Bristol Myers Squibb™

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Chairman of the Board
Patented Medicine Prices Review Board (PMPRB)
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Subject: BMS Response to PMPRB Scoping paper for the consultations on the Board's Guidelines

At BMS, our mission is to discover, develop, and deliver innovative medicines that helps patients prevail over serious diseases. As one of Canada's true innovator companies, we focus on developing first-in-class, and best-in-class, medicines to address unmet patient needs while transforming standards of care. We have a rich history of scientific excellence, transforming outcomes in major diseases such as cancer, cardiovascular disease, HIV and HCV. Just ten years ago, BMS Canada was the first company to bring an immune-oncology (I-O) medicine to Canadians. This led a revolutionary change in the treatment of more than 10 cancers and has resulted in 18 I-O indications for Canadians.

We invest in Canada, and we invest in Canadians. BMS has among the highest number of active Canadian clinical trials site within the top 20 pharmaceutical companies. In 2023, we have 153 active clinical trials in over 100 sites across Canada, enrolling over 2,000 patients. For these patients, it means access to promising new treatment options years ahead of commercialization. For Canadian researchers, they gain first-hand experience with these new molecules, technologies, and therapies. These local trials support a pro-innovation environment with the leading edge of science to make Canada a nation where more patients benefit from innovative or life-saving medicines, and where our research leads to the development and commercialization of new innovations in future years.

In a period of unprecedented life sciences innovation, the need for a predictable and sustainable non-excessive pricing system where medical innovation is valued to enable the launch of new treatments that can benefit Canadians is paramount. The new Guidelines must reflect PMPRB's jurisdiction with respect to excessive pricing due to abuse of patent rights and follow their mandate to provide transparency and predictability to rights holders.

A predictable pricing framework will enable rights holders to protect the value of new medicines and provide an assurance of stable pricing over the commercial life of the product, supporting mid-to-long term business decisions made today for tomorrow's inflow of future innovations. A sustainable PMPRB pricing framework encourages global companies to continue to invest in Canada, not only in completing our regulatory and reimbursement processes to bring medicines into Canada, but also to invest in early-stage research and clinical trials for Canadians who urgently need new treatment options for serious diseases. Breakthrough innovations are the result of decades of work in laboratories and clinical trials long before they are prescribed by a Canadian physician. It is critical that the PMPRB guidelines support prices that reflect the true value of innovation, which is the foundation for an inflow of research and development in the country.

The new Guidelines should accurately reflect PMPRB's jurisdiction on excessive pricing due to abuse of patent rights. A predictable and sustainable, non-excessive pricing system where

medical innovation is valued will enable global companies to assess the viability of bringing new products to Canada. It is critical that the new guidelines provide a reasonable assurance of stable pricing over the expected commercial life of the product through a fair and consistent framework.

In closing, we ask that the PMPRB Board acknowledge input from all its stakeholders included in the policy roundtables and written submissions to ensure a fair and iterative development process before finalizing the new guidelines. Let's learn from the past few years and start working together so we can quickly agree and implement new Guidelines that are predictable, sustainable and enable innovative medicines that bring new hope for Canadians.

Sincerely,

Elaine Phillips
General Manager
Bristol Myers Squibb Canada Co.

* During the BMS Canada presentation to the PMPRB Board on December 6th, BMS was asked to clarify the source of our statistic, "only 44% of all new innovative medicines launched in OECD countries have come to Canada on medicines launched in Canada in the decade ending in 2021". Innovative Medicines Canada (IMC) commissioned an independent data analysis firm IQVIA in September 2022 to report medicines available in EOCD countries over a 10-year period (2012-2021). Source: PhRMA analysis of IQVIA MIDAS and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan Pharmaceuticals and Medical Devices Agency (PMDA) data. August 2022. Note: New medicines refer to new active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2012, and December 31, 2021.

