Department of Health & Social Care

DHSC Reporting Requirements for Medicines Shortages and Discontinuations

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Introduction:

Medicines supply issues have become an increasingly common problem. The Department of Health and Social Care (DHSC) and the pharmaceutical industry have previously published joint best practice guidelines to help mitigate and manage shortages as and when they arise. In January 2019, this voluntary guidance was superseded by mandatory requirements to provide information about the availability of health service medicines and about discontinuation or anticipated supply shortages under Part 6 of the Health Service Products (Provision and Disclosure of Information) Regulations 2018, hereafter "regulations". These requirements aimed to address the ongoing concerns about medicine supply issues and to ensure that DHSC have relevant information at the earliest point possible to help manage supply shortages and discontinuations and mitigate any potential impacts on patients. Marketing authorisation holders ("MAHs") are expected to be fully accountable for their supply chain to the UK market and required to understand the potential impact on UK patients should supplies of their products become unavailable.

This guidance document provides an overview of DHSC reporting requirements of MAHs for medicine supply issues set out in the regulations and consulted upon with the pharmaceutical industry.

DHSC Medicine supply team:

The Department of Health and Social Care (DHSC) has overall responsibility for ensuring the continuity of the supply of medicines in the UK. The team works closely with the Commercial Medicines Unit in NHS England and NHS Improvement (NHSE&I), who have specific responsibilities relating to many medicines procured for hospital use. Together these teams work closely with the MHRA, the pharmaceutical industry, the devolved administrations and others operating in the supply chain to help prevent shortages and to ensure that the risks to patients are minimised when they do arise. When notified of an impending issue, the team will conduct a thorough risk assessment taking account of:

- Nature of the problem
- Anticipated duration of the issue
- Indication (licensed or unlicensed)
- Usage figures (primary and secondary care)
- Estimated market share
- Availability of supply from alternative MAHs of the same product
- Clinical need / guidance
- Availability of clinical alternatives

If an issue is likely to have the potential to impact on patient care, the team will work with companies and other relevant stakeholders to help resolve shortages, for example, by:

- Supporting the expedition of regulatory procedures for products deemed critical

- Working with companies to manage supply of existing stocks
- Identifying and liaising with other manufacturers to increase production of the product concerned and/or clinical alternatives
- Commissioning clinical advice from national experts regarding potential management options
- Identifying sources of product from abroad, and supporting with expediting import for individual patient use
- Advising and facilitating communication within the NHS.
- Escalating, where appropriate to the Medicines Shortages Response Group (MSRG); a multi-disciplinary advisory body who provide oversight and provide support with management and communication plans (further information on MSRG can be found in Annex 1)

Each supply problem has its own characteristics and has to be dealt with on a case-by-case basis. It is important that all stakeholders work together to ensure that a shortage of a product does not cause unnecessary problems for patients and prescribers. Early notification of an issue allows more time for the management options to be considered. Further information about the DHSC medicine supply team and key stakeholders can be found in Annex 1.

What are the responsibilities of the supply chain in relation to ensuring appropriate and continuous supply?

MAHs of medicinal products must take all reasonable steps to ensure appropriate and continued supplies to pharmacies and persons authorised or entitled to supply medicinal products so that the needs of patients in question are met[1]. MAHs are expected to continuously monitor the supply and demand situation of medicinal products. MAHs are expected to develop and maintain resilience in the supply chain and they are expected to develop shortage prevention and response plans. MAHs are advised to utilise current guidance developed by professional organisations (e.g. ISPE Drug Shortages Prevention Plan, Risk-Based Approach for Prevention and Management of Drug Shortages) to reduce the risk of medicine shortages occurring. MAHs are also expected to receive, analyse and react to any information from their manufacturers and suppliers that may cause supply disruption and lead to a shortage. Manufacturers and wholesalers must also ensure, within the limits of their responsibilities under their licences, appropriate and continuous supply of medicinal products to pharmacies and other persons authorised to supply them[2].

