BEFORE THE

COMPETITION COMMISSION OF PAKISTAN

IN THE MATTER OF SHOW CAUSE NOTICE ISSUED TO

M/s. 3N-LIFEMED PHARACEUTICALS

On Complaint Filed By

M/s. RENACON PHARMA LTD

FOR DECEPTIVE MARKETING PRACTICES

(File No. 345/RENACON/OFT/CCP/2021)

Hearings:	01.12.2021 21.02.2022 16.11.2022 25.11.2022 By the Current Bench 28.11.2023 22.05.2024
Commission:	Mr. Saeed Ahmad Nawaz **Member** Mr. Salman Amin **Member**
Present on Behalf of:	
M/s. Renacon Pharma Ltd (Complainant)	Mr. Shahid Rafique Sheikh Advocate High Court
M/s. 3N-Lifemed (Respondent)	Mr. Faizan Saleem Advocate High Court

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ORDER

1. This order disposes of the proceedings initiated pursuant to the Show Cause Notice No. 31/2021 dated 21.09.2021 (the **'SCN'**), issued to M/s. 3N-LifeMed Pharmaceuticals (the **'Respondent'**), for *prima facie* violation of Section 10(2)(a) and Section 10(2)(b) read with Section 10(1) of the Competition Act, 2010 (the **'2010 Act'**).

2. M/s. Renacon Pharma Limited (the **'Complainant')** alleged that the Respondent was engaged in deceptive marketing by disseminating false and misleading information. It was submitted that the Respondent obtained a fake Conformité Européene (**CE**) Mark and Quality Management System (**QMS**) Certification from System Machinery Inspection Services-American Global Standards Pakistan (**SMIS-AGS or AGS**); a non-accredited institution and had been displaying the said Certifications on the packaging of its bicarbonate haemodialysis concentrate (the **'Product'**). Since both these CE Mark and QMS Certification were obtained from a non-accredited body without requisite authorisation, thus the said recognitions were fake, hence, their display on the packaging of the Product constituted violation of Section 10(2)(a), 10(2)(b) read with Section 10(1) of the 2010 Act.

BACKGROUND

The Complaint

3. The allegations leveled in the Complaint against the Respondent are summarized below:

(a) M/s. 3N-LifeMed Pharmaceuticals, the Respondent acquired a license from Drug Regulatory Authority of Pakistan (DRAP) to manufacture hemodialysis concentrate solution on 13.02.2015. In order to compete with the Complainant in the market, the Respondent obtained a fake *Conformité Européene* CE Mark and QMS Certification from American Global Standard, Pakistan (AGS Pakistan); a non-accredited company in Islamabad. Furthermore, the CE Mark being fake was not followed by the designated number of a Notified Body, for example, CE-0120 and CE-1639.

(b) The Respondent's certifications have been issued by System Machinery Inspection Services-American Global Standards Pakistan (**SMIS-AGS or AGS**), that even have no official website.

(c) AGS name and address were only listed on the website of its purported accrediting body, 'American International Accreditation Organization' (**AIAO-BAR**). AGS is

associated with American Global Standard LLC, USA (**AGS LLC-USA**). However, AIAO-BAR itself is not accredited by the New Approach Notified and Designated Organization (**NANDO**) or its affiliates such as the International Accreditation Forum (**IAF**), the United Kingdom Accreditation Service (**UKAS**), or the Pakistan National Accreditation Council (**PNAC**) to qualify as a Notified Body and hence is fake.

(d) Consequently, the Respondent through the use of fake CE Mark and QMS Certification, managed to get supply orders for haemodialysis concentrate solution from big hospitals of Pakistan.

Enquiry Report

4. After evaluating the preliminary evidence available, the Commission authorized an inquiry under Section 37(2) of the 2010 Act and formed an Enquiry Committee (**EC**) on 12.03.2021. The EC concluded its Enquiry Report (**ER**) on 09.08.2021, outlining its findings as follows:

> *"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 standardization and certification.*
>
> *6.2 In view of the analysis, it is concluded that the conduct of the Respondent, through dissemination of false and 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 false CE mark and QMS certification, on the packaging of Part-A and Part-B of haemodialysis concentrate, is found to be disseminating false and 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 in terms of Section 10(2)(b) of the Act."*

Show Cause Notice

5. In pursuance of the ER, the Commission issued a SCN to the Respondent, in the following terms:

> *"5. WHEREAS, in terms of the Enquiry Report in general and paragraph 2.1 and 2.6 in particular, it has been alleged by the Complainant that the Undertaking, in order to compete with the Complainant, obtained a fake CE Mark and QMS*

Certification (European Certification) from a non-accredited company in Islamabad to achieve rapid growth in tender business with hospitals, which is capable of harming the business interest of the Complainant which, prima facie, constitutes violation of Section 10(1) of the Act; and

6. WHEREAS, in terms of the Enquiry Report in general and paragraph 5.21 to 5.39 in particular, it appears that the Undertaking used a false CE Mark on the packaging of its solvent (cane) PART-A and solute (sachet) PART-B of hemodialysis concentrate, obtained from a non-accredited body based in USA, which amounts to dissemination of false and misleading information that is capable of harming the business interest of the Complainant, prima facie, constitutes a violation of Section 10(1), in terms of Section 10(2)(a) of the Act; and

7. WHEREAS, in terms of the Enquiry Report in general and paragraph 5.40 to 5.48 in particular, it appears that the Undertaking used fake QMS Certification on the packaging of its solvent (cane) PART-A and solute (sachet) PART-B of hemodialysis concentrate, disseminated false and misleading information, which has supplied it with a competitive edge of being able to bid on tenders at par with competitors, capable of harming the business interest of the Complainant, prima facie, constitutes a violation of Section 10(1), in terms of Section 10(2)(a) of the Act;

