Pharmaceutical Weighing
Market Surveillance Screening Project

WELMEC Working Group 5

Final Project Report
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1 Contents

1 Project Description

In 2018 and 2019 a Market Surveillance project on non-automatic weighing instruments (NAWI) used for medical weighing to determine compliance with the requirements of 2009/23/EU or 2014/31/EU (NAWI Directive) was carried out under guidance of WELMEC WG5.

This project was a combination of market surveillance and inspection in use. The objective of this operation was to verify that medical weighing instruments fulfil the specific regulation at a European level (market surveillance).

The study was intended to broaden the knowledge base of the risks of non-automatic weighing instruments used for patient weighing in the European Union.

WG5 decided on a comparable approach for the other weighing instrument in the medical sector and have a project on pharmaceutical non automatic weighing instruments (NAWI's), i.e. NAWI's intended to be used for determination of mass for

1. making up medicines on prescription in a pharmacy and determination, and
2. analyses carried out in medical and pharmaceutical laboratories.

This project proposal is set up like the former project on Medical NAWI's. A first version of this plan was on the agenda of the Dublin meeting in 2019 where some anecdotical information was provided (alike to that was found in the medical scale survey) showing that not all off the pharmaceutical NAWIs in use conform to the essential requirements. However, the control setup the industry has for performing their own checks on the NAWIs was thorough, consistent and very well documented. After some discussion in the meeting, it was agreed to carry on with the project description.

2 Project Background

Pharmaceutical NAWI's are used to produce medication and to determine medication dosage. The use of inaccurate or unsuitable pharmaceutical equipment could be detrimental to patient care.

This project, under WELMEC Working Group 5 will explore these issues with the aim of helping the medical sector to improve their standards by raising the importance of weighing equipment in a medical environment form a legal metrologies perspective.

Directive 2014/31/EU, the NAWI-directive relating to the making available on the market of non-automatic weighing instruments applies to all non-automatic weighing instruments, but only when used or intended to be used for the applications listed in points (a) to (g) of Article 1. In these cases, they shall satisfy the essential requirements set out in Annex I of the NAWI-directive.

3 Pharmaceutical Weighing Instrument Classes

There are a number of classes of weighing instruments used in the pharmaceutical sector at present: class I (very sensitive), class II (more sensitive, smaller divisions), Class III and Class IIII (less sensitive, greater divisions). For example, Class II equipment is extremely accurate and should commonly be found in use in this sector.

4 Joint Action

The joint action presented in this proposal will be the first joint action taken in Europe in the field of market surveillance of pharmaceutical weighing NAWI and helps market surveillance authorities to pool resources and expertise. The limited effort required per Member State makes it possible that many members participate in the action.

5 Project Justification

- Make the pharmaceutical sector aware of the relevant requirements of the 2014/31/EU
- The interpretation of the Directive about how to handle the conformity assessment procedure is not uniform. In the pharmaceutical sector, the requirement of the NAWI

directive is not very clear in spite of point (e) from article 1 of 2014/31/EU: (e) determination of mass for making up medicines on prescription in a pharmacy and determination of mass in analyses carried out in medical and pharmaceutical laboratories;
- Lack of expertise about this kind of equipment in some EU countries so they don't do market surveillance in this particular field of the NAWI directive.

6 Project Objectives/Deliverables

- To assess current standards of weighing instruments in laboratories and for the preparation of prescriptive medicines.
- To determine the compliance of non-automatic weighing instruments used for pharmaceutical weighing
- To raise the profile of legal metrology in the pharmaceutical sector
- To make users of pharmaceutical weighing instruments aware of the legal requirements i.e. 2014/31/EU.
- To learn from the control-mechanisms in place in the sector, as an input for future metrological risk assessments.

7 Project Participants

The following countries have participated in this project: Belgium, Germany, Ireland, Slovenia, Spain and Turkey. The project coordination has been carried out by Ireland.

8 Relevant Legislation

8.1 Regulations

The Directive 2014/31/EU on non-automatic weighing instruments, annex I, preliminary observation requires compliance with the essential requirements.
Regulation (EC) No 765/2008 of the European Parliament and the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93.

8.2 Harmonized Standards

EN 45501: 2015 Metrological aspects of non-automatic weighing instruments.

8.3 Guides

WELMEC Guide 5.2 – Market Surveillance Guide (NAWI & MID)
WELMEC Guide 5.3 – Risk Assessment Guide for Market Surveillance: Weigh and Measuring Instruments
The "Blue Guide" on the implementation of EU product rules 2016

9 Instrument Types and Location

This project will focus on class I, II, III and IIII in pharmaceutical settings. ***On a national level, participants can decide which classes they will include in the project.***

This project does not cover weighing instruments used for other than pharmaceutical use.

A minimum of 20 different NAWI's were inspected by each participating Member State. We limit the survey to NAWI's that have been placed onto the market within the last 10 years.

Inspections took place at locations where pharmaceutical weighing NAWI's are in use for their stated purpose, i.e. laboratories, hospital pharmacies and local pharmacies. All relevant laboratory and pharmacy procedures in relation to good hygiene practices were followed.

Before the visit took place, the inspecting officer contacted the relevant person in the facility with responsibility for the pharmaceutical weighing equipment. They agreed in advance a date and time for

the inspection to take place. Therefore, this project's outcome is based on a statistical unbiased, random sample.

10 Visual Inspection and Metrological Testing

The surveillance included a visual inspection and a metrological test to determine the accuracy of the instrument as per elements of EN 45501. Before commencing the visual inspection and metrological test the following information shall be recorded:

- Instrument manufacturer
- Instrument Type
- Instrument Model
- Instrument Serial Number
- Min & Max Capacity
- Verification Scale Interval e
- Scale interval d
- Accuracy Class
- Units of Measurement
- Analogue or Digital
- Software Version (if applicable)
- Instrument Class Specification, see table 1 below:

Table 1: The Specification of the Accuracy Classes of the Instrument

Class	Verification scale interval (e)	Number of verification scale intervals n = Max/e		Minimum capacity (Min)
		Minimum	Maximum	
I	0.001 g ≤ e	50 000	-	100e
II	0.001 g ≤ e ≤ 0.05g 0.1 g ≤ e	100 5 000	100 000 100 000	20e 50e
III	0.1 g ≤ e ≤ 2 g 5 g ≤ e	100 500	10 000 10 000	20e 20e
IIII	5 g ≤ e	100	1000	10e

Source: NAWI Directive – 2014/31/EU

10.1 Visual Inspection

The following NAWI visual inspection was carried out, before conducting the metrological test:

10.1.1 Instrument Setup

- The instrument is affixed to/sitting on a suitably stable platform that does not promote movement. *Record Pass / Fail*
- The instruments pan/platform is level and there are no obstructions to the instruments operation. *Record Pass / Fail*
- The instrument is in a clean and serviceable condition. *Record Pass / Fail*
- Is the NAWI included in a quality system? **Yes / No** If yes, indicate calibration interval.

10.1.2 Conformity to type

- Determine if the instrument has a valid type examination certificate. ***Record Pass / Fail***
- Determine if the instrument has a valid declaration of conformity. ***Record Pass / Fail***

**** For information, all TAC and TC are available on the paying database Emetas (European Metrology Type Approvals Service).***

10.1.3 Data Plate

- *Ensure that the NAWI has a data plate with the legally relevant information.* ***Record Pass / Fail***

10.1.4 Marks

- Ensure that the instrument bears the correct CE and Metrological markings as per 2014/31/EU or 2009/23/EU ***Record Pass / Fail***

- Ensure that the instrument bears a Notified Body number. ***Record Pass / Fail***

10.1.5 Security, marks and seals

- Security mark(s)/seal(s) in place and show no signs of tampering. ***Record Pass / Fail***
- Mark(s)/Seal(s) are applied correctly, as per the instruments type approval document. ***Record Pass / Fail***

10.2 Metrological Inspection

This test was carried out with determination of the error using the method described in Standard NF EN 45501. The metrological results will be compared with the maximum permissible error in service, see table 2. The standard weights or standard masses used for inspection of the instrument shall conform to the metrological requirements of OIML R111 and the correct class of weight should be used in relation to the instrument class.

