



by the Pharmacists' Defence Association

Response

to General Pharmaceutical
Council Fees Rules Consultation

August 2010

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The response of the Pharmacists' Defence Association (PDA)

The Pharmacists' Defence Association (PDA) is a not for profit organisation which is a defence association and a union for pharmacists. The aim of the PDA is to act upon and support the needs of individual pharmacists and, when necessary, to defend their reputation. PDA currently has more than 15,000 members.

The primary aims of the PDA are to;

- Support pharmacists in their legal, practice and employment needs.
- Provide insurance cover to safeguard and defend the reputation of the individual pharmacist.
- Provide representation for its members.
- Proactively seek to influence the professional, practice and employment agenda to support members.
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care.
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists.

The views expressed in this consultation response are those given by more than 600 members of the PDA in a survey carried out in one week in July 2010, supplemented by an expert group of pharmacists, lawyers and barristers to ensure appropriate context. We believe that the views expressed by the PDA most accurately reflect those of the practising pharmacist and as such deserves serious consideration.

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Executive summary

The PDA is arguably the organisation that best represents the views of pharmacist registrants. The RPSGB has been overly influenced by the corporate multiples who express the voice of their shareholders not of their pharmacist employees. The GPhC, as a new organisation, has the chance to renew its relationship with the individuals that it regulates.

In due course the Council for Healthcare Regulation (CHRE) will come under pressure to reduce the cost and increase the effectiveness of regulation by merging professional bodies; the future of a separate GPhC will depend on the support of the profession and the public and this will not be achieved by promulgating the practices of the RPSGB. We believe that the GPhC is in danger of missing this opportunity to review its activities and by doing so change its processes and cost structures.

We believe that addressing underlying issues and redesigning business processes would result in different priorities for the GPhC and a very different fee structure.

Summary response to question 1

We do believe that the level of premises fees should reflect the cost of regulation but we further believe that premises should be subject to more exacting standards and a higher level of scrutiny.

In our experience the environment and quality and quantity of the workforce plays a substantial part in most incidents but this is generally not taken in to account in any investigation. In our view addressing the issues of outdated premises, flawed working practices and inadequate staff levels would decrease the risk to patients and thereby reduce the number of incidents and the cost of subsequent investigations.

This is likely to require higher fees for renewal of premises registration.

Summary response to question 2

We do not accept that pharmacy should bear the cost of controlled drug inspection and monitoring. We believe that the process of inspection and monitoring of controlled drugs distracts inspectors from their prime purpose in visiting premises – that of ensuring that standards are adequate.

Summary response to question 3

We do believe that fees should be more closely aligned with the cost of regulation but we do not accept the rationale that has resulted in the proposed levels of fees.

Technician registration is relatively new and for that reason few fitness to practice cases have been brought against technicians. The compulsory registration of technicians from 2011 coupled with the guidance issued by the Crown Prosecution Service will result in a substantial increase in the number of cases involving technicians. We believe that the proposed differential between pharmacists and technicians is too high.

We believe that the standards for premises have been allowed to become outdated and far too lax. Proper protection of the public requires more exacting premises standards and a tighter regulatory regime. For these reasons we believe that using historical cost structures is misguided and will merely promulgate what has gone before; premises fees will need to be raised if the underlying issues that lead to incidents are to be tackled and patient safety enhanced. In addition, improved premises standards can only benefit the image of pharmacy in the eyes of the public.

Summary response to question 4

We do not agree that a low income fee should not be offered. Over 84% of our members who responded to our survey wanted the low income fee to remain. The value to the profession of the part time pharmacists who qualify for a low income fee must not be underestimated and the GPhC should not risk losing these pharmacists by removal of the reduced fee.

If fewer than 50% of applicants qualify for the reduced fee the application process needs to be looked at.

Summary response to question 5

We do not agree with the level of additional fee for those who want to pay by quarterly direct debit.

Our members do want the option to spread payments but believe that a £20 additional fee is too high.

Summary response to question 6

Reserves

We are concerned that the plan to build up reserves is flawed, is not transparent and does not fall evenly over all categories of renewal.

Reserves are not the best way to guard against the cost of defending a High Court case. Insurance is both cheaper and more flexible.

