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Client Alert

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Key Changes and Business Impact under Ministry of Health (MOH) Regulation No. 5 of 2026 on Health Supplies

This regulation introduces several new provisions while at the same time revoking and consolidating several previous regulations in the healthcare sector. It places greater emphasis on domestic production, pricing transparency, the digitalization of distribution and reporting systems.

In brief

On 4 May 2026, the MOH promulgated MOH Regulation No. 5 of 2026 on Health Supplies ("**MOH Regulation 5**"), which comprehensively introduces several obligations that are entirely new to the Indonesian Health Supplies regulatory framework.

"Health Supplies" is defined as all materials and equipment required to support the implementation of healthcare services. They include pharmaceutical products (i.e., medicines; pharmaceutical ingredients; natural medicinal products, ingredients for natural medicinal products; cosmetics; health supplements; and quasi-drugs), household health products (*Perbekalan Kesehatan Rumah Tangga*/PKRT) and medical devices, as applicable.

MOH Regulation 5 repeals several prior MOH regulations, including those on marketing authorization (MOH Regulation 62/2017), import supervision (MOH Regulation 60/2017), good manufacturing practices (MOH Regulation 20/2017), and traditional medicine (MOH Regulation 6/2012).

Businesses should pay particular attention to the five-year localization deadline (which is already running), the mandatory buffer stock requirement, the six-month shortage notification obligation, the gratification prohibition and its interaction with the new price transparency regime, and the expanded sanctions framework — each of which is addressed in this alert.

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Key takeaways

Health Supplies Prioritization Through Domestic Manufacturing

MOH Regulation 5 strongly prioritizes domestic production of Health Supplies and narrows the circumstances in which imported products may continue to enter the Indonesian market. The regulation reflects a broader policy objective of strengthening national manufacturing capacity and reducing reliance on imports.

1. Domestic Raw Material Sourcing as a Regulatory Requirement

Production facilities are required to prioritize the use of domestically produced raw materials and components, provided that safety, efficacy and quality standards are maintained in accordance with applicable laws and regulations. This requirement also extends to production planning, under which manufacturers must prioritize the use of locally sourced raw materials when preparing their production plans.

2. Limited Circumstances for Importation of Generic Medicines

Generic medicines may only be imported under limited circumstances, including where certain stages or the entirety of the manufacturing process cannot yet be performed domestically, domestic production is insufficient to meet demand, the medicines are required for public health programmes, or in situations involving emergencies, disasters, outbreaks, extraordinary events or public health crises. The MOH may also determine additional circumstances based on an evidence-based assessment.

Similarly, essential Health Supplies designated by the MOH are expected to be produced domestically. Where domestic production is not feasible, the MOH may cooperate with foreign manufacturers or international institutions to ensure supply continuity. While this preserves a pathway for foreign participation, it positions importation as an exception rather than the default means of supply.

3. Priority Health Supplies Must Be Supplied Through Domestic Production

The supply of priority Health Supplies must be prioritized through domestic production, whether developed through research and development or technology transfer arrangements. Priority Health Supplies include essential medicines, generic medicines, plasma derivative products, radiopharmaceuticals, and phytopharmaceuticals (*fitofarmaka*), as determined by the MOH.

This demonstrates the government’s preference for building local manufacturing capability rather than relying on long-term importation.

The Five-Year Localization Requirement for Imported Medicines

1. Mandatory Domestic Production Within Five Years

Under Article 37(3), imported medicines are required to be manufactured domestically no later than five years (arguably counted from when the regulation came into force, on 4 May 2026), or in accordance with an approved technology transfer roadmap under which the medicines become capable of being manufactured in Indonesia. This requirement reflects the government’s objective of reducing reliance on imported medicines and strengthening domestic pharmaceutical manufacturing capacity.

2. Technology Transfer as a Localization Mechanism

The five-year localization requirement may be fulfilled through a technology transfer roadmap, under which the knowledge, processes and manufacturing standards necessary to produce the medicine are transferred to domestic facilities. This underscores the MOH's expectation that companies contribute to the development of local manufacturing capabilities rather than relying indefinitely on imports.

3. Limited Circumstances for Continued Importation

Pending localization, imported medicinal products may continue to be prioritized for use in public health programs, newly developed medicines, and medicines required to meet healthcare needs that cannot yet be met through domestic production. This recognizes that certain products may remain unavailable or insufficiently supplied by local manufacturers during the transition period.

