Canada

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Pharmaceutical regulatory law

1 Which legislation sets out the regulatory framework for the marketing, authorisation and pricing of pharmaceutical products, including generic drugs?

Pharmaceutical products may not be sold in Canada unless they have been granted marketing authorisation by Health Canada, the federal body that administers the provisions of the Food and Drug Regulations made under the Food and Drugs Act, as amended. Under Division 8 of the Food and Drug Regulations, a manufacturer must file a new drug submission (NDS) that contains data establishing the safety and clinical effectiveness of a drug product not previously sold in Canada. If, upon review of an NDS, Health Canada is satisfied that the drug product meets the requirements of the Food and Drug Regulations, Health Canada will issue a notice of compliance (NOC), which authorises the sale of the product. A generic drug manufacturer can obtain an NOC through the approval of an abbreviated new drug submission, which involves the manufacturer filing a more limited submission and demonstrating that the generic drug product is bioequivalent to a previously approved innovative drug product.

The Patented Medicines (Notice of Compliance) Regulations establish a link between the issuance of an NOC for a generic drug and the patents on an innovative drug. In short, if the medicinal ingredient, dosage form, formulation or use of a drug is subject to patent protection, then an NOC for a generic equivalent of the drug will not be issued unless and until the generic manufacturer successfully addresses relevant patent issues in legal proceedings.

The Food and Drug Regulations govern all aspects of the manufacturing, importing, labelling, distribution and sale of drug products in Canada and include general prohibitions on false and misleading advertising. The Competition Act (discussed below) also contains provisions prohibiting misleading advertising and the deceptive marketing of all types of products, including pharmaceuticals. In practice, marketing directed at Canadian health-care professionals is primarily self-regulated in Canada under industry codes of conduct. Advertising prescription drug products to the general public is prohibited under the Food and Drug Regulations, except for representations limited to the name, price and quantity of a drug.

The prices of drug products that are subject to patent protection are federally regulated under the Patent Act and the Patented Medicines Regulations. This legislation controls the introductory price and annual price increases for patented drugs. Patentees are required to file price and sales information upon market entry and twice a year thereafter.

Because health care in Canada is primarily administered at the provincial level, each province has its own legislation relating to the coverage and reimbursement of prescription drugs. Manufacturers typically enter into agreements with each province that establish the price at which a drug will be supplied for use in the public health-care system in that province. The price of a generic drug is generally capped at a percentage of the established price of the equivalent innovative drug.

2 Is there specific legislation on the distribution of pharmaceutical products?

The distribution of pharmaceuticals is regulated at both the federal and provincial levels. The federal Food and Drug Regulations require entities that import or distribute drug products to hold an establishment licence for each facility where these activities take place. At the provincial level, certain provinces (Ontario and Quebec) have enacted 'anti-rebate' legislation to control the drug price and discounts that may be offered in the supply chain as a pharmaceutical product is sold from manufacturer or distributor to wholesaler to pharmacy. In addition, all provinces have legislation that governs the operation of pharmacies, which includes provisions related to dispensing fees, interchangeability of brand and generic products and reimbursement for drugs that are covered by the provincial health insurance plan.

3 Which bodies are entrusted with enforcing these regulatory rules?

Health Canada enforces the provisions of the Food and Drug Regulations and authorises the sale of all drug products in Canada. The Patented Medicine Prices Review Board (PMPRB) monitors the price of patented drugs in order to ensure that prices are not excessive. The price of both branded and generic drug products is regulated by each provincial ministry of health, which controls the listing of drug products on the applicable provincial formulary for public reimbursement purposes.

Most oversight of the marketing practices of drug manufacturers has been undertaken by the pharmaceutical industry itself through complaints to bodies such as the Pharmaceutical Advertising Advisory Board, which reviews advertising directed at health-care professionals under its Code of Advertising Acceptance; Rx&D, the innovator industry trade association that established the Code of Ethical Practices; and the Canadian Generic Pharmaceutical Association, through the administration of the Code of Marketing Conduct Governing the Sale of Generic Pharmaceutical Products in Canada.

4 Which aspects of this legislation are most directly relevant to the application of competition law to the pharmaceutical sector?

