CAS/OTC to ensure consistent messages across HBs e.g. will there be national resources available such as posters/leaflets/social media campaigns/TV
Anonymous 17		Section 4.0 deals with the role of the Common Ailment Service (CAS). From the Respondents's perspective the supply of an appropriate medicine via CAS occurs as a result of pharmacist prescribing. One of the key principles agreed at the introduction of the CAS was that all prescribers would follow the same prescribing guidelines and that patients would not be able to 'play one prescriber off against another' in pursuit of the treatment they desired. The Respondent would therefore want to ensure that this principle remains in place and that, when prescribing guidance has been finalised, a check is made on the guidance within the CAS formulary to ensure that it remains aligned to the guidance provided to GPs and other prescribers. This would of course not preclude NHS Wales from taking a strategic decision to move the treatment for any condition away from GP practices to CAS, which the Respondent would wholeheartedly support. The alignment of guidance would only be necessary where prescribing continues by both professions.
Anonymous 22	Page 7, paragraph 5, final sentence	Advise the wording is altered to reflect the fact that a dental consultation may be more appropriate than GP care, 'further advice on when they should seek GP care **or visit a dentist'**
Anonymous 4		There are lots of occasions where product licences restrict OTC sale. This is noted in consultation draft, but perhaps underestimated. I In practice the vast majority of patients seeking advice for these conditions have already tried OTC products and are looking for "something more". Therefore it is likely that the vast majority of patients who do attend the GP will fall within these general exceptions. An example would be diarrhoea where the OTC treatments state within their product licences .."*If your diarrhoea lasts for more than 48 hours consult your doctor".*
Anonymous 20	5th paragraph	Information about 'red flag' symptoms or when to seek GP care is included in the Common Ailments formulary
		Bullet points 2, 5 and 8 are about supplying POMs – this is outside the scope of this document as it's only talking about limiting supply of OTC medicines, therefore these bullet points are unnecessary.
Anonymous 5		General exceptions – need to have clearer guidance as to when OTC use is appropriate.
Anonymous 23	Page 8 – final bullet point	The recent death of Richard Handley, as a result of chronic constipation, which was unrecognised by his carers, highlighted the potential serious consequences of constipation if not appropriated treated and managed. This section does not give a strong enough message regarding exceptions. Many individuals with a learning difficulty can develop a longstanding problem with constipation and have an element of acquired mega colon/rectum which often masks chronic symptoms. Carers then mistakenly

		believe the individual only has a 'minor' problem with constipation and would thus manage with over the counter laxatives rather than seeking expert advice and ensuring the individual is appropriately assessed and treated.
Anonymous 12		We welcome all of these exceptions; however we are concerned with how, in practice, these exemptions are to be applied consistently. The current wording proposed, is altogether too vague and will only lead to further variance in prescribing. Will there be any evaluation of consistent and fair application of exemptions and will prescribers be liable if these are not found to have been appropriately applied? The undoubted outcome of these proposals will be to actively discourage patients from visiting their GPs to discuss these listed conditions. Where patients are discouraged from visiting their GPs, there will be no opportunity for a GP to assess their eligibility for exemption. This will serve only to widen health inequalities, especially in those on low incomes and those that are socially isolated through age and with physical and/or learning disabilities. Additionally, we strongly believe that it is not, and should not be, the responsibility of GPs to police their patients for proof of their entitlement to exemptions. To that end, we believe that these proposals will place additional burden on GPs at a time when they already face considerable pressure. Feedback from NHS England and NHS Clinical Commissioners during webinars surrounding the consultation in England suggested that those currently entitled to benefits would be exempted on the basis of social vulnerability. Is this the case in Wales? If so, this needs to be made explicitly clear in the guidance.
Anonymous 19		I welcome all of these exceptions; however I am concerned with how, in practice, these exemptions are to be applied consistently. The current wording proposed, is altogether too vague and will only lead to further variance in prescribing. Will there be any evaluation of consistent and fair application of exemptions and will prescribers be liable if these are not found to have been appropriately applied? The undoubted outcome of these proposals will be to actively discourage patients from visiting their GPs to discuss these listed conditions. Where patients are discouraged from visiting their GPs, there will be no opportunity for a GP to assess their eligibility for exemption. This will serve only to widen health inequalities, especially in those on low incomes and those that are socially isolated through age and with physical and/or learning disabilities. Additionally, I strongly believe that it is not, and should not be, the responsibility of GPs to police their patients for proof of their entitlement to exemptions. To that end, I believe that these proposals will place additional burden on GPs at a time when they already face considerable pressure. Feedback from NHS England and NHS Clinical Commissioners during webinars surrounding the consultation in England suggested that those currently entitled to benefits would be exempted on the basis of social vulnerability. Is this the case in Wales? If so, this needs to be made explicitly clear in the guidance.
Anonymous 21		Taken from the NHSE document, in general we thought the comments very sensible and reassuring e.g.: Page7 It is expected that in most cases (unless specified) these minor conditions will clear up with appropriate self-care. If symptoms

		are not improving or responding to treatment, then patients should be encouraged to seek further advice. When implementing this guidance, CCGs will need to supply patients with better information on signposting so that they are able to access the right service. This guidance is not intended to discourage patients from going to the GP when it is appropriate to do so. ….. This may vary by medicine, but could include babies, children and/or women who are pregnant or breastfeeding. Community Pharmacists will be aware of what these are and can advise accordingly.
Anonymous 14	"General Exceptions to the Guidance: - Patients prescribed an over the counter treatment for a long term condition	The vast majority of dry eye certainly falls into this category, and therefore any estimated savings may be wildly inaccurate. There is a real quality of life issues around managing with chronic dry eye. some links from here may prove helpful. https://scholar.google.co.uk/scholar?hl=en&as_sdt=0%2C5&q=dry+eye+quality+of+life&btnG=&oq=dry+eye+qual Dry eye also has symptoms that vary significantly from patient to patient, with some finding it debilitating, and others not really significantly affected. To put a patient in the position where they may not be able to afford medication, and without are left with debilitating symptoms is not prudent heath-care or co-production. This should be mentioned explicitly.
Anonymous 16	In the section-'Note that for vitamins, minerals, probiotics and those self-limiting conditions where there is limited evidence of clinical effectiveness for the treatments used '	Could extra wording be added 'including vitamins for eye conditions such as AMD'.
	General exceptions to the guidance	'Patients on prescription only treatments' is ambiguous
Anonymous 17		The Respondent is mindful of the underlying principles behind the decision to remove prescription charges i.e. that no member of the public should be denied appropriate care based on their ability to pay for that care. A number of appropriate exemptions are listed within the consultation however the Respondent would wish to see a much clearer statement that if a prescriber feels that a patient is likely to go without the medicines that they need for economic reasons that the prescriber should be able to continue to prescribe these items. The situation in relation to the supply of head lice treatment illustrates this concern. Whereas the evidence may indicate that wet combing, if done systematically and regularly, is as effective a treatment as the use of insecticides, in practice it is well understood that a busy mother with a number of young children will struggle to undertake the diligent routines of wet combing that are required and as a result will struggle to eliminate the infestation. If the same mother is not able, for financial reasons, to purchase the quantity of insecticides required to treat the whole family then there is every chance that elimination of the