4. Patent Protection Does Not Remove the Localization Expectation

Medicines that remain protected by patents are subject to the applicable patent laws and regulations. However, patent protection does not exempt a product from the broader policy objective of domestic production. Rather, it governs the rights and exclusivity associated with the product while the localization requirements continue to apply.

5. Pending Technical Guidelines

The MOH is expected to issue technical guidelines governing the technology transfer process and roadmap requirements. Until such guidelines are published, businesses face a degree of regulatory uncertainty regarding the precise implementation of the localization obligation, despite the commencement of the five-year compliance period on 4 May 2026.

While the five-year deadline has already begun, the technical guidelines that would define the precise form, content and approval process for a compliant technology transfer roadmap have not yet been issued. Businesses with imported medicine portfolios should not treat the absence of guidelines as a reason to defer planning. Any time spent waiting for guidelines is time that cannot be recovered within the five-year window. Proactive engagement with the Ministry regarding roadmap expectations is strongly advised.

The Domestic Supply Orientation

Even where the importation of Health Supplies remains permissible under applicable exceptions, the prioritization framework is designed to favor domestically produced products and, in practice, may place imported products at a competitive disadvantage.

1. Preference for Health Supplies With Domestic Content

The Central Government, regional governments, and healthcare facilities must prioritize Health Supplies that use domestically produced raw materials and/or components. Where comparable products are available, preference is given to those with higher domestic content levels (*Tingkat Komponen Dalam Negeri*/TKDN) or local products that have been equipped with marketing authorization. This policy aims to strengthen the domestic healthcare industry, reduce reliance on imports, and promote local manufacturers.

As a result, suppliers that can demonstrate significant local content or have local products that have been equipped with marketing authorization are likely to enjoy a competitive advantage in public procurement and healthcare-related purchasing decisions.

2. Domestic Content Preference Over Price Considerations in Government Procurement

The regulation expressly acknowledges that Health Supplies manufactured using domestically produced raw materials and/or components may be priced higher than comparable imported products. Nevertheless, procuring entities are still expected to prioritize those domestic products.

Accordingly, procurement decisions are not based solely on price. Even where an imported product is offered at a lower price, a domestic alternative that meets the applicable domestic content requirements may be preferred. Consequently, imported products cannot necessarily rely on price competitiveness alone to secure procurement opportunities. Foreign manufacturers may therefore need to consider localization strategies, such as establishing local production facilities, partnering with Indonesian manufacturers, or increasing the local content of their products.

3. Preference for Domestic-Content Health Supplies in the Electronic Catalogue

The electronic catalogue (e-catalogue), which serves as the principal procurement platform for Health Supplies in Indonesia, is required to prioritize products that use domestically produced raw materials and/or components. In practice, products with higher domestic content may benefit from preferential listing, greater visibility, or other procurement advantages within the platform. Given that public healthcare institutions frequently procure Health Supplies through the e-catalogue, a product's inclusion and position within the system can significantly affect its access to the market.

Health Supplies Delivery

1. Delivery Through Licensed Facilities

Health Supplies may be delivered through pharmaceutical service facilities and other facilities that have obtained the required business licenses in accordance with applicable laws and regulations.

2. Introduction of Vending Machine Distribution

The regulation introduces a new distribution channel by allowing certain Health Supplies to be delivered through vending machines. This reflects the government's efforts to increase accessibility and modernize the delivery of Health Supplies, subject to further regulatory requirements and limitations.

3. Expanded Access Through Non-Pharmaceutical Facilities

To further support self-medication and improve public access to basic healthcare products, MOH Regulation 5 permits drug stores to supply over-the-counter and limited over-the-counter medicines to hypermarkets, supermarkets, minimarkets and other facilities designated by the MOH. This is significant development that broadens the availability of commonly used medicines beyond traditional pharmacy settings while maintaining regulatory control over their distribution.

The Use of Electronic Systems in the Distribution and Delivery of Health Supplies

1. Distribution and Delivery Through Electronic Systems

The circulation of Health Supplies may be conducted through electronic systems integrated with the National Health Information System, covering both distribution and delivery activities.

