COMPETITION COMMISSION OF PAKISTAN

ENQUIRY REPORT

(Under the provisions of Section 37(2) of the Competition Act, 2010)

IN THE MATTER OF COMPLAINT FILED BY M/S RENACON PHARMA LIMITED AGAINST M/S. 3N-LIFEMED PHARMACEUTICALS FOR DECEPTIVE MARKETING PRACTICES

BY

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DATED: September 08, 2021

I. BACKGROUND:

1.1 M/s Renacon Pharma Limited (the **"Complainant"**), filed a complaint against M/s 3N-LIFEMED Pharmaceuticals (the **"Respondent"**) with the Competition Commission of Pakistan (the **"Commission"**) for alleged violation of Section 10 of the Competition Act, 2010 (the **"Act"**), about deceptive marketing practices.

1.2 It has been alleged in the complaint that the Respondent has obtained a fake Conformité Européene (CE) Mark and Quality Management System (QMS) certification from a non-accredited company in Islamabad in order to compete with the Complainant in the market. Moreover, the Respondent has not mentioned CE certification number, i.e. CE-0120, CE-1639, etc. on its product label. Similarly, through fake QMS certification, the Respondent achieved rapid growth in its business in hospitals of Pakistan. It was further alleged that such conduct of the Respondent was capable of harming the business interest of the Complainant, which amounts to, *prima facie*, violation of Section 10 (2) (a) of the Act. Moreover, it was alleged that the distribution of false or misleading information to consumers related to character, properties, suitability for use and quality of goods is, *prima facie*, a violation of Section 10 (2) (b) of the Act.

1.3 After attaining the preliminary facts, the Competent Authority initiated an enquiry in accordance with subsection (2) of Section 37 of the Act by appointing Mr. Faiz-ur-Rehman, Deputy Director (OFT) and Mr. Riaz Hussain, Assistant Director (OFT) as enquiry officers (collectively the **"Enquiry Committee"**) to conclude the enquiry. However, during the course of enquiry, the Enquiry Committee was reconstituted by the Competent Authority and the following officers were appointed as enquiry officers; Mr. Faiz-ur-Rehman, Deputy Director (OFT), Ms. Urooj Azeem Awan, Deputy Director (OFT) and Mr. Riaz Hussain, Assistant Director (OFT). The Enquiry Committee was directed to conduct the enquiry on the issues raised in the complaint and to submit the enquiry report by giving its findings and recommendations, *inter alia*, on the following;

i. *Whether the conduct of the Respondent is capable of harming the business interest of the Complainant in, prima facie, violation of Section 10 (2) (a) of the Act?*

ii. *Whether the Respondent is disseminating false or misleading information to consumers, including the distribution of information lacking a reasonable basis, related to the character, properties, suitability for use, and quality of goods in, prima facie, violation of Section 10 (1) in general and in particular, Section 10 (2) (b) of the Act.*

iii. *Whether there is a spillover effect of the conduct of the Respondent?*

2. THE COMPLAINT:

2.1 The Complainant in its complaint to the Commission has made the following submissions. The Complainant is the pioneer producer through R&D of Bicarbonate haemodialysis concentrate

in Pakistan since 1997 and has obtained CE 1639, ISO 9001, ISO 13485, since 2007 through SGS, Europe, the most renowned certifying body in the world. The Complainant submitted that they are paying millions of rupees annually for multiple SGS inspections, apart from spending on QMS requirements and documentation.

2.2 It was alleged in the complaint that a new medical device company 3N-LIFEMED Pharmaceuticals situated in a remote village of Sargodha got licence for manufacturing haemodialysis concentrate solution about 3-years back. In order to compete with the Complainant, it is deploying measures like, **fake CE mark and QMS certifications** from a non-accredited company in Islamabad. **The issuing company apparently is based in the USA, and hence how can they issue EU based** Conformité Européene **(CE) certificate**. There is no number after CE (like CE 0120, CE 1639) for class II-B product {haemodialysis concentrates as medical device fall in class II-B category internationally, and in Class C as per the Drug Regulatory Authority of Pakistan (DRAP)}, which is the number of notified body and must be listed in International (NANDO's) **New Approach Notified and Designated Organizations)** list available online (attached). Because of the fake Quality Management System (QMS) certification, 3N-LIFEMED Pharmaceuticals acquire rapid business from the big hospitals of Pakistan.

2.3 The certificate issuing company (Conformity Assessment Body or CAB) for the Respondent is 'American Global Standards, Pakistan' which has **no website of its own** and its name and address has only been mentioned on the site of its so-called accrediting body **'American International Accreditation Organization (AIAO-Bar)' which is not accredited by IAF/UKAS/NANDOS/PNAC which is a necessity** and hence is a fake company although may be based in USA.

2.4 **The address of Conformity Assessment Body (CAB) 'American Global Standard' in Islamabad could not be found** and the address used is most likely a house localized in a residential area without any office or staff. There is no contact details mentioned on the internet, in this respect. There seems to be no 'quality auditor's team' of 'American Global Standards' in Pakistan.

2.5 The Complainant is having CE/ISO certification since 2007 through SGS, UK, after multiple inspections, implementing all SOPs, preparing thousands of documents and spending millions of rupees each year in order to comply with the International standards for exports.

2.6 In the end, the Complainant stated that the Haemodialysis Concentrates are life-saving product for the dialysis of kidney-failure-patients, and any mis-communication may lead to disastrous results for the patient. They hoped that their grievance is addressed in the best interest of kidney-failure-patients, and the offending company is dealt with as per law.

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3. SUBMISSIONS OF THE RESPONDENT:

3.1 The complaint was forwarded to the Respondent by the Enquiry Committee for comments on March 29, 2021. However, the Respondent requested an extension vide letter dated April 09, 2021, which was granted through a letter dated April 12, 2021. The Respondent finally submitted its comments, through its authorized representatives SALEEM & SALEEM Advocates, Solicitors, Legal and Tax Consultants, through letter dated nil, the contents of which are reproduced below.

3.2 That the titled complaint has been made by the Complainant against the Respondent company with the alleged allegation of fake certification (fake CE mark and QMS certification) from a non-accredited company, which is violation of the Section 10 of the Act.

3.3 That the instant reply is being submitted by the answering Respondent through its duly authorized officer/CEO Mr. Nazir Ahmed, through board resolution, who is fully conversant with the fact and circumstances of the matter.

3.4 That the Respondent is serving in Pakistan since 2004, and established a big name, good reputation and respect in the market and related social business circles. The factory of the Respondent is situated at 45-SB, Abdullah Colony, Sargodha, whereas the head office of the Respondent is at 18/20-N Gulberg-II, Lahore. Till date, no other complaint, allegation or any case/petition has been filed against the Respondent.

3.5 That the introduction of the product i.e. haemodialysis concentrate in the market by the Respondent is fully in accordance with law. It was further submitted that the complaint of the Complainant is misconceived and based on wrong and misguided facts in order to defame and blackmail the Respondent in the market.

3.6 That in the year 2011, the Respondent applied for issuance of license from the Drug Regulatory Authority of Pakistan (DRAP), and ultimately in 2015 the license was issued. The Respondent registered the product in 2016, and its registration is still valid. Therefore, the product of the Respondent is duly registered and approved by DRAP under the Drugs (Licensing, Registering & Advertising) Rules, 1976, and the Drug Regulatory Authority of Pakistan, Act, 2010 (DRAP Act).

3.7 That the titled complaint is not maintainable and entertainable in its present form, hence, the same is liable to be dismissed.

