
Orthodontics on sale: fixed appliances on E-commerce platforms

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Introduction: The sale of orthodontic materials, considered as medical devices, is regulated in order to protect patients. The availability of orthodontic products on e-commerce platforms, however, may go unregulated and compromise patient safety.

Objective: The present study aimed to investigate the sale of fixed orthodontic appliances on a local and global e-commerce platform.

Materials and Methods: A cross-sectional analysis of orthodontic materials sold on Shopee and Amazon was conducted using a specific keyword search for brackets, arch wires and ligatures. After deleting duplicates and irrelevant search results, the top 50 products for each keyword search were analysed. Product name, the type of product, seller, cost, star rating, the number of reviews, the number of sales, shipping location and brand identification were recorded. Brand registration with a medical device regulatory authority was checked. Collected data were tabulated in Google (spread)sheet to derive descriptive statistics and frequency tables.

Results: A total of 800 search results were screened. Three hundred and forty-eight relevant results were identified, approximately two-thirds of which originated from Shopee. Ligatures generated the highest search outcome in both Shopee (39%) and Amazon (80%). Fixed orthodontic materials sold on Shopee resulted in a larger number of reviews, higher star ratings and a lower cost per item compared to those supplied by Amazon. Products on Amazon were more likely to have brand identification (97%) compared to Shopee (5%). None of the identifiable brands on Shopee were registered with regulatory bodies, whereas eight products listed on Amazon were registered. A large portion of shipping locations originated from China for both e-commerce platforms.

Conclusions: Orthodontic brackets, arch wires and ligatures are more readily available on Shopee compared to Amazon. The quality and safety of these products cannot be assured as the majority of the products were either not clearly labelled or their registration was not identified under the regulation of medical devices.

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Introduction

E-commerce has become increasingly popular in the 21st century. As a result of advances in internet coverage and access, as well as an increasing use of smartphones, the number of digital buyers and online transactions increases every year. More recently, the coronavirus (COVID-19) pandemic has also led to a shift in consumer behaviour to favour online shopping as an alternative to physical shopping¹. In 2020, two billion people made purchases online and global retail sales reached more than 4.2 trillion

U.S. dollars.¹ Various e-commerce platforms are available for potential buyers to search, compare and buy online items. The most visited online platform worldwide is Amazon, accounting for 3.68 billion visitors in 2020.²

Malaysia has a high adoption rate with 88% of its population actively using the internet.³ With a total population of around 32.7 million, Malaysia is an appealing market for e-commerce in Southeast Asia because of its fast-growing economy, advanced infrastructure and acceptance of digital technologies.

In 2020, Shopee was listed as the most used Malaysian e-commerce market followed by Lazada. With around 47.3 million annual 'clicks', Shopee is also the leading online shopping platform across Southeast Asia.⁴ A large variety of items may be purchased online and even medical devices can be acquired from these shopping platforms.^{5,6}

The term "medical device" refers to any product intended for therapeutic use. It applies to a range of products from contact lenses to heart pacemakers. Apple Watches beginning from series 4 which was launched in 2018, are wearable technology that is considered as a medical device due to included features to measure the wearer's heart rate, heart rhythm, and blood oxygen saturation.⁷ It is a legal requirement, however, for these devices to be registered with local regulatory authorities to safeguard the health and safety of patients and consumers. The Medical Device Authority (MDA) and the Food and Drug Administration (FDA) are responsible for regulating the sale of medical devices in Malaysia and the United States of America, respectively.^{8,9} Equivalent regulatory bodies in Australia and New Zealand are the Therapeutic Goods Administration (TGA) and the New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE).^{10,11} The level of control depends on the classification of the devices, which are based on potential associated risks to the user. The intended use, duration of use, and the part of the human body involved, are all factors influencing the risk assessment.¹² For instance, an orthodontic arch wire has been categorised by the MDA as a low to moderate risk (Class B) as it is considered relatively invasive (present within a body orifice) and intended for long term use.¹²