However, distribution activities conducted through electronic systems may only be carried out by licensed manufacturers and distributors, while delivery activities may only be undertaken by pharmaceutical service facilities and other facilities holding the required licenses. This ensures that digital channels remain subject to the same regulatory oversight as conventional distribution channels.

2. Participation of Electronic System Providers

Manufacturers, distributors, healthcare facilities and other authorized facilities may develop and operate their own electronic systems or collaborate with third-party electronic platform providers. In particular, facilities authorized to dispense over-the-counter and limited over-the-counter medicines are permitted to do so through partnerships with electronic system providers, subject to applicable regulatory requirements.

These provisions reflect the Ministry of Health's broader objective of accelerating the digitalization of healthcare services while maintaining oversight of the supply chain.

3. Reporting and Integration Requirements

MOH Regulation 5 requires manufacturers, distributors, healthcare facilities and electronic system providers involved in the distribution or delivery of Health Supplies through digital platforms to report their activities through a health information system integrated with the National Health Information System.

As a result, business actors should ensure that their internal systems are capable of capturing and transmitting accurate distribution and delivery data in accordance with regulatory requirements. This reporting obligation underscores the government's shift towards a more integrated, transparent and data-driven healthcare ecosystem.

All arrangements concerning the provision of Health Supplies must be adjusted to comply with the provisions of this regulation within one year after the date of its promulgation, so by 4 May 2027. Companies that have not yet commenced a systems integration assessment are already behind.

Electronic Prescriptions and Digital Health Records

1. Mandatory Integration with the National Health Information System

Healthcare facilities are required to upload issued physical prescriptions into a health information system integrated with the National Health Information System. In addition, electronic prescriptions are to be implemented within healthcare facilities, including facilities providing telemedicine services.

Electronic prescriptions must also be integrated into patients' electronic medical records within the National Health Information System, further supporting the digitalization and interoperability of healthcare services.

2. Exceptions for Certain Medicines

The use of electronic prescriptions does not apply to medicines containing narcotics, psychotropic substances or other products that may be designated by the MOH. These products remain subject to stricter controls due to their nature and potential risks.

Formulary and Essential Products Lists

A key aspect of the regulation that manufacturers should pay close attention to is the new system of formularies and essential products lists, which could have a significant impact on market access.

Under the regulation, the government's national health supply planning process includes a selection of pharmaceuticals, medical devices and other health products. This selection is based on formularies, essential medical device lists, and other product lists established by the MOH.

Healthcare facilities, regional governments and provincial or district health offices may also develop their own formularies and product lists for use within their respective jurisdictions. These lists may be used both for services covered by the national health insurance programme and for services outside the programme.

The MOH may establish a committee to prepare the national formulary and essential medical devices list. Products are evaluated based on factors such as clinical need, scientific evidence of effectiveness and safety, side effects, cost-effectiveness, healthcare service standards, and international reference lists, including those published by the World Health Organization (WHO).

The MOH will also issue technical guidelines on how these formularies and product lists should be prepared and implemented.

From a commercial perspective, this framework is highly important. Products that are not included in the relevant national formulary or essential medical devices list may face significant barriers to accessing the government procurement market, which remains the main purchasing channel for healthcare products in Indonesia. Inclusion on the national formulary is therefore not just an administrative requirement but a key condition for meaningful access to the public healthcare market. Manufacturers, especially medical device companies, should closely monitor future formulary decisions and be prepared to submit supporting clinical and economic evidence where opportunities arise.

Buffer Stock and Shortage Notification Obligations

Two operational obligations under the regulation that are commonly overlooked but carry direct commercial and sanctions consequences are the buffer stock requirement and the mandatory shortage notification obligation.

1. Mandatory Buffer Stock Requirement

The provision of Health Supplies must be carried out effectively and efficiently in accordance with the needs plan. Crucially, the provision of Health Supplies must take into account a buffer stock of at least 10% and at most 30% of the planned requirements.

This mandatory inventory floor — applicable to production facilities, distributors, pharmaceutical management facilities and healthcare facilities — directly affects working capital planning and inventory management. Companies operating lean stock models will need to review and likely increase their inventory positions to comply. Production facilities, distributors, pharmaceutical management facilities and healthcare facilities are required to report supply provision activities through the Health Information System integrated with the National Health Information System.