8. WHEREAS, in terms of the Enquiry Report in general and paragraph 5.49 to 5.61 in particular, it appears that the Undertaking's conduct of using fake CE Mark and QMS Certification on the packaging of its solvent (cane) PART-A and solute (sachet) PART-B of hemodialysis concentrate is found to be disseminating false information to consumers lacking a reasonable basis related to the character and properties of concentrate, prima facie, in violation of Section 10(1) read with Section 10(2)(b) of the Act;"

Submissions

6. The Respondent's submissions, both oral and written, in response to SCN before the Commission, are hereby summarized as follows:

(a) The Commission lacks jurisdiction over the matter, as Drug Regulatory Authority of Pakistan (**DRAP**), being the sector regulator, has the requisite authority to deal with the subject matter.

(b) The Complaint was filed without an affidavit, which is a prerequisite for filing a Complaint.

(c) The Complainant, by filing the Complaint, is attempting to monopolize the local market, blackmail and defame the Respondent, and maliciously attempting to eliminate the Respondent from competition in the product market.

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(d) The Respondent's Product is fully compliant with laws, rules and regulations of DRAP. It has a valid license from DRAP which is proof enough that all the quality standards have been met to manufacture the Product. This fact is admitted in paragraph 5.6 of the Enquiry Report wherein the Enquiry Officers have recognized that any international certification is purely a voluntary act. These standards are not mandatory but secondary requirements for quality assurance.

(e) The Respondent has also registered its products with PNAC-ACS Registrar Pakistan with standards ISO 9001:2015, ISO 13485:2016, ISO 4001:2015, ISO 45001:2018 and OHSAS 18001:2007 in order to assure the quality.

(f) The certifications under question issued by SMIS-AGS are genuine as evident from the letter by SMIS-AGS dated 03.04.2021. SMIS-AGS is accredited from the independent board, AIAO-BAR, USA. It is not possible that a company registered in the USA would issue fake certificates.

(g) The original certificates are available with the Respondent, which can be produced before the Commission as and when required. Moreover, these standards are not mandatory and the companies implement the quality assurance system for their own improvement.

(h) The Respondent entered into an agreement with SMIS-AGS in December 2012 and later in September 2019. However, AGS LLC-USA had terminated the business membership of SMIS-AGS on 05.10.2020 and now no AGS LLC-USA office operates in Pakistan.

(i) The findings of the Enquiry Report are based on misconceived, incorrect, and misguided facts provided by the Complainant. Additionally, the issues framed in the ER are irrelevant, improper, and contrary to the parties' divergent pleadings. The Complainant has failed to attach any solid proof with regard to fake certification or any order or decision which shows that the CE Mark and QMS Certification of SMIS-AGS are fake.

(j) The tenders attached to ER were based on incorrect calculations, information, and facts. The Respondent did not succeed in winning all the tenders mentioned in ER and denied any involvement in interfering with the procurement process.

(k) The Complainant with malafide intent and ulterior motives, sent a letter to the Managing Director of the Public Procurement Regulatory Authority (PPRA) and

Medical Superintendents of various hospitals to tarnish the Respondent's reputation by falsely claiming that it had a fake CE Mark and QMS Certification.

The learned counsel for the complainant made the following submissions before the Bench:

a) that the reply to SCN submitted by M/s. 3N-LifeMed Pharmaceuticals, the respondent was hopelessly time barred;
b) that they never challenged the findings and recommendations of the ER at any stage of the proceedings;
c) that M/s. Renacon Pharma Limited, the Complainant paid Rs. 2.6 million to get the CE Mark Certification for the current year;
d) that CE Mark being used by the Respondent had no number of the Notified Body affixed after it;
e) that AIAO-BAR, USA was not authorized to issue CE Mark as it could only be issued by EU Member Countries;
f) that System Machinery Inspection Services-American Global Standards Pakistan (**SMIS-AGS or AGS**), the subsidiary/affiliate of AIAO-BAR, USA had been issuing fake certificates in Pakistan;
g) that M/s. 3N-LifeMed Pharmaceuticals, the Respondent continued using expired license number on their cans even after its expiry on December 3, 2015;
h) that M/s. 3N-LifeMed Pharmaceuticals, the respondent imported sodium bicarbonate from Novabay Pte. Ltd., Singapore which was not having Good Manufacturing Practices (GMP) Certificate during that period; and
i) that the Respondent imported food grade sodium bicarbonate from China because the country had no GMP Certification for manufacturing of pharmaceutical grade chemical and utilized it to manufacture haemodialysis concentrate solution.

The learned counsel for the Respondent rebutted the learned counsel for the complainant as follows:

a) that M/s. 3N-LifeMed Pharmaceuticals, the respondent were bonafide purchaser of CE Mark and GMP Certificates;

b) that the use of expired license to import sodium bicarbonate from Singapore was a subject matter of DRAP and beyond the jurisdiction of CCP;

c) that the accusation of using any certification after its expiry was false and clarified that the Respondent discontinued using the certifications after their expiry.