10.2.1 Repeatability

Apply approximately 50% of maximum load. Ten weighing's on classes I, II, III and IIII.

Analogue and Digital Indicating Instruments

i. Zero the instrument's indicator.
ii. Apply test load and record indication
iii. Remove the test load.
iv. Zero the instrument indicator
v. Repeat steps (i to iv)
vi. Compare error against MPE (inspection).
vii. **Record Pass / Fail**

10.2.2 Linearity

The linearity test was performed at three different (simulated) loads, min, half max and max.

i. Zero the instrument and add the first test load.
ii. Record the indicated value **I**
iii. Add weights to reach the second load value.
iv. Record the indicated value **I**
v. Repeat steps iv and v for each additional load value.
vi. Compare error against MPE (inspection)
vii. **Record Pass / Fail**

Table 2: NAWI MPE table (Inspection)

MPE (Inspection)	**For loads m expressed in inspection scale intervals e**			
	Class I	**Class II**	**Class III**	**Class IV**
± 1.0 e	0 ≤ m ≤ 50 000	0 ≤ m ≤ 5 000	0 ≤ m ≤ 500	0 ≤ m ≤ 50
± 2.0 e	50 000 ≤ m ≤ 200 000	5 000 ≤ m ≤ 20 000	500 ≤ m ≤ 2 000	50 ≤ m ≤ 200
± 3.0 e	200 000 < m	20 000 ≤ m ≤ 100 000	2 000 ≤ m ≤ 10 000	200 ≤ m ≤ 1 000

11 Recovery of Available Data

During the visit, it was necessary to recover as much information as possible in order to complete the control sheet, the model of which is given in Annex 1. This data can be recovered through the examination of available documents (possibly copy of declaration of conformity, etc.), the visible markings on the various materials present and the information of the holders or users concerning the NAWI.

12 Project Actions

Individual countries to address detected non-compliance in accordance with their national legislation and procedures.

13 Project Summary by Country

13.1 Ireland

96% of NAWI were inspected in high street pharmacies with 4% inspected in general hospitals.

All pharmacists in Ireland are required by law to have a conformity assessed NAWI with an associated set of calibrated weights. Failure to meet these requirements may impact on the awarding and retention of a pharmacy licence.

During this campaign, Ireland encountered a large number of NAWI's in pharmacies that were clearly not in use, and in some cases, had not been used for many years. This is due to the fact that the almost all medicines are now bought in, ready mixed, with no need for on-site weighing. In the small number of cases where NAWI's are still used, they are primarily used for mixing creams which require a low accuracy balance.

All non-compliant instruments were removed from trade use immediately and the pharmacy operators were instructed to take the necessary actions to bring them back into compliance. Legal Metrology are currently working with the Irish Pharmacy Regulator with a view to raising awareness of the legal requirements when operating a NAWI in a pharmacy.

13.2 Belgium

Inspections are almost all performed on location in high street pharmacies in Belgium.

Some years ago, the Belgian Legal Metrology office engaged in a specific campaign with the pharmacy sector with the objective to clarify the requirements regarding NAWI's used in healthcare and guiding the sector to become compliant. Since then, the federation of pharmacists is active in informing on a regular basis their members regarding applicable Legal Metrology requirements.

During this campaign, Belgium did not receive any special reports on NAWI on shelves. As a result of the information campaign with this sector, awareness in the sector is high and the NAWIs in use are registered in our database of instruments in use.

When finding a non-compliance, the user of the instrument is requested either to replace the instrument by a new one, or to correct the issue, with the assistance of a competent technician. After maintenance or repair, a reverfication by an authorised organisation is mandatory. The positive result of such a re-verification is registered in a central database. Inspectors of the Legal Metrology office can monitor the evaluation.

13.3 Slovenia

All inspections took place in street pharmacies. In Slovenia, all NAWI in street pharmacy and pharmaceutical manufacturers are legal instruments and must be verified with a reverification period of 2 years.

Over the past 10 years, Slovenia has worked closely with pharmaceutical manufacturers in relation to the need to operate legally compliant NAWI's in their laboratories. There is now a clear understanding within this sector of the legal obligations and all NAWI's in such laboratories are now verified.

In Slovenia, NAWI's are in regular use in relation to pharmaceutical weighing. All NAWI's located in the pharmaceutical laboratories shall also be legal and properly verified, otherwise they should not be in the laboratory if they are not used.

In case of non-compliance, Slovenia prohibits the use of the NAWI until the non-compliance is resolved.

13.4 Turkey

All inspections took place in street pharmacies.
Weighing instruments used in pharmacies are subjected to periodic verification every two years in accordance with our national legislation Weighing Instruments Verification Regulation. Verification

application is made by the user to the Weighing Instruments Authorized Verification Services authorized by the state and the necessary verification procedures are carried out by these services.

In addition to periodic verifications, weighing instruments are subject to inspection within the scope of annual inspection plan and inspections with complaints. In these inspections, the user is informed that there is a question for the use of these devices in a correctly adjusted and stamped manner throughout the period of use.

It is obligatory to have weighing instruments used in drug production in pharmacies, and it can be said that these weighing instruments are used as needed. The frequency of use varies according to the location of the pharmacies. It can be said that weighing instruments in pharmacies located close to hospitals are used more frequently than weighing instruments in pharmacies operating close to other health centres (family health centres). (Due to the presence of polyclinics such as dermatology in hospitals)

The nonconformities that were identified in this project were related to the Maximum Permissible Errors. In accordance with national regulation, a weighing instrument operating outside the MPE is stopped and allowed to be used, if appropriate, after necessary repair and adjustment. In addition, since the weighing instrument works outside the MPE, the user is given an administrative fine in accordance with the Law No. 3516.

13.5 Spain

All inspections took place in high street pharmacies.

In Spain, not all the street pharmacies need to have a NAWI but only those that can prepare tailor-made master formulas. The NAWI's used in these particular pharmacies must be verified every two years, and a good track record of the reverification periods is kept so the pharmacists are well aware of the legal metrology requirements in these instruments. To support this, all the NAWI's we checked during the project had undergone the corresponding reverification in time.

The NAWI's are in regular use in this kind of pharmacies and Spain only found a couple that were "on the shelves" because they hadn't prepared any tailor-made master formulas for a long time (even though they were re-verifying them all the same).

In our case, the instruments that presented a non-conformity were put out of use until they were repaired (they didn't pass the metrological tests) and re-verified. No penalties were issued as all the NAWI's had a valid re-verification certificate. Manufacturers of the NAWI that did not have the Declaration of Conformity on-site were requested to provide it and it was provided so not further actions were needed.

13.6 Germany

Germany (Rheinland-Pfalz), inspected different locations, such as pharmacies, pharmaceutical and medical laboratories. 60 % of the NAWI we inspected and reported were used in pharmaceutical laboratories, 30 % in pharmacies, and 10 % in medical laboratories.

The knowledge and awareness of the legal requirements of the users of NAWI that were inspected in the pharmacy sector in Germany were all in all great. The responsible persons knew about what they have to do according to law. All of the NAWI inspected were in regular use. The main and simple reason for that is that the storage, and not usage, of the weighing instruments are unnecessary costs that the owners would like to prevent. In some pharmacies, there are very old devices which are used as decoration, but not for measuring.

In one case, a non-compliant weighing instrument was found. It was an old, non-calibratable / non-testable instrument by means of the NAWID respectively law. This device might have weighed correctly, but it wasn't allowed by law to be used in analyses in medical laboratories, to determine the mass in analyses in pharmaceutical laboratories or to manufacture medicine in pharmacies, as well as in any other commercial way. Therefore, as a measure, the user made sure the device wasn't used anymore. They also bought a new and compliant one. The user had to pay a fine for this violation of law.

