

Global Anti-Corruption Compliance Policy



We care about our
people, our clients and
delivering excellence.

Contents

Purpose

Scope

Definitions

References

Policy

1. Overview

2. Ready Reference

3. Key Policy Principles

4. Policy Requirements

5. Roles And Responsibilities

6. Red Flags

7. Risk Assessment

Version History

Purpose

Introductory statement by ICON's CEO

At ICON, we are committed to our core values of Accountability & Delivery, Collaboration, Partnership and Integrity in everything we do.

These are values that we must protect. The work we do carries heavy responsibility to our Sponsors, regulators and patients. No business opportunity should ever be allowed to take precedence over our ethics or integrity. Please also keep in your mind the simple truth - if something seems inappropriate, it probably is.

The policies and procedures set out in this Policy are important to ensure transparency and accountability in relation to our dealings with third parties. This Policy provides you with a broad understanding of our anti-corruption policies and procedures and identifies resources where you can find out more information. You must ensure that you read the Policy, complete the relevant training and, if you have any questions, please do ask them to the relevant people as set out in this Policy.

Scope

This policy applies to all staff within ICON plc.

Definitions

UKBA: The UK Bribery Act 2010.

FCPA: U.S. Foreign Corrupt Practices Act 1977.

PhRMA: Pharmaceutical Research and Manufacturers of America.

Government Official: Government Official, as used in this Policy, encompasses the broadest definitions of officials in anti-bribery legislation. For example, the FCPA prohibits the making of corrupt payments to "any foreign official" (from the perspective of the US) or "any foreign political party or official" or "any candidate for foreign political office." The term "foreign official" is widely defined and covers any officer or employee of a foreign government, including legislative, administrative and judicial positions, a public international organization, or any department or agency thereof. This includes doctors, nurses, pharmacists, healthcare funds and hospital or medical administrators working for a wholly or partially government-owned hospital or clinic or other government owned or state run entity. Even those who work for a government agency or entity for a portion of their time are considered a Government Official.

References

EX002-POL: ICON plc Code of Ethics

LEG002-POL: Global Code of Conduct

LEG003-POL: Global Policy on Interactions with Healthcare Professionals

LEG005-POL: ICON Global Supplier Code of Conduct

LEG006-SOP: Development of Regional Master and Country Level Clinical Trial and Clinical Study Agreements

LEG007-SOP: Negotiation, Finalization and Execution of Study Agreements, Clinical Trial Agreements and Related Site Documents

PRO001-SOP: Global Supplier List - Onboarding and Management

QA001-WP006: Supplier Audits

QA001-WP013: Central Labs (CL) Supplier Quality Assessment

SST002-SOP: Site Selection

POLICY

1. Overview

What is bribery and corruption?

Bribery is the offering or receiving of any benefit or reward for the purpose of securing an undue advantage and corruption is the abuse of a position in order to gain an undue advantage.

Countries around the globe that ICON operates in have increasingly robust national laws prohibiting bribery and corruption. In addition, there are international non-governmental organizations, (e.g., Transparency International) and conventions (e.g, the Convention on combating Bribery and Foreign Officials in Internal Business Transactions (“OECD Anti-Bribery Convention”), signed and ratified by approximately 40 countries and the U.N. Convention against Corruption signed by 140 countries), focused on combating global corruption.

Two key laws are the U.S. Foreign Corrupt Practices Act 1977 (FCPA) and the UK Bribery Act 2010 (UKBA).

In the U.S., the FCPA is a U.S. federal law that prohibits making or promising to make, directly or indirectly, any payment or money or object of value to any foreign official of a government or a political party or candidate for political office, which is for the purpose of inducing or influencing such person to act in any way to assist in obtaining or retaining business.


The FCPA also requires that books, records and accounts be kept in reasonable detail to accurately and fairly reflect all transactions made. The FCPA applies broadly to numerous categories of US and non-US persons and businesses, and in many cases can give rise to liability even where the corrupt act takes place entirely or mostly outside the United States.

The UKBA is broader than the FCPA and prohibits the offering or receiving of any bribes not just those involving foreign public officials. Significantly, the UKBA introduces a corporate offence of failing to prevent bribery by persons associated with a company or performing services on a company’s behalf. The corporate offence applies to any organization carrying on all or part of its business in the UK and may catch acts of bribery and corruption committed overseas. Facilitation Payments as described below are not permitted under the UKBA.