DELIBERATION AND ANALYSIS

7. After hearing the parties and carefully perusing the record, we have formulated the following issues for determination:

I. *Whether DRAP or the Competition Commission of Pakistan has exclusive jurisdiction over the matters taken up in the complaint filed u/s* 37(2) of the 2010 Act;

II. *Whether the Complaint adheres to the procedural requirements, specifically the necessity of an affidavit to be submitted along with the Complaint;*

III. *Whether the use of CE Mark and QMS Certification as displayed by the Respondent on its product packaging are deceptive in violation of Section 10(2)(b) read with Section 10(1) of the Act; and*

IV. *Whether the Respondent's actions have harmed the business interests of the Complainant in violation of Section 10(2)(a) read with Section 10(1) of the Act.*

ISSUE NO. I

8. The Respondent argued that DRAP was the concerned regulator of pharmaceutical companies and DRAP should, therefore, deal with the allegations leveled in the instant complaint through its Director Drug Licensing, Director Quality Assurance and Laboratory Testing, and Director Medical Devices and Medicated Cosmetics under Section 4 of the Drug Regulatory Authority of Pakistan Act, 2012 (the **DRAP Act, 2012**). The Respondent further referred to section 7 of the DRAP Act, 2012 that pertains to the powers and functions of DRAP related to monitoring and enforcement of regulations for advertisement including ban on false advertisement.

9. The Bench has carefully perused sections 4 and 7, and Schedule II, Part B of the DRAP Act, 2012, the DRAP Drugs (licensing, Registering, and Advertising) Rules, 1976, and DRAP Ethical Marketing to Healthcare Professional Rules, 2021 and found that none of the referred

legislations contains any provisions that specifically deal with matters of deceptive marketing covered under section 10 of the Competition Act, 2010 and raised in the complaint filed before the Commission. According to the Preamble to the DRAP Act, 2012 it was promulgated to provide for effective coordination and enforcement of the Drugs Act 1976 (XXXI of 1976) and to bring harmony in inter-provincial trade and commerce of therapeutic goods. DRAP is accordingly mandated to regulate the matters, inter alia, including manufacturing, import, export, storage, distribution and sale of therapeutic goods. DRAP Act 2012, therefore, specifically regulates the quality and safety aspects of the drugs.

10. Conversely, the Competition Act, 2010 is the only special law dealing with prohibitions and protection against anti-competitive behaviours and practices in Pakistan. The Preamble to the Act explicitly states that it provides for free competition in all spheres of commercial and economic activities to enhance economic efficiency and to protect consumers from anti-competitive behavior. Section 10 of the 2010 Act is of fundamental importance in the instant matter because it exclusively deals with deceptive marketing practices detrimental to the interests of consumers, competitors and overall competitive environment as reported by the Complainant in its complaint filed with the Commission. Since, Competition Act, 2010 provides for free competition and DRAP Act, 2012 aims to bring harmony in inter-provincial trade and commerce with a focus on quality and safety, the notion of competition, therefore, stands at a different plinth and pedestal than the concept of harmony in trade or commerce.

11. Whereas, section 59 of the Competition Act, 2010 is a non-obstante clause no such provision exists in the DRAP Act, 2012. This lets the Commission to take cognizance of matters that, inter-alia, include deceptive marketing practices, notwithstanding anything to the contrary contained in any other law on the subject matter. Therefore, the assertion of the Respondent, that DRAP has jurisdiction over the subject matter is not convincing because DRAP Act, 2012 does not impose any bar on the exclusive mandate of the Commission to prohibit and penalize deceptive marketing practices caused by false or misleading dissemination of information. Section 59 of the Competition Act, 2010 reads as follows:

> *"**59. Act to override other laws**:-- The provisions of this Act shall have effect notwithstanding anything to the contrary contained in any other law for the time being in force."*

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12. On the other hand, we are also well cognizant of section 32 of the DRAP Act, 2012, which reads as under:

> *"**32. Act not to override other laws**.- (1) The provisions of this Act shall be in addition to and not in derogation of the provisions made in the Drugs Act, 1976 (XXXI of 1976) and any other law for the time being in force.*
>
> *(2) In case of inconsistency between the provisions of this Act and any other law for the time being in force, the provisions of this Act shall prevail."*

13. Even the heading of Section 32 explicitly states that the DRAP Act, 2012 does not override other laws unless there is an 'inconsistency' between the DRAP Act, 2012 and other laws. Black's Law Dictionary (Sixth Edition) defines the term '*inconsistency*' as '*mutually repugnant or contradictory; contrary, the one to the other, so that both cannot stand, but the acceptance or establishment of the one implies the abrogation or abandonment of the other*'. However, in the instant matter no question of inconsistency between the two laws arises, since both statutes have different scope, which cannot be equated with '*inconsistency*' in the subject matter before the Commission which pertains specifically to the anti-competitive behaviour.

14. The 2010 Act is *lex specialis*, a special statute governing all facets of commercial and economic activity throughout Pakistan to address anti-competitive practices. In legal theory and practice, the principle of *lex specialis derogat legi generali* stipulates that where two laws address the analogous factual scenario, the statute addressing the specific subject matter (*lex specialis*) takes precedence over the statute governing general matters on the same subject (*lex generalis*). Reliance is placed on the Supreme Court of Pakistan's decision in ***Syed Mushahid Shah v. Federation of Pakistan 2017 SCMR 1218***, wherein the honorable Supreme Court observed in Paragraph 10 as follows:

> *"It is a settled canon of interpretation that where there is a conflict between a special law and a general law, the former will prevail over the latter."*

In Para 13, the Supreme Court of Pakistan further elaborated:

> *"When there are two special laws both of which contain overriding clauses, in the case of conflict between the two laws generally the statute later in time will prevail over the statute prior in time. ... **this presumption is not automatic: instead a host of other factors including the object, purpose and policy of both statutes and the legislature's intention, as expressed by the language employed therein, need to be considered** in order to determine which of the two special laws is to prevail."*
> **[Emphasis added]**