14 Project Results

The results of this project can be found below in figure 2 to figure 16.

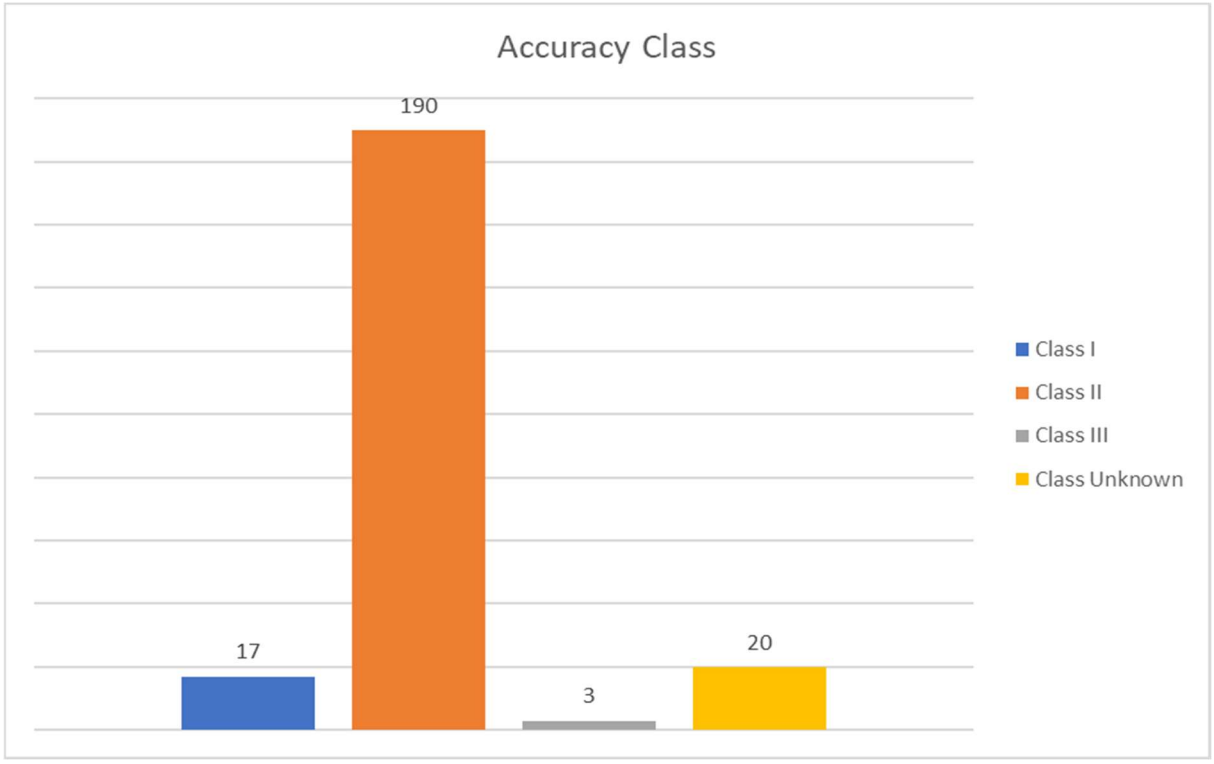

Figure 2. Accuracy Class

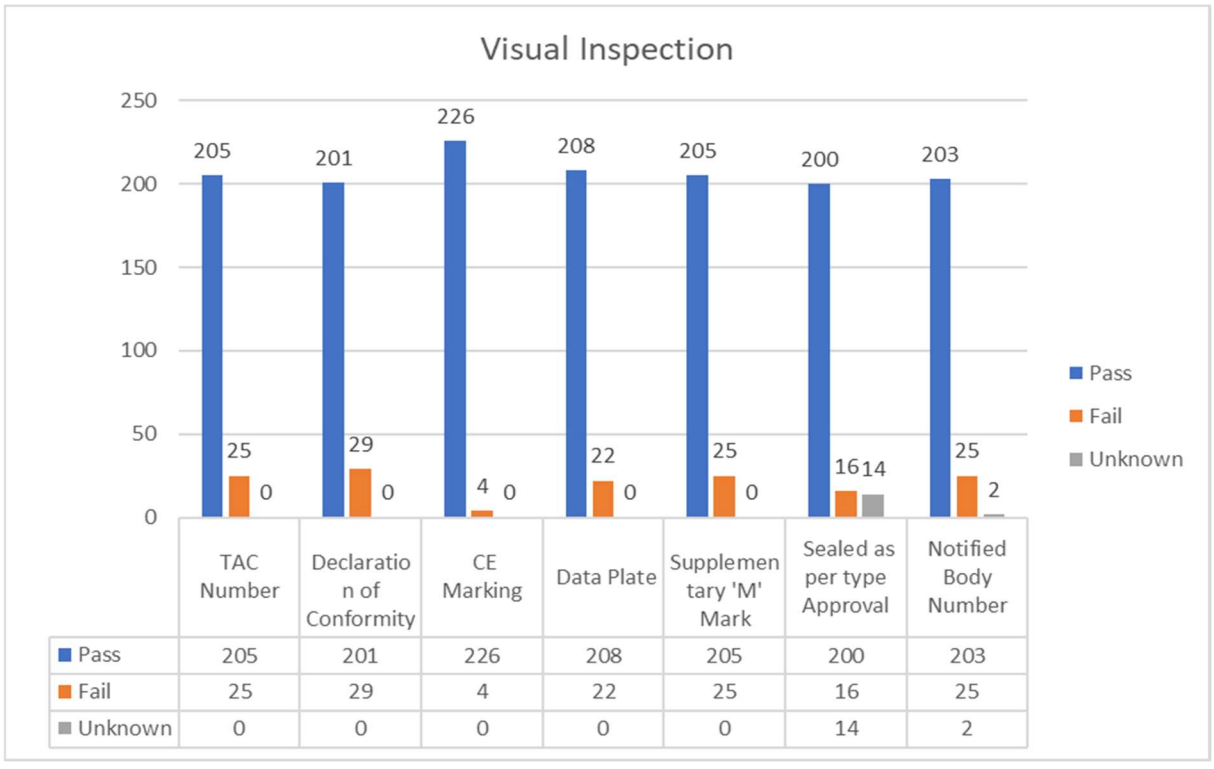

Figure 3. Visual Inspection

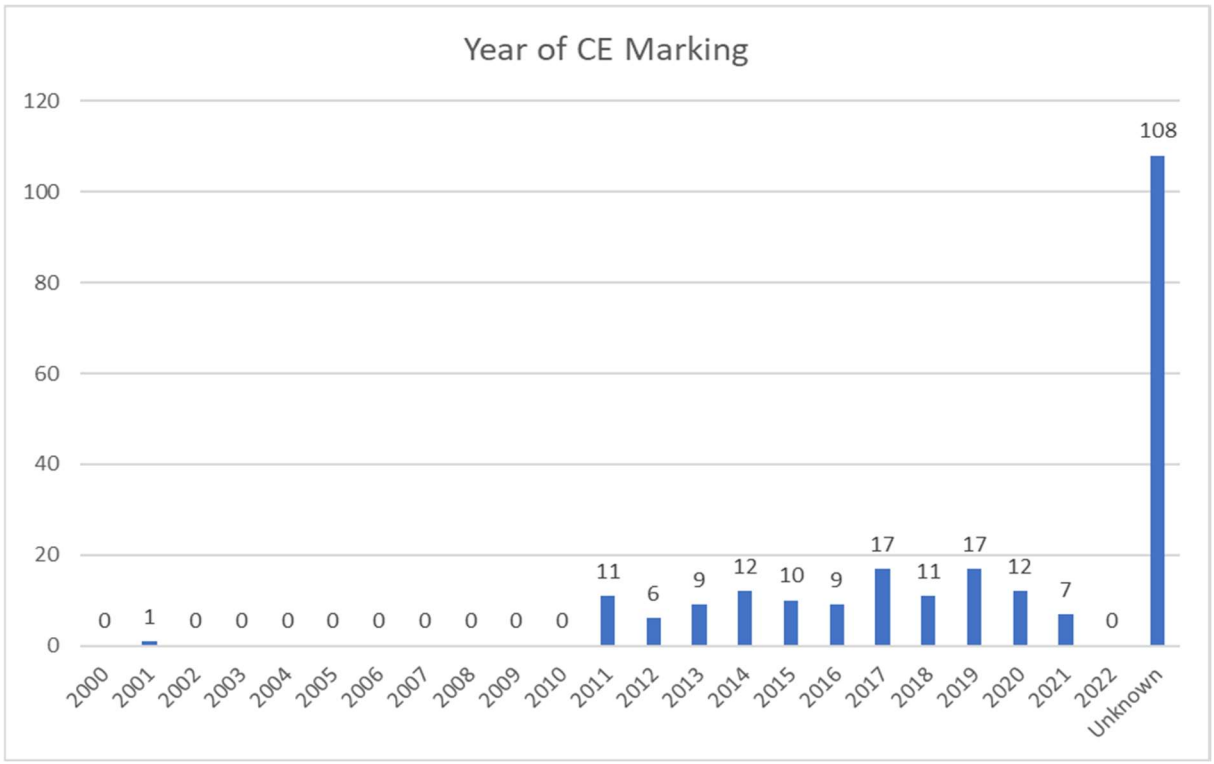