Relevant parts of the Health Service Products (Provision and Disclosure of Information) Regulations 2018

A full copy of the Health Service Products (Provision and Disclosure of Information) Regulations 2018 can be found here: http://www.legislation.gov.uk/uksi/2018/677/contents/made

There are several parts of the Regulations which are relevant to medicines shortages and discontinuations. However, the following two regulations in Part 6 are of particular relevance; regulation 28: Provision of information about availability of health service medicines and regulation

[1] Regulation 78 Human Medicines Regulations 2012/1916
[2] Regulation 43 Human Medicines Regulations 2012/1916

29: Requirement to provide information about discontinuation or anticipated supply shortage of certain health service medicines.

As you are aware, following notification of an anticipated supply shortage or discontinuation, the DHSC medicine supply team will conduct a thorough risk assessment of the issue (see Annex 1). As part of this assessment, the team will need to quickly understand how much stock is available in the market from other suppliers. Where the team is dealing with a sole supplier product or they have already concluded that there is insufficient stock of a product to meet normal requirements (based on primary and secondary care usage data), the team may start to investigate the supply situation for possible clinical alternatives.

Part 6 – Regulation 28: is relevant to information that DHSC may request from companies when there is a supply shortage of a particular presentation of health service medicine3.

Under regulation 28, DHSC may by notice in writing require a manufacturer, a wholesaler or an importer of the particular medicine to provide:
the quantity (if any) of packs of the relevant presentation that is available for supply by the producer, and
the quantity (if any) of any alternative presentation that is available for supply by the producer.

In practice, the medicine supply team would be likely to contact the registered MAH(s) for this information. A company must comply with a regulation 28 information request within 2 working days, regardless of their stock position. Companies that have an active marketing authorisation (MA), but do not currently market the product, may be sent an information request and they should indicate whether they are able to, for example, divert stock from another market or recommence manufacturing.

Regulation 28 reads as follows:

Part 6- Regulation 28: Provision of information about availability of health service medicines

28.—(1) This regulation applies where the Secretary of State considers that there is a supply shortage of a presentation of health service medicine (the "relevant presentation").
(2) Where this regulation applies, the Secretary of State may by notice in writing require any of the following to provide the information mentioned in paragraph (3) about the relevant presentation—
(a)a manufacturer of the presentation,
(b)a person who distributes the presentation (whether by wholesale dealing or otherwise), or
(c)an importer of the presentation.
(3) The information is—
(a)the quantity (if any) of packs of the relevant presentation that is available for supply by the producer, and
(b)the quantity (if any) of any alternative presentation specified in the request that is available for supply by the producer.
(4) A producer who is given a notice under paragraph (2) must comply with the request within the period of two working days beginning—
(a)with the day on which producer is given the request, if that day is a working day;
(b)otherwise, with the first working day after the day on which the notice is given to the producer.

[3] This term is defined in Paragraph 2 of Schedule 1 to the 2018 Regulations

(5) In this regulation, "alternative presentation", in relation to a relevant presentation, means a presentation of health service medicine which is used as a therapeutic alternative to the relevant presentation.

Part 6 – Regulation 29: is relevant to information that manufacturers and importers of health service medicines (other than medicines which are parallel imported) must submit to DHSC if they are aware of an impending supply shortage of a presentation of health service medicine[4] that has the potential to impact patients who take, or may need to take, the medicine. This regulation also applies to companies planning to discontinue the manufacture or supply of a presentation and they consider this could have an impact on patient care. The information to be provided is listed in regulation 29(2) (see below). It must be provided to the DHSC medicines supply team at least six months prior to the shortage or discontinuation happening, or where this information is not available six months in advance, it must be provided as soon as reasonably practicable after the producer makes the decision to discontinue or becomes aware that there may be a supply shortage. Regulation 29 reads as follows:

Part 6- Regulation 29: Requirement to provide information about discontinuation or anticipated supply shortage of health service medicines

29.—(1) This regulation applies where a designated producer of a notifiable presentation—
(a)intends to discontinue the manufacturing or supply of the presentation and considers that this is likely to have a direct impact on any patient who takes, or may need to take, the presentation for the prevention or treatment of a physical or mental illness, or

(b)considers there is likely to be a supply shortage of the presentation which will have a direct impact on any patient who takes, or may need to take, the presentation for the prevention or treatment of a physical or mental illness.