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15. An identical question regarding Commission's jurisdiction and inquisitorial powers was referred to the Commission by the Honorable Lahore High Court, Lahore in W.P. No. 26929 of 2015 in the matter of ***Determination of CCP's Jurisdiction in accordance with the Order of the Court*** and the Commission clarified vide its Order dated 09.11.2015 that:

> *"...under the scheme of the 2010 Act, the Commission has been vested with specific enforcement powers. This includes the power to conduct inquiries, the power to initiate adjudicatory proceedings, and the power to make required order to restore competition and impose financial penalties. Each denotes a particular stage in the enforcement process. An enquiry, for example, is conducted to determine, factually, whether any prima facie violation of the Act has taken place."*

16. The instant proceedings were initiated after a complaint was filed under Section 37(2) of the Act. The Complainant alleged that the Respondents had contravened Section 10 of the 2010 Act by displaying false and misleading information related to certain certifications. As established above, the Commission is vested with powers to address **anti-competitive practices**. This jurisdiction extends to all the matters covered under Chapter II, including Section 10 of the Act prohibiting deceptive marketing practices, which constitutes the subject matter of the instant proceedings.

17. Keeping in view the aforesaid, the Bench holds that false or misleading advertising is a matter of protecting competitors and consumers from anti-competitive behaviour and shall be dealt with under section 10 and section 37 of the 2010 Act. The instant matter is, therefore, within the statutory bounds of the Commission. DRAP Act, 2012 does not override the Competition Act, 2010 with respect to deceptive marketing practices. Hence, the Complaint in the instant matter is maintainable under the Act.

ISSUE NO. II

18. The Respondent asserted that the complaint was improperly filed because it lacked the required affidavit to be submitted by the Complainant. In the absence of the mandatory affidavit, the Complainant's claims, assertions and allegations remained unsubstantiated and stayed unproven. Consequently, the Complainant had failed to meet the burden of proving that the certifications in question were fake.

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19. The procedural requirements for filing a complaint under the Act are given in Regulations 17 and 18 of the *Competition Commission (General Enforcement) Regulations, 2007*, (the "**Regulations**") which state as follows:

> ***"17. Reference and Complaints.-****(1) The Commission shall upon a reference made to it by the Federal Government, conduct enquiries into any matter relevant to the purposes of the Ordinance.*
>
> *(2) Without prejudice to the foregoing where the Commission receives from an undertaking or a registered association of consumers a complaint in writing, it may, unless it is of the opinion that the application is frivolous or vexatious or based on insufficient facts, or is not substantiated by prima facie evidence, conduct an enquiry into the matter to which the complaint relates.*
>
> ***18. Contents of complaint and reference****.-(1) A complaint/reference/application under these regulations shall state –*
>
> *a) Name of the person making complaint/reference/application;*
> *b) Address in Pakistan for delivery of notice/document;*
> *c) Telephone number, fax number and electronic mail address, if available;*
> *d) Mode of service of notice/documents to be used;*
> *e) Name and address(es) of respondent(s); and*
> *f) Name and address of authorized representative, if any;*
>
> *(2) The compliant/reference/application shall contain –*
>
> *a) A brief statement of facts;*
> *b) A summary of the alleged contravention of the Ordinance;*
> *c) A succinct presentation in support of each contravention;*
> *d) Such other particulars as may be specified by the Commission;*
> *e) A schedule listing of all documents/**affidavits**/evidence in support of each of the presentations; and*
> *f) Relief(s) sought."*

20. The above-stated provisions do not prescribe any specific consequence or remedy for failing to attach an affidavit. Moreover, the Regulations have not mandated either the dismissal of a complaint filed without an affidavit, unless it is deemed frivolous or vexatious. Therefore, non-compliance with this particular provision or the omission to file an affidavit with the complaint constitutes a procedural irregularity rather than a fatal error or an illegality. This interpretation is supported by the principle that procedural rules are designed to ensure orderly conduct but should not obstruct the administration of justice unless explicitly stated. Additionally, the mandatory requirement to submit an affidavit with a complaint springs from the need to discourage anonymous complaints and hold the complainant responsible in case of

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frivolous or vexatious allegations. A complaint formally lodged by a competitor undertaking is not expected to be anonymous, frivolous or vexatious.

21. A complaint that fails to comply with procedural requirements, *such as* attaching an affidavit, may be perceived as non-compliant. The superior courts of Pakistan have underscored the importance of adhering to procedural rules but acknowledged that not all procedural lapses warrant dismissal [of a complaint] if the core issue remains unaffected. In ***S.D.O/A.M., Hasht Nagri Sub-Division, PESCO Peshawar v. Khawazan Zad (2023 PLD 174)***, the honorable Supreme Court, while explaining the rules of procedure, has observed that:

> *"Courts always lean in favor of adjudicating the matter on merits rather than stifling the proceedings on procedural formalities. Rules of procedure are meant to facilitate the court proceedings for enforcing the rights of litigants, not to trap them in procedural technicalities for frustrating their rights; they are the tools to advance the cause of justice and cannot be used to cause the miscarriage of justice. Ultimate object of securing the ends of justice, therefore, outweighs the insistence on strict adherence to such rules."*

22. In light of the foregoing observation of the Apex Court, the Bench concludes that the omission of an affidavit, in a complaint that otherwise meets all other formal requirements, constitutes a minor procedural lapse. Such a lapse neither undermines the substantive issues at hand nor does it prejudice the other party. Drawing on the jurisprudence established by the Supreme Court, where the Court emphasized that procedural formalities are the tools to advance the cause of justice and cannot be used to cause the miscarriage of justice, the Bench finds that such minor omission of a procedural requirement does not warrant the dismissal of the complaint. Consequently, the Bench will proceed to adjudicate the case on merits, ensuring that the substantive rights of the parties are fully considered and justice is duly served.