2. Six-Month Shortage Notification Obligation

As part of the mitigation measures against potential health supply shortages, marketing authorization holders are required to submit a report on potential health supply shortages to the MOH no later than six months before the shortage occurs.

This is a strict early-warning obligation. It presupposes that companies have in place sufficiently robust demand forecasting and supply chain monitoring systems to detect a potential shortfall at least six months in advance. An inadvertent failure to notify — even where the shortage itself is subsequently resolved — is a sanctionable violation. Failure to submit the required shortage report constitutes a violation subject to administrative sanctions. Companies should designate a regulatory affairs function specifically responsible for monitoring supply chain indicators against this six-month trigger and maintaining documented evidence of the assessment process.

Price Control and Pricing Transparency

1. The MOH Oversight of Health Supplies Pricing

The MOH is responsible for overseeing the pricing of Health Supplies to ensure that prices remain fair and reasonable for the public, industry participants and the government. This oversight may be exercised through various mechanisms, including centralized procurement, price transparency measures, and the establishment of a framework for the maximum selling price of medicines at healthcare and other relevant facilities.

Price regulation and control is carried out through the consolidation process for Health Supplies, price transparency; and the establishment of the formula for the maximum selling price limit for medicines at healthcare facilities and other facilities.

2. Pricing Transparency Requirements

Manufacturers, distributors and healthcare facilities are required to maintain transparency regarding the pricing of Health Supplies, including any discounts, rebates, incentives or other benefits provided to healthcare professionals or institutions. That information must generally be reported through a health information system integrated with the National Health Information System, or through other reporting mechanisms where system integration is not yet available.

Critically, the disclosure obligation expressly extends to commercial incentive arrangements. Price information includes the amount of price discounts or other incentives given to medical personnel, healthcare workers, healthcare facilities, other facilities, professional organizations and institutions. This means that arrangements that may have previously operated outside the public view — including volume-based rebates, loyalty programmes and institutional grants — will now be subject to mandatory reporting and potential public scrutiny. Businesses should urgently review their commercial incentive structures in light of this requirement.

The regulation also provides a transitional fallback for price disclosure. Submission of price information is to be carried out through a health information system integrated with the National Health Information System. However, where that system is not yet integrated with the National Health Information System, disclosure may be carried out through a health information system or other media. The term "other media" is not defined in the regulation. Until technical guidelines clarify this term, businesses should at minimum ensure that prices are disclosed through their official website and made available in physical form at their facilities.

3. Determination of Maximum Selling Prices

The maximum selling price of medicines is generally calculated based on the procurement cost, including value-added tax (VAT), together with a pharmaceutical service fee. The procurement cost reflects the net acquisition price after taking into account any discounts or incentives, while the pharmaceutical service fee is determined by the MOH.

This maximum selling price formula applies only to medicines at healthcare facilities and other facilities. The regulation's price ceiling mechanism is expressly limited to the formula for the highest selling price limit for medicines. Medical devices and household health products (PKRT) are not currently subject to an equivalent maximum selling price formula, which represents a structural gap in the price control framework for those product categories.

The pharmaceutical service fee — a critical component of the maximum selling price formula — has not yet been determined by the MOH. Until the fee is set, the effective ceiling on medicine prices at healthcare facilities remains uncertain. Pharmaceutical businesses should model a range of pharmaceutical service fee scenarios when preparing financial projections.

4. Reporting and Product Labelling Obligations

Pharmaceutical manufacturers and other production facilities are required to report the maximum selling price of their products through the National Health Information System. The approved maximum selling price must also be reflected on the relevant product packaging or labelling, ensuring greater transparency throughout the supply chain.

The product labelling obligation is a continuing day-to-day manufacturing requirement. Any change to the applicable maximum selling price will require both a system update and a physical packaging change — with the attendant lead times and costs associated with label redesign and depletion of existing stock.

5. Ongoing Obligation to Update Pricing Information

Where there is a change to the applicable maximum selling price, the relevant business actor must update and resubmit the pricing information through the prescribed reporting system. This ensures that pricing data maintained by the government remains accurate and up to date.