BMS Canada Response
Scoping Paper for the Consultations on the Board's Guidelines

PMPRB Questions	BMS Canada
1.1: What elements of the 2010 Guidelines should be retained? Which ones and why?	The development of new Guidelines should reflect PMPRB's jurisdiction with respect to excessive pricing due to abuse of patent rights. The 2010 Guidelines relied too heavily on the median which is not aligned with the definition of excessive under the revised basket. The Highest International Price (HIP) is the only standard consistent with the PMPRB's legal mandate to ensure prices are not excessive. The PMPRB must establish a predictable pricing framework that allows for a fair and consistent approach to establishing and protecting the value of new medicines. The 2010 PMPRB guidelines acknowledged and permitted price increases on already approved drugs enabling manufacturers to align with the Consumer Price Index (CPI). Inflation is also included in the Patent Act and should continue to be permissible by PMPRB when assessing whether a price is excessive or not.
1.2: Should new Guidelines continue to categorize medicines by therapeutic class comparator characteristics (TCC) such as the Level of Therapeutic Improvement?	No. The Highest International Price (HIP) is the only standard consistent with the PMPRB's legal mandate to ensure prices are not excessive. In Canada, scientific reviews are conducted by other agencies whose mandate is to assess therapeutic improvement. BMS and other Canadian rights holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating draft guidelines. Engaging in a collaborative consultation process will enable the PMPRB to consider broad input and expertise as part of a constructive and fair process.
1.3: Should the Board accord more weight to one or more of the factors set out in s. 85 of the Act in designing the Guidelines?	Without more context and detail on how the Guidelines will be formulated, it is difficult to comment on what weight to give any factors set out in s. 85 of the Act. BMS and other Canadian rights holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating draft guidelines. Engaging in a collaborative consultation process will enable the PMPRB to consider broad input and expertise as part of a constructive and fair process. The new Guidelines should reflect the PMPRB's jurisdiction with respect to excessive pricing due to the abuse of patent rights, and that the Highest International Price (HIP) test is the only standard that is consistent with the PMPRB's mandate to ensure prices are not excessive.
1.4: If international prices are used as the initial triage measure for commencing investigations, what price levels within the PMPRB11 should be used as the triage	We are unclear about the term "initial triage" which appears to suggest that further review could be involved and introduce uncertainty. Without more context and detail on reformulated Guidelines, it is difficult to comment. BMS and other Canadian rights holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating new draft guidelines. I would reiterate that the Highest International Price (HIP) is the only standard consistent with the PMPRB's legal mandate to ensure prices are not excessive. The

measure? (e.g. HIP or MIP?)	new Guidelines must enable a predictable and sustainable, non-excessive pricing system where medical innovation is valued to enable the launch of new treatments.
1.5: How should the PMPRB conduct an initial review and monitor the prices of patented medicines that have few or no international prices?	This will depend on the overarching framework proposed. BMS and other Canadian rights' holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating reformulated guidelines. Pending the outcome of discussions from a technical working group, different options tied to the HIP rule could be applied once an international price(s) for the product is available.
1.6: Would an expedited price review (e.g., within 90 days after initial Form 2 submission) of a new medicine based solely on international prices being below the MIP accelerate introduction of innovative medicines? How soon after an expedited review should a full price review take place?	This will depend on the overarching framework proposed. BMS and other Canadian rights holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating reformulated guidelines. I would reiterate that the Highest International Price (HIP) is the only standard consistent with the PMPRB's legal mandate to ensure prices are not excessive. The new Guidelines must enable a predictable and sustainable, non-excessive pricing system where medical innovations are valued to enable the launch of new treatments.
2.1: Should the Guidelines distinguish between medicines that existed as of July 2022 (existing medicines) and medicines introduced afterwards (new medicines)?	Canada needs predictable pricing that allows for a fair and consistent framework to establish and protect the value of new medicines. A predictable pricing framework means that there is an assurance of stable pricing over the commercial life of the product, supporting mid-to-long term business decisions made today to ensure the continued inflow of future innovations. Furthermore, it is our belief that all medicines introduced prior to any new finalized Guidelines should be allowed to retain their price and to be fully grandfathered until the end of the PMPRB's jurisdiction at patent expiry. Only medicines introduced after the new Guidelines are implemented should be subject to new guidelines.
2.2: What approach should the Board take with respect to existing medicines with prices above the HIP of the PMPRB11? Should the Board review these prices, and if so, how soon?	It is our belief that all medicines introduced prior to any new finalized Guidelines should be allowed to retain their price and to be fully grandfathered until the end of the PMPRB's jurisdiction at patent expiry. Only medicines introduced after the new Guidelines are implemented should be subject to new guidelines.