Similar to other medical devices, the sale of orthodontic products on e-commerce platforms, is increasing.⁶ A search on Lazada or Shopee will identify the availability of orthodontic products, ranging from personal home care products to orthodontic equipment and materials intended for professional use. It is not uncommon for these items to be distributed from overseas and sold at very cheap prices. Many items may have bypassed regulatory bodies and are sold freely over the internet, which potentially jeopardises the safety of the consumer. Unqualified individuals have also purchased orthodontic materials and equipment commonly known as 'fake braces' or 'fashion braces' to provide illegal treatment.¹³ Hence, the present study aimed to investigate the sale of fixed ortho-

odontic appliances on a local and global e-commerce platform.

Materials and methods

Ethical approval was granted by the Medical Ethics Committee, Faculty of Dentistry, Universiti Malaya (DF CD2113/0039(L)). This was a cross-sectional analysis of orthodontic material sold on the most common local e-commerce platform; Shopee, and the most common global platform; Amazon. Data collection was carried out from the 13th to 27th June 2021. To narrow the search, only the three main components of orthodontic fixed appliances were studied: brackets, arch wires, and ligatures. The following keywords were entered:

1. Bracket: orthodontic bracket/dental bracket/ braces bracket
2. Arch wire: orthodontic arch wire/orthodontic wire
3. Ligature: orthodontic ligature/orthodontic ligature tie/orthodontic o-ring

A pilot study was conducted to identify the top ten search results to test the keywords and data extraction. The selected keywords were applied to generate search results from Shopee and Amazon. A Zip Code local to the United States of America was used when searching on Amazon to simulate a local American buyer. The search results were arranged according to 'relevance' under Shopee and 'featured' under Amazon. The top 50 search results from each keyword search were recorded and screenshots were taken for record purposes. Duplicate entries and non-relevant entries were identified and excluded from the analysis. Data collected included the name of the product, the seller, the type of product, the cost per item, star rating, the number of reviews, number of sales, shipping location, and brand identification. The cost per item displayed in United States dollars (USD) was converted to Ringgit Malaysia (RM) at a conversion rate of 4.22 (Morningstar 20.7.2021, 12.00 pm) for ease of comparison between both e-commerce platforms. The product URL link or ASIN number was recorded to facilitate retrieval of the product page for data checking. Brand names identifiable on the product images or listed under the product description were cross-checked with local medical device authorities; the MDA for Shopee, and the FDA for Amazon. The identification of product registration under MDA was readily available at <https://mdar.>

mda.gov.my and <https://accessgudid.nlm.nih.gov> for FDA.

The analysis was repeated for each orthodontic component, i.e. brackets, arch wires, and ligatures, for Shopee and Amazon. The data were tabulated in Google (spread)sheet to generate descriptive statistics and frequency tables.

Results

After screening 800 search results, 348 relevant results were identified (Table I), with approximately two-thirds originating from Shopee. Ligatures ranked highest in the results from Shopee (39%) and Amazon (80%).

Figure 1 indicates that the majority of the ligatures were of the conventional type. Similarly, more metal conventional brackets were offered on Shopee (77%) and Amazon (95%). There were three times more stainless steel arch wires offered on Shopee, than nickel-titanium wires.

Fixed orthodontic products available on Shopee generally received a greater number of reviews, higher star ratings, and cost less per item compared to those from Amazon. Figure 2 shows the average number of reviews posted for each orthodontic component category. Brackets and arch wires had a higher number of average reviews on Shopee (84 and 68 respectively) compared to Amazon (19 and 0 respectively).

Using a 5-star rating system, customers gave the highest average star rating of 4.87 (Shopee) and 4.36 (Amazon) for brackets (Fig. 3). There were no reviews or star ratings for arch wires catalogued on Amazon, as all three relevant search results lacked sales transactions.