(2) Where this regulation applies, the designated producer must provide the following information to the Secretary of State—
(a)the name of the presentation,
(b)the reasons for which the manufacturing or supply is to be discontinued or, as the case may be, the producer considers there is likely to be a supply shortage,
(c)the quantity of the presentation which the producer has available for supply,
(d)where the producer considers there is likely to be a supply shortage—
(i)the anticipated duration of the shortage;
(ii)any steps taken by the producer to address it,
(e)the producer's estimated share of the market,
(f)whether the presentation is made available under an NHS framework contract, and
(g)the name and contact details of a representative of the producer.
(3) The information must be provided—
(a)where the producer intends to discontinue the manufacturing or supply of the relevant presentation—
(i)at least six months before the day on which the manufacturing or supply will cease, or
(ii)where the decision to discontinue the manufacturing or supply is made less than six months before the day on which manufacturing or supply will cease, as soon as reasonably practicable after the producer makes the decision;

[4] Notifiable presentation is defined in regulation 29(4)

(b)where the producer considers there may be a supply shortage of the relevant presentation—
(i)at least six months before any anticipated impact on any patient who takes the presentation is realised, or
(ii)where the producer becomes aware of the likely supply shortage less than six months before the producer considers any anticipated impact will be realised, as soon as reasonably practicable after the producer becomes aware that there may be a supply shortage.

(4) In this regulation—
"notifiable presentation" means a presentation of health service medicine in respect of which a marketing authorisation has been granted other than a presentation of such medicine in respect of which a parallel distribution notice(1) with the United Kingdom as the Member State of destination has been given;
"designated producer", in relation to a notifiable presentation, means—
(a)the UK producer who holds the marketing authorisation for the presentation, if that producer manufactures the presentation;
(b)otherwise, a UK producer who manufactures the presentation or imports the presentation and supplies it by way of sale;
"marketing authorisation" has the meaning given in regulation 8(1) of the 2012 Regulations.

Who is responsible for reporting this information?

Each company should nominate a person, with a designated deputy, as the contact point for supply issues. Nominated persons will be responsible for notifying the DHSC under regulation 29 and responding to information requests under regulation 28. They should be sufficiently senior to have an overview of the supply situation for any particular product and have direct contact across the organisation with key teams who can provide updates on the product in question e.g. regulatory teams. Companies are invited to provide DHSC with the contact details of the nominated person as soon as possible so that we can update our internal record.

What do we mean by a supply shortage under regulation 28 and 29?

A supply shortage of a presentation of health service medicine occurs when supply does not meet patient demand at national level.

What do we mean by a discontinuation under regulation 29?

A discontinuation of a health service medicine occurs when a manufacturer or importer of the presentation intends to permanently stop supplying a product to the UK market.

Likelihood of there being an impact on patients for the purposes of the information requirements in regulation 29?

A manufacturer or importer of a particular presentation of a health service medicine is expected to know when an anticipated supply shortage or discontinuation would be likely to have a direct impact on patients. This requires knowledge of their markets and routinely monitoring scheduled

deliveries against forecast demand. Examples include: a presentation not being available for patient access at the point of dispensing, a patient having to switch to an alternative formulation of their medicine/a substitute or a patient's health deteriorating as a result of missing their dose. The sooner DHSC is made aware of anticipated supply disruptions, the more time the medicines supply team will have to work through management options. DHSC is aware that companies normally carry at least 2 weeks of buffer stock, so we anticipate that supply shortages of 2 weeks or less would be unlikely to have a direct impact on patients. We would suggest companies should report an issue, therefore, if any of the following examples apply:
If a manufacturer or importer of the presentation is unable to supply the UK market for more than two weeks and has held a market share above 20% for the last three months of market supply
If a manufacturer or importer of the presentation has a market share above 20% and wishes to temporarily cease supply to the UK market for more than two weeks due to commercial reasons
If a manufacturer or importer of the presentation is the sole supplier of the product in the UK and unable to supply the UK market for more than two weeks

The above examples are illustrative only and we would encourage manufacturers or importers to approach the medicines supply team to discuss individual circumstances if they are unsure whether the requirement to provide information under regulation 29 applies.

Should companies consider the therapeutic indication?