The PhRMA Code also sets forth standards and principles for healthcare companies in their interactions with healthcare professionals in order to protect patients from undue influences on healthcare professionals’ medical decisions. A link to the PhRMA Code is posted on the Legal homepage of MyICON.

ICON officers and employees should specifically comply with the Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA Code) and any equivalent applicable local industry Codes.

<http://www.phrma.org/principles-guidelines/code-on-interactions-with-health-care-professionals>



ICON does not tolerate bribery or any form of corruption. This prohibition applies even in countries where bribery is common practice and local legal and/or cultural standards allow it.

What is the purpose of this Policy?

- This Policy provides you with a broad understanding of ICON's anti-corruption program. As such, it must be read in conjunction with our Code of Ethics, Global Code of Conduct and Global Policy on Interactions with Healthcare Professionals, available in ICON's EDMS (Electronic Document Management System).

What does the Policy contain?

- The Policy highlights the procedures we must all follow to ensure (i) our dealings with third parties are transparent and (ii) that all necessary written records are in place to ensure that we can demonstrate the appropriateness of our dealings or rebut allegations of corruption in any of those dealings. This Policy also sets out where responsibility lies for the implementation and ongoing review of this Policy and explains the risk assessment that was carried out in order to design an anti-corruption program that is appropriate to ICON's business.

Why is this Policy important?

- The consequences for ICON, its officers and employees of non-compliance with anti-corruption legislation are high, as offences under the legislation carry substantial civil and criminal penalties for both individuals and organizations. Penalties can include imprisonment, unlimited fines, confiscation of profits and other civil actions against ICON. Another consequence is the risk of damage to ICON's and our employees' reputation and ICON's share value.

What does the Policy mean for ICON employees?

- All employees must read and comply with the Policy, complete the relevant Ethics training module and abide by the requirements of the Policy.

What does this policy mean for ICON's third parties?

- ICON holds its third parties to high standards. Suppliers and contractors, including consultants or other agents, are prohibited from engaging in bribery. They are expected to comply with all applicable anti-corruption laws and regulations and act in accordance with the broad principles set out in ICON's Supplier Code of Conduct.

What should you do if you suspect a violation of the Policy?

- Any violation or suspected violations of the Policy should be reported as soon as possible. Reports should be made to your line manager. If you are uncomfortable or unable to discuss a specific compliance concern with your line manager, you may also report it to ICON's Anti-Corruption Officer at legalcompliance@iconplc.com.

- Alternatively, you may also report a violation or suspected violation on a confidential or anonymous basis through ICON's Ethics Line. If ICON's Ethics Line platform is not available in your country, you may contact ICON's internal telephone number (+353 1 2912500) or email (complaints@iconplc.com). Both communication channels are monitored by authorized members of ICON's Office of General Counsel. Such communications should be made in accordance with ICON's Ethics Line Charter available on MyICON homepage.

In all instances where a concern is raised on a confidential or anonymous basis, every effort will be made to ensure that information relating to a reported violation is kept confidential and communicated on a need-to-know basis only.

Is this Policy more red-tape, hindering our ability to provide services to our clients?

- No, this Policy is key to our ability to work with our clients in a way that allows them to have confidence in ICON as a service provider of integrity, with staff that is appropriately trained on standards of ethics and compliance. Indeed, our clients are under an obligation to ensure all the companies in their supply-chain have appropriate ethics and anti-corruption policies. The Policy is not about creating needless bureaucracy, but ensuring that we can actively evidence and demonstrate adherence to laws and regulations that are of critical importance in the life sciences industry. The controls outlined in this Policy are designed to be practical and not overly bureaucratic, but effective.

2. Ready Reference

Key Principles

- Provision of a lawful service which meets a legitimate business need.
- Vetting of suppliers.
- Details of services and fees must be in writing.
- Invoicing and approval of payment processes.
- Retention of documentation for at least five (5) years.
- Training of Staff.
- Monitoring and auditing of Program.
- Documentation recording fees in fair market value range.