Figure 4. Year of CE Marking

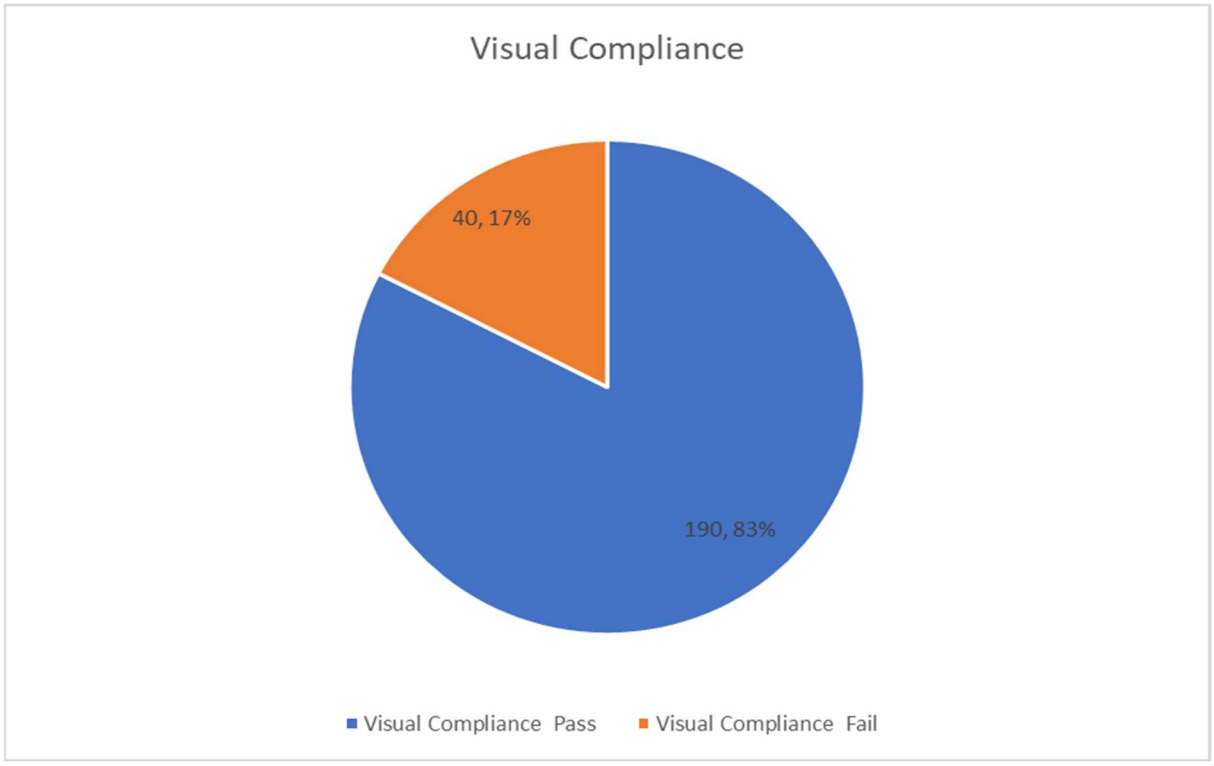

Figure 5. Visual Compliance

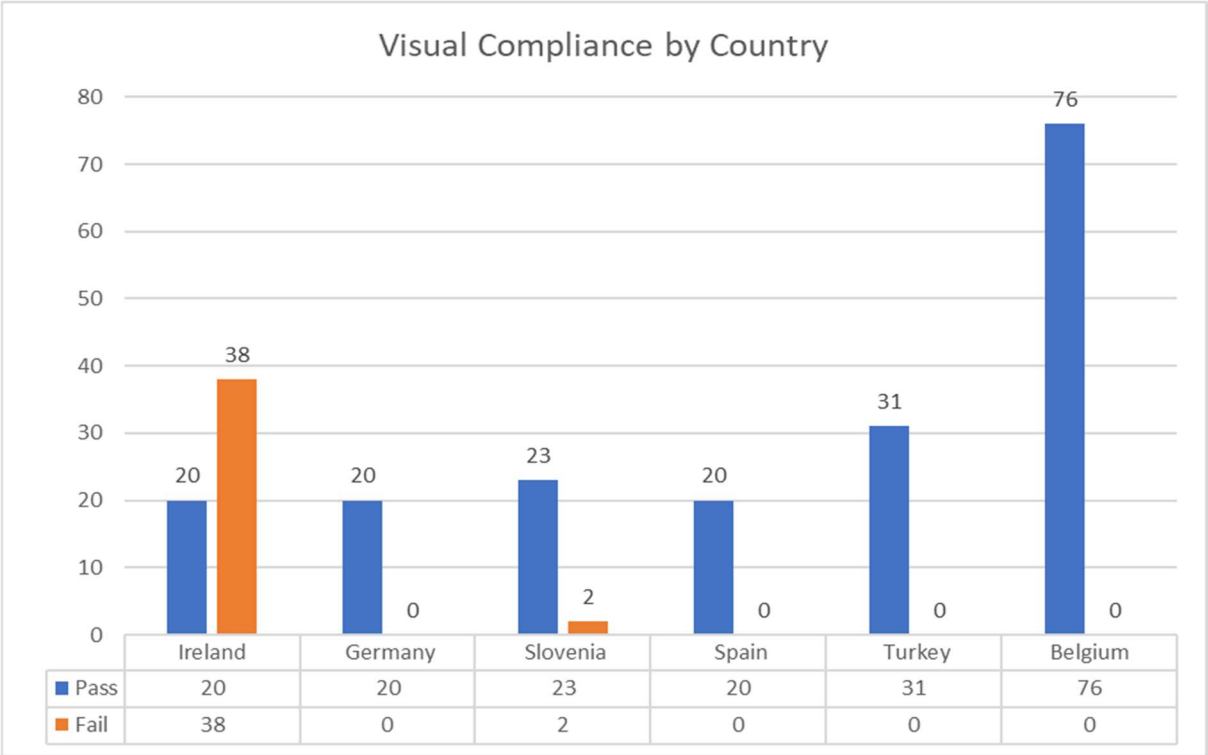

Figure 6. Visual Compliance by Country

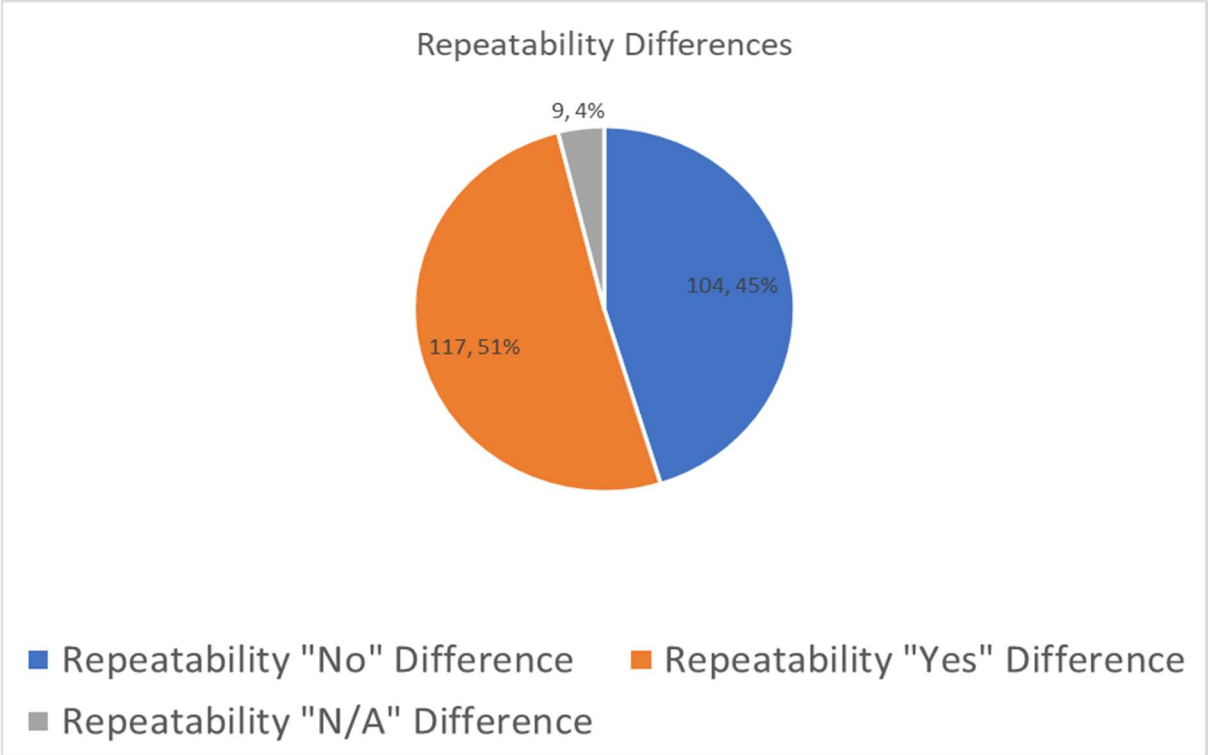

Figure 7. Repeatability Differences