The effect of the levy to build up reserves is not transparent; there is no clarity about the absolute amount or percentage of fees that will be allocated to reserves.

However it is clear that no allowance for the build up of reserves has been applied to the premises fee which merely reflects last years fee plus inflation and the controlled drugs levy. This is inequitable and must be rectified.

The level of fees

The level of fees set for pharmacists is too high. Pharmacists are subsidising the regulation of technicians and paying the price of inadequate regulation of premises. Furthermore there is no evidence of business process re-engineering which should drive out costs and prepare the GPhC for having to part-fund the CHRE.

Preamble

The RPSGB is the professional regulator and leadership body combined and as a result of its registration and regulatory responsibilities, membership is compulsory if potential registrants wish to use the name of, and practice as, a pharmacist; however its pan-pharmacy role makes it difficult for it to represent any one group fully and as firmly as may be required.

Other well known pharmacy organisations represent the owners and contractors and represent the views of their shareholders; they do not reflect the views or values of the pharmacists employed in their members' branches.

The PDA currently provides the most authoritative voice of the profession of pharmacy as represented by the pharmacists who comprise the profession. Pharmacists join the PDA by choice, recognising the value that is provided to them through the services we offer and we are the largest of such organisations by some way.

As we have said before in our various submissions we believe that the establishment of the GPhC is an opportunity to look at the way that the profession is regulated. It is the opportunity to produce something that is a model for healthcare regulation and that is sufficiently flexible to cope with a rapidly changing healthcare landscape. This fees rules consultation gives another demonstration of how that opportunity is being missed.

A new organisation has the opportunity to look at what it needs to do; how it needs to fulfil those functions; and how it can do so at the best possible cost. It cannot do this by simply promulgating the activities and processes of the body that preceded it. However the fees rules demonstrate that this is exactly what has been done. The consultation document claims that fees are proportionate to the cost of regulation but the evidence that the philosophy has been followed is scant; some fees are transparently based on this years RPSGB figures. For example premises fees are clearly last year plus 2.5% for inflation, plus £45 for controlled drugs inspection; the relative level of pharmacist and technician fees reflect a history of unregulated technicians and do not anticipate changes in working practices or legislative guidance; and the level of all fees reflect the lack of any business process re-engineering

The government's decision to separate the CHRE from the DH will result in additional costs being borne by the different regulatory bodies overseen by the CHRE. They will have to fund that cost either out of operational savings or additional charges on their registrants. We believe that the GPhC must take the former route and minimise any additional cost to its members.

Over time the RPSGB has lost the confidence of its members who have become cynical about its ability to apply regulation fairly and efficiently. Our survey revealed that our members are hopeful that the GPhC will perform better than the RPSGB but are prepared for disappointment. We believe that it is essential that the GPhC demonstrates its value to the profession and must engender the trust and confidence of those it regulates. If it fails to do so, pressure to reform the regulatory regime, perhaps through merger of regulatory bodies, will grow.

Further, the regulator must have the confidence of the public – the people it is intended to protect. We have substantial evidence that the public are concerned that the current pharmacy regulator has pursued the individual pharmacist and has not addressed the root cause of many errors – the working environment. Our evidence demonstrates that the public are well aware that pharmacists are often working under intolerable pressure in often inadequate working conditions and they fail to see why employers are not held accountable. The GPhC must demonstrate that it has the insight and courage to address these issues or it will lose the confidence of the public and pressure on the CHRE to reduce costs and increase effectiveness will grow.

We believe that a dedicated regulator for pharmacy should be of benefit to pharmacists and technicians but this needs to be proved to both the public and the profession. This can only be done by doing things differently to the RPSGB and addressing the true underlying issues. This must be reflected in the cost of renewal for pharmacist, technicians and premises.

Response to consultation questions

Question 1.

Do you agree with the principle that the premises fees we set should cover the costs associated with the regulation of pharmacy premises?

- Agree
 Disagree
 Unsure

Comments:

We agree with the principle that the level of premises fees should cover the cost associated with regulation and inspection of premises but are concerned that the GPhC does not have the necessary framework or skills within the inspectorate to provide the level of scrutiny to satisfy its role in protection of patients.