6. Price Monitoring and Public Complaints

The MOH carries out monitoring and evaluation of health supply price controls on producers, distributors, healthcare facilities and other facilities. The public may report information concerning health supply prices that are not in accordance with the applicable provisions to the MOH. Where violations are found through monitoring and evaluation or through public reports, the MOH will take follow-up action in accordance with the results of an assessment.

The introduction of a public complaint mechanism fundamentally changes the enforcement landscape for pricing. Any competitor, patient or civil society actor may now trigger a ministerial investigation by submitting a complaint about pricing non-compliance. Reports may be submitted to the MOH, governor, regent/mayor, or a designated official, who is required to guarantee the confidentiality of the complainant's identity except for law enforcement purposes. Upon receipt of a report, the MOH or relevant official will establish an ad hoc panel committee to follow up on the report.

Companies should implement proactive internal price compliance monitoring programmes — regularly auditing prices charged across their distribution chain against reported maximums — so that any inadvertent overpricing can be identified and corrected before it generates a public complaint or regulatory investigation.

Gratification Prohibition

A provision that may not receive as much attention, but has potentially significant compliance implications, is the regulation's express prohibition on gratification in connection with the distribution of health products.

The regulation prohibits pharmaceutical facilities, manufacturers, distributors and healthcare facilities from engaging in gratification when carrying out the distribution of Health Supplies. Any violation is subject to sanctions under the applicable laws and regulations.

This prohibition should be considered alongside the mandatory reporting of incentives and discounts under Article 108(3) (discussed above under Price Control and Pricing Transparency). Together, these provisions create a stricter compliance framework. Disclosing an incentive or discount through the price reporting system does not make an arrangement lawful if it would otherwise be considered prohibited gratification under Indonesian anti-corruption laws. At the same time, the reporting requirement means that commercial arrangements that may previously have remained private will now be more visible to regulators and potentially subject to greater scrutiny.

As a result, companies should review their existing incentive and engagement programmes to identify any compliance risks. This includes hospitality arrangements, educational grants, advisory and consultancy fees, speaker engagements and volume-based rebates. Particular attention should be given to whether any such arrangements could be viewed as gratification under Law No. 20 of 2001 on the Eradication of Corruption Crimes and related regulations.

Technology Transfer, Research and Innovation

Production facilities are expected to develop and apply scientific and technological capabilities through research, development and innovation. They may collaborate with other production facilities, research institutions and educational institutions to support these efforts. Accordingly, technology transfer is no longer merely a commercial consideration but an increasingly important regulatory expectation, particularly for businesses seeking to maintain access to the Indonesian market for imported medicines and other Health Supplies.

To encourage research, development and innovation, the Central Government may provide fiscal and non-fiscal incentives to Health Supplies manufacturers, researchers and other relevant stakeholders in accordance with applicable laws and regulations. These incentives signal the government’s commitment to fostering domestic innovation and manufacturing capacity. For businesses willing to invest in local research and development, technology transfer and production capabilities, the regulatory framework may therefore present not only compliance obligations but also commercial opportunities.

As noted above, while the five-year localization clock is running, the technical guidelines governing the technology transfer roadmap process have not yet been issued. Businesses should monitor the Ministry's publication of these guidelines closely and be prepared to submit their roadmaps promptly once the requirements are clarified. Delays in doing so — particularly where the five-year window is already partially elapsed — could leave businesses without an approved roadmap at the point of enforcement.

Sanctions

MOH Regulation 5 establishes a comprehensive administrative sanctions regime applicable to all licence holders and business actors in the Health Supplies sector. An understanding of the full scope of this regime is essential for risk assessment.

1. Triggering Violations

Administrative sanctions may be imposed on any marketing authorization holder and/or business actor that commits any of the following violations:

- Failure to comply with Good Manufacturing Practice (GMP) requirements
- Failure to include the required labelling
- Distribution of pharmaceutical preparations and medical devices not in accordance with Good Distribution Practice
- Failure to submit the required distribution or delivery activity reports
- Carrying out promotions or advertising not in accordance with applicable requirements
- Failure to conduct a recall of non-compliant products
- Failure to destroy products that are required to be destroyed
- Failure to produce or import Health Supplies to maintain availability and access
- Failure to submit production and/or import reports
- Failure to submit the required shortage notification report
- Failure to submit the required activity reports
- Failure to conduct pharmacovigilance and vigilance
- Failure to submit health supply price information as required
- Failure to include the maximum selling price information on product labelling

2. Available Sanctions

Administrative sanctions include warnings, temporary suspension of business activity through the freezing of the business licence, imposition of an administrative fine, imposition of police enforcement measures, and revocation of the business licence.