3.1: How often should price reviews be conducted? (1-5 years). i. Should they be different for small molecules (average 10-year exclusivity period) versus biologics (average 20+ year exclusivity period)? ii. Should they be different for medicines for rare diseases?	This will depend on the overarching framework proposed. We believe that Canada needs predictable pricing that allows for a fair and consistent framework to establish and protect the value of new medicines. A predictable pricing framework means that there is an assurance of stable pricing over the product patent life, supporting mid-to-long term business decisions made today to ensure the continued inflow of future innovations. We believe that medicines that were launched under the previous Guidelines should continue to follow the agreed terms until the patent expiry; and new medicines should be assessed against the maximum price threshold for a concrete time period, without being subject to reassessment or re-benching in future reporting periods or under new guidelines. By implementing these principles, there would be a reasonable assurance of stable pricing over the expected patent life of the product.
3.2: What criteria besides time should be used to trigger a price review? i. Approval of a significant new indication? ii. Significant change to the therapeutic class comparators? Availability of new/stronger evidence related to benefit vis-à-vis therapeutic class comparators? iii. Departure from identified pricing thresholds?	Canada needs predictable pricing that allows for a fair and consistent framework to establish and protect the value of new medicines. A predictable pricing framework means that there is an assurance of stable pricing over the product's patent life, supporting mid-to-long term business decisions made today to ensure the continued inflow of future innovations. Medicines that were launched under the previous Guidelines should continue to follow the agreed terms until the patent expiry; and new medicines should be assessed against the maximum price threshold for a concrete time period without being subject to reassessment or re-benching in future reporting periods or under new guidelines. By implementing these principles, there would be a reasonable assurance of stable pricing over the product's expected patent life. BMS and other Canadian rights holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating draft guidelines.
3.3: Should the relative weighting given to different section 85 (Patent Act) factors change over the lifecycle of a medicine?	Medicines that were launched under the previous Guidelines should continue to follow the agreed terms until their patent expiry; and new medicines should be assessed against the maximum price threshold for a concrete time period without being subject to reassessment or re-benching in future reporting periods or under new guidelines. The new Guidelines should reflect PMPRB's jurisdiction with respect to excessive pricing due to the abuse of patent rights, and that the Highest International Price (HIP) test is the only standard that is consistent with the PMPRB's mandate to ensure prices are not excessive.
3.4: How should the PMPRB treat the allowable Consumer	Medicines that were launched under the previous Guidelines should continue to follow the agreed terms until the patent expiry. The development of new Guidelines should reflect PMPRB's jurisdiction with respect to excessive pricing

Price Index increase in the context where international list prices are decreasing?	due to the abuse of patent rights, and that the Highest International Price (HIP) test is the only standard that is consistent with the PMPRB's mandate to ensure prices are not excessive. New drugs should be subject to international pricing review using the highest international price at introduction. This can set a predictable ceiling for the life of the patent, subject to CPI adjustments. CPI is reflected in the Patent Act and should continue as per the 2010 PMPRB guidelines which acknowledge and permit price increases on already approved drugs to enable manufacturers to align with the Consumer Price Index (CPI).
3.5: What is the ideal timing for scientific review and therapeutic comparator identification? At what price review stage(s) should scientific review be applied?	We cannot comment on specifics without knowledge of the new overarching system and proposed role for comparators. BMS and other Canadian rights' holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating draft guidelines. Scientific reviews are not aligned PMPRB's mandate or the Patent Act. In Canada, scientific reviews are conducted by other agencies whose mandate is to make reimbursement decisions based on market factors and relative value. There is no crossover of roles for the PMPRB whose legal mandate is to ensure prices are not excessive. The new Guidelines should reflect PMPRB's jurisdiction with respect to excessive pricing due to the abuse of patent rights, and that the Highest International Price (HIP) test is the only standard that is consistent with the PMPRB's mandate to ensure prices are not excessive. The new pricing framework needs to take into account the value of a medicine in the healthcare system today, while enabling an environment for long-term investment by its multiple stakeholders, including research institutions, clinical investigators and innovative biopharma companies bringing new medicines to the country.
Question 4.1: Are the criteria published in the 2010 Guidelines for commencing an investigation still appropriate (assuming adjustment to PMPRB11)?	We cannot comment on specifics without knowledge of the new overarching system. BMS and other Canadian rights' holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating draft guidelines.
Question 4.2: How much detail should the Guidelines set out regarding what happens once an investigation is opened?	We cannot comment on specifics without knowledge of the new overarching system. BMS and other Canadian rights' holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating draft guidelines. The principles of fairness to patentees and transparency on the standards that Staff would apply and predictability on the outcomes require the new Guidelines to clearly spell out as much of the details that will apply.