3.8 Moreover, it was submitted that there is no question of fake certification, when the Respondent has a valid license issued by DRAP in its favour for manufacturing the product. Furthermore, the certifications under question issued by the System Machinery Inspection Services-

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American Global Standards (SMIS-AGS) are also genuine as evident from the letter by SMIS-AGS dated 03.04.2021 and original certificates of the same are also available with the Respondent. The Respondent is licensed and authorized to manufacture pharmaceutical grade products and the license was issued after fulfilment of all codal formalities and satisfaction of the regulatory authorities. That the manufacturing of the product is taking place in a lawful manner and the Respondent has no intention to deceive the general public by using fake certificates. Hence, the titled complaint is liable to be dismissed being meritless.

3.9 That the entire complaint is based on baseless claims that have no legal standing and the Complainant has miserably failed to prove that the Respondent has contravened the provisions of Section 10 of the Act. It was also submitted that the Complainant has come to this Hon'ble Commission with unclean hands on the basis of a concocted story and without any locus standi to institute the titled complaint.

3.10 That even otherwise, without prejudice to hereinabove, the titled complaint is barred by jurisdiction, as the matter at hand falls within the regulatory ambit of DRAP since pharmaceutical manufacturers have to be mandatorily enlisted with DRAP before producing/manufacturing, sale/distribution in the market. Needless to say that the Respondent has valid license in its favour with regard to production and manufacturing of the product. Hence, the titled complaint is liable to be dismissed.

3.11 It was further stated that the titled complaint is not maintainable and just a wastage of precious time of the Hon'ble Commission since DRAP is a regulatory body for pharmaceutical companies under DRAP Act. As per Section 4 of the DRAP Act, Director Drug licensing, Director Quality Assurance, Laboratory Testing, Director Medical Devices and Medicated Cosmetics are incharge of their respective division and shall be responsible of their respective duties and work. The Section 7 of the DRAP Act, 2012, authorizes the authority to check, enforce, monitor or regulate all the affairs of pharmaceutical companies in any manner whatsoever. For the sake of brevity, relevant provisions of Section 7 of the DRAP Act is reproduced here below:-

> *7. **Powers and functions of the Authority.** --- The powers and functions of the Authority shall be to, ---*
> *(c) issue guidelines and monitor the enforcement of, ---*
> *(i) licensing of the manufacture of therapeutic goods;*
> *(ii) registration of the therapeutic;*
> *(iii) regulation for the advertisement;*
> *(x) regulation, enforcement and monitoring of advertisement rule and ban on false advertisement;*

3.12 That the certificates issuing authority is a registered company in the USA, and its head office is located in USA 1187 Coast Village Road, Suite No.495, Montecito, CA 93108781-405-2871. SMIS-AGS is accredited from the independent board AIAO-BAR (American International Accreditation Organization-Bureau of Accredited Registrars) USA. It is difficult that a company registered in the USA issues fake certificates. In this regard, SIMS-AGS has sent a letter to the Respondent on 03.04.2021. The Respondent further submitted that the original certificates were available with the Respondent, which can be produced before this Hon'ble Commission as and when required.

3.13 That the titled complaint is based on false and misleading facts and has been filed with ulterior motive just to harass the Respondent. That the Complainant has failed to disclose necessary facts and information before this Hon'ble Commission which is in itself a proof of the malafide on part of the Complainant. The titled complaint has been instituted mischievously just to tarnish the reputation of the Respondent and is liable to be dismissed.

3.14 That it is against the established principles of justice, the spirit of the Act and Article 18 of the Constitution of the Islamic Republic of Pakistan (the "Constitution") to allow another undertaking to curtail the business of the Respondent on the basis of unsubstantiated claims. In essence, through the titled complaint, the Complainant is attempting to drive the Respondent out of the market in order to capture its market share. Hence, the titled complaint is liable to be dismissed.

3.15 It was submitted that the Complainant's factory is established in a 1 kanal marriage hall situated in a residential Area of Lahore without the approval of DRAP. Needless to say that the Complainant is very famous in blackmailing and harassing the other companies/competitors like it did to Jash Pharma previously.

3.16 It was further submitted that the Respondent established in the year 2004 at 45-SB Abdullah Colony, Sargodha. Since its inception the Respondent established a big name and reputation in allied business and social circle.

3.17 The Respondent sent an email to the SMIS-AGS, USA based company for explaining the position and status of the certificates under discussion. In response to that email, the SMIS-AGS sent a letter dated 03.04.2021 through which categorically denying the allegation of the Complainant with the assertion that it is not possible that the company registered in USA issues any fake certificate. The said company of the USA also attached copies of all certificates for ready reference. Therefore, the Complainant has no legal authority and locus standi to institute the subject complaint.

3.18 It was stated that the letter issued by SMIS-AGS (USA based company) negated the allegations levelled in the complaint and the letter clearly displays the web address, name and address of

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the company. It would not be out of place to mention here that the said certification is registered from Pakistan National Accreditation Council (PNAC) which is working in USA whereas NANDOS is working in UK.

3.19 In furtherance, it was submitted that these standards are not mandatory and the companies implement the system for their own improvement. That the titled complaint is a wastage of precious time of the Hon'ble Commission and this fact alone shows the malafide intention and ulterior motive of the Complainant.

3.20 It was submitted that SMIS-AGS, in its letter, categorically stated that AGS LLC-USA had terminated the business membership of SMIS-AGS Pakistan on October 5, 2020. That the titled complaint is a pack of lies and has been filed to blackmail and harass the Respondent and SMIS-AGS.

3.21 It was further stated that the regulatory authority (DRAP) paid multiple visits in a year in the pharmaceuticals factories in order to maintain check & balance, quality of product/medicine, validity/authenticity of license and certificates.

3.22 It was stated that the Respondent has valid license issued by the DRAP for manufacturing the product and the certification issued by the SMIS-AGS are also genuine as evident from their referred letter and original certificates are also available with the Respondent. The Respondent is licensed and authorized to manufacture pharmaceutical grade products. That the Respondent has no intention to deceive the general public by using fake certificates. The registration/approval was allowed to the Respondent after fulfilment of all codal formalities and satisfaction of the regulatory authorities and the manufacturing of the product is taking place in a lawful manner.

3.23 Under the facts and circumstances mentioned above, it was therefore, most respectfully prayed that the titled complaint may kindly be dismissed with exemplary costs, in the interest of justice. In the end, it was stated that any other relief which this Hon'ble Commission deems fit and appropriate may also be awarded.

3.24 The Respondent was further inquired, vide email dated 11th of Aug, 2021, for information on its distribution/supply chain. Moreover, the Respondent was asked to submit its Board Resolution in support of its comments.

3.25 A reply was received, vide email dated 20th of Aug, 2021, wherein the Respondent submitted a flow chart of its supply chain. The Respondent also submitted that since it was a sole proprietorship, a Board Resolution was not required by it.

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4. REJOINDER:

4.1 The Respondent's reply was forwarded to the Complainant for a rejoinder vide letter dated April 23, 2021. The said rejoinder was received through a letter dated May 26, 2021, the contents of which are summarized in the following paragraphs.

4.2 It was submitted that the Respondent has submitted reply with an intention to de-track the real matter brought before the Commission regarding mis-leading information pertaining to quality certifications of the products by manoeuvring and mis-representing the real facts. Also without fulfilling the requirement of law in legal manners, Respondent adopted un-authorized procedure to get "Quality certification" of products, and submitting documents of companies, which are not authorized to issue such certificates as per globally recognized procedure.