ISSUE NO. III

23. It is clarified in the very outset that the Bench is neither competent to nor interested in enforcing CE Mark and QMS Certification Standards. A warning on the EU website is reproduced hereunder to set the context about CE Marking right:

"Watch out for voluntary certificates!

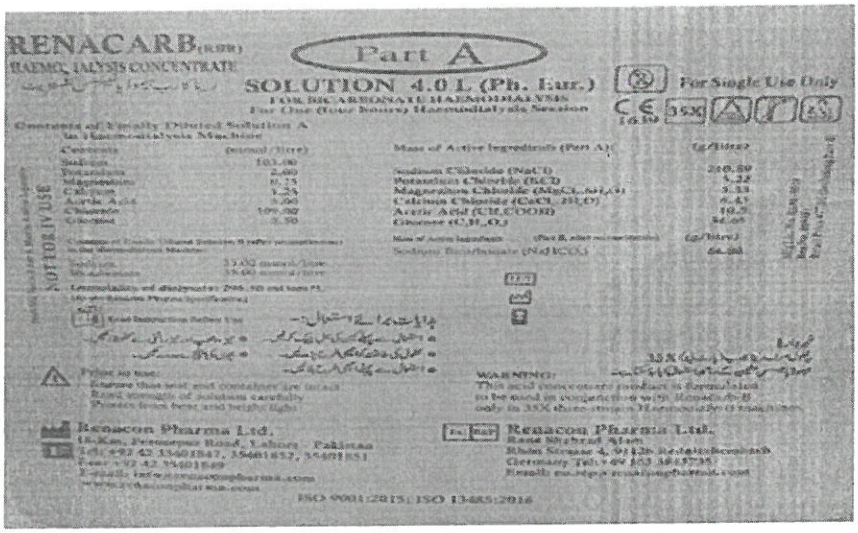
If you need to involve a notified body, you can only put CE marking on your product if it has been tested and it passed the conformity assessment procedure from the EU harmonisation legislation. Unfortunately some certification bodies who are not notified bodies under EU law issue certificates in areas beyond their competence, and call them "voluntary certificates". Those certificates are issued without any product checks and are not covered by any legislation. Therefore, do not confuse them with conformity assessment certification by notified bodies within their area of competence. Also, it is not acceptable for voluntary certificates to bear a CE marking."[1]

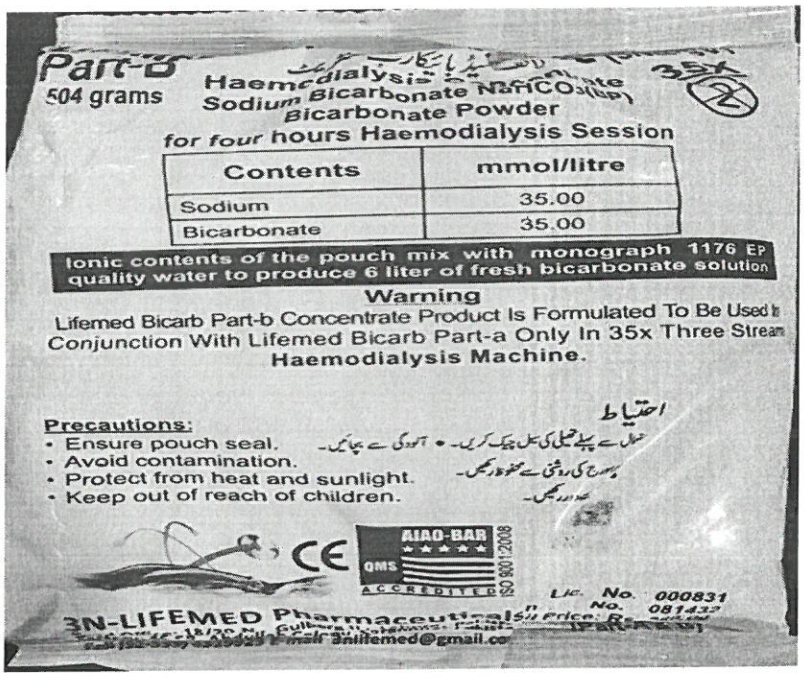
24. As far as Quality Management System (QMS) is concerned, it is a collection of business processes focused primarily on meeting customer requirements and enhancing their satisfaction. QMS can be considered as 'standards' developed by different organizations for use of specific technology for manufacturing. Certification is thus awarded by such organizations on the basis of a product's compliance with those standards. QMS certification also symbolizes the achievement of efficiency and effectiveness in an organization's management processes. There are numerous QMS developed by various organizations around the world, such as Baldrige Performance Excellence Program, European Foundation for Quality Management (EFQM), European Quality in Social Service (EQUASS) and International Organization for Standardization (ISO) etc.