The federal marketing authorisation regime, the PMPRB and provincial reimbursement legislation influence the nature and extent of competition in the Canadian pharmaceutical sector in respect of drug pricing and as between innovators and generic drug manufacturers. Industry codes are also relevant – they govern marketing practices directed at health-care professionals (such as physicians and pharmacists) and control comparative claims relating to drug safety and efficacy.

Competition legislation and regulation

5 Which legislation sets out competition law?

The Competition Act, as amended, is a federal statute of general application that establishes Canada's competition law regime. Broadly divided into criminal and civil matters, the Competition Act addresses four major topic areas.

Agreements between competitors

The Competition Act has a dual-track regime for agreements between competitors. Section 45 creates a per se criminal offence for hard-core cartel-like agreements between competitors. Section 90.1 is a civil provision that allows the Commissioner of Competition (the Commissioner), the head of Canada's Competition Bureau (which carries out investigations under the Competition Act), to challenge agreements between competitors that do not fall within the scope of the criminal section 45 offence but

that may prevent or lessen competition substantially (effectively, a rule of reason-type analysis).

Unilateral conduct
Certain business practices may be challenged by the Commissioner where they have a sufficiently negative impact on competition. These include abuse of dominance and vertical restraints, including refusals to deal, price maintenance, exclusive dealing, tied selling and market restrictions.

Deceptive marketing practices
The Competition Act contains consumer protection provisions relating to deceptive marketing. Egregious forms of misleading advertising, deceptive telemarketing, multilevel marketing and pyramid selling are criminal offences. Less serious forms of deceptive marketing, such as less egregious misleading advertising, misrepresentation about a product's performance or efficacy and bait and switch selling, may be subject to civil prohibition orders and administrative monetary penalties.

Mergers
All mergers in Canada can be reviewed by the Commissioner in order to determine whether they should be challenged on the grounds that they are likely to prevent or lessen competition substantially. Mergers that exceed specified financial thresholds are subject to a mandatory pre-merger notification requirement.

6 Are there guidelines on the application of competition law that are directly relevant to the pharmaceutical sector?

As a law of general application, the Competition Act does not contain pharmaceutical industry-specific provisions and does not apply differently to the pharmaceutical industry than to other sectors of the Canadian economy.

In 2000, the Commissioner published Intellectual Property Enforcement Guidelines, which articulate the approach of the Commissioner to the interface between competition law and intellectual property rights. Among other things, the guidelines describe how the Commissioner will determine whether conduct involving intellectual property raises issues under the Competition Act. An update to the guidelines was issued in September 2014. A further update is expected within the next year.

7 Which authorities investigate and decide on pharmaceutical mergers and the anti-competitive nature of conduct or agreements in the pharmaceutical sector?

The Competition Bureau conducts inquiries into both criminal and civil matters, including mergers (civil) in the pharmaceutical (and other) sectors and agreements and other arrangements (civil and criminal) between pharmaceutical (and other) competitors.

However, the Competition Bureau is a law enforcement agency only. Penalties for conduct contrary to the Competition Act are imposed by the Competition Tribunal (in respect of civil matters) or by the courts (in respect of criminal matters). Applications to the Competition Tribunal are initiated by the Commissioner and, with respect to certain civil matters (not including abuse of dominance or mergers), by private parties. Criminal prosecutions are initiated by the Director of Public Prosecutions of Canada based, in part, on the recommendation of the Commissioner.

8 What remedies can competition authorities impose for anti-competitive conduct or agreements by pharmaceutical companies?

Penalties for unilateral anti-competitive conduct by pharmaceutical (and other) companies include prohibition orders and, in some cases, administrative monetary penalties of up to C$10 million. Penalties for civil deceptive marketing also include restitution orders. Price fixing and other cartel-like agreements between competitors are punishable upon conviction by imprisonment for terms not exceeding 14 years and fines not exceeding C$25 million per count, or both. Criminal deceptive marketing is punishable, upon conviction on indictment, by imprisonment for a term not exceeding 14 years and a fine in the discretion of the court, or both, and, upon summary conviction, by imprisonment for a term not exceeding one year or a fine not exceeding C$200,000, or both.

In 1999, the Federal Court of Canada imposed fines totalling more than C$85 million on five pharmaceutical companies that participated in conspiracies to fix the price of vitamins and certain food additives, including a fine of more than C$50 million on Hoffman-La Roche.