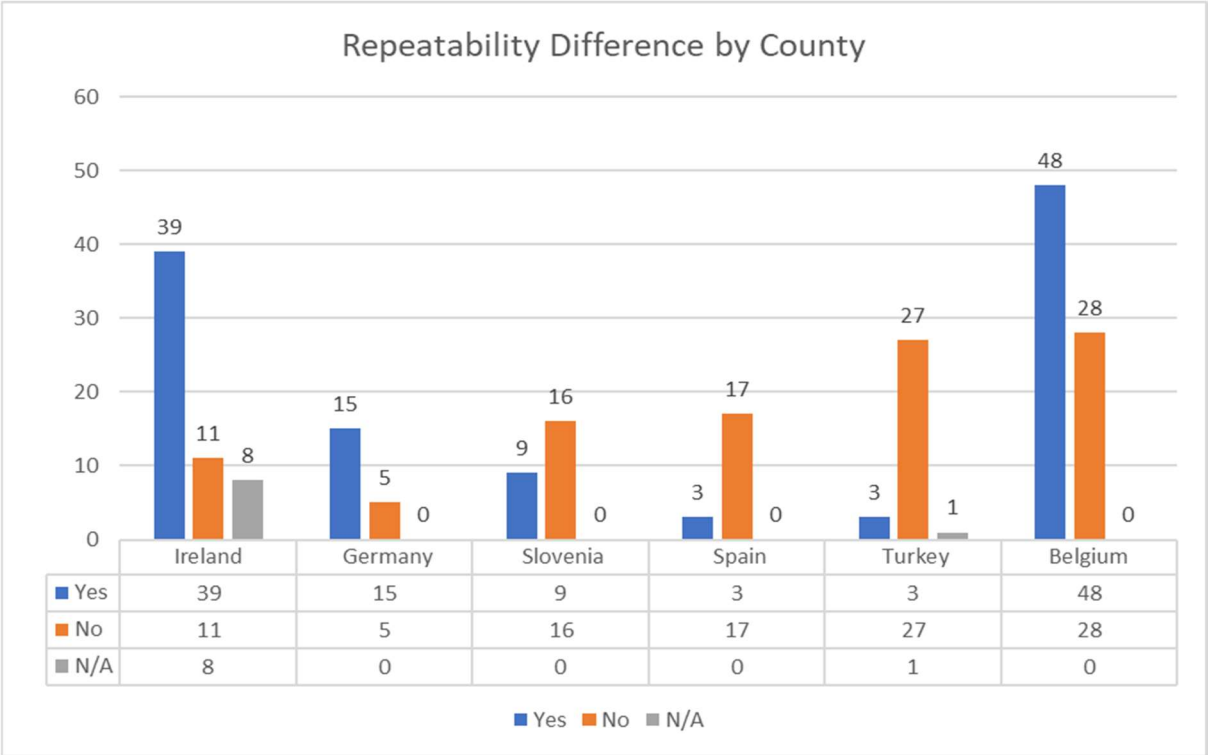

Figure 8. Repeatability Difference by County

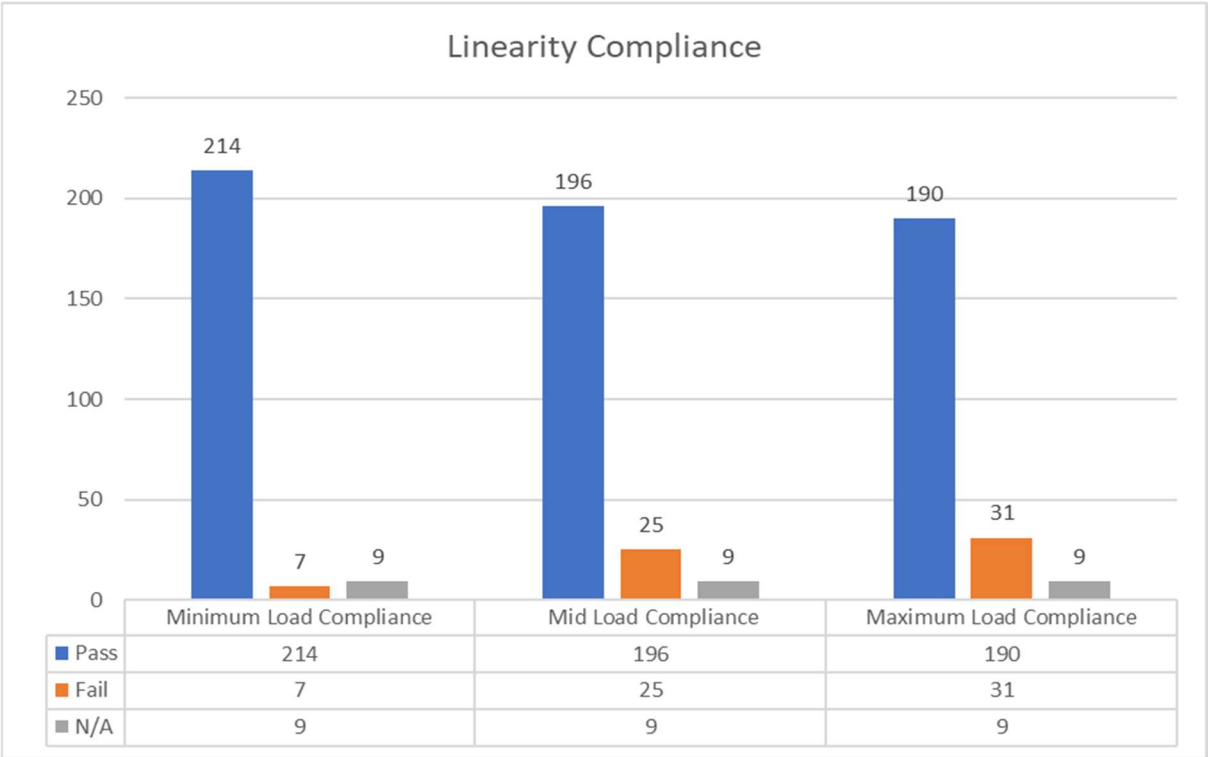

Figure 9. Linearity Compliance

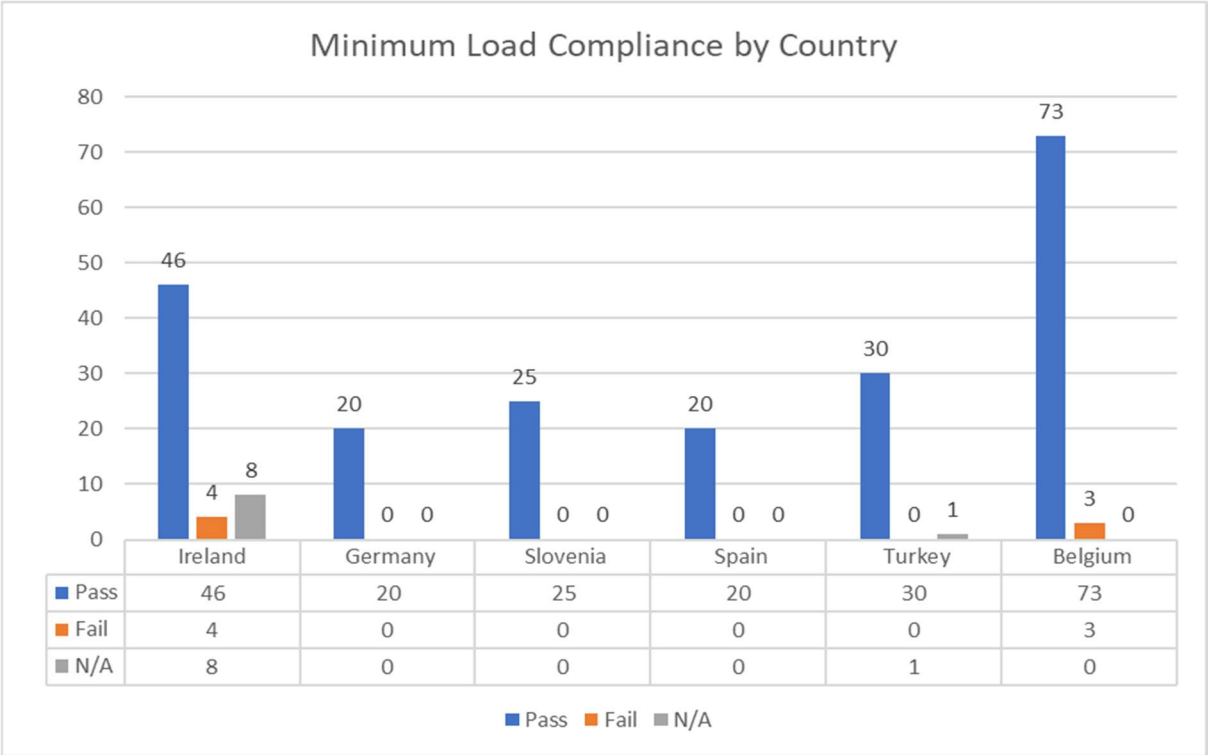

Figure 10. Linearity Compliance: Minimum Load Compliance by Country