		infestation will not occur increasing the risk of spreading the infestation to the wider community. It is for this reason that the Respondent would wish to ensure that any guidance produced would not prevent the prescriber from using their clinical judgement as to the most appropriate way forward.
Anonymous 20	1st paragraph 1st sentence	It isn't just where 'alternative means for item attainment are available', it's also where the use of the product at all isn't appropriate
	2nd paragraph 2nd sentence	Suggest rewording as 'However, this does not necessarily represent the potential savings available
	2nd paragraph 3rd sentence	Suggest rewording as 'Alternative supply mechanisms for some conditions within NHS Wales, for example via the Common Ailments Service, also levy costs against the overall NHS Wales budget'.
	5th paragraph 2nd sentence	I don't think you can say 'over the counter conditions' they are conditions that can be treated with products that are available over the counter
Anonymous 5		Re NHS expenditure on OTC products – we don't know what has been included and the values are therefore misleading. Also a number of the meds would be for chronic conditions e.g. paracetamol in pain, dry eyes, GORD, constipation, emollients so values provided are meaningless. Also many of these drugs are used for conditions that aren't self-limiting.
Anonymous 15		Additional, significant health inequalities may arise as a result of products not being available on prescription. The proposals set out could also lead to health inequalities in populations that are currently "just about managing". The Respondent would like to put forward a number of proposals which would address in part the current challenges highlighted in the consultation document. Community pharmacy contractors are paid for pharmaceutical products and services, through the Drug Tariff. The Respondent suggests that NHS Wales make full use of the Drug Tariff particularly sections Part XV, Part XVIIIA & Part XVIIIB (Borderline Substances, The Blacklist, The Selected List) <u>Borderline Substances</u> In certain conditions, some foods and toilet preparations have characteristics of drugs and the Advisory Committee on Borderline Substances advises as to the circumstances in which such substances may be regarded as drugs. Prescriptions issued in accordance with the Committee's advice should then be endorsed "ACBS". <u>The Blacklist</u> Products that are not considered effective for prescribing ought to be "blacklisted". Items that are not listed in this section can be prescribed. <u>The Selected List</u> These are items that may only be prescribed for the patient groups and for the purpose listed in the Drug Tariff.
		Broadly, the Respondent is supportive of the recommendations outlined in the "Eight of the thirty-five conditions" that have been classed as self-limiting, however, the Respondent suggests that in some cases, the patient may not be able to distinguish between acute or chronic, and that appropriate care and compassion is shown when the patients seeks to make an appointment with the GP.
Anonymous 16	To be actioned in section 1.0 or 6.0	Include a bullet point list of conditions covered for easy reference.

Anonymous 17		Not every item allowed to be prescribed is within the CAS formulary and this can be confusing for patients. For example– we have been advised of instances where GPs have “stopped prescribing for hayfever” – but the medicines that the patient found worked for them are not in the CAS formulary (and they had tried all the items that were included) Painkillers – it would be helpful to have clarity on when patients should/shouldn’t be prescribed a 32 pack size of paracetamol (4 days supply) from a pharmacy. Anyone being advised to take painkillers for longer than 5 days potentially should be prescribed the medicine? (again this issue happened in North Wales where patients were directed to a pharmacy to buy) If there is to be a further move to supply via CAS then the well documented IT Issues with the CAS service need to be addressed. For example a repeat functionality to “speed up” the process rather than requiring a new consultation for each supply of items that can be repeated. Sore Throat – It will be important to ensure that the new Sore Throat Test & Treat Service is aligned with CAS. Dry eye – this is often a long-term condition but CAS will only allow one episode in 12 months (optometrists do not recommend hypromellose on advice from their Regional Optical Committee) Indigestion – only 2 episodes a year (this was another issue in North Wales where GPs referred patients to their pharmacy). The Respondent would suggest that all conditions not included in CAS, but included in the consultation, are included in CAS going forward e.g. migraine/ insect bites and stings
Anonymous 4		If all sore throats are *"self-limiting and will clear up on their own without treatment*"? - Then why are we introducing NHS funded "test and treat" services with antibiotic options?
Anonymous 20		Did we decide that the link to the Common Ailments Formulary could only go to the front page and not to the specific section? NHS Choices is now just called NHS These comments apply to all the conditions
Anonymous 17		Sore Throat – It will be important to ensure that the new Sore Throat Test & Treat Service is aligned with CAS.
Anonymous 4		if antiviral creams are helpful as described ... Antiviral creams are available over the counter from pharmacies without a prescription and if used correctly, these can help ease symptoms and speed up the healing time Then why does the Common Ailments formulary state ..?? Topical antiviral treatments are not included in the formulary because there is no good quality evidence that they are effective in reducing pain or healing times. There is no joined up approach, and these disparities just lead to the pharmacists advice being brought in disrepute. I can advise on the limitations of treatment and sell (or not sell) a cold-sore product with a supporting leaflet in about 2 minutes;

		indeed my pharmacy technician and assistant colleagues can equally provide the service. However through engaging Choose Pharmacy CAS it is 20 minutes of the pharmacists and patient's time with a no product supplied consequence. How can this be appropriate?
Anonymous 20		CKS states that 'The recommendation not to routinely prescribe topical antivirals in primary oral herpes simplex infections is based on the fact that CKS **found no good-quality evidence from randomized controlled trials (RCTs) that these agents are effective in reducing pain or time to healing compared with placebo or no treatment'**. This is also referenced in Common ailments Formulary – therefore I'm not sure that you can say 'Antiviral creams are available over the counter from pharmacies without a prescription and if used correctly, **these can help ease symptoms and speed up the healing time'.**
Anonymous 1		Conjunctivitis- no exceptions given at all?
Anonymous 4		Conjunctivitis: (presumably "infective conjunctivitis" although not stated). Contradiction between consultation advice > However, almost half of all simple cases of conjunctivitis clear up within ten days without any treatment. reconcile with the CAS advice > Most people with bacterial conjunctivitis get better without treatment within 5–7 days, Can't both be right! How are we supposed to give expert advice when we are given inconsistent advice ourselves? To be frank the "almost half" statement isn't at all convincing when suggesting that antibiotics not be provided!
Anonymous 5		Conjunctivitis – telling GPs not to prescribe yet pts can obtain free via CAS (not in line with antibiotic guidelines)
Anonymous 18		Allergic conjunctivitis is a chronic condition and would not fall under the General exceptions category. I suggest removal. The statement that the "substance that cause the allergy should be avoided" does demonstrate a lack of understanding of the allergens that cause allergic conjunctivitis. One cannot avoid the Earth's atmosphere. Red flag symptoms should include any painful red eye. Red flag symptoms have not been expanded in any section.
Anonymous 9		We disagree with the recommendation to advise health boards/trusts that a prescription for treatment of conjunctivitis should not routinely be offered in primary care as the condition is self-limiting and will clear up on its own without the need for treatment. We are of the opinion that this advice would be used as a steer to health boards/trusts that schemes to diagnose, manage and treat dry eye and conjunctivitis are not required, as people should use self-care measures and visit the pharmacy as stated in this proposal. A high proportion of minor eye conditions appointments relate to dry eye and conjunctivitis, so we could reasonably see health boards/trusts decommissioning on that bases, without the acknowledgement that these schemes differentially diagnose the red flag conditions and triage urgent pathologies that present with similar symptoms to conjunctivitis. The most common reasons for patients needing a minor eye condition assessment are 'red eye' (36.7% of patients), 'painful white eye' (11.1%), 'flashes and floaters' (10.2%)[1]. Ocular lubricants are most commonly supplied (29.7% of all patients seen), followed by topical antibiotic drops (12.1%)[1].