Every year the PDA advises, represents and defends many pharmacists who are investigated under the RPSGB disciplinary processes. The default position for the RPSGB is to pursue the pharmacist judged to be in a position of accountability in all circumstances where an untoward incident has occurred. In our experience the environment and the working practices in the pharmacy are generally a significant underlying causative factor but these are most often ignored in the investigation. For example, the PDA submitted a complaint to the RPSGB about the working conditions in the branch of a large pharmacy multiple. The complaint included a detailed analysis of the contribution that the environment and staff policies played in the cause of an incident. The response from the RPSGB was as follows

"You anticipate that our investigation will resolve a number of broad professional issues regarding the employer's responsibilities and good working practices.

We do not deny that such issues are a concern and do need resolving, but we do not believe that the inspectorate and the RPSGB's fitness to practice process are the right and appropriate instruments in achieving the outcome that you hope for". It is significant that the RPSGB did not specify what would be the "appropriate instrument".

The refusal to take seriously the importance of environment follows through in to the decisions resulting from the investigation which rarely focus on rectifying the true cause but concentrate on the punishment of the individual. Thus issues inherent in the system are not addressed and unsafe working practices are perpetuated and ingrained.

The PDA is also increasingly involved in disputes between pharmacists and employers over Responsible Pharmacist regulations with respect to premises. Pharmacists are required to use their professional judgement in assessing whether premises standards, staff levels, staff competence or working practices meet with acceptable standards. However when they do so and request for shortfalls to be remedied they are frequently subjected to hostile reaction by line management, intimidation to attempt to make them back down, and disciplinary action if they persist in attempting to address issues that they believe impact on patient safety. (Q1 continued overleaf)

(Q1 continued)

The current inspection regime concentrates mainly on the inspection of Controlled Drug procedures and registers and pays scant attention to more general standards and working practices. Where inspectors do take a more general approach their ability to act is limited by the quality of the standards as applied to premises and working practices. Premises may meet minimum standards but may fall well short of providing adequate working facilities; standard operating procedures (SOPs) may be in place and follow the required format but fail to provide the optimum processes for that pharmacy; staff levels may meet those set in the contract but fail to be adequate to provide an acceptable level of support over the course of a day or week; and staff competences may be inadequate for the range and volume of services provided. These are matters with which the pharmacists at the operational face of the profession are all too familiar, but that the regulator has so far been unwilling to address.

The inspection regime should take in to account all of these factors and view each pharmacy on its own merits. Corporate design parameters cannot be allowed to take precedence over providing a pharmacy of adequate size and layout to meet local circumstances. Similarly corporate SOPs and staff policies must not be allowed to override local conditions and requirements.

Premises standards and inspection regimes must be designed to deliver operating environments that enable pharmacists and pharmacy staff to operate safely and effectively such that the contribution of the environment to individual and system stress is removed. Premises fees should reflect the cost of establishing and maintaining such a system not just perpetuating the status quo. It is likely that higher fees for premises would result but this should enhance patient safety and reduce the number of untoward incidents.

Question 2.

Do you agree with the proposed increase in premises fees which will enable us to apply a consistent approach to Controlled Drug monitoring in Great Britain?

- Agree
 Disagree
 Unsure

Comments:

The RPSGB took over the monitoring controlled drugs from the Home Office in 2007. The rationale at that time appears to have been to reduce the number and variety of inspectors who had a right of access to pharmacies. The RPSGB received funding from the Home Office to carry out the necessary tasks.

We fail to see why Home Office funding should be withdrawn and why pharmacy should bear the cost of monitoring of controlled drugs at this or any other time.

Controlled Drugs (CD) legislation and regulation are under the purview of the Home Office. As such the Home Office should be accountable for monitoring controlled drug use and it should continue to fund these activities. If the Home Office were to re-assume the duties on monitoring it would incur some cost. If it wishes to subcontract these activities to another agency it should pay. To expect pharmacy to pay is unrealistic.

It may appear to make some sense to combine them with the pharmacy inspection regime. However this must not be to the detriment of establishment, inspection and maintenance of premises standards (see response to Q1 above). Our observation of recent inspection visits is that most concentrate on the CD aspects almost completely with scant attention being paid to the broader working environment. We believe that this has been detrimental to the maintenance of adequate working conditions within pharmacies.

Question 3.