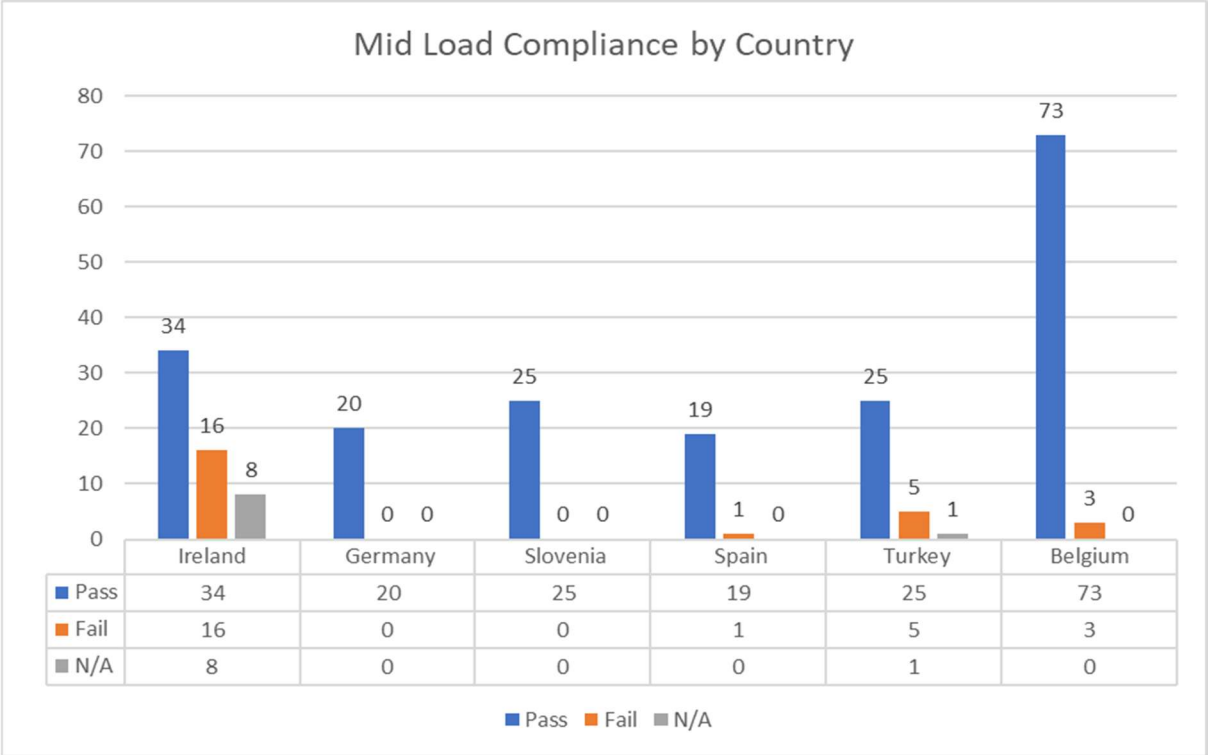

Figure 11. Linearity Compliance: Mid Load Compliance by Country

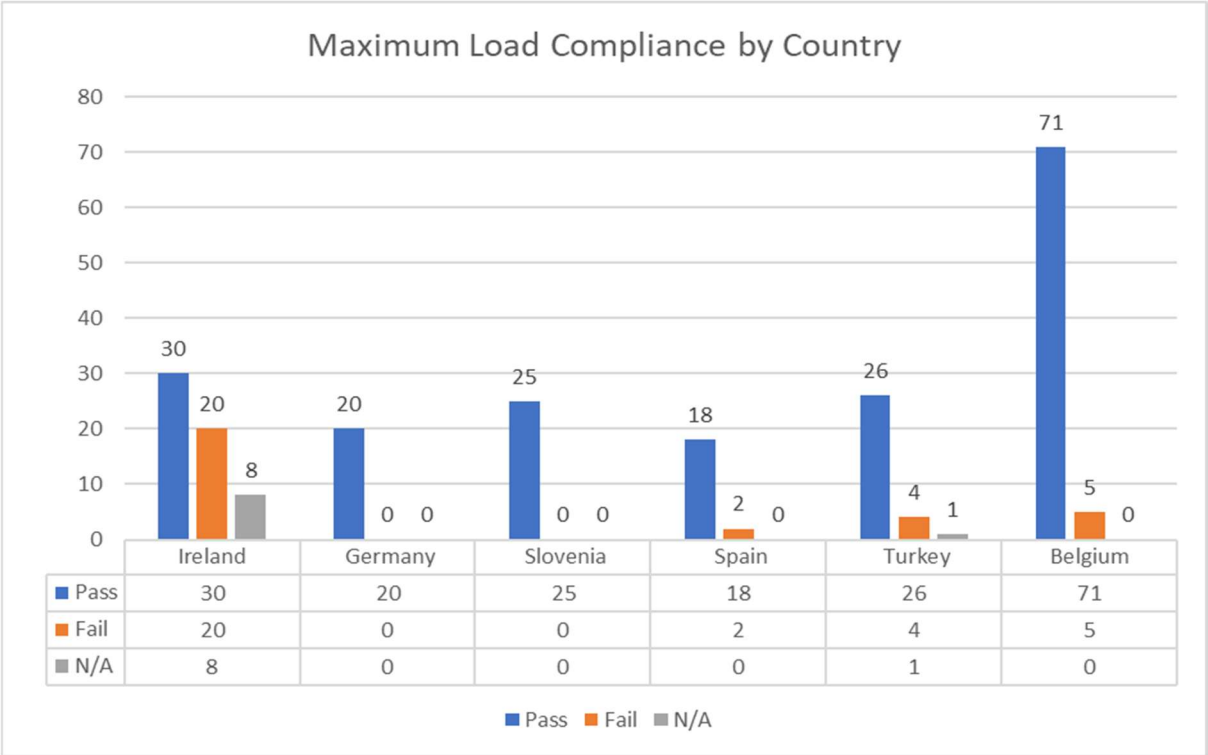

Figure 12. Linearity Compliance: Maximum Load Compliance by Country

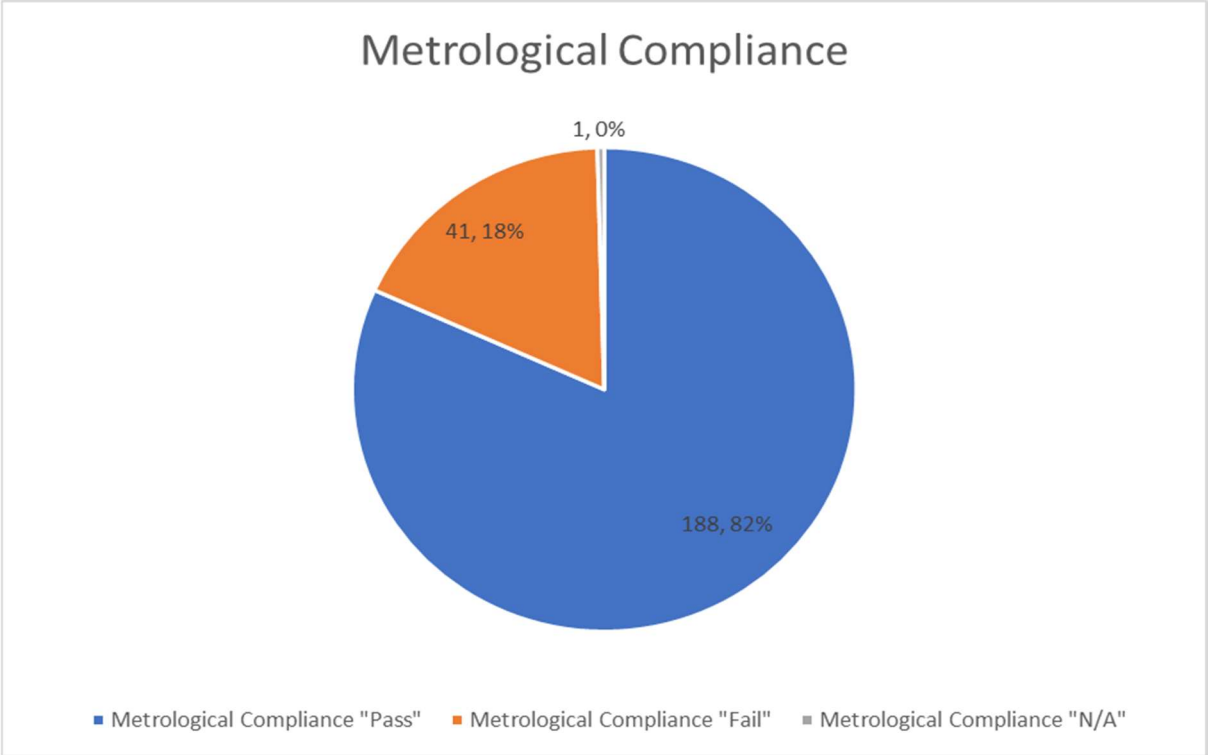