9 Can private parties obtain competition-related remedies if they suffer harm from anti-competitive conduct or agreements by pharmaceutical companies? What form would such remedies typically take and how can they be obtained?

Section 36 of the Competition Act establishes a private right of action for any person that has suffered loss or damage as a result of conduct contrary to the criminal provisions of the Competition Act (or breach of a civil prohibition order). The affected person or persons may sue for and recover damages from the person or persons who engaged in the conduct in an amount equal to the loss or damage proved, together with costs. Unlike in the United States, there is no ability to sue for and recover treble damages in Canada. For the most part, proceedings under section 36 tend to take the form of class action proceedings where applicants claim damages for losses resulting from conduct contrary to section 45 (price fixing, etc) of the Competition Act.

In addition, there is a limited private right of application to the Competition Tribunal in respect of certain reviewable matters, including refusals to deal, price maintenance, exclusive dealing, tied selling and market restrictions. However, the remedies available in respect of these applications are limited to prohibition orders – monetary damages are not available.

10 May the antitrust authority conduct sector-wide inquiries? If so, have such inquiries ever been conducted into the pharmaceutical sector and, if so, what was the main outcome?

There is no provision in the Competition Act granting the Commissioner or the Competition Bureau the power to conduct sector-wide inquiries. That said, in 2007, the Competition Bureau conducted a generic drug sector 'study' as part of its role as an advocate for competition. Participation in the study was voluntary. More recently, in November 2013, the Competition Bureau hosted a one-day workshop on antitrust issues in the pharmaceutical industry with a view, in part, to informing its approach to pharmaceutical antitrust enforcement in the future. See Update and trends for further developments.

11 Is the regulatory body for the pharmaceutical sector responsible for sector-specific regulation of competition distinct from the general competition rules?

Not directly. As noted above, the federal marketing authorisation regime, the PMPRB and provincial reimbursement legislation influence the nature and extent of competition, including drug pricing, in the Canadian pharmaceutical sector. However, neither Health Canada nor provincial pharmaceutical regulatory authorities regulate competition distinct from the general competition rules under the Competition Act, which are enforced by the Commissioner and adjudicated by the Competition Tribunal and the courts.

12 Can antitrust concerns be addressed with industrial-policy type arguments, such as strengthening the local or regional research and development activities?

Industrial-policy type arguments are not relevant considerations under the Competition Act, although they are often made in order to explain the rationale for a merger or other conduct.

13 To what extent do non-government groups play a role in the application of competition rules to the pharmaceutical sector?

Non-governmental organisations, trade associations and consumer groups are often consulted by the Competition Bureau in its review of mergers in the pharmaceutical sector and as part of its inquiries in respect of both civil and criminal matters. They can also play a role in bringing allegations of anti-competitive conduct to the attention of the Competition Bureau. Private antitrust litigation by such groups is rare in Canada.

Review of mergers

14 To what extent are the sector-specific features of the pharmaceutical industry taken into account when mergers between two pharmaceutical companies are being reviewed?

Sector-specific features of the Canadian pharmaceutical industry, including the regulatory framework for the authorisation, pricing and sale of drug products, are relevant considerations in assessing pharmaceutical mergers in Canada. This reflects the fact that the considerations in assessing mergers under the Competition Act include the availability of acceptable substitutes for the products supplied by the merging parties (which, in the case of pharmaceutical mergers, is affected both by Canada's intellectual property regime and the federal marketing authorisation regime); the competitive dynamics within an industry; and the regulatory barriers to entry.

In a technical backgrounder issued following its 2005 review of Johnson & Johnson's acquisition of the consumer health-care business of Pfizer Inc, the Competition Bureau specifically referenced the regulatory restrictions imposed by Health Canada that limit the entry of over-the-counter drugs from abroad and Canadian bilingual packaging and labelling requirements as factors that were relevant in the outcome of its review. It noted that the net effect of these factors are 'not insignificant barriers to entry from the US'.

15 How are product markets and geographic markets typically defined in the pharmaceutical sector?

Typically, product markets in pharmaceutical mergers are narrowly defined based on the therapeutic use of the relevant product(s). Geographic markets tend to be broadly defined to include all of Canada.