		We would suggest adding in this consultation an acknowledgement of the role that optometrists play in self-care and management. Optometrists are the best placed professional to advise people on self care and the professional who people should go to if a condition in fact does not self limit or has a red flag. Both the dry eye and conjunctivitis sections should recognised optometrists as professionals who can help support peoples self care. Secondly optometrists should be stated in this document as the professional people should access if self care does not work, or if they have a red-flag symptom. This would support the aim of reducing unnecessary GP appointments. 1.Evgenia Konstantakopoulou, Robert A Harper, David F Edgar, Genevieve Larkin, Sarah Janikoun, John G Lawrenson, Clinical safety of a minor eye conditions scheme in England delivered by community optometrists, 10.1136/bmjophth-2017-000125 Published 20 February 2018
Anonymous 11		Suggests re-wording Section 1.3 Treatment is not usually required for bacterial conjunctivitis as it is self limiting and symptoms typically last for only 7-10 days. Treatment for acute allergic conjunctivitis that occurs sporadically due to allergen contact is not required as symptoms last for a few hours. There are several self-care measures that may help with symptoms including cold compresses and avoidance of allergen for acute allergic conjunctivitis. Optometrists are the best placed professional to advise on self care and determine cause in red flag symptoms or where the condition is ongoing i.e. not self limiting. These patients are entitled to a free Eye Health Examination at an accredited optometrists practice. A list of optometrist practices that are accredited is available at Eye Health Examination Wales (ADD LINK). If treatment is needed, then treatment is dependent on the cause: • In severe bacterial cases, antibiotic eye drops can be used to clear the infection. • Allergic conjunctivitis that is re-occurring and lasts longer than a few hours can usually be treated with anti-allergy medications such as antihistamines and mast cell stabilisers. Treatments for conjunctivitis can be purchased over the counter. However, almost half of all simple cases of conjunctivitis clear up within ten days without any treatment. Public Health England (PHE) advises that children with infective conjunctivitis do not need to be excluded from school, nursery or child minders, and it does not state any requirement for treatment with topical antibiotics. Recommendation: Advise health boards/trusts that a prescription for treatment of bacterial and acute allergic conjunctivitis should not routinely be offered in primary care as the conditions are self-limiting and will usually clear up on its own without the need for treatment. Optometrists are best placed to determine cause in red flag symptoms and for advise on self care. Patients are entitled to a free Eye Health Examination at an optometrist practice. (ADD LINK).

		Patient exemptions: • ‘Red Flag’ symptoms.
Anonymous 14		A high proportion of EHEW appointments relate to dry eye and conjunctivitis so we could see that this advice will overlook the acknowledgement that EHEW can offer differential diagnosis for red flag conditions and allows for triage of urgent pathologies that sometimes present with similar symptoms to conjunctivitis. We would suggest adding in to this advice (as has been done in some limited way so far) of the vital role that the EHEW accredited optometrist plays in the self care and management. Optometrists are the best placed professional to advise on self care and the professional to go to first if the condition does not self limit or has a red flag. Both the dry eye and conjunctivitis sections should highlight the role of EHEW. This would support the aim of reducing unnecessary GP appointments and using the principles of co-production and prudent healthcare Treatment is not usually required for bacterial conjunctivitis as it is self limiting and symptoms typically last for only 7-10 days. Treatment for acute allergic conjunctivitis that occurs sporadically due to allergen contact is not required as symptoms last for a few hours. There are several self-care measures that may help with symptoms including cold compresses and avoidance of allergen for acute allergic conjunctivitis. Optometrists are the best placed professional to advise on self care and determine cause in red flag symptoms or where the condition is ongoing i.e. not self limiting. These patients are entitled to a free Eye Health Examination at an accredited optometrists practice. A list of optometrist practices that are accredited is available at Eye Health Examination Waleshttp://www.eyecare.wales.nhs.uk/home If treatment is needed, then treatment is dependent on the cause: 1. In severe bacterial cases, antibiotic eye drops can be used to clear the infection. 2. Allergic conjunctivitis that is re-occurring and lasts longer than a few hours can usually be treated with anti-allergy medications such as antihistamines and mast cell stabilisers. Treatments for conjunctivitis can be purchased over the counter. However, almost half of all simple cases of conjunctivitis clear up within ten days without any treatment. Public Health England (PHE) advises that children with infective conjunctivitis do not need to be excluded from school, nursery or child minders, and it does not state any requirement for treatment with topical antibiotics. **Recommendation:** Advise health boards/trusts that a prescription for treatment of bacterial and acute allergic conjunctivitis should not routinely be offered in primary care as the conditions are self-limiting and will usually clear up on its own without the need for treatment. Optometrists are best placed to determine cause in red flag symptoms and for advise on self care. Patients are entitled to a free Eye Health Examination at an optometrist practice http://www.eyecare.wales.nhs.uk/home **Patient exemptions:**

		'Red Flag' symptoms. Evgenia Knonstantakopoulou, Robert Harper, David F Edgar, Genevieve Larkin, Sarah Janikoun, John G Lawrenson; Clinical safety of a minor eye conditions scheme in England delivered by community optometrists, 10.1136/bmjophthal – 2017-000125. Published 20 February 2018
Anonymous 4		Coughs ands Colds: No mention of OTC options - just because a condition is self-limiting it doesn't mean that it isn't distressing or disabling for a time. Are we saying here that all OTC products are totally ineffective?? Or is the NHS position now that any condition that is self-limiting shouldn't be treated!
Anonymous 20		Reference 2 link doesn't need to say accessed October 2017
Anonymous 18		A distinction needs to be made between "Cradle cap" and seborrheic dermatitis in infants as a whole. This is a subset of seborrheic dermatitis and the exception is appropriate (not getting better or causing distress). To prevent a large proportion of infantile and maternal dermatoses, suggest stopping "Bounty Packs" being forced upon new mothers in Welsh hospitals.
Anonymous 5		Haemorrhoid treatments – why supply via CAS. Mixed messages between CAS and OTC
Anonymous 4		: Just a personal point of note (and warning) - my son had colic which was dismissed with no treatment for nearly 6 years before he was admitted to Alder Hey Hospital for surgery for a congenital intestinal malrotation! Just perhaps reinforces my concerns about the qualification of the diagnostician and dismissing common aliments and "minor ailments".
Anonymous 4		Men get cystitis too. GP referral needed: Messages need to be clear and unambiguous.
Anonymous 16		Cystitis – ensure access to patient info leaflet form Target "Treating Your Infection – Urinary Tract Infection (UTI)" via primary care
Anonymous 4		CAS formulary says Once appropriate treatment for person has been determined then further supplies should be obtained through the GP. Reconcile this with from the consultation document a prescription for treatment of contact dermatitis should not routinely be offered in primary care as the condition is appropriate for self-care. Hydrocortisone is the only CAS/OTC steroid option and is unlikely to be strong enough for areas like palms of hands and soles of feet. NICE CKS states — *choice of topical corticosteroid depends on the specific clinical situation including the age of the person and severity, location and extent of dermatitis.*
Anonymous 7		There seems to be a confusion of irritant dermatitis and allergic contact dermatitis. It also contradicts recent NICE guidelines (July 2018).We are concerned that chronic conditions which have not responded to over the counter prescriptions should be