Do you agree with our intention for the fees we set to be more closely related to the cost of the activity?

- Agree
 Disagree
 Unsure

Comments:

The differential between pharmacists and technicians

In general we would agree that fees should be aligned to the cost of an activity. Furthermore the rationale for all fee structures should be clear and transparent to all. In this respect we do not understand some of the levels of fees or the differences between pharmacists and technicians.

We understand the difference between the costs of scrutiny; an EEA pharmacist application will have been received education and training under a known and accredited system. Qualifications for technicians are less well structured and should be subject to greater scrutiny.

The costs of application for pharmacists and technicians should be the same as the processes should be identical.

However we fail to see why the cost of initial entry on to the register or renewal should be so much higher for pharmacists than they are for technicians. We note that "*The Council considers that it is appropriate to maintain a differential between renewal fees for pharmacists and pharmacy technicians, bearing in mind current indications of the levels of practice risk associated with the two professions as reflected in the small number of fitness to practise cases involving pharmacy technicians received by the RPSGB to date*". However we believe that the differential is too great.

The current regime reflects the regime that automatically pursues the pharmacist wherever there is an incident that is referred for investigation. The pharmacist is always deemed to be **accountable** for an incident even if they are not actually **responsible** for the incident. The fact that technicians have not been the subject of investigation reflects in part the relative "newness" of technician registration but more importantly, that the role of the full pharmacy team has not been properly considered.

Voluntary registration of technicians is a recent innovation and it does not become compulsory until 2011. The regulator has no jurisdiction or powers over non-registered staff and could not investigate any incident involving a technician or issue any sanction against them.

The fee levels set for pharmacists and technicians reflect the old way of thinking and we are disappointed that this will be promulgated in the GPhC. We believe that there is no justification for believing that the likelihood of fitness to practice investigations will be any less in number or cost than for pharmacists.

We firmly believe that if incidents were investigated in a more just way the contribution of the pharmacist would be considered within the context of the team and the environment. This would result in a very different cost structure and a more equitable differential between the fees for pharmacists and technicians. (Q3 continued overleaf)

(Q3 continued)

The recent guidance from the Crown Prosecution Service leads us to believe that there will be a substantial increase in the number of incidents rightly citing technicians as having responsibility for errors. The guidance says *"if a person can prove that he or she exercised all due diligence to secure that the (Medicines Act) would not be contravened and that contravention was due to the act or default of another person, he or she has a defence to a criminal charge"*. Thus, in the situation where a pharmacist has carried out a clinical check on the prescription then handed over responsibility for the dispensing, checking and handing out of a prescription to a suitably qualified technician, a technician responsible for an error may find him/herself liable to referral to the regulator or subject to a criminal charge

If the PDA is right in its assumptions about the resources that the GPhC will require to regulate technicians, on review it is unlikely that the GPhC would almost double fees for technicians. The burden would then fall on pharmacists through the fee directly or through the additional levy needed to maintain reserves.

We note that the differential between Optometrists and Dispensing Opticians is much lower. While we recognise that Dispensing Opticians often practise in their own right without supervision from an Optometrist the level of risk that they carry is much lower. Pharmacy technicians do practise in their own right in hospital and as a major part of the team in a community pharmacy; a similar differential would appear to us to be more equitable.

Of the members who responded to our survey 70% accepted that pharmacists should pay a higher fee; however they believed that the differential was too high and expressed a view that a difference of circa £40 would be more acceptable.

The premises fee

In our various submissions to the GPhC we have argued that the regulator must take this opportunity to carefully consider how it regulates the profession in all its aspects. We believe that how premises are regulated needs to be reviewed urgently and radically and that the result would be an increase in premises fees.

An argument that premises are monitored by PCTs under the pharmacy contract has been made. However with the demise of the PCTs we believe that it is essential that the GPhC steps forward to lead a proper regime of professionally led inspection. The implication if it fails to do so is that another body will fill that void and that fragmentation of standards will occur.

In our response to question 1 above we made the point that environmental factors play the greatest role in errors made in the pharmacy. Over time the volume and complexity of the pharmacy workload has increased tremendously but the size, layout and working practices in the pharmacy have not kept pace with such changes.