Key Controls

Compliance	Transparency	Financial Controls
<ul style="list-style-type: none"> - PRO001-SOP - SST002-SOP - LEG003-POL - LEG007-SOP - Staff training modules 	<ul style="list-style-type: none"> - Written evidence of services and fees. - Documentary evidence of work supplied. - Records kept on file for at least five (5) years. - Storage of vendor service agreements. - Use of Grantplan per SSU policy. 	<ul style="list-style-type: none"> - Invoices following delivery of services. - Approval process for invoices and reimbursement claims. - No cash payments. - Restrictions on receiving and giving gifts. - Charitable contributions/research grants approval process. - Accuracy of company records.

3. Key Policy Principles

All ICON Officers and employees are required to strictly comply with anti-corruption laws and regulations in the countries in which they work for ICON. Certain clients may also impose specific restrictions on gift giving, hospitality or travel. You must ensure that your actions and conduct comply with applicable local laws and any specific contractual obligations entered into by ICON in relation to the work you are completing.

Prohibited Payments

No employee shall pay, offer, authorize, or promise to pay, indirectly or directly, anything of value to any third party, including any Government Official, political candidate, or political party for the purpose of inducing or influencing such person or entity to, in any way, assist ICON in obtaining or retaining business or securing any improper advantage.

No employee shall pay, offer, authorize, or promise to pay, directly or indirectly, anything of value to any other person, such as a supplier, consultant or third-party agent, while suspecting or having reason to believe that the payment or promise to pay will be offered or given to any Government Official, political candidate, or political party for the purpose of inducing or influencing such person or entity, in any way, to assist ICON in obtaining or retaining business or directing business to any person or securing any improper advantage.

Examples of Prohibited Payments and Conduct include:

- Unnecessary travel in a contract in order to induce an official or other individual with decision making authority to enter into an agreement with ICON.
- Payment of a “gratuity” or other after-the-fact discretionary payment to a Government Official for services provided to ICON or its employees.
- Discussions with any party regarding either the giving or offering of any benefit or reward or the abuse of a position, for the purpose of securing any undue or improper advantage for ICON.

3.1 Facilitation Payments

Small payments or gifts of nominal value to Government Officials that are made to expedite or obtain the performance of routine, non-discretionary governmental actions which are ordinarily or commonly performed by a Government Official are sometimes called “facilitation payments” or “grease payments.” Such payments to Government Officials in their personal capacity are **unlawful** under the UKBA and prohibited under this Policy. Therefore they **should not be paid under any circumstances.**

Payment to a Government agency or regulator for legitimate business purposes (as opposed to paying an employee or official of such an agency or regulator in his or her personal capacity) is permitted. If you are asked for, or requested to make a Facilitation Payment, please report it in accordance with the “What should you do if you suspect a violation of the Policy?” section above.

An example of a Facilitation Payment is:

– An unauthorized “expediting” fee to a Government Official in his/her personal capacity (as opposed to paying the relevant government body) to obtain or fast-track a permit, visa or other service.

3.2 Travel, Meals and Entertainment

Employees may give or accept meals and other entertainment to or from business related contacts only if reasonable, appropriate and infrequent. Meals or other entertainment, which are intended to secure or appear to secure preferential treatment, business influence or improper commercial advantage for the party providing or paying for the meal or other entertainment are prohibited.

As with the gift giving, particular vigilance is required in the case of paying for or authorizing the payment of expenditures related to travel, meals, or entertainment of a Government Official.

These expenditures are only permissible if they are:

(1) in accordance with local law, meaning the law of the jurisdiction where the expenditure is made; (2) for reasonable and bona fide business expenses not made for a corrupt purpose; (3) in an amount no greater than would be permitted for the travel, meals, and entertainment of the employee; (4) directly related to either the promotion, demonstration, or explanation of ICON's services; and (5) not made for the benefit of family members, spouses, or other guests of the Government Official.

All such expenditures must be fully transparent and also clearly and properly documented and recorded.

3.3 Gifts

Employees must not give or accept gifts, payments, discounts, favors or personal services to or from third parties where these would, or might appear to improperly influence them in connection with their work. It is important to note that the intention that accompanies the gift is critical and the timing of the gift is important. Any such expenditure must be clearly and properly documented.