Although companies are responsible for reporting all medicine shortages and discontinuations regardless of the product's perceived criticality or the availability of alternative medicines, we do also expect companies to consider the therapeutic indication and potential patient groups that will be affected when assessing the impact that a supply issue may have on a patient. We advise that manufacturers should be particularly vigilant if:

There are no or limited clinical alternatives
The process of switching a patient over to a therapeutic alternative and the required monitoring may have a detrimental effect on the patient for example, additional blood tests or new adverse reactions being experienced as a result of a new drug
The medicine in question is one where the MHRA states that a patient should be maintained on the same brand of a drug for example category 1 and 2 anti-epileptic drugs
Where the medicine is used in life saving conditions such as anaphylaxis
If the patient group affected is likely to be a vulnerable population such as neonates, paediatrics, the elderly, mental health patients, oncology patients and people with learning disabilities where the supply issue has a potential risk for public health e.g. vaccines

How should the regulation 29 information be notified?

Previously, MAHs will have reported impending shortages or discontinuations by completing information on a spreadsheet and submitting these to the relevant DHSC email addresses.
In October 2020, this process was superseded by the Discontinuation and Shortages (DaSH) reporting portal. All discontinuation and shortage notifications should now be submitted via the DaSH reporting portal which is available via:

https://report-discontinuations-shortages.service.dhsc.gov.uk

If not already done so, MAHs can register for DaSH reporting portal access by contacting:

DASH@dhsc.gov.uk

New MAHs must share their company information plus relevant contact details for their first two admin users to be set-up to use DaSH. A form can be found here for sending the required information to DHSC.

Annex 2 contains all of the required information which should be completed by the company's nominated contact and submitted via DaSH.

What happens to the information that is submitted?

DHSC Medicines Supply Team will acknowledge receipt of the information submitted and conduct a thorough risk assessment in order to determine the potential impact and management options (see Annex 1). Companies may be approached for further information.
DHSC recognises that the information submitted is confidential and commercially sensitive and must be handled in accordance with the statutory restrictions on disclosure in s264B of the National Health Service Act 2006.

ANNEX 1: Department of Health and Social Care Medicines Supply Team

Introduction

Our team in DHSC deals specifically with medicine supply problems, both in the community and hospitals. We work closely with the MHRA, the pharmaceutical industry, NHS England and Improvement and others operating in the supply chain to help prevent shortages and to ensure that the risks to patients are minimised when they do arise.

The following document provides an overview of our team and our processes. It also provides information about supply issues as well as an insight into how we are notified and how we assess and manage shortages. It concludes with some examples of the ongoing strategic work that we are undertaking and some work streams that we are hoping to undertake in the future.

Further information can be found at here. Please note, this guide is aimed at healthcare professional and only covers national, secondary care and primary care processes for managing medicines shortages in the NHS in England. Although devolved administrations are not directly within the scope, the document includes some information on DHSC's information sharing with the devolved administrations.

Background

The production of medicines is complex and highly regulated, and materials and processes must meet rigorous safety and quality standards. Difficulties can arise for various reasons, from malfunctioning equipment on the production line, to packaging materials that fail to meet the required specification. Sometimes batch failures occur for no obvious reason, necessitating a thorough investigation to get to the root of the problem. All of these can lead to shortages of medicines. Shortages can also arise due to difficulties in obtaining raw materials, or from an imbalance between supply and demand. If one manufacturer has a supply problem, it can have a knock-on effect on companies of other similar products.

The globalisation of the pharmaceutical industry means that medicines are often manufactured in just one or two sites worldwide. Production schedules have to be planned months in advance and this along with the move to "just in time manufacture" to reduce the cost of stockholdings, means that there is little flexibility in the system when problems do arise. Due to the global nature of many of these issues, in a shortage situation the UK may have to compete for limited supplies of medicine in the global market.

Occasionally sudden changes in prescribing practice, particularly if implemented across several regions or nationally, can cause supply problems if not discussed in advance with the companies involved. They will have forecasted production based on historic demand several months in advance and will be unlikely to have significant reserves of their products if not alerted to a potential change well in advance.

All of this means that some supply problems with medicines are relatively common.

Risk Assessment and Management

Once notified of an issue we will then carry out a thorough risk assessment in order to determine the potential impact and therefore what type of management options we should deploy to manage the issue. Our risk assessment will take into account several factors including the nature of the problem, the expected duration of the issue, the volume of usage of the product / estimated market share and the indication (both licensed and unlicensed) for the product.