25. The perusal of record has revealed that the Respondent acquired CE Mark from System Machinery Inspection Services-American Global Standards Pakistan (**SMIS-AGS or AGS**) vide No. AGS-P-130030-CE with initial payment of Rs. 25,000/ for a period from 10.05.2020 to 09.05.2021 and it was renewable @ Rs. 10,000/- per annum. Similarly, it obtained QMS Certification from the same organization vide No. AGS-P-130030-Q for a consideration of Rs. 20,000/- for the period from 20.09.2012 to 06.03.2021 with renewal charges of Rs. 10,000/- per annum. On the contrary M/s. Renacon Pharma Limited. the Complainant acquired CE Mark from SGS, Pakistan (Private) Limited with an initial payment of Rs. 947,646/- and paid Rs. 6,921,600 for its validation/updating till the year of hearing. The Complainant paid Rs. 243,432/- as initial fee to SGS Pakistan (Private) Limited for QMS Certification and spent

[1] https://europa.eu/youreurope/business/product-requirements/labels-markings/ce-marking/index_en.htm

approximately Rs. 10,42,500/- for its validity till the current year. Come what may it seems impossible to have the conformity assessment, file the technical documentation and notify the declaration of conformity for CE Mark or QMS Certification with paltry expenses as it was done by the Respondent. The same aspect substantiated when the particulars are checked for the bank account wherein the referred annual amount was paid, which turned out to be a personal account, which is also dormant since long as per confirmation received form the bank by the Respondent.





26. With respect to QMS certification, the Respondent failed to provide a valid ISO 9001:2008 Certificate, as advertised on its product packaging. Instead, it relied on certificates with discrepancies, including but not limited to identical certificate numbers for different standards, which raises doubts about their authenticity. Particularly considering that, the certificates were issued by AIAO-BAR, an entity not recognized as an accreditation body by ISO or the International Accreditation Forum Inc. (IAF). Furthermore, the inclusion of both CE mark and ISO evaluation on the same certificate further substantiates their counterfeit nature.

27. During the course of inquiry, the Respondent, however, obtained various ISO Certificates from M/s ACS Registrars Pakistan (Pvt) Limited. But these certifications do not absolve the Respondent from proving the genuineness of ISO 9001:2008 certification at the time when the Complaint was filed.

28. The Respondent contended that it was a *bona fide* acquirer of certifications from SMIS-AGS Pakistan and thus not liable for any deception or misleading the consumers. However, this defense is unconvincing because of a nominal fee in contrast to industry standards, paid by the Respondent and that too into a personal bank account of an individual for obtaining the CE Marks. This nominal amount for an ISO certification should have been a concern about the authenticity of the services of SMIS-AGS and required due diligence should have been carried out by the Respondent. In compliance of the principle of 'caveat emptor' (buyer beware) and the need for due diligence, the Respondent had a responsibility to verify the legitimacy of the

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services it acquired. Failure to do so negates its claim of being a *bona fide* purchaser, as established in legal precedents. Once the instant complaint had been filed the Respondent confessed to have realized that SMIS-AGS Pakistan was not authorized to award CE Mark or QMS Certification and discontinued to renew its certifications.

29. The Bench shall now revert to alleged violation of section 10(2)(b) of the Act, which deals with dissemination of false or misleading information to consumers. This includes information that *lacks a reasonable basis* pertaining to the price, character, method or place of production, properties, suitability for use, or quality of goods. Such practices are prohibited under Section 10(1) of the Act.

30. ***In the matter of China Mobile Limited and Pak Telecom Mobile Limited (2010 CLD 1478),*** commonly referred to as **the Zong Order**, the Commission has outlined its analytical methodology for determining whether a promotion constitutes a deceptive marketing practice in terms of Section 10 of the Act. In Para 35 of the Zong Order, the Commission emphasized that:

> *"[i]n evaluating representations, we are required to look at the complete advertisement and formulate our opinions on the basis of the net general impression conveyed by them and not on isolated scripts,"*

Additionally, in Para 23, the Commission has expounded the expressions 'false information' and 'misleading information' as follows:

> *"**False information** can be said to include: oral or written statement 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** 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."*

31. When evaluating marketing or promotional activities by advertisers, the Commission assesses the overall or net general impression conveyed in this process. The assessment includes examining express, implied, absolute, or qualified claims in documents and

advertising mediums, whether or not accompanied by disclaimers and disclosures. Advertisers are required to substantiate the claims made in the advertisements.

32. The Commission has addressed the issue of substantiation of advertising claims and whether the information distributed "lacks a reasonable basis" in its Order dated 23.02.2010 ***in the matter of Procter & Gamble Pakistan (Pvt.) Limited (2010 CLD 1685).*** The Commission observed that:

> *"...the advertiser must have some recognizable substantiation for the claims made prior to making an advertisement. This doctrine is borrowed from the U.S. jurisprudence on the subject (Pfizer Inc., 81 F.T.C. 23 (1972). The advertiser must possess the level of substantiation claimed, which constitutes a 'reasonable basis."*

33. It is not necessary to demonstrate intent or actual consumer deception to prove a violation of Section 10(2)(b) of the Act. It is sufficient to show that the advertisement was likely to mislead consumers, as stated in the Zong Order (pp. 55).

34. In ***Federal Trade Commission v. Wellness Support Network, Inc., 2014,*** the FTC sued WSN for making false claims about their diabetes treatment products. WSN advertised these products as "clinically proven" and endorsed by the American Diabetes Association (**ADA**) without any scientific evidence or ADA authorization. The court found WSN's claims unsubstantiated and deceptive under Section 5(a) of the Federal Trade Commission Act, 1914. It ruled in favor of the FTC, ordering WSN to cease such claims and imposing financial penalties. This case emphasized the need for truthful, substantiated advertising and the FTC's role in enforcing consumer protection laws.