		included. We also consider that insufficient consideration has been given to severe conditions which might impact on schools etc if it spreads e.g head lice or ringworm. This illustrates the point made under p 5 above *[see section 3.0 Self Care]*.
Anonymous 18		Remove this section completely. It is clear that the nature of contact dermatitis is not understood by the author of this section. Irritant dermatitis is not the same as allergic contact dermatitis. Removal of “an irritant” from the environment is not the management of irritant contact dermatitis. Contact dermatitis accounts for 4-7% of all dermatology consultations1. 27% of the general population is sensitised to a contact allergen2. Irritant dermatitis often manifests (as suggested) as hand eczema and this is difficult to treat in usual dermatology clinics, let alone self care3. The suggestion that you can easily identify the substance causing the irritancy or the allergen and simply avoiding it goes against the current understanding of contact dermatitis. It has been known for at least 20 years that too few people are being investigated for contact dermatitis and this is leading to a large economic burden to society4. In short, not enough people are being seen for contact dermatitis. Very potent topical steroids are routinely needed (only available on prescription) and people should be encouraged to see their doctor about it to get referred to a specialist. The advice given in the document also contradicts the advice given in the July 2018 NICE recommendations which have been used as a reference in the very document. Throughout the document, there is no criteria for defining what constitutes “Mild”, “Moderate” or “Severe”. Many scoring systems exist and yet not a single one is alluded to. The Respondent has responded to the consultation that is ongoing in England on the misunderstanding of contact dermatitis in this section. Please find embedded.[Attachment removed to maintain anonymity of the respondent]. Contact Dermatitis April 2018.pdf 1. Bourke J, Coulson I, English J. Guidelines for the management of contact dermatitis: an update. Br J Dermatol 2009: 160:946–953 2. Diepgen T L, Ofenloch R F, Bruze M et al. Prevalence of contact allergy in the general population in different European regions. Br J Dermatol 2016: 174: 319–329 3. Ibler KS, Jemec GB, Diepgen TL, et al. Skin care education and individual counselling versus treatment as usual in healthcare workers with hand eczema: randomised clinical trial. BMJ. 2012;345:e7822. Published 2012 Dec 12. doi:10.1136/bmj.e7822 4. Bhushan M, Beck M H. An audit to identify the optimum referral rate to a contact dermatitis investigation unit. Br J Dermatol 1999: 141: 570–572
Anonymous 8		Irritant and contact dermatitis are different and have different triggers. Mild irritant dermatitis is common and the advice sound. You need to remove the words allergen and contact dermatitis. Recommendation – if contact dermatitis, if suspected, should be referred to a dermatologist for investigation and management advice.

Anonymous 7		There seems to be a confusion of irritant dermatitis and allergic contact dermatitis. It also contradicts recent NICE guidelines (July 2018).We are concerned that chronic conditions which have not responded to over the counter prescriptions should be included. We also consider that insufficient consideration has been given to severe conditions which might impact on schools etc if it spreads e.g head lice or ringworm. This illustrates the point made under p 5 above *[see section 3.0 Self Care]*.
Anonymous 18		No exceptions have been listed for Dandruff. Suggest adding: • Symptoms not being controlled by over the counter treatments • Chronic conditions • Diagnostic uncertainty
Anonymous 8		Suggest recommend that if resistant to treatment or worsening could indicate an underlying dermatosis – then appropriate to see GP and onward referral if necessary (there conditions other than seborrheic dermatitis that can cause scaling of the scalp)
Anonymous 4		consultation document recognises.... OTC treatments can help replace lost fluids or reduce bowel motions. But CAS allows "advice only". Athough Loperamide doesn't affect the time course of diarrhoea symptoms, it can allow patients to carry on with their lives in the interim. Product licences for OTC Loperamide and Rehydration sachets says... If your diarrhoea last for more than 48 hours consult your doctor. So following the product licences the patient has to be referred.
Anonymous 20		It's not clear what the statement 'This recommendation does not apply to children' refers to – is it just the sentence that precedes it or the whole thing?
Anonymous 16		**2.3 Diarrhoea (adults)** should this state 'adults excluding frail elderly' as per NICE?
Anonymous 1		I note the advice about dry eyes- there are no exceptions-how about a patient with Sjogren's.
Anonumous 4		Dry eyes: Observation that EHEW accredited optometrists are often advising hyaluronate based products, and/or preservative-free products to patients who respond poorly to simple lubricants. This is in accordance with NICE CKS guidance.... *If symptoms are not relieved with the initial formulation try a different product or consider adding transient gels or hypo-osmolar eye drops containing hyaluronate and lipids.* However these products are not inexpensive at up to £25 per pack and many patients may struggle to afford.
Anonymous 20	Explanation 4th paragraph	Need to delete one 'be'
		Delete word 'accessed'

Anonymous 9		We disagree with the recommendation to advise health boards/trusts that a prescription for treatment of dry or sore eyes should not routinely be offered in primary care as the condition is appropriate for self-care. See previous comment [see conjunctivitis]
Anonymous 11		Add the following to this section: Where the diagnosis of dry eye is unclear, there are Red Flag symptoms or where the patient does not respond to self care or OTC medications, the patient should be seen at an optometrist practice, under the Eye Health Examination Wales (EHEW service. A list of optometrist practices that are accredited is available at Eye Health Examination Wales website (ADD LINK).
Anonymous 14		There are health studies that highlight the direct and indirect costs of dry eye treatment. Whilst we are content as a profession to charge privately for this treatment please refer to: Steinman, MA, Sands LP and Covinsky KE. J GEN INTERN MED (2001) and J yu, CV Asche and CJ Fairchild. (2011) The economic burden of dry eye disease in the USA; a decision tree analysis In Wales, the Eye Health Examination Wales (EHEW) service allows a GP to refer a patient to an optometrist if they have any ocular condition such as dry eye – treatment with the appropriate health care professional in this case will be at the expense of the practice who can spend significant time counselling the patient to manage their dry eye. This must be funded and the optometrist cannot be expected to pay for this service themselves. Not being able to offer this service deprives the patient and increases the risk of health inequalities. Where the diagnosis of dry eye is unclear, there are Red Flag symptoms or where the patient does not respond to self care or OTC medications, the patient should be seen at an optometrist practice, under the Eye Health Examination Wales (EHEW service. A list of optometrist practices that are accredited is available at Eye Health Examination Wales website http://www.eyecare.wales.nhs.uk/home
Anonymous 16		**Dry eyes** we feel the guidance is ambiguous. Many patients in primary care are prescribed drops for dry eyes on the recommendation of an optician. According to the general exceptions these pts would be excluded and could be prescribed. Therefore there will not be a vast impact on reducing costs. Can the guide include a clear recommendation as to whether these products should be prescribed by a GP following optician recommendation? Should this be supplied by the WEC scheme and not CAS?
Anonymous 17		Dry eye – this is often a long-term condition but CAS will only allow one episode in 12 months (optometrists do not recommend hypromellose on advice from their Regional Optical Committee)
Anonymous 4		if the problem isn't resolved within the 3/7 days stipulated on the various product licences (Urea-hydrogen Peroxide/Olive oil) then what? Many surgeries no longer irrigating. I might advise using drops for a more prolonged period but this is not covered by product licences nor by CKS advice https://cks.nice.org.uk/earwax#!scenario *"Prescribe ear drops for 3–5 days initially, to soften wax and aid removal*.
Anonymous 7		There seems to be a confusion of irritant dermatitis and allergic contact dermatitis. It also contradicts recent NICE guidelines (July 2018).We are concerned that chronic conditions which have not responded to over the counter prescriptions should be included. We also consider that insufficient consideration has been given to severe conditions which might impact on schools etc if it spreads e.g head lice or ringworm. This illustrates the point made under p 5 above *[see section 3.0 Self Care]*.