Shopee's average price for orthodontic products was significantly less than Amazon (Fig. 4). The category

with the greatest discrepancy was brackets, with a difference of RM73. There were only three relevant search results for arch wires in Amazon but they were excluded in the average cost comparison as the pricing displayed also included add-on items.

A comparison of the number of products with brand identification between the two e-commerce platforms is shown in (Fig. 5). Products on Amazon were more likely to have brand identification (97%) compared to Shopee (5%). None of the identifiable brands on Shopee were registered with regulatory bodies, whereas eight products on Amazon were registered.

Orthodontic products sold on Shopee were shipped from China (87%), Malaysia (9.2%), or Indonesia (3.8%); whereas those sold on Amazon were shipped from China (47.7%), the United States of America (USA) (1.8%), Israel (0.9%) or an Amazon warehouse which is likely to be in the USA (49.5%).

Discussion

Conventionally, clinicians purchase orthodontic products directly from representatives of dental supply companies or via official supplier websites. Clinical products can now be purchased online from local or international suppliers through a variety of e-commerce platforms. A 2018 Goldman Sachs industry survey estimated that approximately 11% of the dental supply market has shifted to online transactions.¹⁴ The Medical Device Act 2012 (Act 737) states that all suppliers in Malaysia must register medical devices in their inventory with the MDA.¹⁵ When medical devices are imported, it becomes the responsibility of a local representative to ensure that the products are registered with local authorities. Those who fail to comply may be fined up to RM300,000 and or receive a jail term of not more than three years.¹⁵ Dental professionals who knowingly purchase counterfeit dental material or equipment may be held accountable for any adverse patient effects.¹⁶

Regulating online platforms can be challenging due to the sheer number of sellers and products. A study of Tmall, a leading e-commerce platform in China, revealed the widespread sale of medical devices, specifically dementia-related health products on its website.⁵ Similarly, the present study found orthodontic products available on Shopee and Amazon sites. It was also found that more sellers were promoting

Table I. Number of search results (*n*) for each orthodontic component keyword search.

Orthodontic components	<i>n</i> (%)	
	Shopee	Amazon
Bracket	68 (28.45)	19 (17.43)
Archwire	77 (32.22)	3 (2.75)
Ligature	94 (39.33)	87 (79.82)
Total	239	109