Figure 13. Metrological Compliance

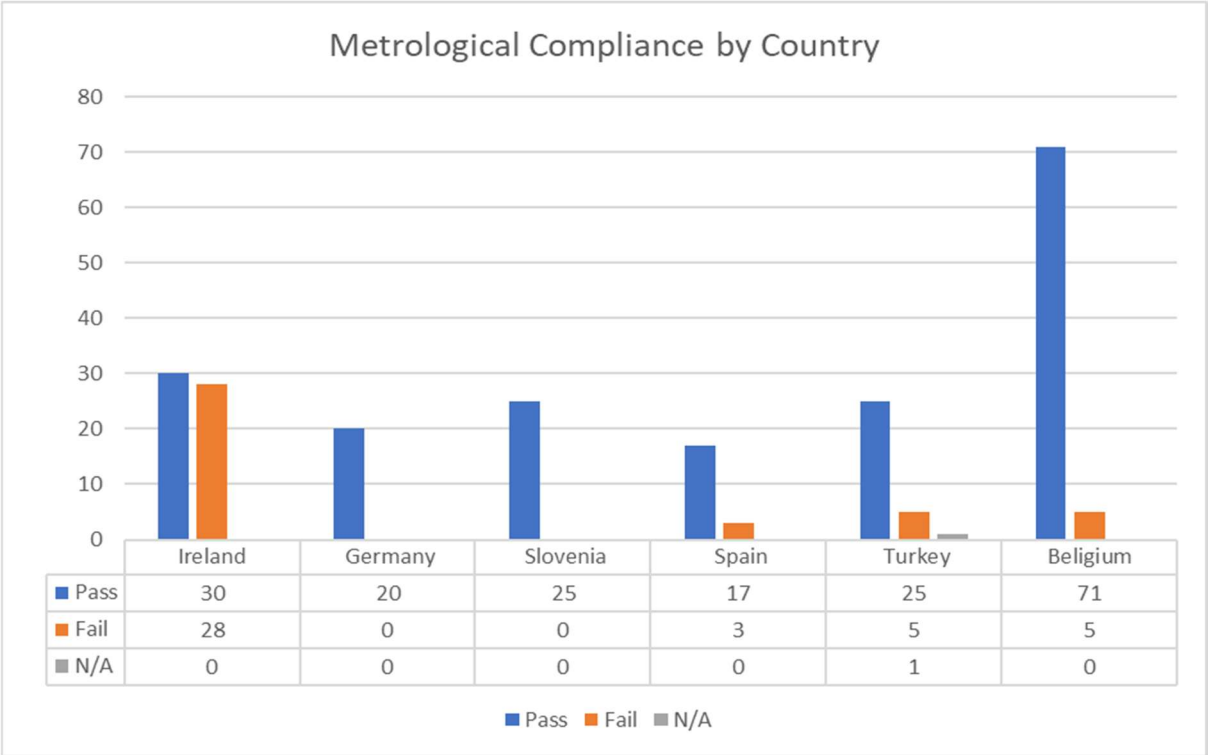

Figure 14. Metrological Compliance by Country

Note: Turkey were unable to test one instrument as it was a Class I instrument, and this is therefore recorded as n/a.