Anonymous 18		General exceptions need to be included: • Severe sweating not responding to over the counter treatments • By definition, the sweating is excessive. Could this be a sign of carcinoid syndrome, B symptoms for lymphoma or a malignant spinal cord tumour?
Anonymous 4		fine to manage within CAS as long as at least 6 months between episodes and no more than 2 infestations per year. But how do we tell the lice this!! In all other cases people will have to pay £10 plus for an effective treatment.
Anonymous 20		Not sure that saying that 'chemical treatment is only recommended in exceptional circumstances' is true. Common Ailments Formulary says it's first line in those with Afro or tightly curled hair in whom wet combing would be difficult and 2nd line after wet combing has been tried unsuccessfully for 2 weeks – I don't think either of these can be described as 'exceptional'
	2nd paragraph 2nd sentence	It's not correct to say that 'everyone in the household needs to be treated at the same time – even if they don't have symptoms'. All those in the household and anyone else who's had head to head contact with the infested person should use a detection comb to check for live head lice. All those with evidence if live head lice should be treated simultaneously.
Anonymous 7		There seems to be a confusion of irritant dermatitis and allergic contact dermatitis. It also contradicts recent NICE guidelines (July 2018).We are concerned that chronic conditions which have not responded to over the counter prescriptions should be included. We also consider that insufficient consideration has been given to severe conditions which might impact on schools etc if it spreads e.g head lice or ringworm. This illustrates the point made under p 5 above *[see section 3.0 Self Care]*.
Anonymous 18		Patient exceptions should include: • During recurrent outbreaks in institutional settings as this may discourage some from treating altogether and as such it will be a wasted effort for those that do. • Failure to fund prescription treatment of head lice outbreaks in schools in deprived areas would result in public health problems in these schools. Chronic head lice infestation in deprived communities has been associated with secondary effects such as anaemia and developmental delay. • Severe , refractory cases would need medical attention
Anonymous 8		See BAD document (sent separately) on this and other conditions mentioned in response
Anonymous 4		how many missed ulcers or myocardial infarction (esp. in patients over 55y.o.) may occur if patients with severe or persistent symptoms avoid seeing the GP? There is a risk if the advice to not prescribe, translates into advice to not consult. I think this is a real risk.
Anonymous 17		Indigestion – only 2 episodes a year (this was another issue in North Wales where GPs referred patients to their pharmacy).
Anonymous 20	Explanation 3rd paragraph 1st sentence	Repetition of 'help' and 'helping'
	Explanation 3rd paragraph 4th sentence	Repetition of 'only'

Anonymous 23	Patient exemptions	Due to the insidious nature of constipation in individuals with a learning disability and the fact that they may not recognise /report symptoms or problems with defecation in the early stages constipation in this group of individuals should always be taken seriously and never considered a 'minor' condition. Individuals with a learning difficulty should be considered an exception in the first instance until they have been appropriately assessed by a health care professional
Anonymous 12		The inclusion of constipation alongside such other conditions as dandruff, as well as the assertion that "it can be effectively managed with a change in diet or lifestyle", trivialises what is potentially a very serious condition, that if left untreated, can lead to fatal complications. The consultation classifies constipation as "infrequent" or "minor". However, these are not medically recognised classifications and we consider that this lack of clarity will only serve to increase the variation that this consultation seeks to address. All chronic and serious constipation begins with what would be here described as "infrequent" or "minor". Similarly, "infrequent" constipation may also be very serious. Constipation can escalate from what, here, would be considered "minor" to the need for emergency treatment within a matter of hours. Constipation can lead to faecal impaction, which can in turn lead to serious impaction of the hard-faecal mass onto the colonic wall, which may cause ulceration, lower gastrointestinal bleeding or perforation. Constipation can also be a symptom of other serious conditions which may not have been diagnosed, such as cancer, Parkinson's Disease, and diabetes and can cause episodes of serious conditions such as hepatic encephalopathy and should therefore be investigated by a health care professional. If constipation is not effectively treated, it may become necessary to perform manual evacuation. As well as having serious implications for the patient's health, manual evacuation creates a feeling of considerable loss of dignity and distress for the patient and is delivered at considerable economic cost, as well as placing increased strain on specialist nursing resources, families and social care services. Constipation already represents a significant burden on NHS resources in terms of nursing time, investigation, intervention, medication and on-going management. If relying on patients to self-diagnose and self-treat, this will increase A&E admissions and subsequently GP visits, and the costs associated with resource use.
		We strongly believe that access to safe and effective medicines should be on the basis of clinical need and not on the ability to pay. We therefore strongly believe that any patients suffering from constipation should be prescribed the treatment that they need based on clinical judgement. With regards to recommendations for constipation, it is essential that pregnant and postnatal women, the very young, the elderly and physically frail, those with long-term conditions and co-morbidities, those with learning and physical disabilities and those in receipt of free prescriptions are exempted.