4.3 That the Respondent, for obtaining these "quality certification" used agreements, arrangement and understandings other than the recognized practice, with an intention to de-fraud and mislead the general public while the same is against the established international norms.

4.4 That the Respondent did not respond under the law nor explained how their certificate awarding company is not even registered in Pakistan as per law with (PNAC) or present in the NANDO List. It was submitted that the Respondent had "illegally and wrongfully gained" the business through "false certifications" and the same is recoverable from them while they are also liable to be prosecuted and fined.

4.5 That the Respondent knowingly abused its legal position, moral commitments and engaged in deceptive marketing practices as prohibited under the law. Even Respondent deceitfully presented its products by showing false certification of ISO 9001, CE in respect of production, supply, distribution, acquisition or control of goods with an object to capture relevant market of the products by misleading and misrepresenting in the market.

4.6 That the annexures appended with the reply of the Respondent are irrelevant with respect to the present complaint before the Hon'ble Commission and have only been submitted to de-track the real matter brought before the Hon'ble Commission.

4.7 It was submitted that the main issue raised was of fake international quality certification of the Respondent (issued by non-accredited company) in order to acquire business. Instead of addressing the actual issues, reply by the Respondent consists of mostly irrelevant arguments, and documents like FBR Tax doc., local manufacturing license, drug registration, DRAP certificates, payment receipts, license renewal application, LCCI Certificate, etc., Moreover other irrelevant documents to prove that SMIS-AGS, Pakistan (certifying body) is a genuine company like photographs of staff and clients which are completely irrelevant.

4.8 Moreover, that the status of the awarding body can be verified online through established forums like "Pakistan National Accreditation Council" (PNAC); online NANDO List; "International Accreditation Forum" (IAF) list, etc. The reply by the Respondent indicates that the Respondent is not even aware of the basic concept of the international authentication of quality certifications and accreditation with recognized international established forums.

4.9 That as per Government tender regulations, CE mark and ISO 13485 certificates are required for evaluation of a company, hence these hold a value shown on Bid Evaluation Criteria while Respondent has mentioned that these are just a "formality". Hence, the Respondent's objection is nullified. Moreover, non-accredited "ISO 9001 & CE" quality certificates are also important tools for marketing which are being used by the Respondent for several years for this purpose and that the Respondent is misleading and marketing the products otherwise, for "wrongful gains".

4.10 That in the USA and all over the world there are a lot of unauthorized organizations issuing fake or unauthenticated degrees and certifications as a business for years and years. This comes under white collar crime and difficult to identify until special attention is drawn to it due to any incident and/or a specialized scrutiny is carried out. It was submitted that for this reason the Complainant is affirmative that the Hon'ble Commission has power & jurisdiction to conduct a discreet inquiry & culprits would face the consequences for committing such illegal and unlawful acts.

4.11 Moreover, that the website of Respondent's "International" certifying company "SMIS-AGS" (smis-ags.com) is not functional. Another website of same company SMIS-AGS is (smis-cert.com) but it has nothing mentioned on the "Accreditation" page. Unlike any established and authentic company, SMIS-AGS, is using a Gmail address in its correspondence (ags.pakistan@gmail.com). Moreover, SMIS-AGS, Pakistan, is not accredited by PNAC (Pakistan National Accreditation Council) and this can be verified from PNAC list.

4.12 That the SMIS-AGS Pakistan has been accredited by AGS, USA which internationally has been accredited by AIAO-BAR, USA (American International Accreditation Organization-BAR). That this accrediting company has to be accredited by 'International Accreditation Forum' (IAF), however, that is not the case in this matter.

4.13 That the Respondent has two different companies namely 3N-LIFEMED and 3N-LIFEMED Pharmaceuticals with different addresses listed on one certificate of ISO 9001 issued by SMIS-AGS. It is not permissible as per international regulations that two different companies are issued one certificate of ISO 9001, while management system of companies is different. ISO 9001 is a management certificate and is not a product quality certificate. Therefore, two certificates of ISO 9001, issued to the Respondent by SMIS-AGS, Pakistan, contain a list of products which is against the norms of law and ISO 9001 certificate features can be verified

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easily from accredited companies like SGS and other sources also available online: www.iso.org/files/ live/sites/isoorg/ files/store/en/PUB100304.pdf.

4.14 That on one very irrelevant & unlawfully "combined" certificate of ISO 9001, "CE" mark is displayed to cheat & mislead the customers. CE is always a separate certification and has number of its issuing body in front of it (like CE 1639 issued by SGS). Moreover, it is very ridiculous/ strange that on one "combined" ISO 9001/CE Certificate, the chemical analysis and other laboratory tests conducted without the specification of samples have been mentioned as being satisfactory while ISO 9001 is a quality management certificate. All this misrepresentation has been created to deceive the customers.

4.15 It was submitted that such act is against the government policy and is a sensitive matter related to health of general public. It is suggested that both ISO certification of the Respondent (issued by SMIS-AGS) should be sent to PNAC, Pakistan, for verification and label may also be sent to DRAP for authentication of CE.

4.16 Furthermore, it was submitted that the Respondent has CE mark on its label obtained from SMIS-AGS, as has also been mentioned on the website of the AGS-Global, USA, without any number in front of CE. AGS-Global, USA, being an American company cannot issue CE certificates as it is not accredited by any conformity assessment body (CAB) present in any of the 27-countries in Europe (e.g. SGS, Pakistan a subsidiary of SGS, Switzerland, is a notified body and is accredited by BELAC in Belgium which is present in NANDO list available online). The genuine 'CE Mark' issued by an authentic accredited body has always a number in front of it which indicates the number of notified body like CE 1639 issued by SGS, Belgium, present in NANDO list verifiable online.

4.17 It was submitted that in case of CE mark issued by European conformity Assessment body (CAB) there must be a representative in any of the European country whose name and address must be mentioned on the label while there is no such thing present on the label of the Respondent.

4.18 Therefore, in view of these admissible evidences, it was alleged that both the certificates issued absolutely against the established international standards have just been "Sold" by SMIS-AGS, Pakistan, against a sum of money, which the Respondent has been using to its advantages for several years. "CE" mentioned on the label of the Respondent is totally irregular, unlawful and misconceived just to deceive the customers for gaining business by misleading, to achieve "illegal and wrongful gain". In essence, none of these companies have been accredited by any 'Conformity Assessment Body' (CAB) in EU for CE certification.

4.19 That for the verification about the authenticity/ accreditation of "AGS, LLC, USA", and its accrediting body "AIAO-BAR", the following online links are available clearly negating the Respondent's plea of fairness:

a. www.isobench.org verifying the legitimacy of certificates shows that accreditation body (AB) accrediting AGS, LLC, USA is not recognized (Annex 13 a, b).
b. www.bbb.org showing that AGS, LLC, USA, is not accredited (Annex 14).
c. SUNDAY Business Systems showing that accrediting body AIAO-BAR, USA, is non-accredited (Annex 15 a, b).
d. www.Conwaybusinessservices.com clarifying the role of genuine international bodies like IAF and authentic accrediting system worldwide (Annex 16).
e. **Copies of Renacon Pharma's genuine ISO/CE certificates by SGS are attached for comparison,** which clearly mention the authentic accreditation bodies and their members like UKAS verifiable online (Annex 17 a, b, c, d,e,f).