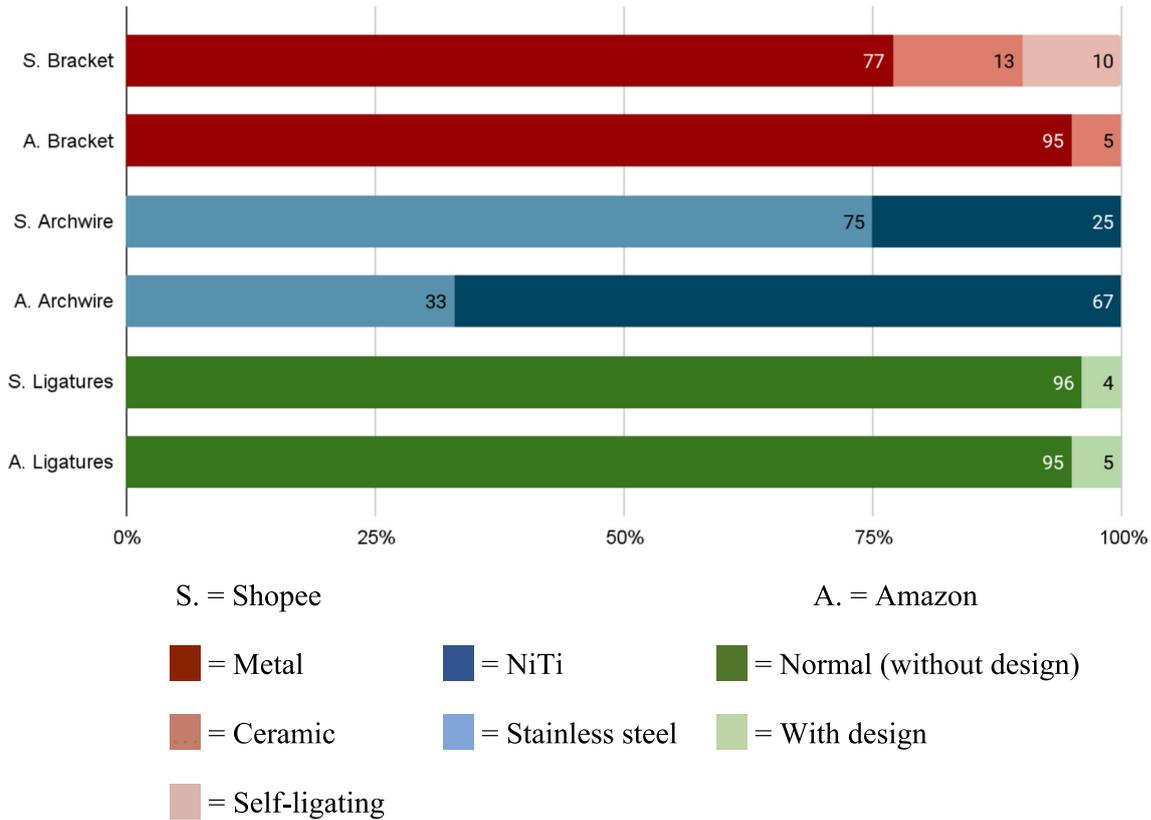


Figure 1. Percentage of types of orthodontic products according to category.

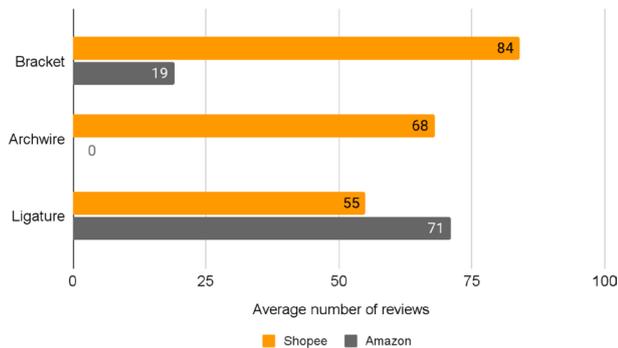


Figure 2. Average number of orthodontic component reviews on Amazon and Shopee.

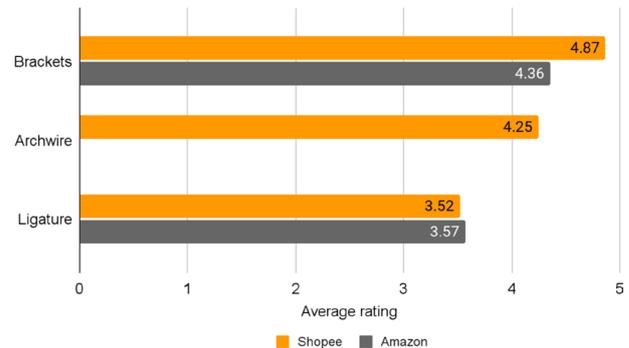


Figure 3. Average star rating of orthodontic products on Amazon and Shopee, using a 5-star rating system.

orthodontic products, specifically, components of fixed appliance systems on Shopee compared to Amazon. This could be due to the implementation of the Professional Health Care Program by Amazon in which products for professional or prescription use may only be sold by sellers participating in the program and to appropriately licensed healthcare customers who have Amazon Business accounts.¹⁷ This undoubtedly influenced the study's findings, as a personal account was used to simulate a public consumer when searching

through Amazon's catalogue. Although fewer relevant search results were generated from Amazon compared to Shopee, it was evident that orthodontic products were being sold despite efforts to regulate their sale. On Shopee, unregistered medical devices are classified as prohibited items due to infringement of local regulations. Sellers with violations risk having their listings removed, being issued penalty points, or the termination of their accounts with the possibility of legal action.¹⁸ It is clear that despite such policies,