Over the last 15 years prescription volume has increased year on year by around 5%; this compound growth has resulted in the number of prescriptions per average pharmacy almost doubling. This has put greater pressure on the space needed to hold stock and dispense prescriptions.

At the same time new technology has been introduced which, while improving governance, has not resulted in a decrease in the time needed to dispense a prescription. Furthermore it has reduced working space and added a source of heat to the environment.

At the same time the profitability of dispensing has fallen making pharmacy owners less willing to invest in their premises and less willing to displace other merchandise to make pharmacy areas of sufficient size to cope with the business.
(Q3 continued overleaf)

(Q3 continued)

The combination of these factors has resulted in most pharmacies being too small; have a layout that is not designed to maximise patient safety; be uncomfortably hot and with inadequate ventilation; and have too few adequately trained support staff. It is these environmental and working practice that are the route cause of most errors.

The GPhC is unique amongst regulators in having the responsibility of inspecting premises but it is not the case that other healthcare premises are unregulated. All healthcare professions have premises standards and are subject to an inspection regime by the Care Quality Commission. In general these premises standards are much more exacting than those for pharmacy; they require more detail to be provided on registration and are inspected with more vigour; and any report resulting from an inspection looks at all aspects of the operation.

We believe that the GPhC must follow a similar model to that operated by the CQC. The pharmacy premises standards should be more detailed and demanding, thereby building on work done by the National Patient Safety Agency. The inspectorate must be required to look at the quality of not just the physical aspects of the premises but of its working practices and staff structures.

It is likely that this will require an increase in the level of fees for premises but we firmly believe that it would also result in lower costs of administration for individual registrants as working environments improve and the number of incidents requiring investigation reduce.

Of the members who responded to the survey 80% believed that the premises fee is set too low to allow for adequate standards and inspection. Over 100 respondents provided additional comments and the following best expresses that body of opinion.

"I have always been of the view that the environment in which pharmacists practice will impact on patient safety and am encouraged that GPhC is to inspect and regulate standards.

The GPhC must take the regulation of premises and the procedures set in place, the number one priority as this is the issue which will directly impact on patient safety.

The GPhC has to directly issue guidance on the resources needed to ensure that the procedures set in place are achievable. It is too important to leave it to companies to decide what resources are needed as they have to balance patient safety with profits. From past experience in several industries it has been profits which comes first and not patient safety.

The GPhC should not consider the current schedule of inspections as necessarily being adequate but must budget for an acceptable risk assessed programme which gives the public and the profession confidence that owners are being held to account in fulfilling their responsibilities by providing the safest working conditions possible".

Question 4.

Do you agree that we should not offer a low income fee?

- Agree
 Disagree
 Unsure

Comments:

Pharmacists who have a low income may be in that situation because they are parents with young children; carers for older people or people with disabilities; they may be involved in charitable work or other socially valuable low/no pay work. These people should be encouraged to remain in the profession and add value to the profession and their colleagues.

It is important that we keep a flexible part-time workforce available which can be used to maintain public access to pharmaceutical services whilst ensuring that full-time pharmacists are not working excessive hours. Furthermore these part-time pharmacists provide an invaluable pool of experience and expertise. They also provide a resource on which to draw in the event of an emergency – a factor recognised in the Pandemic flu plans established by the DH in 2008/09.

A lower annual renewal fee contributes towards keeping them active and should be available to them. Removing the lower fee would discourage them from staying on the register, would reduce the pool of pharmacists available and would increase demands and stress on the rest.

Of the members who responded to our survey over 84% said that there should be a low income fee. This question solicited some the strongest comments

“Pharmacy as a profession depends on a large part-time workforce, to cover holidays and emergencies. It will discourage many part-timers from making themselves available if they have to pay the full fee as well as their insurance. It will become more cost effective to simply come off the register. This could ultimately affect the public’s access to pharmaceutical care.”

“We mustn’t disincentivise those part-time pharmacists who play a crucial role in supporting their full-time colleagues.”

“It would become financially not worthwhile for me to remain on the register and practising whilst I have caring responsibilities for my children and father. I likely will work more in time and would suggest that it is better I continue practising on a part time basis.”