4.20 The Respondent has "wrongfully earned and gained" tens of millions of rupees by providing false certificates and has been mis-leading clients about CE certification and Complainant only informed the Competent Authority on the basis of true admissible evidence under Qanoon-e-Shahadat, which is not equivalent to undue harassing at all as has been claimed by the Respondent in its reply.

4.21 That the Complainant is one of the pioneer producers of all types of 'Bicarbonate Haemodialysis Concentrates' in South Asia since 1997 purely through R&D while being the first in Pakistan. Hence, it has helped discourage the "imports, and save a lot of foreign exchange" bringing down the cost to a very low level for kidney-failure dialysis patients, thereby, providing health facility to the general public in the best interest of the country. Renacon Pharma belongs to prestigious and ethical Treet-Packages group of companies (www.treetgroup.com) and strongly adheres to Gov. Rules and Regulations as regards all taxes, salaries, allowances, custom duties, factories regulations, DRAP regulations, etc.

4.22 That the Respondent, after knowing that these false and fraudulent certificates would be exposed, immediately switched to "ACS Registrars", Pakistan, accredited by PNAC, for fresh certificates of ISO and others, issued on March 3, 2021, while genuine CE mark has still not been obtained. It was submitted that if the previous SMIS-AGS were to be genuine (being valid till 2022), the Respondent would not have applied for similar fresh certificates from another company. The Complainant referred to an evaluation of THQ hospital, Chichawatni, as an example, which rejected the CE Certificate of the Respondent after knowing the facts.

4.23 That the Complainant has got genuine certifications (ISO 9001; ISO 13485; CE 1639) since 2007 through SGS, UK/ SGS, EU, the most prestigious and renowned company globally for quality certification, spending millions of rupees each year; undergoing multiple Inspections

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and training sessions, and preparing thousands of quality assurance documents. These certifications verify that the Complainant is performing as per International Standards.

4.24 That the Complainant's factory was established in 1997, away from main city and given manufacturing license by the Ministry of Health in 1998, when the surrounding area had only fields and factories. However, now it has additionally become a commercial and residential area as well. Within one-kilometre span from the Complainant on Ferozepur Road, Lahore, there are at least ten pharmaceutical manufacturing facilities including Glaxo Smith Kline (GSK), SIZA Pharma, Himont Pharma, Mass Pharma, PDH Pharma, Standpharm, etc. The company is presently availing area of more than 4 Kanals including warehouses.

4.25 The Complainant has also acquired 10 acres of land in the modern industrial zone, Faisalabad Industrial Estate Development Management Company (FIEDMC), and the new state of the art facility is under construction (grey area completed) while machinery/ lab equipment are being acquired from Europe, China and Korea. The present facility will likely to be shifted to FIEDMC by the end of this year as it is already working to its maximum capacity.

4.26 In response to Respondent's submission regarding a rejected sample, the Complainant submitted that the samples from government institutions are sent to 'Drug Testing Laboratory' (DTL) in routine and out of thousands of samples of pharmaceutical companies including multinationals, a few reports may show minor variations, may be due to erroneous testing method by DTL or sometimes mistakes by the company quality control departments.

4.27 That the Complainant is the market leader in Pakistan and has been exporting its products to about 20-countries for the past 14-years without any complaint from overseas where quality criteria are always very strict.

4.28 In view of the above circumstances, it was most respectfully prayed that Complainant has submitted undeniable evidence, according to Qanoon-e-Shahadat as admissible evidence. Therefore, the complaint may kindly be accepted that the quality certification of the Respondent is not recognized internationally. Moreover, ISO 9001 and CE certification issued by AGS may be declared against the law, rules and regulations and responsible may kindly be penalized by imposing fine under the law. Furthermore, direction may be issued for prosecuting the Respondent and responsible under the law. Any other relief which this Hon'ble Commission may consider fit & proper may kindly be awarded.

4.29 The Complainant, vide letter dated 23rd of June, 2021, submitted additional documents pertaining to government tenders won by the Respondent against the Complainant in 2020-21, and recent copies of rejection of Respondent's tender documents based on fake certifications by THQ Hospital, Chichawatni and DHA, Jhelum. (The list of tenders won by the Respondent against the Complainant are attached as **Annex - A**).

4.30 Another letter dated 30th of June, 2021, was received from the Complainant submitting the previously alleged packaging of the Respondent and a new label design of the Respondent as additional supporting documents to the complaint. It was further submitted that the Respondent had deleted the ISO and CE mark from their new label, which was evidence of their false claim.

4.31 The Complainant, vide letter dated 2nd of Aug, 2021, was asked to submit the Respondent's latest packaging along with purchase receipts and details of its product distribution channel. The Complainant was also requested to submit if any ISO Certification was mandatory under the DRAP law for the purpose of manufacture and sale of dialysis concentrate along with any other information relevant to the case.

4.32 The Complainant, vide letter dated 5th of Aug, 2021, submitted Respondent's fresh packaging with receipts of purchase. The packaging/product received consisted of a Part-A and Part-B, from which only Part-A had originally been alleged by the Complainant. It further submitted that there is no mandatory ISO certification required under DRAP law for the manufacture and sale of the dialysis concentrate. Moreover, it submitted that the Respondent's batches from the year 2021 represented a manufacturing license number that had expired in the year 2020.

5. ANALYSIS:

5.1 The Enquiry Committee was given the mandate to conduct an enquiry regarding the issues raised in the complaint and to submit the enquiry report by giving its findings and recommendations, *inter alia,* on the following issues:

i. *Whether the conduct of the Respondent is capable of harming the business interest of the Complainant in, prima facie, violation of Section 10 (2) (a) of the Act?*

ii. *Whether the Respondent is disseminating false or misleading information to consumers, including the distribution of information lacking a reasonable basis, related to the character, properties, suitability for use, and quality of its products in, prima facie, violation of Section 10 (1) in general and in particular, Section 10 (2) (b) of the Act.*

iii. *Whether there is a spillover effect of the conduct of the Respondent?*

5.2 Before moving forward, it is necessary to establish the difference between false and misleading information. The Commission, in its order held against **M/s CMPak Limited**[1], has defined ***"False"*** and ***"Misleading"*** information as deceptive marketing practices in the following manners:

[1] http://cc.gov.pk/images/Downloads/ZONG%20-%20Order%20-%2029-09-09%20.pdf

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False Information:

'False information' can be said to include: oral or written statements or representations that are; (a) contrary to truth or fact and not in accordance with the reality or actuality; (b) usually implies either conscious wrong or culpable negligence; (c) has a stricter and stronger connotation, and (d) is not readily open to interpretation.

Misleading Information:

"Whereas 'misleading information' may essentially include oral or written statements or representations that are; (a) capable of giving wrong impression or idea, (b) likely to lead into error of conduct, thought, or judgment, (c) tends to misinform or misguide owing to vagueness or any omission, (d) may or may not be deliberate or conscious and (e) in contrast to false information, it has less onerous connotation and is somewhat open to interpretation as the circumstances and conduct of a party may be treated as relevant to a certain extent."

5.3 The above reference suggests that any information distributed via marketing campaign can mislead consumers if it is vague in any way or has omitted certain information, even if such a conduct is not deliberate. Consequently, distribution of misleading information is capable of giving a wrong impression with respect to a good or service which could induce a consumer into distorted decision making, hence, causing consumer injury, amounting to deceptive marketing practices in terms of Section 10 (2) (b) of the Act.

5.4 Similarly, any information distributed via marketing campaign, which results in the flow of business/economic value away from a competitor/s or helps gain an undeserved competitive advantage in the market, thereby harming business interest of undertakings, amounts to deceptive marketing practices in terms of Section 10 (2) (a) of the Act.