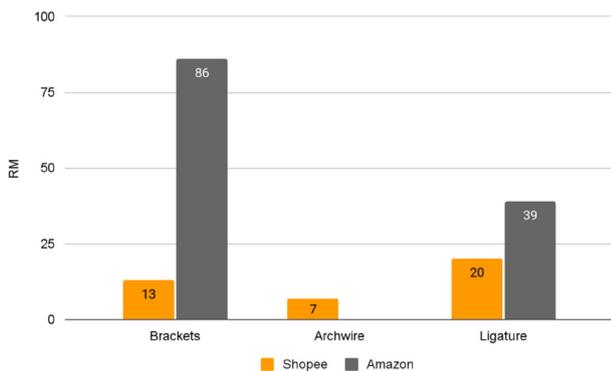


Figure 4. Average price (RM) of orthodontic products on Amazon and Shopee.

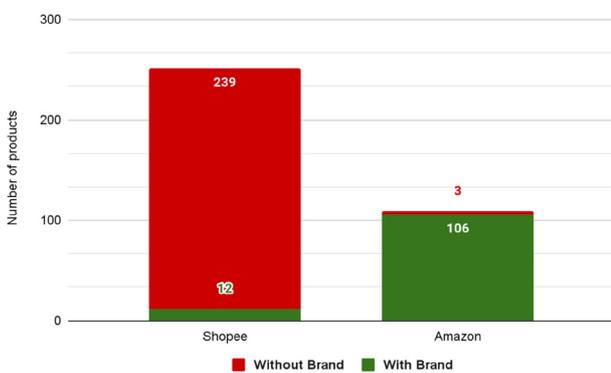


Figure 5. Brand identification between e-commerce platforms.

prohibited items are still being sold on the platform. The leading e-commerce platform in Australia, eBay, adopts a similar approach to Shopee in which penalties and suspensions are given to sellers who promote medical devices that do not have a valid Australian Register of Therapeutic Goods (ARTG) number.^{19,20}

Orthodontic ligatures appeared to be the highest-selling item on both platforms, with arch wires and brackets sold on Shopee not far behind. Keyword searches on Amazon yielded lower results for brackets and search results were almost non-existent for arch wires. The majority of ligatures sold were the conventional elastomeric type (95%) which were also found to be cheaper than other designs. The other designs included colourful Kitty, Mickey or Flower-shaped ligatures which are commonly associated with 'fake braces' or 'fashion braces', as the emphasis is placed on appearance rather than function and the ability to maintain adequate oral hygiene. Products on Shopee were more likely to have no identifiable brand name in the product description or on the images provided. It is a legal requirement for medical devices to have appropriate labelling and packaging to

convey safety and performance-related information to consumers.²¹ Furthermore, only eight products from Amazon were identified as registered with the FDA, whereas none of the products found on Shopee were registered with the MDA. Products that are registered should bear the registration number on their packaging.²¹ Both the MDA and FDA have compiled a list of registered medical devices readily available to the public online, in order to improve transparency and to encourage the reporting of unregistered products.

The orthodontic items listed online were relatively cheap and most were shipped directly from China. With roughly 50% of global e-commerce transactions, China had the largest e-commerce market throughout 2021.²² This is concerning because it was reported in 2015 that, at least two out of five products sold online in China, were counterfeit or of poor quality.²³ Without appropriate item registration, it is unclear if the products are safe to use. A local study identified increased metal ion release from orthodontic brackets bought from online suppliers.²⁴ The brackets are also presented with rough surfaces, making them prone to corrosion and breakage.²⁵ Two deaths in Thailand have been linked to the use of 'fake braces', which are commonly sold online.²⁶ Dentists and the public in the United Kingdom have been advised about buying dental equipment using the internet after the Medicines and Healthcare products Regulatory Agency (MHRA) enforcement officers raided and seized several potentially dangerous counterfeit dental instruments.²⁷ An additional potential hazard is the existence of online grey market products. This refers to registered products sold by unauthorised distributors who have obtained the items through the black market. Hence, there is no guarantee that the products have been stored or transported correctly, according to the manufacturer's guidelines, and therefore potentially compromise product efficacy and patient safety.²⁸