For example, diaper rash ointment was identified as a relevant product market in the 2005 Johnson & Johnson/Pfizer matter referenced above. Similarly, influenza vaccines (subdivided into individual product categories based on their application to different diseases) were identified as a relevant product market in the review of GlaxoSmithKline Inc's acquisition of ID Biomedical in 2006.

16 In what circumstances will a product and geographical overlap between two merging parties be considered problematic?

The Competition Bureau's Merger Enforcement Guidelines (MEGs) establish 'screening' thresholds to identify and distinguish mergers that are unlikely to have anti-competitive consequences from those that require a more detailed analysis. In general, the MEGs provide that the Commissioner will not challenge a merger on the basis of a concern related to the unilateral exercise of market power where the post-merger market share of the merged firm would be less than 35 per cent.

Mergers that give rise to market shares that exceed the screening threshold are not necessarily problematic. Rather, the Competition Bureau examines various qualitative factors (including industry regulation, barriers to entry, effective remaining competition and the availability of acceptable substitutes to the products of the merging parties) in order to determine whether the merger is likely to create, maintain or enhance market power and thereby prevent or lessen competition substantially.

Competition is assessed with respect to both actual and potential competition. In the pharmaceutical context, potential competition would typically reflect either the anticipated approval of drug products in the developmental pipeline or the anticipated entry of generic drug products following patent expiry.

17 When is an overlap with respect to products that are being developed likely to be problematic?

Overlaps in 'pipeline products' (the competition in respect of which will be eliminated by a merger) will give rise to issues under the merger provisions of the Competition Act in circumstances in which the products are likely to receive regulatory approval and to be sold in Canada within a reasonable period of time following completion of the transaction; and the merged entity will be able to exercise market power in respect of the products post-merger.

For example, in connection with the 2009 merger between Merck and Schering-Plough, the Competition Bureau required the parties to divest a drug then in development for the treatment of chemotherapy-induced and post-operative side effects with a view to protecting future competition for the supply of products used in the treatment of these medical conditions.

18 Which remedies will typically be required to resolve any issues that have been identified?

The Competition Bureau prefers structural remedies (ie, divestitures) to behavioural remedies when seeking to address merger-related competition concerns. For example, following its review of Novartis's then-proposed acquisition of Alcon in 2010, the Competition Bureau entered into a consent agreement with the Novartis that provided for the sale of assets and associated licences related to the sale in Canada of certain ophthalmic products. This remedy reflected the Canada-specific nature of the Competition Bureau's concerns in this case.

In other cases, such as the 2013 acquisition of Life Technologies by Thermo Fisher Scientific, the Competition Bureau concluded that no further remedial action by the merging parties would be required since a remedy obtained in another jurisdiction (in this case, the European Union) addressed its concerns.

19 Would the acquisition of one or more patents or licences be subject to merger reporting requirements? If so, when would that be the case?

Acquisitions of patents are asset acquisitions under Part IX of the Competition Act (pre-merger notification) and are notifiable if both the following financial thresholds are exceeded: the parties to the transaction, together with their affiliates, must have assets in Canada, or annual gross revenues from sales in, from or into Canada, that exceed C$400 million; and the aggregate (gross book) value of the patents, or the annual revenues from sales (if any) generated by the patents, exceed (in 2015) C$86 million (the transaction-size threshold is adjusted annually based on changes in the average of the nominal gross domestic products).

The acquisition of a licence may or may not be an asset acquisition under Part IX depending upon the licence terms. For example, a perpetual, exclusive licence granted in circumstances in which the licensor does not retain any residual interest would likely be regarded as tantamount to an asset sale and would be subject to notification. A more limited licence likely would not be notifiable.

Anti-competitive agreements

20 What is the general framework for assessing whether an agreement or practice can be considered anti-competitive?

Agreements between competitors can be assessed under either section 45 of the Competition Act (criminal competitor agreements) or section 90.1 (civil competitor agreements). Under section 45, certain agreements between competitors, including agreements to fix prices, allocate markets or customers or limit output or supply, are illegal per se. In other words, there is no requirement to prove any anti-competitive effect beyond the agreement itself. Under section 90.1, agreements between competitors can be challenged by the Commissioner where they are likely to prevent or lessen competition substantially – a test that is essentially the same as the test for assessing mergers under section 92 of the Competition Act.