5.5 The alleged product in the complaint is a Haemodialysis concentrate. Dialysis concentrate consists of purified water, glucose and electrolytes. The concentration of electrolytes closely resembles that which occurs naturally in the blood. Dialysis fluid is prepared from the concentrate according to the individual patient's needs to help regulate their electrolyte and acid–base balance and remove metabolic waste products[2]. It is classified and licensed as a medical device by the Drug Regulatory Authority of Pakistan (DRAP). Furthermore, medical products are marketed below-the-line to health professionals within Pakistan.

5.6 It is pertinent to mention here that in order to be able to manufacture a pharmaceutical product within Pakistan, an undertaking is required to have a valid license from DRAP, unless otherwise specified under DRAP regulations. Therefore, any and every kind of international certification acquired with respect to Haemodialysis concentrates is purely a voluntary act. If an undertaking is in possession of a valid license from DRAP, it is proof enough that all the

[2] https://www.fmc-au.com/therapy-systems-and-services/chronic-hemodialysis/disposables/dialysis-concentrates-and-solutions

quality standards have been met to manufacture a certain product. Therefore, absence of voluntary certifications does not imply that the quality of the product has been compromised.

5.7 In order to draw analysis on the given mandate, it is necessary to understand the process of accreditations and the meanings of CE mark and QMS certifications. We will take these further individually to draw an understanding of each process.

CE MARK:

5.8 The letters "CE" are the abbreviation of French phrase "Conformité Européene" which in literal terms means "European Conformity"[3]. CE involves a statement issued by the manufacturer, stating that the product complies with the basic criteria of the European Union.

5.9 Depending on the risks, for some product groups, the manufacturer's statement must be confirmed by means of testing by an independent third party, called a Notified Body. If there is compliance with all the applicable criteria stipulated in the European Standards for the relevant product, then there is a legal ***"assumption of conformity to the requirement originating from the directive".*** A test conducted by an independent third party, on the basis of the prevailing European standards, confirms that assumption of conformity. Apart from that, it may also be obligatory to comply with several directives and different European Standards.

5.10 CE conformity marking consists of:

- The CE conformity marking shall consist of the initials 'CE' in exact proportion.
- If the CE marking is reduced or enlarged, the proportions must be respected.
- Where apparatus is the subject of other Directives covering other aspects and which also provide for the CE conformity marking, the latter shall indicate that the appliances are presumed to conform to those other Directives.
- However, where one or more of these Directives allow the manufacturer, during a transitional period, to choose which arrangements to apply, the CE marking shall indicate conformity only to the Directives applied by the manufacturer. In this case, particulars of the Directives applied must be given in the documents, notices or instructions required by the Directives and accompanying such apparatus.
- The various components of the CE marking must have substantially the same vertical dimension, which may not be less than 5 mm[4].

5.11 The European Commission states that letters 'CE' appear on many products traded on the extended Single Market in the European Economic Area (EEA). They signify that products sold in the EEA have been assessed to meet high safety, health, and environmental protection requirements. CE marking also supports fair competition by holding all companies accountable to the same rules.

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[3] CE Marking & Certification (hollandshielding.com)

[4] https://hollandshielding.com/CE-Marking?gclid=EAIaIQobChMIusyjjpe98QIVzbHtCh2fDwTgEAAYASAAEgJvU_D_BwE

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5.12 It further states that by affixing the CE marking to a product, a manufacturer declares that the product meets all the legal requirements for CE marking and can be sold throughout the EEA. This also applies to products made in other countries that are sold in the EEA.

5.13 However, not all products are required to obtain a CE marking. It is compulsory only for most of the products covered by the New Approach Directives and it is forbidden to affix CE marking to products other than listed in the Blue Guide.

5.14 However, it is to be brought into consideration that a CE marking does not indicate that a product has been approved as ***safe*** by the EU or by another authority. It does not indicate the origin of a product either.[5] Therefore, it is safe to deduce that the marking does not authenticate the quality of the product.

QMS CERTIFICATION

5.15 A Quality Management System (QMS) is a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction. It is expressed as the organizational goals, processes, documented information and resources needed to implement and maintain it.

5.16 The QMS regime of ISO 9000 family of standards is the most widely implemented worldwide, whereas ISO 9001:2015 is the most recent revision of the ISO 9001 QMS, replacing ISO 9001:2008 as of September 2018[6].

5.17 In accordance with ISO 17021, accredited certification bodies are required to issue certified organisations with certificates that are reflective of a 3-year certification cycle. Certifications can be issued for longer than this period providing the requisite external audits are performed and the certification cycle is followed. QMS typically issues certificates over the period of a ten year contract.

5.18 From the first consultation with ISO specialists through to certification, the process can take as little as 45 days. However, this does depend on the size and complexity of the business applying for an ISO 9001 certification.

5.19 A QMS certification is acquired to streamline management processes, free errors and free up valuable management time. Therefore, the certification is achieved to make management processes more efficient and effective. It is a 3-step process based on a Gap Analysis and its implementation, leading to certification[7].

[5] https://ec.europa.eu/growth/single-market/ce-marking/
[6] https://www.qmsuk.com/iso-standards/iso-9001#faqs
[7] https://www.qmsuk.com/iso-standards/iso-9001#process

i. ***Whether the conduct of the Respondent is capable of harming the business interest of the Complainant in, prima facie, violation of Section 10 (2) (a) of the Act?***

5.20 Based on the preceding paragraphs, we will now draw an analysis on both CE Mark and QMS certification of the Respondent in light of Section 10 (2) (a) of the Act in the following paragraphs, individually.

CE MARK

5.21 According to the list provided by the European Commission for information on CE marking for specific countries, national authorities of Pakistan, such as Pakistan National Accreditation Council (PNAC) do not exist on the list. [8] This signifies that companies in Pakistan, who wish to export their product to the EEA or to comply for their self-satisfaction with the European Standards, need to obtain a CE mark through a notified body that has been accredited elsewhere internationally and falls within the list of the European Commission.

5.22 A notified body means a third party organization that has been appointed by the national authorities. For products that present higher safety risks such as gas boilers, safety cannot be checked by the manufacturer alone. In such cases, a notified body has to perform the safety check. The manufacturer may affix the CE marking to the product only once this has been done[9].

5.23 In view of the Para 5.21 and 5.22 above, it is evident that any organization accredited by the PNAC, does not have the relevant expertise to provide CE marking to a manufacturer in Pakistan. Therefore, **Nando (New Approach Notified and Designated Organizations) Information System,** is an act whereby a Member State informs the Commission and the other Member States that a body, which fulfils the relevant requirements, has been designated to carry out conformity assessment according to a directive. Notification of Notified Bodies and their withdrawal are the responsibility of the notifying Member State[10].

5.24 Therefore, any notified body on the NANDO's list, operating in Pakistan, has the authority to carry out assessments of manufacturers and issue a CE marking likewise.