3. Police Enforcement Measures

Police enforcement measures consist of market withdrawal, damages, destruction, closure or blocking of electronic systems and/or other internet media, and closure of access to business licence applications.

In addition to the above, police enforcement measures may also take the form of other actions aimed at halting the violation and/or for security purposes, including inclusion in a blacklist for licensing and procurement purposes.

The blacklisting sanction is particularly severe. Inclusion on the blacklist for licensing and procurement purposes could effectively exclude a business from the e-catalogue and from participation in government procurement — which, as noted above, is the dominant purchasing channel for Health Supplies in Indonesia.

4. Application of Sanctions

Administrative sanctions are imposed cumulatively or progressively based on the level of risk of the violation in accordance with applicable regulations. The procedure for imposing administrative sanctions is implemented in accordance with applicable laws and regulations.

The regulation does not specify minimum or maximum administrative fine amounts — these are left to be determined by lower-level regulations or the MOH's discretion. The absence of specified fine ranges creates some uncertainty but also underscores the importance of proactive compliance, given that the severity of financial penalties will ultimately depend on the assessment of risk by enforcement authorities.

5. Separate Sanctions for Plasma Fractionation Facilities

Plasma destruction standards are subject to a separate administrative sanctions regime, consisting of written warnings, temporary prohibitions, market withdrawal orders, product destruction orders, and temporary suspension of business activities. The regulation specifies that written warnings under this regime may be imposed at most twice, with a 14-business-day compliance window following each warning.

Conclusion

MOH Regulation 5 encourages business actors in Indonesia's healthcare sector to adopt a more domestically oriented approach, placing strong emphasis on the use of local materials and partnerships, while also promoting the digitalization of Health Supplies circulation and reporting through integrated national electronic systems. At the same time, the regulation introduces price control measures aimed at maintaining price stability, alongside requirements for transparency and the reporting of maximum selling prices.

The regulation presents a compliance landscape that is both broader and more operationally complex than the provisions it replaces. The areas of highest immediate compliance risk are:

(a) The five-year localization clock — already running since 4 May 2026 with no technical guidelines yet published

(b) The buffer stock requirement — a mandatory 10–30% inventory floor that affects working capital across the supply chain

(c) The six-month shortage notification obligation — requiring robust demand forecasting systems and clear internal escalation protocols

(d) The gratification prohibition and incentive disclosure obligation — operating in tandem to expose commercial incentive programmes to both regulatory scrutiny and potential sanctions

(e) The digital reporting integration deadline — requiring full compliance with the National Health Information System by 4 May 2027

(f) The maximum selling price labelling obligation — a day-to-day manufacturing compliance requirement with immediate packaging change implications

(g) The public complaint mechanism — which fundamentally lowers the threshold for triggering a ministerial pricing investigation

Companies looking to strengthen their position in Indonesia's healthcare market should think beyond compliance and focus on aligning with broader market trends. Building local partnerships and using domestically sourced materials can offer a competitive edge, especially as the market increasingly favours local production and is influenced by pricing controls.

MOH Regulation 5 takes effect upon its promulgation, with any necessary compliance adjustments to be completed by no later than 4 May 2027. Businesses are strongly advised to conduct a comprehensive regulatory gap assessment without delay and to develop an action plan addressing the key areas of change identified above.

In conducting that assessment, businesses should pay particular attention to the following questions:

(a) Which products in our portfolio are imported medicines subject to the five-year localization requirement, and do we have a viable technology transfer pathway for each?

(b) Are our current inventory management policies compliant with the 10–30% buffer stock mandate?

(c) Do we have systems capable of generating a six-month shortage forecast with sufficient reliability to meet the notification obligation?

(d) Does our commercial incentive programme comply with the gratification prohibition, and are we prepared for mandatory disclosure of all discounts and incentives given to medical personnel and institutions?

(e) Are our IT systems capable of integration with the National Health Information System by 4 May 2027?

(f) Have we reviewed our product labelling to ensure it will reflect the maximum selling price once it is determined?

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