Question 4.3: Should the PMPRB continue to use Undertakings as an investigation closure mechanism?	Yes. We believe that Voluntary Compliance Undertakings (VCU) are an effective mechanism to quickly resolve many of the minor pricing issues that can arise over the PMPRB's jurisdiction and should continue to be offered.
Question 5.1: What efficiencies could be gained by co-ordinating decisions and timelines of the PMPRB with those of the Canadian Agency for Drugs and Technologies in Health (CADTH), Institut national d'excellence en santé et services sociaux (INESSS) and pan-Canadian Pharmaceutical Alliance (pCPA) or insurers (public and private)?	The PMPRB's legal jurisdiction is to oversee excessive pricing due to abuse of patent rights, as opposed to other agencies whose mandate is to assess reimbursement based on market factors and relative value. There is no crossover of roles for the PMPRB whose legal mandate is to ensure prices are not excessive.
Question 5.2: How can the PMPRB optimize its presence within the Canadian bio/pharmaceutical ecosystem to support a whole of government approach to issues relating to patented medicines?	The PMPRB's legal jurisdiction is to oversee excessive pricing due to abuse of patent rights. The new Guidelines must reflect PMPRB's jurisdiction with respect to excessive pricing due to abuse of patent rights and follow their mandate to provide transparency and predictability to patentees. In a period of unprecedented life sciences innovation, there is a strong need for a predictable and sustainable non-excessive pricing system where medical innovation is valued to enable the launch new treatments to benefit Canadians.
Question 6.1: What is your experience with innovative medicines and their list prices in Canada?	
Question 6.2: What role do the PMPRB Guidelines play in your decision-making process in Canada and globally (if applicable)?	Global companies assess the viability of bringing new products to each country where they operate. When the value of innovation is recognized, the country is supported and, possibly prioritized as an early launch market to bring innovations to their populations even faster. It is critical that the PMPRB guidelines support prices that reflect the overall research and development investment in Canada, which will be attractive to support an inflow of innovation into the country. Canadians are disadvantaged when medical innovation is devalued.
Question 6.3: Canada and the world are facing a generation of new high-priced drugs	The PMPRB's legal jurisdiction is to oversee excessive pricing due to abuse of patent rights. The new Guidelines must reflect PMPRB's jurisdiction with respect to excessive pricing due to abuse of patent rights and follow their mandate to provide transparency and predictability to patentees.

for the treatment of rare diseases. Should the PMPRB view the question of whether the prices of these medicines are "excessive" through a different lens than other types of medicines? What quality of evidence should the Board consider when conducting its scientific review of these medicines?	BMS and other Canadian rights' holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating reformulated guidelines. Engaging in a collaborative consultation process will enable the PMPRB to consider broad input and expertise as part of a constructive and fair process.
Question 6.4: How can the PMPRB better engage with you?	BMS and other Canadian rights' holders can provide meaningful insights and expertise through technical working groups where multiple factors can be considered before circulating draft guidelines. Engaging in a collaborative consultation process will enable the PMPRB to consider broad input and expertise as part of a constructive and fair process.