5.25 In the instance of this particular enquiry, the Complainant has acquired the services of SGS Pakistan, which is a subsidiary of the SGS Group, a Swiss multinational company, accredited by the United Kingdom Accreditation Service (UKAS)[11]. UKAS is duly notified by the European Commission on the NANDO's list and has the authority to appoint/accredit independent bodies like SGS Group to conduct assessments for the purposes of conformity with the European Standards[12]. A sample of the Complainant's packaging is reproduced hereunder for reference:

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[8] https://ec.europa.eu/growth/single-market/ce-marking/in-your-country_en

[9] Manufacturers | Internal Market, Industry, Entrepreneurship and SMEs (europa.eu)

[10] https://ec.europa.eu/growth/tools-databases/nando/

[11] https://www.ukas.com/wp-content/uploads/schedule_uploads/00011/04947/0005Management-Systems.pdf

[12] https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=ab.detail&ab_id=240449

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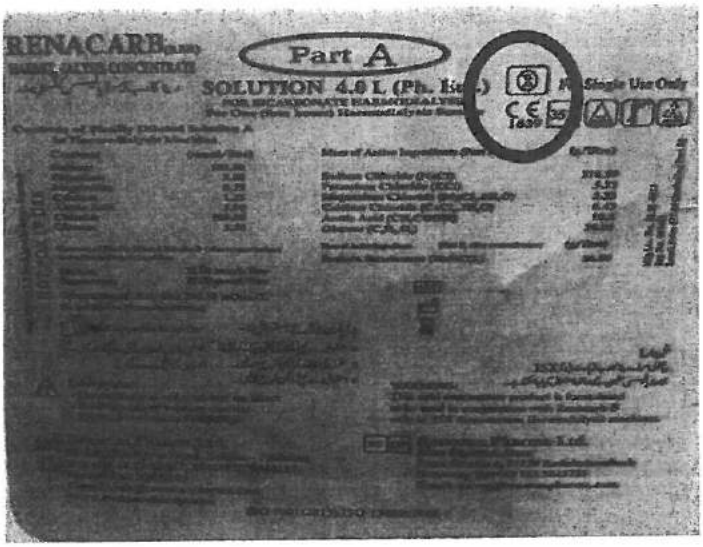

5.26 The Respondent deploys below-the-line marketing strategy by using its packaging as a source of advertising, as is the case with all medical products in Pakistan. The packaging of the Respondent's product depicts a CE mark on the bottom left corner of the packaging, a sample of which is reproduced hereunder for reference:

5.27 During the course of enquiry, it came to light that the dialysis concentrate consists of a Part-A and Part-B, wherein Part-A is a solvent and Part-B is a solute and both have to be mixed to the patient's requirement before being used in the haemodialysis machine. In this regard, the image in Para No. 5.26 above is a representation of the Part-A of the product. An image of Part-B, also depicting the CE mark and ISO certification, is given hereunder:

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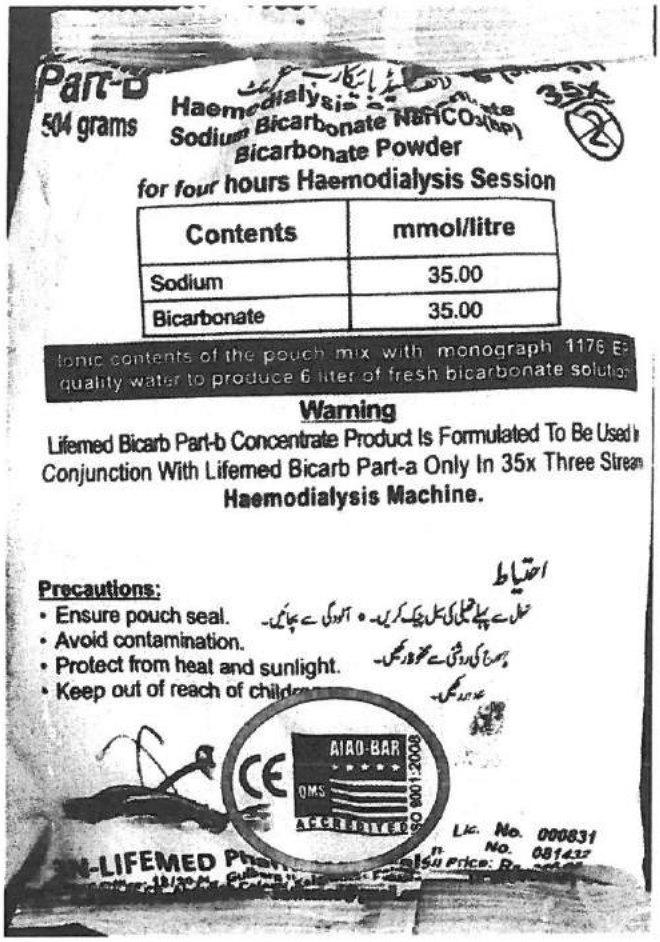


5.28 In case of the Respondent, it submitted that it had acquired the services of American Global Standards, Pakistan, a subsidiary of American Global Standards LLC. (AGS), for its CE mark. As evidence, it had submitted its Certificates issued by the AGS and a letter of authentication from the same, accompanied by accreditation of AGS with AIAO-BAR. (Attached as Annex-B, C & D respectively).

5.29 An excerpt from the AIAO-BAR's website states; *"The AIAO-BAR is a trade organization that accredits conformity assessment bodies in accordance with internationally recognized guides and standards. Headquartered in Los Gatos, California, AIAO-BAR connects EU, Asia, and other emerging regions to the US economy by meeting the growing need for internationally recognized accreditation services"*[13].

5.30 From Para 5.29 above, it is evident that the AIAO-BAR is an accreditation body for standardisation with American Standards. Whereas, the CE mark provides for conformity with the European Standards. Therefore, AIAO-BAR does not possess the authority to accredit any independent body for assessment for issuance of a CE mark.

[13] https://www.aiao-bar.org/

5.31 Similarly, AIAO-BAR is not a notified body as per the NANDO's list by the European Commission[14]. Therefore, AIAO-BAR does not have an authority to certify or appoint another for assessment for a CE mark, thereby rendering the CE certification of AGS as void.

5.32 Moreover, the AGS has also disclosed in the letter of authentication (attached as Annex - C) to the Respondent, that it has terminated the services of AGS, Pakistan since 5th of October, 2020. The same can be validated from the website of AGS as it does not contain any official address of Pakistan anymore[15].

5.33 Furthermore, the allegation of the Complainant as to the absence of the CE mark number, use of unauthorized procedures to procure the CE mark, licensing with DRAP and invalid address of AGS in Pakistan become irrelevant to the case when it is proven that the CE mark is, *prima facie,* unauthorized. Furthermore, with reference to Para No. 4.32 above, the Complainant had alleged that the Respondent had been using an expired manufacturing license number 000831 on its batches manufactured in year 2021. However, the fact of the case is that the Respondent, although using an expired license number from previous year, was in possession of a valid manufacturing license number ELM-0026 from DRAP in 2021. Moreover, display of an expired license number while in possession of a renewed license number does not fall within the ambit of Section 10 of the Act.

5.34 On the basis of analysis drawn above, it can be concluded that the Respondent has indeed used, *prima facie,* a fake CE mark on its product, both Part-A and Part-B. Also, from the understanding developed above regarding false and misleading information, it is evident that the use of a CE mark on the packaging by the Respondent is contrary to the truth or fact, thereby a false information.

5.35 Based on the Respondent's plea as to the conformity with European Standards being a voluntary service cannot be taken into account as the mere depiction of a false mark falls under deceptive marketing practices. The Respondent had a choice to not conform with the European Standards if it did not have an intention to export its product to the EEA. However, if it chose to represent the CE mark voluntarily, it should have followed through all necessary protocols to obtain the same.

5.36 Moreover, undertakings go through the tedious process of obtaining these certifications while incurring heavy costs along the process and such misrepresentations render the efforts worthless.