Anonymous 19		The inclusion of constipation alongside such other conditions as dandruff, as well as the assertion that "it can be effectively managed with a change in diet or lifestyle", trivialises what is potentially a very serious condition, that if left untreated, can lead to fatal complications. The consultation classifies constipation as "infrequent" or "minor". However, these are not medically recognised classifications and I consider that this lack of clarity will only serve to increase the variation that this consultation seeks to address. All chronic and serious constipation begins with what would be here described as "infrequent" or "minor". Similarly, "infrequent" constipation may also be very serious. Constipation can escalate from what, here, would be considered "minor" to the need for emergency treatment within a matter of hours. Constipation can lead to faecal impaction, which can in turn lead to serious impaction of the hard-faecal mass onto the colonic wall, which may cause ulceration, lower gastrointestinal bleeding or perforation. Constipation can also be a symptom of other serious conditions which may not have been diagnosed, such as cancer, Parkinson's Disease, and diabetes and can cause episodes of serious conditions such as hepatic encephalopathy and should therefore be investigated by a health care professional. If constipation is not effectively treated, it may become necessary to perform manual evacuation. As well as having serious implications for the patient's health, manual evacuation creates a feeling of considerable loss of dignity and distress for the patient and is delivered at considerable economic cost, as well as placing increased strain on specialist nursing resources, families and social care services. Constipation already represents a significant burden on NHS Wales resources in terms of nursing time, investigation, intervention, medication and on-going management. If relying on patients to self-diagnose and self-treat, this will increase A&E admissions and subsequently GP visits, and the costs associated with resource use.
		I strongly believe that access to safe and effective medicines should be on the basis of clinical need and not on the ability to pay. I therefore strongly believe that any patients suffering from constipation should be prescribed the treatment that they need based on clinical judgement. With regards to recommendations for constipation, it is essential that pregnant and post-natal women, the very young, the elderly and physically frail, those with long-term conditions and co-morbidities, those with learning and physical disabilities and those in receipt of free prescriptions are exempted.
Anonymous 21	Explanation	"Constipation can affect people of all ages and can be just for a short period of time. It can be effectively managed with a change in diet or lifestyle". COMMENT Children should be excluded from the "of all ages" because the NICE CG99 states the following: Para 1.5.1 "Do not use dietary interventions alone as first-line treatment for idiopathic constipation." Para 1.4.2: "Start maintenance therapy if the child or young person is not faecally impacted." Para 1.4.3: "Offer the following oral medication regimen for disimpaction if indicated: Polyethylene glycol 3350 + electrolytes,

		using an escalating dose regimen (see table 4), as the first-line treatment[3]. …… We are also concerned that the phrase "infrequent constipation" is open to misinterpretation in children, especially those with disabilities. For instance faecal impaction can be associated with overflow diarrhoea, which could be misinterpreted as resolution of the constipation, whereas early assessment by a healthcare professional would recognise this as chronic constipation with faecal impaction. 3rd Paragraph "Laxatives are not recommended for children unless they are prescribed by a GP. This guidance applies to short term, infrequent constipation caused by changes in lifestyle or diet such as lack of water or movement or changes in diet". We SUGGEST separating this paragraph for the reasons stated above – see NICE CG99 - and an addition: "Laxatives are not recommended for children unless they are prescribed by a GP, therefore children with constipation require early assessment by a healthcare professional. Next paragraph: This guidance applies to short term, infrequent constipation in adults caused by changes in lifestyle or diet such as lack of water or movement or changes in diet."
	Recommendations	We SUGGEST that this should read: "Advise health boards/trusts that a prescription for treatment of simple constipation will not routinely be offered to adults in primary care as the condition is appropriate for selfcare.
	Patient Exceptions	There is an additional issue of children with chronic constipation, especially those with disabilities, and when they transition from paediatric to adult services; also some laxatives are prescription only until 12 years of age. We SUGGEST deleting the two bullet points and replacing them with: • Children with constipation require early assessment by a healthcare professional, because of a high risk of this developing into a chronic problem, they are, therefore, excluded from this guidance. Young people who transition from paediatric to adult care, and children who attain the age at which certain medications can be obtained over the counter should continue to receive their same prescription medication thereafter and be monitored by healthcare professionals.
Anonymous 13		The working group was set up to highlight the risks posed by constipation to people with learning disabilities. While an uncommon event, constipation has been known to cause death because of an unrecognised mega rectum/colon which leads to the storage of large volumes of stool. Eventually the dilated bowel becomes ischaemic or spontaneously perforates leading to death. We are concerned that the term 'Infrequent constipation' may mislead carers and family members who may confuse 'infrequent stool' with 'infrequent constipation' and believe the condition is self-limiting. For this reason we think it might be safer to drop the term 'infrequent'. We note warnings have been added to other conditions for example 'infrequent migraine' and we would ask that it is similarly added to constipation – see suggestion below. We also suggest a slight change in wording:

		2.9 Constipation Explanation: Constipation can affect people of all ages and **when it is** just for a short period of **time,it** can be effectively managed with a change in diet or lifestyle. Pharmacists can help if diet and lifestyle changes aren't helping. They can suggest an over the counter laxative. Most laxatives work within 3 days. They should only be used for a short time only. Laxatives are not recommended for children unless they are prescribed by a GP. This guidance applies **only** to short term, infrequent constipation caused by changes in lifestyle or diet such as lack of water or movement or changes in diet. **If constipation persists, or if there is abdominal pain, please to seek advice from the GP**. Recommendation: Advise health boards/trusts that a prescription for treatment of simple constipation will not routinely be offered in primary care as the condition is appropriate for selfcare.
Anonymous 16		**£1,634,927 expenditure on laxatives** (This figure is the 2017–2018 expenditure in primary care.) . Care not to over predict the saving this could make as many patients prescribed laxatives chronically for clinical reasons such as prevention of constipation if on long term opiate.
Anonymous 24		We are encouraged to read that laxatives are not recommended for children unless prescribed by a GP. It is imperative that if a child presenting with symptoms of constipation is treated. Constipation is not always self-limiting and delayed appropriate treatment at an early stage can result in faecal impaction, causing severe abdominal pain and a common cause of emergency admissions to hospital. First line treatment for constipation in children is administration of a macrogol (NICE CG99). These are only available on prescription in paediatric doses and usually need to be given over an extended periods of time. Emergency admissions to secondary care for faecal impaction can be avoided by appropriate treatment in the community. Administration is stressful for the children and families concerned and very expensive for the NHS. Treatments as part of a good preventative programme should therefore remain available to all patients through primary care prescription to ensure that children and young people with constipation are provided with the optimum treatment at an early stage and parents do not delay in using appropriate medication through not being able to afford purchasing them over the counter.
Anonymous 4		Infrequent Migraine - define "infrequent". In any cases of Migraine CKS advises... ***Offer combination therapy*** *Oral sumatriptan (50 mg or 100 mg) is suitable for most people. Zolmitriptan, naratriptan, rizatriptan, eletriptan, almotriptan, and frovatriptan are alternatives*