“As a profession we totally rely on part-time pharmacists - and we mustn’t forget that the older pharmacists have a wealth of knowledge which is only passed down to the younger pharmacists when the two get to interact - AT WORK! We mustn’t lose these fantastic pharmacists by making them feel they are being forced to pay a higher retention fee.”

If over 50% of claimants are not entitled to the reduced fee we would suggest that it is the claims process that is at fault and that it should be made clearer. We would urge the GPhC to look at its processes before penalising pharmacists who provide a valuable contribution to the profession.

Question 5.

Do you agree with the proposed additional fee for those pharmacy professionals who choose to pay by quarterly direct debit?

- Agree
 Disagree
 Unsure

Comments:

For most fees and payments there is a discount for paying by direct debit but for the GPhC renewal fees there appears to be no incentive to pay by direct debit. Indeed the proposal to levy an additional £20 cost for quarterly instalments is a positive disincentive.

We would like to see the justification for the proposed £20 additional cost in terms of the additional administrative burden and cash flow implications.

We recognise that the costs of administration of quarterly direct debits are higher than an annual payment. However we believe that the level of the additional fee is too high. This is of concern particularly for pharmacists registering for the first time as they are already required to pay £362 for the first year.

Of the members who responded to our survey 87% were in favour of the option to pay on a quarterly basis; most expressed a view that there should be a monthly option and the general consensus was that an additional cost of £5 would be more realistic.

Question 6.

Do you have any other comments you wish to make?

Reserves

We are very concerned about the rationale used in establishing reserves and the transparency of the effect of that rationale on fee levels.

The consultation document states that *"The cost of regulation can vary significantly from year to year, depending for example, on whether we need to defend a case in the High Court, and having reasonable reserves should allow us to minimise borrowing and to smooth out variations in costs."*

In some respects the PDA and the GPhC are in a very similar business albeit too often on different sides of the fence. The sensible way to protect against the cost of a High Court case is to take out insurance not to build up reserves. The GPhC rightly recognises that costs can vary from year to year; if the GPhC has to defend several cases in the first year relying on reserves will put it in heavy debt whereas insurance would cover all actions without impacting on business continuity. Furthermore this would be a better way of using registrant's money than accruing a large cash balance in the bank. Our research into the annual cost of such insurance suggests that it should cost no more than £20,000.

We do recognise the need for some level of reserve albeit substantially lower than would be needed if the GPhC were to defend High Court cases out of reserves. Almost 90% of the members who responded to our survey believed that the government should fund the reserves needed; however there is recognition that in the current economic climate this is unlikely and 63% of respondents thought that a levy on fees is a fair way to build up the reserves.

We firmly believe that the GPhC must be open and honest with its registrants over the proportion of fees that will be used to fund reserves and that the burden should be borne across the board. We are concerned that the levy as proposed falls mostly on individual pharmacists. We are particularly concerned that premises fees do not take in to account any increase for reserves. Deducting the £45 increase for monitoring of controlled drugs the premises fee becomes £172 – just 2.5% more than the current premises fee; this is merely the inflationary increase quoted on page 4 of the consultation document. Thus pharmacy owners appear to be exempt from the reserve levy. This is not acceptable and must be rectified. (Q6 continued overleaf)

(Q6 continued)

The level of fees

The level of fees for pharmacists appears to us to be far too high for four reasons;

1. The technician fee is set too low as outlined in our response to question 3 above.
2. The premises fees are set too low as outlined in our response to questions 1 and 3 above.
3. We believe that the case for reserves has been overstated and too much has been built in and in the wrong places as outlined above.
4. The whole structure of these fees has been based on the custom and practice of the RPSGB. There has been an opportunity for the GPhC to look at everything it does and redesign its business processes and that opportunity appears not to have been taken. As one of the respondents to our survey put it.

"I'm sad as a pharmacist to see how we struggle to live like all other people and have a system set out to make lives worse. I'm sad that the previous society morphed into GPhC without a noticeable business process reengineering"

We agree with that sentiment. Our experience is that the cost of fitness to practice cases has risen fourfold over recent years and that cases take up to 18 months to be heard. Our Research suggests that streamlining this process would save up to 75% of its cost and result in speedier resolution of cases to the benefit of the public, the individuals involved and the profession. We are confident that other business processes could also be streamlined with potentially similar cost savings.

Further information is available from:

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