5.37 The Complainant submitted in its complaint that the tenders circulated for procurement of Haemodialysis Concentrate by hospitals require undertakings in possession of a CE mark to bid on them. A sample tender document submitted by the Complainant is attached as Annex-E for reference.

5.38 Therefore, the bids or business the Respondent unjustly made through the depiction of the false CE mark, during the course of its unauthenticated certification period, is a harm to the business

[14] https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=ab.main
[15] https://www.americanglobal.org/contact/

interest of the Complainant and other undertakings in the relevant market. *(Tenders won by the Respondent in year 2020-21 are attached as Annex-A).*

5.39 Therefore, the conduct of the Respondent is, through representation of a false CE mark on its packaging of Part-A and Part-B of haemodialysis concentrate, capable of harming the business interest of the Complainant, *prima facie*, in violation of Section 10 (1) in general and in particular, Section 10 (2) (a) of the Act.

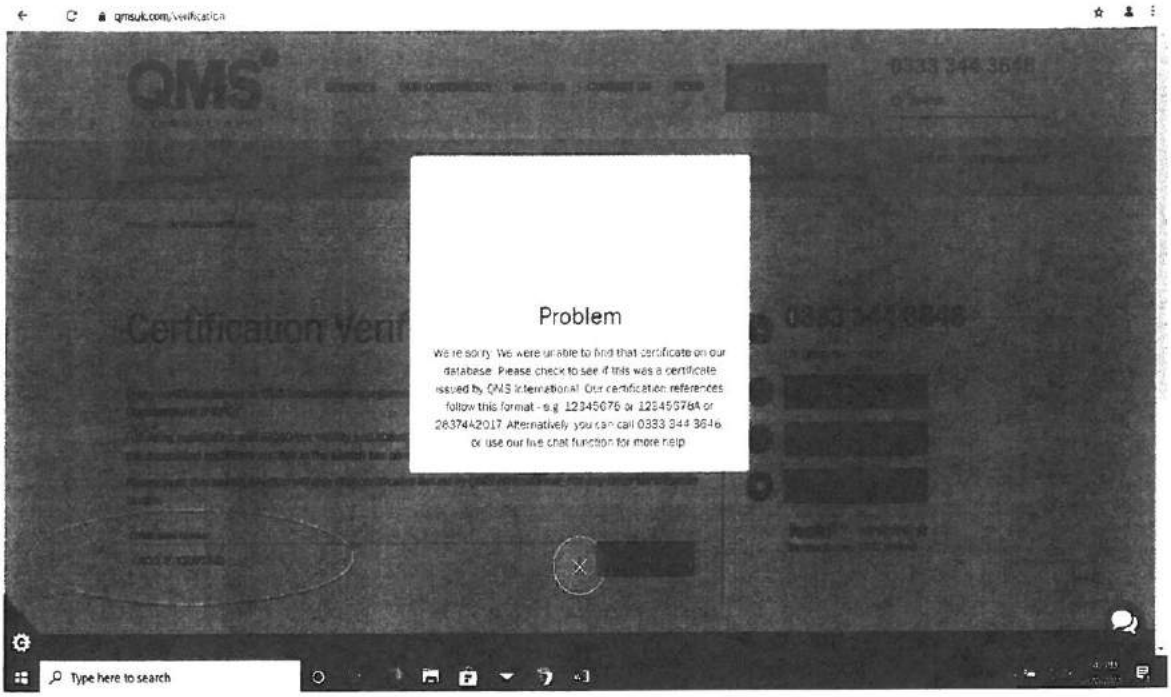
QMS CERTIFICATION

5.40 Referring to the packaging of the Respondent in Para No. 5.26 and 5.27 above, it contains a mark at the bottom of both packaging depicting a flag with QMS ISO 9001:2008 certification number. However, neither of the certificates provided by the Respondent are certified as ISO 9001:2008.

5.41 One of the certificate bearing certification number AGS-P-130030-CE shows an ISO 17025 certification. Whereas, the second certificate numbered as AGS-P-130030-Q is an ISO 9001:2015 certification. A third certificate with the same certification number shows compliance with ISO 45001:2018. (Certificates are attached as Annex-B).

5.42 Therefore, the Respondent, at the time of the complaint, was not in possession of an ISO 9001:2008 certification. It is also to be noted that the three certificates produced by the Respondent, acquired from AGS, all bear the same certification number for different ISO certifications. Moreover, one of the certificates allows the Respondent to use a CE mark based on an ISO evaluation.

5.43 Furthermore, since the Respondent represents a QMS certification on its packaging, the same can be verified from the QMS website, which has an online verification facility based on certification numbers. Upon entering the Respondent's QMS certification number in the space provided, it was found that no such certificate had been issued by QMS itself. Therefore, representing the letters 'QMS' on the mark itself is unauthorized. The verification can be seen in the picture below:



5.44 It is pertinent to mention here that during the course of inquiry, the Respondent, through ACS Registrars Pakistan, acquired ISO Certifications, specifically;

- ISO 9001:2015 (Quality Management)
- ISO 13485:2016 (Medical Devices)
- ISO 14001:2015 (Environmental Management)
- ISO 45001:2018 (Occupational Health & Safety)
- OHSAS 18001:2007 (Occupational Health & Safety)

5.45 However, at the time of the complaint, the Respondent was not in possession of a QMS certification and ISO 9001:2008 certification. Therefore, the representation of both on its packaging is unauthorized and false. Similarly, reiterating Para No. 5.35 to 5.38 above, the display of false QMS Certification by the Respondent has supplied it with a competitive advantage of being able to bid on tenders at par with its competitors, who have actually invested time and money to obtain valid certifications.

5.46 Therefore, the bids or business the Respondent unjustly made through the display of a false QMS certification, during the course of its unauthenticated certification period, is a harm to the business interest of the Complainant and other undertakings in the relevant market.

5.47 Moreover, the Commission, it its Order held against **M/s Jotun Pakistan (Pvt.) Limited**[16], states that;

> *"To prove conduct under Section 10 (2) (a) of the Act, it is not necessary to show actual harm to competitors. It is sufficient to show the existence of a deceptive*

[16] http://cc.gov.pk/images/Downloads/jotun_pakistan.pdf

marketing practice that has the potential to harm the business interest of the competitors. Among such deceptive marketing practices is the distribution of claims lacking reasonable basis that are essentially designed and used to gain an unfair advantage over competitors."

5.48 Based on the above it is evident that the Respondent is, through representation of a false QMS certification on its packaging of Part-A and Part-B of haemodialysis concentrate, capable of harming the business interest of the Complainant, *prima facie*, in violation of Section 10 (1) in in terms of Section 10 (2) (a) of the Act.

ii. Whether the Respondent is disseminating false or misleading information to consumers, including the distribution of information lacking a reasonable basis, related to the character, properties, suitability for use, and quality of its products in, prima facie, violation of Section 10 (1) in general and in particular, Section 10 (2) (b) of the Act?

5.49 To draw an analysis under Section 10 (2) (b) of the Act, it is necessary to define what is meant by the word 'consumer'. The Commission, it its Order held against **M/s CMPak Limited**[17], states that;

"Therefore, from OFT's perspective, the consumer to whom such information is disseminated has to be the 'ordinary consumer' who is the usual, common or foreseeable user or buyer of the product. Such a consumer need not necessarily be restricted to the end user."

5.50 Therefore, a consumer may be taken within the meanings of an end consumer, which in this case may be a kidney failure patient, as well as a buyer, which may include all the businesses buying haemodialysis concentrate for resale or for service provision to kidney patients in dialysis centres and hospitals.