Aperçu de la présentation de BMS
Table ronde sur les politiques du CEPMB du 6 décembre 2023
François Villeneuve, vice-président, de l'équipe de l'Accès au marché et de la Tarification chez Bristol Myers Squibb

Bonjour, je m'appelle François Villeneuve. Je suis le vice-président, de l'équipe de l'Accès au marché et de la Tarification chez Bristol Myers Squibb. Je travaille dans le secteur biopharmaceutique depuis 28 ans et j'ai donc été témoin et j'ai participé à de multiples processus de consultation avec le CEPMB au cours des dernières années. Je vous remercie de nous donner l'occasion de vous faire part de notre point de vue en tant que société novatrice qui offre de nouveaux traitements aux Canadiens atteints de maladies graves. Chez BMS, nous croyons fermement que la collaboration entre tous les intervenants en soins de santé produira les meilleurs résultats pour la population canadienne. En invitant le secteur à participer à cette phase de consultation sur les nouvelles lignes directrices, le CEPMB accomplit une étape positive vers l'élaboration de lignes directrices justes et durables. En tant que détenteurs de brevets, nous sommes évidemment particulièrement investis, car nous serons directement touchés par les résultats de ces discussions. L'élaboration de nouvelles lignes directrices doit refléter le mandat du CEPMB qui est de s'assurer que les prix des médicaments brevetés ne sont pas excessifs. Mandat qui a d'ailleurs été récemment confirmé en court fédérale. Nous croyons aussi qu'il est primordial d'assurer la transparence et la prévisibilité pour les détenteurs de brevets en ce qui concerne le processus de triage et d'évaluation des prix. Au cours des prochaines minutes, je vous ferai part de trois principes fondamentaux que nous jugeons nécessaires afin de créer un environnement dans lequel les sociétés novatrices d'échelle mondiale puissent apporter leurs recherches et leurs médicaments essentiels au Canada.

Le premier principe est celui de la prévisibilité.

Depuis 1966, le Canada est fier d'offrir des soins de santé universels à toute sa population. La Loi canadienne sur la santé s'appuie sur les principes de l'administration publique, de l'accessibilité, de l'universalité et de l'intégralité. Pourtant, en 2021, moins de la moitié des nouveaux médicaments lancés par les pays de l'OCDE sont arrivés au Canada. Ce qui semble loin de nos ambitions. Le Canada a besoin d'une évaluation prévisible du prix qui permet un cadre juste et uniforme pour établir et protéger la valeur des nouveaux médicaments. Un cadre de tarification prévisible signifie qu'il y a une assurance de prix stables pendant la durée de vie commerciale du médicament breveté, afin que des décisions commerciales à moyen et à long terme puissent être prises par les détenteurs de brevets. Nous croyons qu'en pratique et façon concrète, les médicaments qui ont été lancés en vertu des lignes directrices précédentes devraient continuer de suivre les modalités convenues à ce moment, et ce, jusqu'à l'expiration du brevet. Le prix des nouveaux médicaments doivent être évalués en fonction de leur nature non-excessive, tel que stipulé dans le mandat du CEPMB et par conséquent au seuil de prix maximal, et non médiane pour une période concrète et sans faire l'objet d'une réévaluation ou d'un nouvel établissement de référence au cours des futures périodes de déclaration ou en vertu de nouvelles lignes directrices. La mise en œuvre de ces principes offrirait une assurance raisonnable de prix stables pour la durée de vie totale du médicament breveté.

Le deuxième principe est la durabilité.