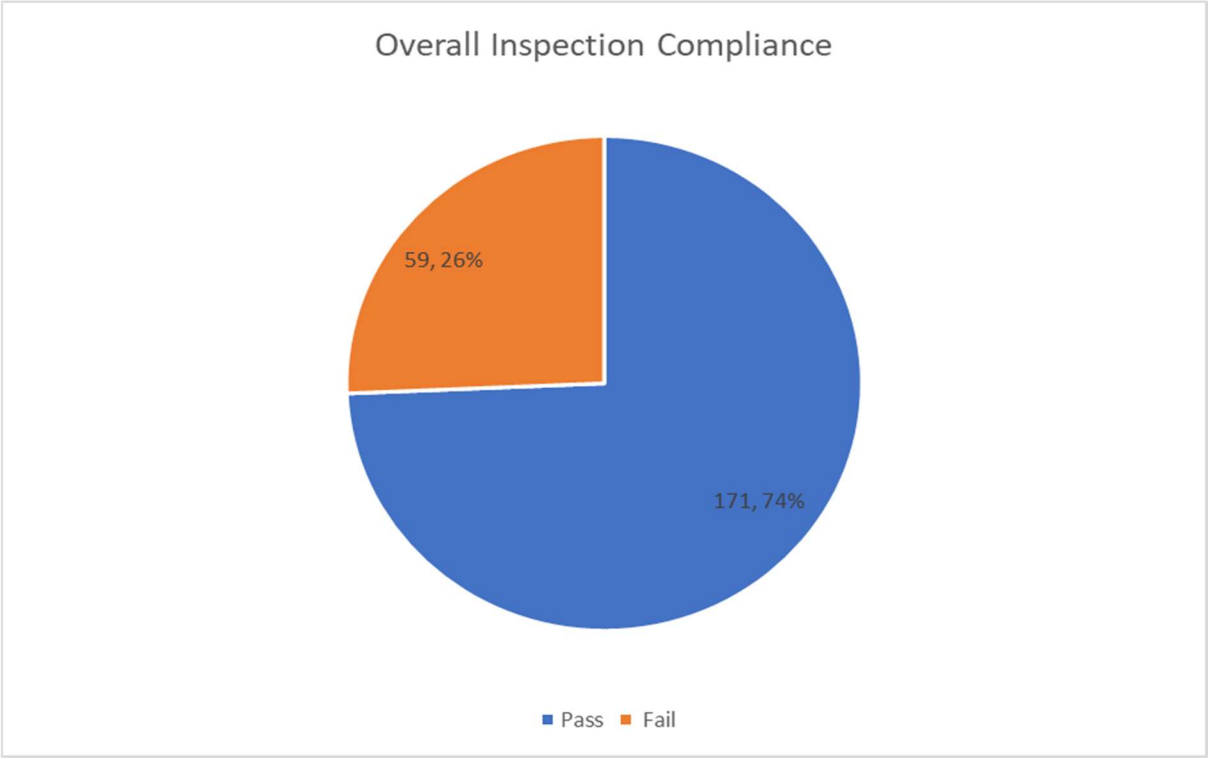

Figure 15. Overall Inspection Compliance

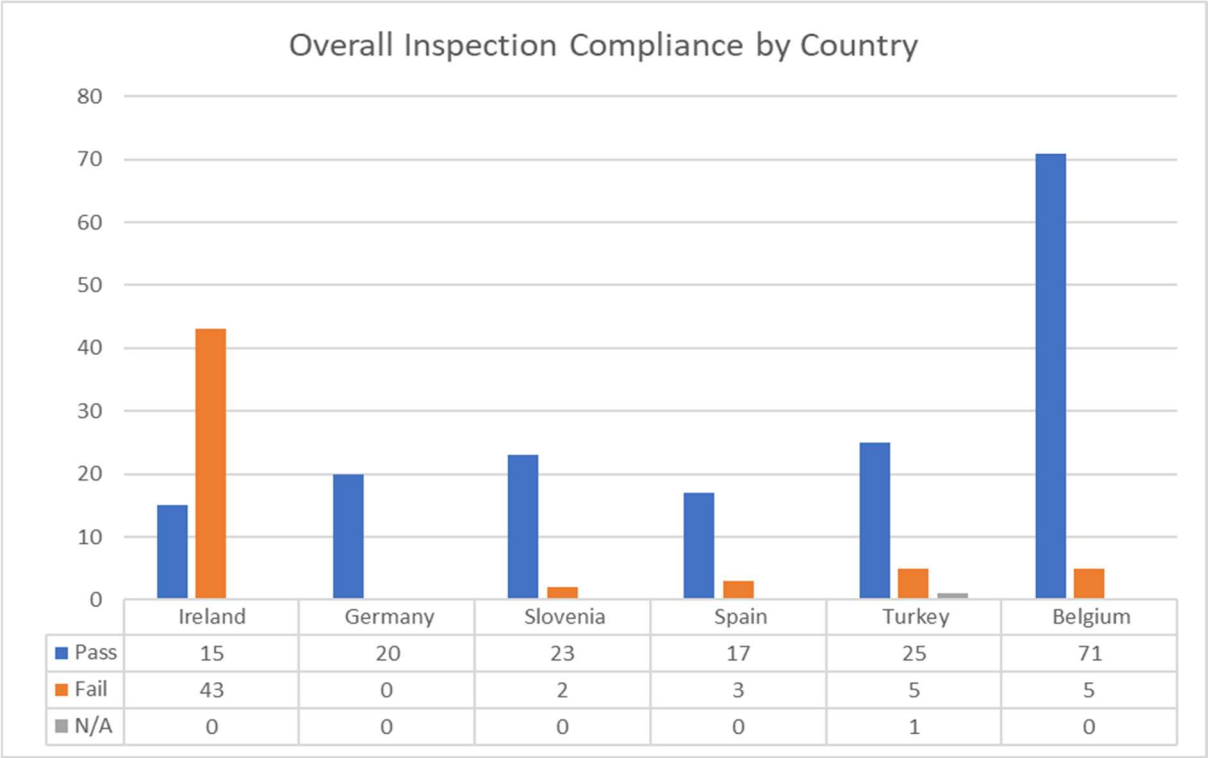

Figure 16. Overall Inspection Compliance by Country

Annex 1: Project Control Sheet

Examination of Pharamaceutical NAWI Devices (2021 Project)	
Office	
Inspector	
Date of Control	

Device Identification	
Instrument Manufacturer	
Instrument Type	
Instrument Model	
Instrument Serial Number	
Min Capacity	
Max Capacity	
Verification Scale Interval e	
Accuracy Class	
Units of Measurement	
Software Version (if applicable)	

Visual			
Instrument setup on a stable platform/surface	Yes	No	
Instrument setup on a level platform/surface	Yes	No	
Instrument is clean and serviceable condition	Yes	No	
Instrument included in a quailty system	Yes	No	
Instrument Calibration Interval			

Conformity to Type			
Number of Type Approval Certificate			
Declaration of Conformity	Yes	No	

Data Plate, Marks and Seals			
Data Plate with legally relevant information	Yes	No	
CE Mark	Yes	No	
Supplementary Metrology Mark, M	Yes	No	
Notified Body Number	Yes	No	
Sealed as per Type Approval Certificate	Yes	No	

Metrological Inspection: Repeatability

	Test	Reading		Test	Reading	
		OK	Not OK		OK	Not OK
	1			6		
	2			7		
Load Applied: kg	3			8		
	4			9		
	5			10		

Metrological Inspection: Accuracy

Load Value L	Indicated Load I (g)	Additional charge until indication change ΔI (g)	Instrument Error	MPE	Instrument Compliant	
					Yes	No
					Yes	No
					Yes	No