5.51 To draw an analysis under Section 10 (2) (b) of the Act, both the patients and buyers will be analysed hereunder, separately.

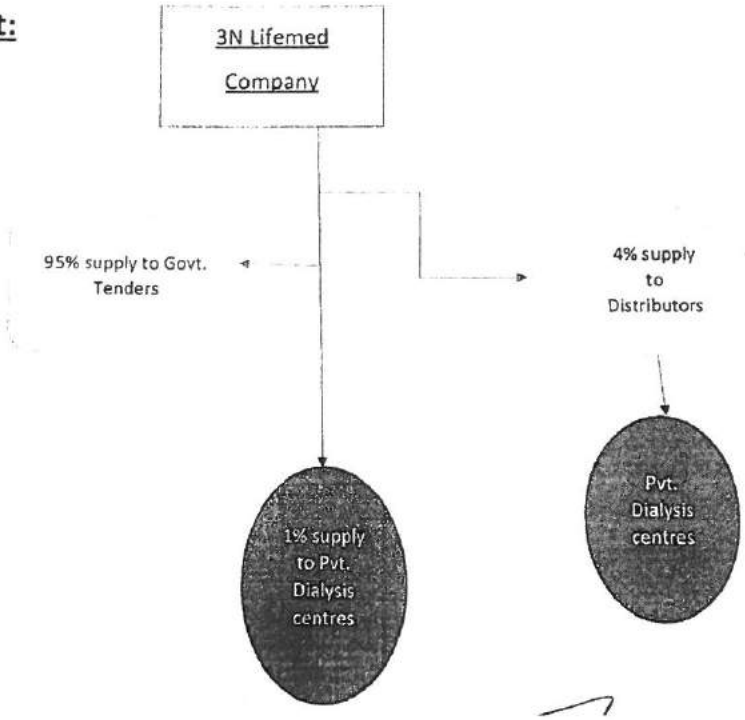
5.52 For this purpose, it is essential to understand the nature of the product. As referred to above, the product i.e., haemodialysis concentrate, is categorized as a medical device under the relevant laws of DRAP.

5.53 Therefore, it is evident that the concentrate is in no way consumed, administered or used by a patient as a drug. The concentrate is only used as a solvent in the haemodialysis device. The concentrate does not enter the human body at any stage of the procedure.

[17] http://cc.gov.pk/images/Downloads/ZONG%20-%20Order%20-%2029-09-09%20.pdf

5.54 Moreover, the Respondent was asked to submit a basic flowchart of its supply chain from manufacturer to the end user. The following supply chain was produced by the Respondent, as given below:

Flowchart:



5.55 In light of the supply chain above, it becomes clear that the product under consideration is neither marketed nor sold to the patient directly. In fact, the product is a business to business (B2B) product, sold purely to other commercial undertakings or buyers. In this instance, 95% of the product moves from the manufacturer to government hospitals via tendering, and only a mere 5% ends up at privately owned dialysis centres.

5.56 This clearly proves that the product is never prescribed to, bought by, consumed or used in any other way by the patient. The product is purely sold to and is used by health professionals for the purposes of a medical procedure.

5.57 Since the product is never marketed to, sold to or used by a patient, the provision of Section 10 (2) (b), i.e., dissemination of false or misleading information to the consumers, does not apply to a patient.

5.58 However, as evident from the flow chart above, the product is marketed to and bought by hospitals and private dialysis centres for the purpose of provision of a service. Therefore, for the purposes of this enquiry, hospitals, distributors and privately owned dialysis centres will be taken within the meanings of a consumer, as established in the Order of CMPak Limited (reference Para 5.49).

5.59 Therefore, from the analysis drawn above, the product is sold to consumers via tendering to govt. hospitals as well as distribution to privately owned dialysis centres. In reference to Para No. 5.39 and 5.48 above, the Respondent has been selling its concentrate through the display of a fake CE mark and QMS certification.

5.60 In both the cases, the purchase of the Haemodialysis concentrate by consumers under the false pretence of a CE Mark and a QMS Certification is, dissemination of false information to consumers regarding the character and properties of the concentrate. However, the suitability for use or quality of the concentrate, as established above, does not get affected with the presence or absence of a CE mark or QMS certification.

5.61 Therefore, the Respondent, through the representation of a false CE Mark and QMS Certification, on the packaging of Part-A and Part-B of haemodialysis concentrate, is found to be disseminating false information to consumers lacking a reasonable basis related to the character and properties of the concentrate, *prima facie*, in violation of Section 10 (1) in terms of Section 10 (2) (b) of the Act.

iii. Whether there is a spillover effect of the conduct of the Respondent?

5.62 As regards the effect of anti-competitive behaviour spilling over territorial limits of other provinces is concerned, it is noted that the product of the Respondent is sold nationwide via tendering to hospitals in Punjab, Sindh, Baluchistan and KPK, removing the intra provincial territorial boundaries.

5.63 Similarly, the product is also sold in the market apart from tendering in a limited number to privately owned dialysis centres, therefore, not restricted to a particular area or province.

5.64 A similar case was inspected by the Australian Competition & Consumer Commission (ACCC), where **M/s Mosaic Brands Limited**[17], in relation to representations concerning Health Essentials Products, contravened relevant sections of the Australian Consumer Law (**ACL**).

5.65 Mosaic Brands admitted that at various dates between March 2020 and July 2020, it engaged in misleading or deceptive representations regarding KN95 Kids Safety Face Mask sold as 'FDA/CE Certified', when it was not the case; and a Velcare hand sanitizer sold as approved by the World Health Organisation, when this was not the case either.

5.66 Mosaic Brands was directed by the ACCC to pay penalties, follow a strict compliance program with the ACCC with regular reporting and offer refunds to customers affected by its deception.

[17] https://www.accc.gov.au/public-registers/undertakings-registers/mosaic-brands-limited

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5.67 In reference to Para No. 4.30 above, the Complainant had submitted a new packaging/ label of the Respondent. The Respondent had, *prima facie*, removed the CE mark and QMS certification from its new label during the course of this enquiry. The act alone implies that the Respondent was aware of its false representation of both the CE mark and QMS certification on its packaging.

6. CONCLUSION & RECOMMENDATION:

6.1 The Respondent's product, through the use of unauthorized and false CE mark and QMS Certification, is in total disregard to the global standardisation and certifications.

6.2 In view of the analysis, it is concluded that the conduct of the Respondent, through dissemination of false or misleading representation relating to CE mark and QMS certification on the packaging of Part-A and Part-B of haemodialysis concentrate, *prima facie,* has the potential to inflict harm on the business interest of the Complainant, in violation of Section 10 (1) in terms of Section 10 (2) (a) of the Act.

6.3 In light of the facts, it is also concluded that the Respondent, through the representation of a false CE mark and QMS certification, on the packaging of Part-A and Part-B of haemodialysis concentrate, is found to be disseminating false or misleading information to consumers lacking a reasonable basis related to the character and properties of the dialysis concentrate, *prima facie*, in violation of Section 10 (1) in terms of Section 10 (2) (b) of the Act.

6.4 To ensure free and fair competition in the market undertakings should be stopped from marketing their products in deceptive and misleading manner. The undertakings should be encouraged to resort to the marketing practices that are transparent and give consumers/customers true and correct information. Therefore, in light of the above mentioned findings, it is recommended that the Commission may consider initiation of proceedings against M/s 3N- LIFEMED Pharmaceuticals under Section 30 of the Act for the, *prima facie*, violation of Section 10 of the Act.

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