– Accepting Gifts

Employees may not accept gifts that might appear to influence our business decisions. Accepting such gifts may be illegal. If you are offered a gift, consider carefully not just whether you think it would influence your judgment, but also how others would view it. If you have any doubt, do not accept the gift or seek advice from your manager or Human Resources Representative. In general, employees may accept gifts of nominal value as they are unlikely to be seen as influencing behavior. Employees should also avoid a pattern of accepting frequent gifts or business courtesies from the same persons or companies.

– Giving Gifts to non-Government Officials

Employees may not give gifts to suppliers, customers, competitors or other work related parties, unless infrequent, appropriate and of modest value. As referred to above, employees should be aware that the intention that accompanies the gift is critical and the timing of the gift is also important.

– Giving Gifts to Government Officials

In cases where employees are considering giving a gift to a Government Official, employees must be aware that particular vigilance is needed and that specific restrictions apply to such cases. Employees may not give gifts to Government Officials unless they are also infrequent and of “nominal value,” as a courtesy, as customary for the occasion and as permitted under local law.

Such gifts must not secure or appear to secure any preferential treatment, be given in an attempt to win business, or influence official action or obtain an improper commercial advantage (either for ICON or any ICON client). Gifts of “nominal value” are valued at 50USD or less, or an amount equal to the local buying power equivalent.

3.4 Political Contributions

Corporate funds, services, or facilities may not be paid or given to any candidate for political office, political party, officer or employee thereof without prior company approval. Please refer to the Global Code of Conduct Policy (LEG002-POL), which contains further guidance and is available in the EDMS.

3.5 Valuation and Combining Transactions

For the purposes of determining the approval requirements of this Policy, payments made in a currency other than U.S. dollars must be converted to U.S. dollars at the then-prevailing exchange rate. Goods and services must likewise be converted to a monetary value in U.S. dollars for the purpose of determining compliance with this Policy.

Making transfers of anything of value in installments with the intent to evade any approval requirement in this Policy is strictly prohibited. If such transfers of anything of value are reasonably related, they will be considered as a single transfer for purposes of determining approval levels required by this policy.

3.6 Anti-facilitation of tax evasion

ICON is committed to upholding all laws relevant to countering tax evasion in all the jurisdictions in which we operate, including the UK Criminal Finances Act 2017. ICON takes a zero-tolerance approach to facilitation of tax evasion. It is not acceptable for employees (or someone on your behalf) to:

- (a) engage in any form of facilitating tax evasion;
- (b) aid, abet, counsel or procure the commission of a tax evasion offence by another person;
- (c) fail to promptly report any request or demand from any third party to facilitate the fraudulent evasion of tax or any suspected fraudulent evasion of tax by another person, in accordance with this policy;
- (d) engage in any other activity that might lead to a breach of this policy; or
- (e) threaten or retaliate against another individual who has refused to commit a tax evasion offence or who has raised concerns under this policy.

If you believe or suspect that a conflict with ICON's anti-facilitation of tax evasion policy has occurred, or may occur in the future, you must immediately report this in accordance with the section entitled "What should you do if you suspect a violation of the Policy?" above (for example, if an employee, supplier or healthcare professional asks to be paid into an offshore bank account, without good reason or in violation of local law OR a supplier asks to be paid in cash, indicating

that this will mean the payment is not subject to tax OR a third party to whom we have provided services or who has provided services to ICON asks us to change the description of services rendered in a way that seems designed to obscure the nature of the services provided)


3.7 Reporting

Any employee who becomes aware of information indicating or suggesting that an employee, consultant or agent has violated this Policy or any anti-corruption law should immediately report that information as set forth in "What should you do if you suspect a violation of the Policy?" section above. Under no circumstances will a good faith report of such information be the basis for retaliatory action against the employee making the report.

3.8 Accurate Books and Records

Employees must ensure that the company's books and records accurately and fairly reflect, in reasonable detail, all transactions and dispositions of assets. Accounts and other records of transactions must be complete and accurate. This includes any gifts, charitable donations and expense claims submitted. No undisclosed or unrecorded fund or asset may be established or maintained for any purpose.

Employees must also ensure that ICON's internal accounting controls are adhered to in order to ensure that transactions are executed in accordance with required internal spend authorizations.



Company records must be retained for as long as required by law and managed to meet our business needs.

4. Policy Requirements

This section sets out the requirements which apply under this Policy and is divided into three categories:

(1) Compliance; (2) Transparency; (3) Financial Controls.