Overall, most products in the present study received positive ratings of above three stars, with one ligature product from Amazon receiving over 1245 reviews. The impression was that the products were being purchased and were viewed favourably. However, it is of concern that the results of the present study may be affected by fake product reviews. Fake reviews can be bought in private internet groups such as Facebook, to significantly improve star ratings. A recent study by He et al. found that low-quality products were more likely to manipulate star ratings to deceive consumers.²⁹

The findings of the present study suggest that the enforcement of medical device regulations on e-commerce platforms is still considered poor, especially in Malaysia. It is important to raise public awareness about the importance of verifying with regulatory agencies before purchasing medical products on e-commerce platforms. That the search for orthodontic materials was limited to brackets, arch wires, and elastomeric ligatures provides an additional limitation of the present study. Furthermore, searches were conducted on only two online platforms, Shopee and Amazon, hence the full extent of orthodontic material being sold on e-commerce platforms is unknown. Moreover, some data extrapolated in this study may be vulnerable to fake reviews and transactions.

Conclusions

From a consumer perspective, Shopee has a larger selection of orthodontic brackets, arch wires and ligatures compared to Amazon. A large number of the products were either not clearly labelled or were not registered with appropriate regulatory organisations for medical devices. Consumers are advised to avoid online orthodontic purchasing due to the questionable quality and safety of products that have not been registered.

Conflict of interest

The authors declare that there is no conflict of interest.