		Be aware that OTC products containing Sumatriptan have been unavailable (at least through our wholesalers) for over 12 months. Other popular OTC treatments such as Migraleve Pink have also been unavailable for many months. This sort of thing is not uncommon where prescription only versions are available but OTC versions are long term out of stock. This needs to be considered.
Anonymous 4		We have seen a number of insect bites (typically horse-fly) where oral steroids have been needed; tick bites - will removal of tick advice, and provision of Lyme disease advice, be assured if patients self-manage?
Anonymous 20	Explanation 2nd sentence	Aren't 'creams for itching' antihistamines?
Anonymous 4		OTC benzoyl peroxide is preferred first-line choice - cost £20 per 60g tube. ? prohibitive to many. CAS allows limited supply but often insufficient for full course if applied correctly.
Anonymous 7		If mild acne is not resolved properly at an early stage, it can lead to a more severe form with attendant long term physical and psychological consequences for the patient. This appears to us to be insufficiently reflected in the document.
Anonymous 18		By definition, this is a long term condition and should be exempt under section 5.0 Failure to treat may lead to: • Scarring • Severe psychological distress There is evidence that treatment of mild acne prevents development of more severe scarring acne. Acne can have profound social and psychological effects, the severity of which is not necessarily related to the clinical severity of the condition. Even mild acne can be significantly disabling. Multiple studies have demonstrated the significant impact of acne and how it affects emotions, daily activities, social activities, study/work, and interpersonal relationships [Hazarika N, Archana M. The Psychosocial Impact of Acne Vulgaris. Indian J Dermatol. 2016, 61(5): 515–520.]. This excess psychosocial morbidity can be reduced by effective treatment [Tan J. Psychosocial Impact of Acne Vulgaris: Evaluating the Evidence. Skin Therapy Letter. 2004;9(7)]. Furthermore, acne is associated with a greater psychological burden than a variety of other disparate chronic disorders. Failure to treat mild acne may lead to more severe acne, which is associated with severe depression and poor economic performance. Lower income families / individuals may not be willing or able to pay for OTC acne treatments.
Anonymous 8		Recommend that if acne fails to respond, worsens or having significant psychological impact should seek medical help
Anonymous 4		Dry skin; the CAS allows a maximum of only 2 x 500g per year. OTC purchase is expensive and often prohibitive. Underuse will lead to poor disease management and more acute flare-ups requiring steroids. CKS states: • *Emollients are typically under-prescribed and under-used. This results in suboptimal treatment of dry skin and eczema, and may increase the occurrence of flares [NICE, 2007a] q* • *Advise the person to use emollients liberally and frequently, even when their skin appears improved or is clear.* ○ *It is recommended that 250–500 g of emollient be applied every week* 500g of Doublebase per week purchased by a patient would cost £260 per year

Anonymous 7		As “itch” covers a wide range of potential conditions, greater precision is required in the definition.
Anonymous 18		Itch should be removed as a symptom of mild dry skin as it may indicate an inflammatory process. Patient exceptions should include: • Presence of eczema • Family history of eczema, asthma or hay fever • Long term dry skin The sections states using over the counter treatments as a long term basis in this section. However, chronic conditions are also under “General Exceptions” and his contradicts the principles laid out in section 5.0 (page 7) In addition, substitutions to topical moisturisers should not be made without consultation with a patient. The best moisturiser is one the patient uses. Some companies have tried to pass off similar moisturisers as being generic alternatives and occasionally, changes have appeared on prescriptions without patient consultation. A simple check of the ingredients shows them to be different. Changing without consultation and consent will lead to treatment failure and potential allergy.
Anonymous 8		Guidance refers to mild dry skin. Reference to Eczema – atopic should be omitted as it may cause confusion. The concern is that this could be interpreted that emollients should not be prescribed for patients with eczema which is a chronic condition.
Anonymous 16		Should this include creams for dry heels –we see lots of this prescribed e.g. dermatonics
Anonymous 20		Remove ‘accessed October 2017’
Anonymous 20	Explanation	This is duplicated from condition above but needs to be adapted – shouldn’t refer to managing sun burn symptoms
		[Submitted separately to the above] I realise that I have missed the deadline for comments but I’ve just become aware of a further issue that might need considering. I can’t now find the consultation document on the website but from my comments I think there was something about sunscreens. There is an article in the current edition of the British Porphyria Association newsletter that suggests that patients with erythropoietic protoporphyria are having difficulty obtaining supplies of Dundee cream which they need to have prescribed for sun protection. Although it’s not clear it could be because of the low priority for funding process in England. Just conscious that we don’t want to have the same problems in Wales. I’m attaching a scan of the article from the newsletter. Happy to discuss if that would help.  SKM_754e19011613080.pdf
Anonymous 7		The increase in sun related skin cancers requires, in our view, a financial commitment to preventative measures, including sunscreens, and more extensive public information. In the long term this will be self evidently cost effective.
Anonymous 18		I am pleased to see that sun protection will be prescribed for sun exacerbated photodermatoses and other pre-existent

		conditions. However, sun protection is one area where we need to be increasing spending, of that there is no doubt. Skin cancer is on the rise in the UK and metastatic disease often requires prescription of the 3 most expensive drugs on the NHS budget. Public health campaigns like “Don’t be a Lobster”, “SCkin” and others should be funded as well as more access to sunscreens.
Anonymous 4		Hay-fever -Exceptionally for the CAS this is a condition where adequate quantities are permitted and steroid nasal sprays (Beclometasone under PGD) for over 6 year old. Referral to the GP will still be needed if symptoms uncontrolled after 1-2 weeks.
Anonymous 18		Hay fever is both Allergic conjunctivitis and rhinitis (not just rhinitis) are chronic conditions and therefore is exempt by the recommendation in section 5.0.
Anonymous 4		Burns - infection prevention through appropriate dressings may be overlooked if no treatment provided by GP.
Anonymous 25		The comment on **‘Antiseptic creams and treatments for burns should be included in any products kept in a medicine cabinet at home’** In general although this would be deemed in most cases, acceptable, I’m afraid the experiences of clinicians dealing with this scenario in general practice is quite different. This is because the antiseptic creams and treatment have often been opened and previously used and have been hanging around bathroom cabinets or the like, often for years, with their sterility questionable! It seems common sense does not prevail in this scenario and we find that an otherwise relatively clean burn then becomes infected due to this self- care intervention. I, personally would much rather patients keep well away from creams and antiseptics and use a fluid / lotion cleanser with water such as liquid Savlon.
Anonymous 20	Explanation 3rd paragraph	Doesn’t make sense – antiseptic creams etc can’t be included in any products…
Anonymous 4		Pain conditions; Advise health boards/trusts that a prescription for treatment of conditions associated with pain, discomfort and mild fever will not routinely be offered in primary care as the condition is appropriate for self-care. the vast majority of patients attending the GP with pain conditions have already tried OTC products without the desired effectiveness. The options OTC are very limited; basically only 3 drugs and even then Codeine restricted to 3 days maximum; the BNF used to make the point that us to 20% of patients benefit from trying alternative NSAIDs so prescribed options may be appropriate.
Anonymous 20	Explanation 2nd paragraph	Duplication of ‘at home’
	Explanation 3rd paragraph	Some of the conditions included here as examples are also included as their monographs
Anonymous 26		I think that this consultation is relevant for us as we are part of the front end clinicians in primary care managing minor conditions associated with pain (aches, sprains, strains, back pains, cervicogenic headaches, MSK injuries and other joint pains). The interesting part of this consultation for recommendation rationale at 2:18 is that ‘’in most cases of these conditions’’. Since there are different clinicians (GP’s, Physio’s, Nurse’s and paramedics etc.) assessing and prescribing patients at various