4.1 Compliance

Activity	Requirement	Comment
Engaging a third party supplier	The policy for engaging a supplier as set out in PRO001-SOP and related supplier engagement SOPs must be adhered to in full.	As stipulated in PRO001-SOP, only suppliers listed on the Global Suppliers List may be used. Unless subject to an exception, which has been appropriately recorded and approved, all PRO001-SOP suppliers must sign the Ethics and Compliance Acknowledgment and Certification form (PRO001-SOP-F01) and undergo World-check screening before they can be added to ICON's Global Supplier List.
Assessment of Suppliers	PRO001-SOP procedure in relation to assessment of Preferred Suppliers must be adhered to. QA001-WP013 and QA001-WP006 Procedures in relation to assessment of suppliers must be adhered to.	As provided for in PRO001-SOP, the VCAR system may be used to report ethical concerns for preferred suppliers.
Interactions with Healthcare Professionals	SST002-SOP must be adhered to. LEG006-SOP and LEG007-SOP must be adhered to in relation to the contracting process with investigators. ICON's Global Policy on Interactions with Healthcare Professionals (LEG003-POL) must be adhered to.	This process is set out in LEG006-SOP, Development of Regional Master and Country Level Clinical Trial and Clinical Study Agreements; and LEG007-SOP, Negotiation, Finalization and Execution of Study Agreements, Clinical Trial Agreements and Related Site Documents. An external tool is available to generate investigator payments. Further information is available from the Study Start-Up Unit. This Policy is available in the EDMS.
Training	All staff to complete training on ICON's Global Code of Ethics, Code of Conduct and Anti- corruption Compliance Policy through ICON iLearn.	Training is supplemental by reference materials on MyICON and supplemental training for key departments/offices.

4.2 Transparency

Activity	Requirement	Comment
Contracting with a supplier	<p>Services and fees to be provided by a supplier must be recorded in writing.</p> <p>All supplier service agreements must be filed and available for review/inspection.</p> <p>Documented evidence of work supplied must be retained on file by the user department.</p>	<p>All supplier contracts must contain a clear description of the services to be provided and fees to be paid. Clauses providing for a right to audit, a right to terminate and covering anti-corruption compliance are included in ICON's template supplier contract.</p> <p>User departments must ensure that copies of agreements should be uploaded to the MSA eRoom as provided for in PRO001-SOP.</p>

4.3 Financial Controls

Activity	Requirement	Comment
Record-keeping	All documentation required under the Anti-Corruption Policy must be retained on file for at least five (5) years, or longer if required by law.	Such documentation must be available for review/inspection.
Payments to a Supplier	<p>Invoices can only be submitted for processing following delivery of services, unless pre-payments are contractually agreed.</p> <p>Invoice approval process must be adhered to in full.</p> <p>Restrictions on payments which can be made to Healthcare Professionals as set out in the Global Policy on Interactions with Healthcare Professionals (LEG003-POL) must be adhered to.</p> <p>ICON does not make cash payments to suppliers; all payments from ICON are processed via ICON's financial systems and subject to dual approval controls and record keeping procedures.</p> <p>Processes applicable to reimbursement of expense claims must be adhered in full.</p>	<p>If pre-payments are agreed, the user department must follow up with the supplier to ensure that services are delivered per the contract.</p> <p>Details of these processes are available from the Finance department.</p> <p>The Global Policy on Interactions with Healthcare Professionals is available in the EDMS.</p> <p>In the event that any petty cash is kept at local offices for sundry office expenses, it must be supervised by a designated individual and reported on to the central finance function.</p> <p>Details of these processes are available from the Finance department.</p>

4.3 Financial Controls

Activity	Requirement	Comment
Gifts/Charitable contributions	Employees may not give or receive gifts to suppliers, customers, competitors or investigators unless as infrequent and appropriate gifts of modest value. All proposed charitable contributions by ICON must be approved in advance and in accordance with internal approval requirements.	Please refer to the Global Code of Conduct (LEG002-POL) and Global Policy on Interactions with Healthcare Professionals (LEG003-POL), which contain further guidance and are available in the EDMS.
Research/Educational Grants	Requests to support research or educational programs can only be approved by ICON's senior leadership team so such requests should be referred to the relevant divisional President for consideration.	
Accounts and Records	Inaccurate, false or misleading entries should never be made in company accounts/records.	