In order for reviewable trade practices, such as tied selling and exclusive dealing, to be considered problematic, the practice must be engaged in by a major supplier or must otherwise be widespread in a market, and it must have an exclusionary effect in a market with the result that competition is or is likely to be lessened substantially. In general, a substantial lessening of competition refers to circumstances in which a person, either alone or together with others, is able to exercise market power. The exercise of market power refers to the ability of the person to maintain prices above an otherwise competitive level for a significant period of time.

Update and trends

The current hot topic in Canadian antitrust enforcement in the pharmaceutical sector is the treatment of patent litigation settlement agreements. In September 2014, the Commissioner released a paper on Patent Litigation Settlement Agreements in Canada at the conference on Global Antitrust Challenges for the Pharmaceutical Industry at George Mason University. Concurrently, the Competition Bureau released a White Paper that provides a 'Canadian perspective on the issue'.

The White Paper was unanticipated given that the Competition Bureau had previously indicated its intention to address patent litigation settlements as part of a second round of updates to its Intellectual Property Enforcement Guidelines, the first round of updates to which were also released in September 2014. By issuing the White Paper, the Commissioner has sent a strong signal to the pharmaceutical industry that he intends to closely scrutinise patent litigation settlement agreements that come to his attention, although, unlike in the United States, there is currently no requirement that these agreements be filed with the Competition Bureau.

21 Describe the nature and main ramifications of any cartel investigations in the pharmaceutical sector.

For the most part, cartel investigations in the pharmaceutical sector in Canada to date have been limited to investigations triggered by (or coordinated with) cartel investigations (and, in some circumstances, guilty pleas and the imposition of antitrust penalties) in other jurisdictions. Likely because of the global nature of the pharmaceutical industry, Canada-only investigations have been rare. They generally have not become public until guilty pleas have been entered and penalties (typically, fines) have been announced by the Competition Bureau. Class action litigation and related settlements have invariably followed.

22 To what extent are technology licensing agreements considered anti-competitive?

In general, technology licensing agreements are not considered to be anti-competitive in Canada. Agreements alleged to substantially prevent competition that otherwise would have developed between the parties could potentially be challenged under section 90.1 (civil competitor agreements) of the Competition Act, but this has not occurred to date.

23 To what extent are co-promotion and co-marketing agreements considered anti-competitive?

Co-promotion and co-marketing agreements are generally not considered to be anti-competitive in Canada, provided the parties do not compete in the sale of the relevant product (that is, one party assists the other party in promoting or marketing the product, but all sales of the product are ultimately made by or for the account of the other party). If the parties were to compete in the sale of the relevant product, a co-promotion or co-marketing arrangement could be problematic if it had the effect of allocating customers or markets or if there was agreement between the parties regarding the price at which the product would be sold. In these circumstances, the agreement would raise serious issues under section 45 (criminal competitor agreements) of the Competition Act.

24 What other forms of agreement with a competitor are likely to be an issue? Can these issues be resolved by appropriate confidentiality provisions?

Under section 90.1 of the Competition Act, any agreement or arrangement between competitors that substantially prevents or lessens competition in a market can be challenged by the Commissioner. While there is no jurisprudence under section 90.1 – the provision was only enacted in 2009 – it could potentially apply to a variety of agreements between competitors, including joint ventures and other collaborative arrangements.

25 Which aspects of vertical agreements are most likely to raise antitrust concerns?

In the pharmaceutical context, tying and bundling requirements in supply agreements are the vertical restraints most likely to raise antitrust concerns (typically, under abuse of dominance). In most cases, the issue will be whether the requirements are predatory, exclusionary, disciplinary or otherwise designed to have a negative impact on the competitors of a dominant firm. Exclusive dealing requirements can raise similar issues.

26 To what extent can the settlement of a patent dispute expose the parties concerned to liability for an antitrust violation?

There are no reported instances in Canada of a patent settlement having been challenged on the basis of antitrust concerns, such as pay-for-delay. Nevertheless, in the right circumstances – for example, a settlement involving a significant payment to a generic manufacturer that cannot be justified on any reasonable, commercial basis – a patent settlement could be challenged under either section 45 (criminal competitor agreements) as an agreement to restrict product output or supply or under section 90.1 (civil competitor agreements) of the Competition Act.