		surgeries, it might be difficult to generalize these cases. For e.g. Headache can be a tension headache, cluster headache, migraine, cervicogenic, exertional or even GCA! and encouraging patients to use OTC without being able to clinically differentiate these cases can be tricky. I believe as advanced physios in primary care our clinical assessments are designed to guide patients with most of these mechanical MSK pains and I think we are already do this.
Anonymous 22		There is a risk, if Table 1 is read in isolation, that the prevailing message be that prescriptions should *never* be issued for mouth ulcers. Instead, we suggest the wording is amended to reiterate that this only applies to OTC products, 'Advise health boards/trusts that a prescription for the treatment of mouth ulcers, **for an agent available over the counter**, should not routinely be offered in primary care...'
Anonymous 4		Nappy rash; candidal nappy rash is not uncommon, but the CAS only allows a pharmacist to provide treatment after trying topical hydrocortisone (which may potential to worsen the condition if used alone)
Anonymous 20	Explanation	Why mention that 'barrier creams can be purchased at the supermarket'? You haven't given that as an option previously
Anonymous 21	Recommendations	"Advise health boards/trusts that a prescription for treatment for nappy rash will not routinely be offered in primary care as the condition is appropriate for self-care. " This ignores the common problem of fungal infections, which require oral and topical treatment. We SUGGEST that this should be replaced with: "If nappy rash does not clear up after 3 to 7 days with the use of routine hygiene recommendations, advice should be sought from a healthcare professional"
Anonymous 22		Again, suggest adding '**for an agent available over the counter'** to the recommendations in order to avoid confusion
Anonymous 4		Oral thrush; Oral Thrush is a minor condition that can be treated without the need for a GP consultation or prescription in the first instance. It is common in babies and older people with dentures or those using steroid inhalers. It can easily be treated with over the counter gel. So what gel is that? Presumably Daktarin Oral Gel 15g - not withstanding potential drug interactions, a patient would have to buy at least 5 tubes to fulfil the CAS/licenced dose advice of continuing for 7 days after treatment. That's about £30 minimum unless we flout the *"CAS is not intended to be viewed as a "free medicines supply" service"* advice and drag the patient through CAS to give a PGD supply of the POM - (actually its one of the few places that CAS is useful). Plus under the CAS we can only treat those who have *"an obvious precipitant such as recent broad -spectrum antibiotics, inhaled steroids, dentures or diabetes"* - all others are excluded under the PGD.
Anonymous 18		Patient exceptions to include not getting better with standard therapies. I say this specifically as this may be an indication of another underlying immunosuppressive illness.
Anonymous 22		Toothpastes with ~1,500 parts per million fluoride are not typically described as 'high fluoride', as this is the norm for family toothpastes. 'High fluoride toothpastes' is a description usually reserved for toothpastes with 2,800 or 5,000 ppm fluoride, which

		are only available on prescription. To our knowledge there are no toothpastes with a fluoride concentration around ~1,500 ppm in the BNF, therefore we are concerned that this recommendation does not provide clear guidance to prescribers.
Anonymous 4		Dental caries; Most high fluoride toothpastes are prescription only medicines and so this condition would be excluded
Anonymous 20	Explanation 1st sentence	This is worded as being aimed at patient – not appropriate in this document
Anonymous 5		Head & neck cancer patients - ? exemption
Anonymous 16		The comments re high fluoride tooth paste (2800ppm and 5000ppm) could be clearer as only available on prescription and prescribing these formulations is being promoted as good practice mainly for adult patients with high caries rates or where prevention is of paramount importance. Normal strength toothpaste (1450ppm) is bought over the counter and not prescribed as far as I am aware. Most prescriptions will be issued by dentists with the exception of the circumstances we covered previously when a doctor may be asked by a consultant to prescribe high fluoride toothpaste for instance after head and neck cancer therapy.
Anonymous 20	Explanation 2nd paragraph Final sentence	Agree 'they' (ringworm and athlete's foot) are contagious but you only need to 'practice good foot hygiene' if you have athlete's foot
Anonymous 7		There seems to be a confusion of irritant dermatitis and allergic contact dermatitis. It also contradicts recent NICE guidelines (July 2018).We are concerned that chronic conditions which have not responded to over the counter prescriptions should be included. We also consider that insufficient consideration has been given to severe conditions which might impact on schools etc if it spreads e.g. head lice or ringworm. This illustrates the point made under p 5 above *[see section 3.0 Self Care]*.
Anonymous 18		These diseases are both fungal infections and treated with the same range of drugs. Scalp fungal infections in children could become epidemic in schools in less affluent parts of the UK, as is seen in some developing countries. It is not often recognised and treated late in children and this can lead to permanent alopaecia. Athlete's foot if untreated predisposes towards cellulitis, a severe bacterial infection of the leg, expensive to treat, which often then becomes a recurrent problem. Recurrent cellulitis results in lymphoedema of the leg which then leads to leg ulceration in the elderly and costs a vast amount of money to treat, with in-patient hospital stays and prolonged courses of antibiotics. Fungal infections are becoming more common as obesity and diabetes increase, particularly in the less affluent British population. Failure to treat the diseases of obesity would lead to longer term costs. It is relatively low cost to treat fungal infections. Failure to recognise and treat them is leading to severe sequelae which are expensive.
Anonymous 22		Guidance published by the MHRA on the 13th December '18 states that 'all oral lidocaine-containing products with an infant teething indication are becoming pharmacy medicines... Pharmacists should only recommend use of these products when local non-medicinal treatments such as a teething ring or massaging the gum have failed to provide sufficient relief.' We therefore recommend adding a sentence, **'Pharmacists should only recommend use of these products when local non-medicinal treatments such as a teething ring and/or paracetamol have failed to provide sufficient relief'**
Anonymous 20		Only teething in babies not mild toothache is in the Common Ailments Formulary
Anonymous 16		I also wish to flag the MHRA recent alert around teething gels. A recent publication by the Drug Safety Update (DSU) identifies

		some potential risks associated with the use of teething gels which contain lidocaine. As a result oral lidocaine products for infant teething can only be sold in pharmacies where advice can be given by the pharmacist https://www.gov.uk/drug-safety-update/oral-lidocaine-containing-products-for-infant-teething-only-to-be-available-under-the-supervision-of-a-pharmacist
Anonymous 20	Explanation 1st paragraph 1st sentence	This is worded as being aimed at patient – not appropriate in this document
	Explanation 2nd paragraph 2nd sentence	This is worded as being aimed at patient – not appropriate in this document
Anonymous 2		The Respondent confines its response to medicines and does not take a view on these items.
Anonymous 9		We agree with the recommendation to advise health boards/trusts that probiotics should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness.
Anonymous 16		This should not be routinely prescribed – change to must not be prescribed
Anonymous 2		The Respondent confines its response to medicines and does not take a view on these items.
Anonymous 20	Patient exemptions	Why are some bullet points in italics?
Anonymous 5		Too many exemptions to clearing understand the spend
Anonymous 9		We agree with the recommendation to advise health boards/trusts that vitamins and minerals should not be routinely prescribed in primary care due to limited evidence of clinical effectiveness.
Anonymous 16		3.2 Vitamins and minerals We feel that this could be expanded to include reference to vitamin D specifically, taking into account guidelines to prescribe maintenance dose vitamin D e.g. Desunin Also include a recommendation about prescribing vitamins for bariatric surgery pts; glucosamine, vitamin b12
Anonymous 15		Patients must not be withheld prescriptions if the healthcare professional feels that one is needed from a treatment and/ or cost perspective.
Anonymous 15		Patients must not be withheld prescriptions if the healthcare professional feels that one is needed from a treatment and/ or cost perspective.
Anonymous 10		It is noted that patient information resources include the NHS England leaflets. It would be helpful if a patient information leaflet could be developed for NHS Wales as part of this document. This should cross reference the common ailments service where appropriate.