35. The Respondent's use of the CE Mark and QMS Certification without proper accreditation is comparable to WSN's false claims of ADA endorsement, as seen in the *FTC* case mentioned above. The analogy can be drawn for the following reasons:

(a) The Respondent has affixed the CE Mark and QMS Certification on its Product's labelling and packaging, despite the fact that these products have not undergone the necessary conformity assessment procedures by an accredited agency. Such conduct constitutes an unauthorized use of the CE Mark and QMS Certification, which misrepresents the product's compliance with established standards.

(b) By displaying the CE Mark and QMS Certification, the Respondent has falsely implied that the product has been certified as meeting specific standards or has received approval from a recognized certifying body when, in fact, it has not. This amounts to

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the dissemination of misleading information, which is intended to create a false impression of the product's compliance and reliability.

(c) The Respondent's actions undermine the integrity of the regulatory framework established to ensure product safety and quality. By falsely representing that the product meets recognized standards or has obtained specific endorsements, the Respondent engages in deceptive practices that not only mislead procuring authorities/consumers but also distort fair competition in the human health related products' market.

36. The Respondent's misuse of the CE Mark and QMS Certification without prior substantiation amounts to a clear violation of Section 10(2)(b) of the Act, which prohibits the dissemination of false or misleading information that lacks a reasonable basis regarding the character or quality of goods. By falsely representing its products as compliant with recognized EU standards and implying that they have been certified by an accredited body, SMIS-AGS, when they have not, it is established that the Respondent has engaged in deceptive marketing practices. Such actions not only mislead consumers but also distort fair competition for the competitors who have actually adhered to the required standards. The Respondent's conduct is a direct infringement of the statutory obligations under Section 10(2)(b), warranting legal accountability and corrective measures to ensure compliance with the law and the protection of consumer rights.

37. The Bench concludes that the Respondent's representation of the CE Mark and QMS Certification is in violation of Section 10(2)(b) read with Section 10(1) of the Act. The Respondent has never obtained these certifications from accredited agencies. This conduct may be interpreted as a deliberate attempt to mislead procuring authorities/consumers regarding the product's adherence to stringent regulatory standards, potentially leading to legal repercussions under consumer protection laws and relevant statutes governing product certification and advertising.

ISSUE NO. IV

38. Having held that the subject CE Mark and QMS Certification were fake, we now move on to analyze whether deception by the Respondent has caused any harm to the business interests of the Complainant. During the proceedings the Complainant emphasized that fake certifications provided a competitive advantage to the Respondent enabling it to bid on tenders at par with its competitors which have actually obtained genuinely valid certifications by

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ensuring due compliance to the requirements therein, besides, expending the substantial cost, time and complying with the processes involved therein. Tender notices are also annexed with ER which stipulate CE mark and QMC certification as mandatory requirement for winning a tender. On the other hand, the Respondent contended that neither EC nor the Complainant placed on record an evidence any report from third party or presented any data to substantiate the assertion that the Respondent had actually gained undue benefit in the market.

39. Admittedly, the Respondent took part in tender processes at par with the Complainant and even got supply orders in some of those tenders. This fact alone reveals that the Respondent had benefitted on the basis of false CE Mark and QMS Certification by becoming eligible for the tender and submitted bid documents with same CE Marks and QMS Certification. The Respondent initially asserted that retaining CE certification was voluntary practice but subsequently admitted that in certain tenders the procuring organization had included the referred certification(s) in the eligibility criteria for the bidders. Be it voluntary or mandatory, in either case the Respondent was required to have a valid CE Mark and QMS Certificate for using, failing which it is an act of deceptive marketing pursuant to section 10(2) of the Act. However, as held earlier, the subject mark and certification are fake which means that the Respondent attempted to get the undue commercial advantage in tendering process.

40. The Complainant has submitted that there were very limited players in the market supplying the referred Product to public and private sector hospitals. It has attached documentary proof of two rejections of the eligibility of the bidders by the procuring organization due to non-provision of valid CE mark. The minutes of meeting of *Redressal Grievance Committee for Procurement of Drugs / Medicines FY 2020-21* of DHQH Jehlum and THQH Chichawatni also reflect that Respondent failed to produce verified certificates by a recognized EU body which was a prerequisite for eligibility, hence was not considered eligibile.

41. On 12.02.2024, the Complainant presented before the Commission a list of forty seven (47) tenders won by the Respondent in year 2020-21, amounting to Rs.113 Million. As per the Complainant, if the Respondent had not relied on allegedly fake marks, it would not have been able to win the tenders. Hence, the Respondent unduly put the Complainant at competitive disadvantage by using fake marks. Furthermore, the Complainant also put forward its financial statements for years 2019-22 which show that, on account of usage of fake marks, annual financial growth of the Complainant for the year 2019-20 and 2020-21 has been substantially

lower than the year 2021-22, when it rose again after exposing of the Respondent's fake certifications. Against this background, the Complainant argued that the other tenders won by the Respondent caused substantial loss to its business during the years 2019-2020, and later started recovering when the acts of deceptive marketing by the Respondent were notified to the stakeholders as reflected below:

Year	2019	2020	2021	2022
In million (Rs.)	417.77 Growth down	522.386 Much lower than expected	544.969 Growth recovering	715.382 Increased after exposing 3N

42. This conduct of the Respondent undermined rightful efforts of the Complainant in terms of spending time and money on genuine mark and certifications for making its name stand out in the competitive market. It is held by the Commission earlier in its order dated 21.12.2012 ***In the Matter of M/s. DHL Pakistan (Pvt) Limited***, that "*it is important to recognize that part of business' identity is goodwill it has established with consumers, while part of the product's identity is the reputation it has earned for quality and value*".