Anti-competitive unilateral conduct

27 In what circumstances is conduct considered to be anti-competitive if carried out by a firm with monopoly or market power?

In Canada, the conduct of a dominant firm that is engaged in a practice of 'anti-competitive acts' can be challenged by the Commissioner where the practice has had, is having or is likely to have the effect of preventing or lessening competition substantially in a market. While the Canadian jurisprudence on the interpretation of sections 78 and 79 (abuse of dominant position) of the Competition Act would appear to be in flux at the present time as a result of a number of recent decisions, anti-competitive acts have traditionally been regarded in Canada as practices that reflect a predatory, exclusionary or disciplinary intent and have such an effect on competitors of a dominant firm.

28 When is a party likely to be considered dominant or jointly dominant?

Under sections 78 and 79 of the Competition Act, a person is (or persons are) considered to be dominant if it (or they) substantially or completely control, throughout Canada or any area thereof, a class or species of business. This has been interpreted by Canadian courts to mean that the person or persons must be able to exercise market power. Canadian abuse of dominance jurisprudence requires that, in order to be considered dominant, a person or persons must hold a significant share of a relevant market. While the Competition Bureau's enforcement perspective is that dominance can occur at market shares in excess of 35 per cent, most cases in which dominance has been considered have involved parties with very high market shares, often in the range of 80 per cent or more. While dominance could exist at market share levels anywhere above 50 per cent, dominance is less likely to be found at market share levels below 50 per cent.

29 Can a patent holder be dominant simply on account of the patent that it holds?

Simply holding a patent would not give rise to dominance. If the patent holder were engaged in the sale of the patented product, it might be considered dominant if the relevant product market were restricted to its product. However, in these circumstances, the person arguably could not engage in a practice of anti-competitive acts because its patent monopoly would mean that it would face no competitors in that market. If the relevant product market were defined to include other products beyond the scope of a patent (for example, a class of products), dominance could be found on the basis described above.

30 To what extent can an application for the grant of a patent expose the patent owner to liability for an antitrust violation?

Assuming a bona fide application for the grant of a patent, this action would not expose a patent owner to liability for an antitrust violation in Canada.

31 To what extent can the enforcement of a patent expose the patent owner to liability for an antitrust violation?

There is no history in Canada of patent enforcement having been successfully challenged as an antitrust violation.

32 To what extent can certain life-cycle management strategies expose the patent owner to liability for an antitrust violation?

To date, there are no examples of life-cycle management strategies having exposed a patent owner to liability for an antitrust violation in Canada.

33 Do authorised generics raise issues under the competition law?

In general, no. Absent some other agreement between the parties, authorising the generic manufacture of an innovative drug does not give rise to issues under the Competition Act.

34 To what extent can the specific features of the pharmaceutical sector provide an objective justification for conduct that would otherwise infringe antitrust rules?

Canadian antitrust jurisprudence includes a regulated conduct doctrine, which attempts to address the 'conflict' that can arise between regulatory requirements (established under federal or provincial legislation or by self-regulatory organisations) and the requirements of Canadian competition law. The conflict between price regulation and price fixing is an example. While there is no Canadian jurisprudence in which the regulation of the Canadian pharmaceutical industry has been found to justify conduct that otherwise would have infringed the Competition Act, the regulated conduct doctrine would clearly be applicable in appropriate circumstances.

35 Has there been an increase in antitrust enforcement in the pharmaceutical sector in your jurisdiction? If so, please give an indication of the number of cases opened or pending and their subject matters.

There has not been increased antitrust enforcement in the pharmaceutical sector in Canada in recent years. However, in November 2013, the Competition Bureau held a one-day workshop on antitrust issues in the pharmaceutical industry with a view, in part, to informing its approach to pharmaceutical antitrust enforcement in the future. Increased pharmaceutical antitrust policy initiatives and possibly increased enforcement, are the expected outcomes. See 'Update and trends' for further developments.

36 Is follow-on litigation a feature of pharmaceutical antitrust enforcement in your jurisdiction? If so, please briefly explain the nature and frequency of such litigation.

Follow-on litigation is a common feature of antitrust enforcement in Canada. However, there have been relatively few pharmaceutical antitrust enforcement actions in Canada in recent years with the result that there has been limited follow-on pharmaceutical antitrust litigation.

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