The sooner we are notified of an issue the better as there will be more options available for its management. We will use a host of tools to help mitigate and manage any issues which might include working with the MHRA to expedite regulatory procedures, working with manufacturers to manage remaining supplies and expedite the delivery of further stock, working with alternative MAHs to meet additional demand, commissioning clinical advice on alternative options from specialist groups and in some cases working with specialist importer companies to obtain unlicensed products from abroad. Where secondary care medicines are affected, we will work through this management plan in close collaboration with the CMU team and will also work closely with the regional procurement specialists to seek their advice on potential management options.

DHSC may also seek the support of the Medicines Shortage Response Group (MSRG), an advisory body consisting of a multi-disciplinary group, including clinicians, with members from across DHSC, NHSE&I, the Devolved Administrations and the wider NHS. The MSRG supports the DHSC Medicines Supply Team and the NHSE&I Commercial Medicines Unit with the management of supply issues that are categorised as high impact (Tier 3) or critical (Tier 4) medicines supply issues. MSRG also provides advice on issues categorised as Tier 1 or 2 when requested. Further information on our classification of tiers can be found here.

MSRG also advises on whether the development of a Serious Shortage Protocol (SSP) would be beneficial to help mitigate a shortage and provides a recommendation to the National Medical Director and Chief Pharmaceutical Officer on this basis. The National Medical Director and Chief Pharmaceutical Officer then provide the final recommendation to Ministers.

An SSP is an additional tool to manage and mitigate medicine and medical devices shortages. Protocols are developed with input from expert clinicians but are only considered in exceptional circumstances.
An SSP enables community pharmacists to supply a specified medicine or device in accordance with a protocol rather than a prescription, with the patient's consent and without needing to seek authorisation from the prescriber. An SSP is only used in certain cases where, in the opinion of Ministers, it would help manage the supply situation and if clinicians advising Ministers think it is appropriate.

The diagram below summarises some of the routes through which we are notified, the types of information we take into account for our risk assessments and then the various management options which we might choose to use.