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References

- Coppola D. E-commerce worldwide—statistics & facts [Internet]. Statista 2021. [cited 20 April 2021]. Available at: <https://www.statista.com/topics/871/online-shopping/#dossier-chapter1>.
- Clement J. Top retail websites by global traffic 2020 [Internet]. Statista 2021. [cited 15 April 2021]. Available at: <https://www.statista.com/statistics/274708/online-retail-and-auction-ranked-by-worldwide-audiences/>.
- Müller J. Malaysia: internet penetration rate [Internet]. Statista; 2021. [cited 17 August 2021]. Available at: <https://www.statista.com/statistics/975058/internet-penetration-rate-in-malaysia/>.
- Müller J. Malaysia: top 10 e-commerce sites 2020 [Internet]. Statista; 2021. [cited 20 April 2021]. Available at: <https://www.statista.com/statistics/869640/malaysia-top-10-e-commerce-sites>.
- Woo B. Dementia-related products on an e-Commerce platform. *JMIR Biomed Eng* 2020;5:e17514.
- Naing A, Abd, Rahman A. Orthodontic product sold via online marketplaces in Malaysia. *Malays Dent J* 2021;1:106–12.
- Phaneuf A. Latest trends in medical monitoring devices and wearable health technology [Internet]. *Business Insider* 2021. [cited 17 August 2021]. Available at: <https://www.businessinsider.com/wearable-technology-healthcare-medical-devices>.
- Medical Device Authority Background [Internet] Malaysia: Ministry of health Malaysia; 2021. [updated 19 Nov 2021; cited 22 Nov 2021]. Available at: <https://portal.mda.gov.my/introduction/background.html>.
- Food and Drug Administration. Overview of Device Regulation [Internet]. US. 2020 [updated 9 April 2020; cited 22 Nov 2021]. Available at: <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/overview-device-regulation>.
- Therapeutic Goods Administration Medical devices overview [Internet] Australia: Australian Government Department of Health; 2020. [updated 16 April 2020; cited 22 Nov 2021]. Available at: <https://www.tga.gov.au/medical-devices-overview>.
- New Zealand Medicines and Medical Devices Safety Authority Medical Devices [Internet]. New Zealand Government Ministry of Health; 2015. [updated 15 Jan 2015; cited 22 Nov 2021]. Available at: <https://www.medsafe.govt.nz/other/about.asp>.
- Medical Device Authority Guidance on the rules of classification for general medical devices. [Internet]. Ministry of Health Malaysia. 2014 [cited 22 Nov 2021]. Available at: <https://portal.mda.gov.my/doclist/guidance-document.html>.
- Mohd Nor N, Wan Hassan W, Mohd Yusof Z, Mohamed Makhbul M. Fake braces by quacks in Malaysia: a major concern. *Ann Dent University of Malaya* 2020;27:33–40.
- Drucker S, Gregg S. Online purchasing: How to avoid “Grey-market” dental products [Internet]. *Compendium of continuing education in dentistry*. 2019 [cited 22 Nov 2021]. Available at: <https://www.aegisdentalnetwork.com/cced/2019/09/onlinepurchasing-how-to-avoid-gray-market-dental-products>.
- Medical Device Authority. Penjualan peranti perubatan melalui platform e-dagang [Internet]. Mda.gov.my. 2021 [cited 17 August 2021]. Available at: <https://www.mda.gov.my/announcement/608-penjualan-peranti-perubatan-melalui-platform-e-dagang.html>.
- Christensen GJ. Are you using “gray-market” or counterfeit dental products? *J Am Dent Assoc* 2010;141:712–5.
- Medical devices and accessories [Internet]. Sellercentral.amazon.com. 2021 [cited 10 September 2021]. Available at: <https://sellercentral.amazon.com/gp/help/external/200164650>.
- Seller Education Hub [Internet]. Seller.shopee.com.my. 2021 [cited 10 September 2021]. Available at: <https://seller.shopee.com.my/edu/article/619>.
- Archibald D. Australia Ecommerce [Internet]. International Trade Administration, U.S Department of Commerce; 2020. [cited 22 Nov 2021]. Available at: <https://www.trade.gov/market-intelligence/australia-ecommerce>.
- Customer Service. Medical devices policy [Internet]. Ebay. Available at: <https://www.ebay.com.au/help/policies/prohibited-restricted-items/medicine-medical-devices-healthcare-products-policy?id=4322>.
- Medical Device Authority. Requirements for labelling of medical devices. 2018.
- International Trade Administration China-Country Commercial Guide [Internet]. U.S Department of Commerce; 2021. [cited 22 Nov 2021] Available at: <https://www.trade.gov/country-commercial-guides/china-ecommerce>.

23. Jourdan A, Perry M. Over 40 percent of China's online sales counterfeit, shoddy: Xinhua [Internet]. *www.reuters.com*. 2015 [cited 24 September 2021]. Available at: <https://www.reuters.com/article/us-china-counterfeits-idUSKCN0SS02820151103>.
24. Nasir S, Mohamad Amran M, Abidin Mustaffar M. Metal release of standard and fake orthodontic braces: an in vitro study. *IMJM* 2021;20:75–80.
25. Nasir S, Bakar N, Samad R. Elemental and microstructural analysis of fake, real, and standard orthodontic brackets. *J Phys: Conf Ser*. 2018;1073:1–6.
26. Malik S. Deadly Fashion Braces Are Big in Thailand [Internet]. *Vice.com*. 2021 [cited 24 September 2021]. Available at: <https://www.vice.com/en/article/nn47z8/deadly-fashion-braces-are-big-in-thailand>.
27. BDJ. Fake dental products on eBay. *Br Dent J*. 2012;213:268.
28. Drucker S, Gregg SM. Americas dental. Online purchasing how to avoid “Gray-market” dental products. *Compendium* 2019;40 Available at: <https://www.aegisdentalnetwork.com/cced/2019/09/online-purchasing-how-to-avoid-gray-market-dental-products>.
29. He S, Hollenbeck B, Proserpio D. The Market for Fake Reviews. 2021. Available at SSRN: <https://ssrn.com/abstract=3664992>.