Le concept de durabilité pour les détenteurs de brevet comporte deux volets; il exige des politiques de prix qui sont « tolérables » et « pouvant être maintenues à un certain niveau ». En tant que détenteurs de brevet, le nouveau cadre de tarification doit tenir compte de la valeur d'un médicament dans le système de soins de santé d'aujourd'hui, tout en permettant à ses multiples intervenants d'investir à long terme, y compris les établissements de recherche, les chercheurs cliniciens et les sociétés biopharmaceutiques novatrices qui offrent de nouveaux médicaments au pays. Les sociétés novatrices comme BMS investissent au Canada de nombreuses façons, y compris en recherche et développement, en lançant des essais cliniques avec des instituts de recherche locaux et en assurant un accès compassionnel aux médicaments avant qu'ils ne soient remboursés par le système de santé public. Nous soutenons un environnement favorable à l'innovation à la fine pointe de la science afin de faire du Canada une nation où un plus grand nombre de patients bénéficient de médicaments novateurs ou d'importance vitale.
Un cadre de tarification durable pour le CEPMB encouragerait les sociétés mondiales à continuer d'investir au Canada, non seulement en terminant nos processus réglementaires et de remboursement pour importer les médicaments au Canada, mais aussi en investissant dans les essais de recherche cliniques à un stade précoce pour les Canadiens qui ont besoin de toute urgence de nouvelles options de traitement pour des maladies graves.

Le principe no 3 est la valeur de l'innovation.

L'investissement de temps et de ressources dans la recherche médicale est un travail de longue haleine. Les innovations révolutionnaires sont le résultat de décennies d'essais cliniques en laboratoire bien avant qu'elles ne soient prescrites par un médecin canadien. La récente pandémie en est un parfait exemple. Une grande partie de la recherche qui a mené à la mise au point rapide de vaccins contre la COVID-19 était en cours depuis des décennies dans le secteur biopharmaceutique novateur. Il est essentiel que les lignes directrices du CEPMB soutiennent des prix qui reflètent l'investissement global en recherche et en développement au Canada, qui seront assez attrayants pour soutenir l'innovation au pays. Les entreprises d'échelle mondiale évaluent la viabilité de la commercialisation de nouveaux produits dans chaque pays où elles exercent leurs activités, et ce, selon plusieurs critères variés. Ceci étant dit, Lorsque la valeur de l'innovation est reconnue, le pays est soutenu, voire considéré comme prioritaire en tant que marché de lancement précoce pour offrir les innovations à sa population encore plus rapidement. Au cours de la décennie qui s'est terminée

en 2021, seulement 44 % de tous les nouveaux médicaments novateurs lancés dans les pays de l'OCDE sont arrivés au Canada. Ces pourcentages se comparent à 85 % aux États-Unis et à 59 % au Royaume-Uni. Les Canadiens sont désavantagés lorsque l'innovation médicale est dévaluée. Les lignes directrices canadiennes sur l'établissement des prix doivent tenir compte de la valeur que les médicaments apportent aux Canadiens et à notre système de soins de santé – hier, aujourd'hui et demain. Ce n'est que lorsqu'un proche reçoit un diagnostic dévastateur, mettant sa vie en danger, qu'ils apprécient vraiment la disponibilité des médicaments novateurs qui ont été découverts et mis au point au cours d'un cycle de 20 ans.

La collaboration est dans la nature des entreprises biopharmaceutiques. Des centaines de collaborateurs sont nécessaires pour découvrir et mettre au point nos médicaments. Le CEPMB, en tant que partie prenante du gouvernement, doit également collaborer et s'engager à mettre en place un cadre prévisible et durable ainsi qu'un processus inclusif au sein duquel les détenteurs de brevets puissent fournir des renseignements pertinents concernant l'établissement des lignes directrices qui auront une incidence directe sur leurs activités futures. Pour conclure, nous demandons au CEPMB de tenir compte des commentaires de tous les intervenants ayant participé aux tables rondes afin d'assurer un processus d'élaboration juste et itératif avant de finaliser les nouvelles lignes directrices. Apprenons des dernières années et travaillons ensemble afin que nous puissions rapidement nous entendre et mettre en œuvre les nouvelles lignes directrices.

Chez BMS, nous sommes reconnaissants d'avoir la possibilité de donner des commentaires, et nous aimerions poursuivre le dialogue pour fournir des points de vue et une expertise supplémentaire en participant à des groupes techniques nous permettant ainsi d'aller plus en détails et d'avoir un processus de réelle collaboration visant à reformuler les lignes directrices. Notre objectif collectif doit être de continuer de veiller à ce que les patients canadiens aient accès en temps opportun à tous les médicaments novateurs dont ils ont besoin, lorsqu'ils en ont besoin.

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