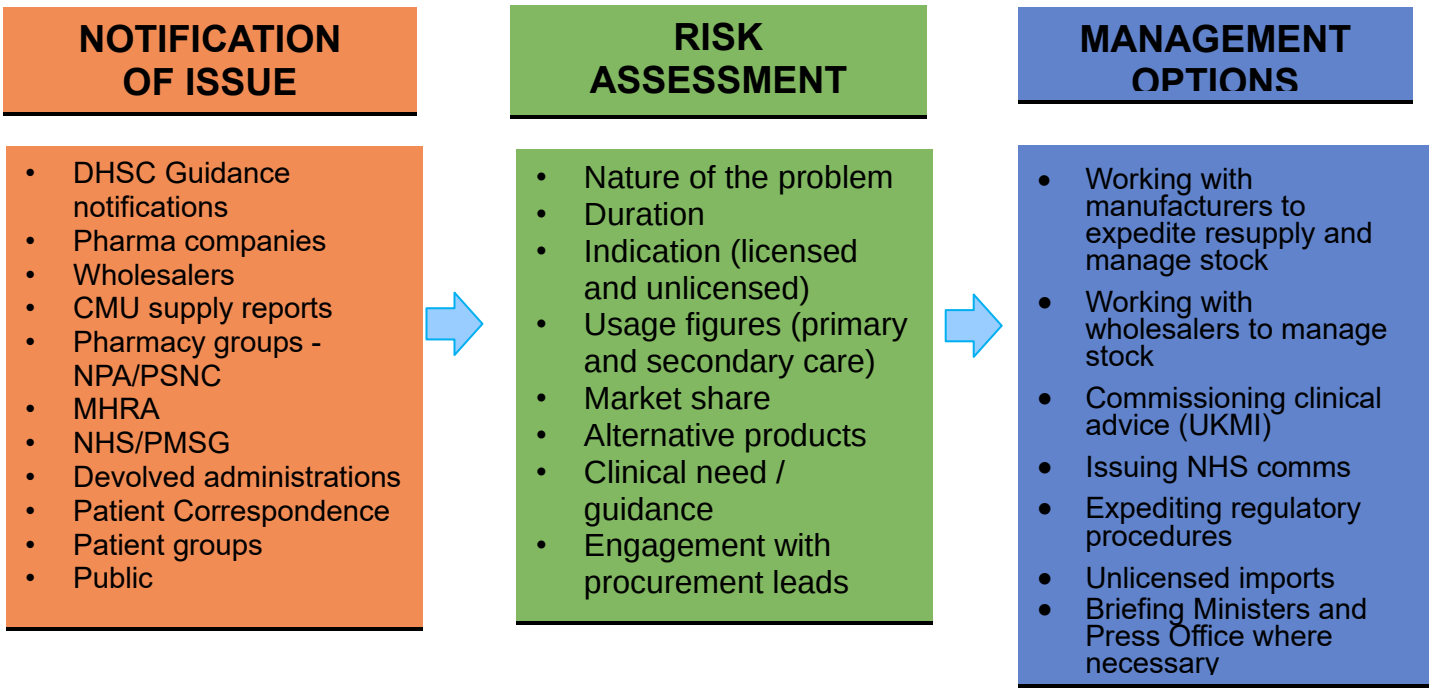

Figure 1 – Some examples of notification routes, risk assessment information and potential management options

Communication

Every shortage is different, and the type of communication will depend on a number of factors such as whether the product is mainly used in primary or secondary care, the potential duration of the shortage, the availability of equivalent or similar alternatives and the criticality of the shortage in terms of impact on patients. We work closely with companies and others in the supply chain in these situations to provide advice on whether / how best to communicate a supply problem.

In some cases, for example, the company will send a “Dear Healthcare Professional” letter to affected clinicians and pharmacists, while in others, a note in the pharmaceutical/ trade press might be sufficient. In most cases, companies alert the wholesalers and other customers when a product is unavailable.

The timing of any communication on shortages is critical. The supply situation for a product can sometimes change very quickly and there can be little or no time to give advanced warning. In other cases, if advance warning of a potential shortage is given, it can encourage panic buying and can precipitate the very problem that everyone is trying to avoid.

In order to communicate messages about supply issues, we have good working relationships with several networks and groups. For secondary care, we use established networks through the CMU networks to cascade messages to regional procurement leads and Trust Chief Pharmacists, who will then disseminate these messages locally. For primary care we have recently improved our communication routes into this sector. We are now able to reach all community pharmacies and GP practices via NHSE/I networks, and over 200 Clinical Commissioning Groups via the PRESQIPP network.

To extend the reach and accessibility of important information we upload relevant updates and information on individual issues to the Specialist Pharmacy Services (SPS) website, which NHS staff can access.

We also work closely with specialist clinical groups, including the Advisory Committee on Antimicrobial Prescribing, Resistance and Healthcare Associated Infection (APRHAI) group, the Paediatric Expert Reference Group via the MHRA and many others when the issue necessitates this. Furthermore, we have established links with the National Patient Safety team at NHSI and will discuss any relevant issues and cascade communications via their Medication Safety Officer (MSO) network.

We have good links with the Devolved Administrations and ensure that relevant issues are communicated to them as appropriate.

Contact Details:

Previously, MAHs will have reported impending shortages or discontinuations by completing information on a spreadsheet and submitting these to the relevant DHSC email addresses.
In October 2020, this process was superseded by the DaSH reporting portal. All discontinuation and shortage notifications should now be submitted via the DaSH reporting portal.

For matters not related to the reporting of shortages or discontinuations please contact the Medicine Supply Team using the email address below:

DASH@dhsc.gov.uk

For issues with the portal, users should notify one of their company's registered administrators. If the issue is a genuine error or outage of the portal, there are instructions in the DaSH MAH Administrator Manual on how to mark technical issues and direct to: DASH@dhsc.gov.uk

ANNEX 2: REGULATION 29 INFORMATION REQUIRED

The following information is required;

- Name of Producer
- Name and contact details of Producer's nominee
- Shortage/Discontinuation
- Name of the presentation
- Reasons for which the manufacturing, or supply, is to be discontinued or there is likely to be a supply shortage
- The quantity of the presentation which the producer has available for supply
- Date of expected discontinuation or supply shortage
- Anticipated duration of the shortage
- Any steps taken by the producer to address it;
- The producer's estimated share of the market
- Whether the presentation is made available under an NHS framework agreement

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Medicines and Pharmacy Directorate

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