43. The Supreme Court of India in ***Bajaj Auto Ltd. v. TVS Motor Company Ltd. AIR 2009 SCW 6018*** has held that deceptive marketing practices, such as false advertising, not only mislead consumers but also cause substantial harm to the business interests of competitors. The Court recognized that the potential harm to the competitor's business is a logical consequence of the deceptive act, even if actual harm is not explicitly demonstrated.

44. In view of the above, the Bench holds that the dissemination of false and misleading information, has caused harm to business interests of the Respondent in violation of Section 10(2)(a) of the Act. This conclusion aligns with both Pakistani and Indian legal precedents, which recognize the detrimental impact of deceptive marketing on fair competition and the business interests of compliant competitors. This principle shall be applicable unless exceptional circumstances warrant a different interpretation in a specific case. Such circumstances could potentially absolve the undertaking from liability under Section 10(2)(a) of the Act, however, the mitigating factors/circumstances will have to be explicitly revealed and justified. The Respondent is, therefore, held liable for breach of Section 10(2)(a) read with Section 10(1) of the Act.

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PENALTY/DIRECTIONS

45. In respect of penalty, we are cognizant of the fact that the violation period continued from 10.05.2019, when the alleged fake certificates was obtained, till 20.03.2021 when the Respondent stopped printing the alleged mark for its product as confirmed during the hearing. This translates into a period of twenty-two (22) months in total, which is definitely long enough duration for the Respondent to establish a deceptive impression in the relevant market. The sales figure of the Respondent for the said period amounts to approximately Rs.20,000,000/- (Rupees Twenty Million), which is a monetary gain reaped by the Respondent at the behest of actions which are harmful to the consumers, as well as, for the competitors in the relevant market. Besides, the actual cost of the Respondent's competitors, who spent considerable amount of money in order to get valid certifications, is also a relevant factor. Hence, these acts of the Respondent were in violation of Section 10(1) read with Section 10(2)(a) and 10(2)(b) of the Act.

46. Moreover, the Bench is also cognizant of the factor that the subject product is used for dialysis of kidney patients. Since these patients are on periodic kidney dialysis and are among one of the most vulnerable segment of the society, therefore, the Bench is of the view that the matter of any deceptive certification is highly sensitive for such consumers and the gravity of violation becomes even more severe.

47. The Guidelines of the Commission on "*Imposition of Financial Penalties (Fining Guidelines)*" stipulate that the objective of imposition of financial penalties should be to deter the undertakings from engaging in anti-competitive practices and to reflect the seriousness of the infringement. Further, it is also mentioned in the referred Guidelines that the quantum of penalty depends upon the seriousness of the infringement, duration thereof, aggravating or mitigating factors too. Accordingly, the Bench in the backdrop of the Fining Guidelines has examined the referred violations of the Act committed by the Respondent and observed that the deceptive marketing claims were made regarding products, which are used for kidney patients, and being the competition regulators it is imperative to take strict action with respect to any such claims which do not exist in actual and can mislead procuring organisations rendering kidney dialysis services to the patients. Therefore, considering the seriousness of the violation, duration of the violation, the actual cost borne by the competitors in acquiring these actual certifications, unfair competition caused in the relevant market and in order to deter the Respondent or any other undertakings from engaging in such like practices in future, we have

determined that the penalty is inevitable to be imposed on the Respondent that commensurate with these factors.

48. Though the matter of violation warrants a maximum penalty, however, keeping in view the fact that the Respondent is ready to reproach, has stopped the usage of fake certificates since March 2021 and ready to comply with the Act, we are inclined to take these corrective measures into consideration also. Accordingly, given due consideration to all the aforementioned facts and circumstances, the Bench hereby imposes:

(a) a penalty in the amount of Rs.10,000,000/- (Rupees Ten Million Only) for violation of Section 10(2(a) read with Section 10(1) of the Act; and

(b) a penalty in the amount of Rs.10,000,000/- (Rupees Ten Million Only) for violation of Section 10(2)(b) read with Section 10(1) of the Act.

49. The Respondent is hereby liable to deposit a cumulative penalty of Rs.20,000,000/- (Rupees Twenty Million Only) in the designated official account for the purpose. The Respondent after the deposit of the penalty amount will file a Compliance Report to the Registrar on the aforementioned directions not later than 30 days. In event of failure therewith shall entail an additional penalty of Rs.100,000/ (Rupees One hundred thousand only) per day of violation.

50. The Respondent is also hereby directed to immediately cease, if any, the use of the unauthorized CE Mark and QMS Certification on its product packaging and in its submissions to any procuring authority/office. The Respondent is also directed to cease and desist in future from taking part in any misleading marketing practice concerning its Product and restrain from making and/or marketing claims in a manner which may give the consumer an impression of false certification or conformity to any standards, if the facts are contrary.

51. The Bench has also duly considered the matter alleged by the Complainant during the hearings with regard to import and utilization of food grade sodium bicarbonate instead of pharma grade in the manufacturing of bicarbonate haemodialysis concentrate by M/s. 3N-LifeMed Pharmaceuticals. This aspect remained unrebutted by the Respondent during the proceedings. Therefore, the Bench directs that a copy of this Order be forwarded to DRAP and FIA to investigate into the unrebutted allegations on the Respondent and for necessary actions at their end, as deemed appropriate, under relevant legal/regulatory framework as applicable in this regard.

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52. In terms of above, the SCN No. 31/2021 dated September 21, 2021 is disposed of.

Saeed Ahmad Nawaz
(Member)

Salman Amin
(Member)

ISLAMABAD, ON THE 08th DAY OF NOVEMBER 2024.