5. Roles and Responsibilities

Below are roles and responsibilities relating to the implementation and development of the Policy.

5.1 Anti-Corruption Officer and Legal Counsel

- Designs FCPA compliance program.
- Drives implementation of the Policy.
- Provides supplementary documents such as FAQs and reference materials.
- Under the direction of ICON's Office of General Counsel, directs and oversees audits and "deep dives" relevant to this Policy.
- Sends reports made under the Policy to Internal Audit for investigation.
- Supports Internal Audit in any investigations conducted into reported breaches.
- Retains the files and records relating to any such investigation and prepares summary report to the General Counsel on a regular basis.
- Reviews reports of records related to completion of ICON's global Ethics training.
- Addresses queries related to the Policy.
- Reviews this Policy and related materials from time to time to ensure they are up-to-date.

5.2 Internal Audit

- Include anti-corruption compliance in their "key risk" matrix and factor in necessary audit points in their annual audit programs including reviewing adherence to invoice approval process and whether invoices submitted tie in with contract description and fees agreed in contract.
- Lead investigations into reports made under this Policy.
- Audit adherence to record keeping obligations as required under the Policy.
- Report the results of investigations under the Policy to the General Counsel and Audit Committee of the Board.

5.3 Quality Assurance

- Conduct pre-audits as set out in PRO001-SOP.
- Audit of IRBs.

6. Red Flags

The U.S. Department of Justice has identified several factors as potential corruption “red flags”. Examples are listed below. If any one or more of these exist or come to light during due diligence or otherwise during the course of ICON’s business they should be reported in accordance with the “What should you do if you suspect a violation of the Policy?” section above:

- A refusal by a third party to adhere to ICON’s Supplier Code of Conduct, in the absence of their own equivalent code or standards.
- A third party requests ICON to prepare false invoices or any other type of false documentation.
- If ICON becomes aware that a third party has convictions or charges for violation of local or foreign laws or regulations relating to corruption and/or the award of government contracts.
- Unexplained or inadequately explained termination of the business relationship by another company that may suggest unethical behavior.
- Requests for over-invoicing or that all or a part of a payment be paid in another country in cash or otherwise untraceable funds.
- Over reliance by suppliers on political/government contacts rather than relying on knowledgeable staff and investment of time to deliver the services contracted to ICON.
- A desire to keep the business relationship secret.
- A potential third party supplier offers an incentive in order to receive confidential information during a pre-bidding or bidding stage.
- A client requests that an ICON employee provide a benefit or item of value to a clinical investigator that is not transparently reflected in the written agreement with the investigator or because the client employee does not want to be seen providing this directly.
- A demand for direct payment or other benefit from a local or national Government Official, before the official or his/her agency will take certain action, such as: approve a local regulatory or work permit authorization application; clear items through customs; settle a tax dispute; or provide a report favorable to ICON or its clients.
- A supplier offers a benefit to an ICON employee to overlook “out of spec” or inferior goods or services.

7. Risk Assessment

ICON conducts periodic risk assessments to underpin and design this Policy and to provide areas of focus in its implementation. In conducting our periodic risk assessments, ICON has identified the below as areas of focus for ICON's business:

7.1 Regular interactions with Government Officials

One of the main perceived anti-corruption risks connected with ICON's business is that corrupt payments may be made which seek to influence the outcome of a trial or a particular aspect of a trial. Therefore, particular attention is warranted in the following areas:

- Negotiation of contracts with PIs (on behalf of Sponsors).
- Dealing with ECs/IRBs (on behalf of Sponsors.)
- Import/Export (on behalf of Sponsors).
- Engaging consulting services (sometimes on behalf of Sponsors).

7.2 Engagement of Sub-Contractor CROs

Another key area of risk for ICON is the engagement of sub-contractor CROs as the service delivery by these entities can impact the outcome of a trial and generally involves frequent dealings with Government Officials.

7.3 Engaging Contractors

Particular attention should be paid to the use of consultancy contracts. This is an area where there is a perception that corrupt or inflated payments could be "disguised". Such contracts should never be entered into in connection with any agreement to enhance ICON's business and the controls referred within the Policy must be adhered to in full.



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