Medicines Evaluation Board

Public Assessment Report
Scientific discussion

Eltrombopag STADA 25 mg, 50 mg and 75 mg film-coated tablets (eltrombopag olamine)

NL/H/6507/001-003/DC

Date: 18 August 2026

This module reflects the scientific discussion for the approval of Eltrombopag STADA 25 mg, 50 mg and 75 mg film-coated tablets. The procedure was finalised on 4 July 2026. For information on changes after this date, please refer to section 'steps taken after finalisation' at the end of this PAR.

Table of Contents

I. INTRODUCTION....4
II. EXECUTIVE SUMMARY....4
II.1. Rationale for the product....4
II.2. About the product....5
II.3. General comments on the application....5
II.4. General comments on compliance with GMP, GLP, GCP and agreed ethical principles....5
III. QUALITY ASPECTS....6
III.1. Introduction....6
III.2. Active Substance....6
III.3. Medicinal Product....7
III.4. Discussion on chemical, pharmaceutical and biological aspects....8
IV. NON-CLINICAL ASPECTS....8
IV.1. Introduction....8
IV.2. Ecotoxicity/environmental risk assessment (ERA)....8
IV.3. Discussion on the non-clinical aspects....9
V. CLINICAL ASPECTS....9
V.1. Introduction....9
V.2. Pharmacokinetics....10
V.3. Summary Pharmacovigilance system....11
V.4. Risk Management Plan....11
V.5. Discussion on the clinical aspects....12
VI. USER CONSULTATION....13
VII. POST-APPROVAL COMMITMENTS (PAC's)....13
VIII. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION....13
IX. RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION....13
IX.1. List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC....13
IX.2. List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC....14

List of abbreviations

AE	Adverse Event
AI	Acceptable Intake
ANOVA	Analysis of Variance
BCS	Biopharmaceutics Classification System (-based biowaiver)
BE	Bioequivalence
CBG /MEB	College ter Beoordeling van Geneesmiddelen / The Medicines Evaluation Board
CHMP	Committee for Medicinal Products for Human Use
CMD(h)	Coordination group for Mutual recognition and Decentralised procedure for human medicinal products
CMS	Concerned Member State(s)
DCP	Decentralised Procedure
EDMF	European Drug Master File
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
ERP	European Reference Product
GLP	Good Laboratory Practices
GMP	Good Manufacturing Practice
HCV	Hepatitis C Virus
ICH	International Conference of Harmonisation (of Technical Requirements for Pharmaceuticals for Human Use)
ITP	Immune Thrombocytopenia
LALA	Locally applied, locally acting products
MAH	Marketing Authorisation Holder
PAR	Public Assessment Report
PD	Pharmacodynamics
Ph.Eur.	European Pharmacopoeia
PK	Pharmacokinetics
PL	Package Leaflet
PSURs	Periodic safety update reports
QC	Quality control
RH	Relative Humidity
RMP	Risk Management Plan
RMS	Reference Member State
SAA	Severe Aplastic Anaemia
SmPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy
USP/NF	United States Pharmacopoeia/National Formulary

Note: *Not all abbreviations may apply for this PAR.*

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Eltrombopag STADA 25 mg, 50 mg and 75 mg film-coated tablets, from STADA Arzneimittel AG.

The products are indicated for the treatment of adult patients with primary immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

The products are indicated for the treatment of paediatric patients aged 1 year and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins).

The products are indicated in adult patients with chronic hepatitis C virus (HCV) infection for the treatment of thrombocytopenia, where the degree of thrombocytopenia is the main factor preventing the initiation or limiting the ability to maintain optimal interferon-based therapy.

The products are indicated in adult patients with acquired severe aplastic anaemia (SAA) who were either refractory to prior immunosuppressive therapy or heavily pre-treated and are unsuitable for haematopoietic stem cell transplantation.

A comprehensive description of the up-to-date indications and posology is given in the SmPC.

II. EXECUTIVE SUMMARY

II.1. Rationale for the product

The marketing authorisation has been granted pursuant to Article 10(1) Generic medicinal product application of Directive 2001/83/EC, which concerns a generic application.

To demonstrate bioequivalence with the reference medicinal product, the MAH has submitted data on a bioequivalence study and has requested a biowaiver. See Section V. Clinical aspects.

In this decentralised procedure the reference medicinal product is Revolade 25 and 50 mg film-coated tablets, which has been authorised in the EEA via the centralised procedure EU/1/10/612 by Novartis Europharm Limited since 11 March 2010. In the Netherlands, Revolade 75 mg film-coated tablets has been authorised via procedure EU/1/10/612 since 19 September 2013.

This application has been assessed with The Netherlands as Reference Member State (RMS) and Belgium, Czechia, Luxembourg and Portugal as concerned Member States (CMS).

Assessment of similarity with authorised orphan medicinal product(s) under market exclusivity
According to Article 8(1) of Regulation (EC) No 141/2000, no marketing authorisation can be granted for a product similar to an orphan medicinal product for a period of ten years, when this concerns a similar medicinal product with the same therapeutic indication. Therefore, the MAH has provided a similarity assessment between Eltrombopag STADA and the current orphan products authorised in the EU (Wayrilz). This orphan product and its indications is: for

the treatment of immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments.

The assessment included the comparison of the therapeutic indication, active substance, mechanism of action and principal (molecular) structure. After consideration of the MAH arguments, Eltrombopag STADA is considered not similar to the orphan product.

Therefore, the existence of any market exclusivity for Wayrilz, in the treatment immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments, does not prevent the granting of the marketing authorisation for Eltrombopag STADA.

II.2. About the product

Pharmaco-therapeutic group (ATC Code): B02BX05
Dispensing status: Medical prescription.

II.3. General comments on the application

N.A.

II.4. General comments on compliance with GMP, GLP, GCP and agreed ethical principles

The RMS has been assured that acceptable standards of GMP are in place for these product types at all sites responsible for the manufacture and assembly of this product.

For manufacturing sites within the Community, the RMS has accepted copies of current manufacturer authorisations issued by inspection services of the competent authorities as certification that acceptable standards of GMP are in place at those sites.

For manufacturing sites outside the Community, the RMS has accepted copies of current GMP Certificates of satisfactory inspection summary reports, ‘close-out letters’ or ‘exchange of information’ issued by the inspection services of the competent authorities (or those countries with which the EEA has a Mutual Recognition Agreement for their own territories) as certification that acceptable standards of GMP are in place at those non-Community sites.

GMP active substance
Regarding the statement on GMP for the active substance a statement/declaration is provided from the manufacturer(s) responsible for manufacture of the medicinal product and batch release situated in the EU.

III. QUALITY ASPECTS

III.1. Introduction

Eltrombopag STADA are film-coated tablets containing 25 mg, 50 mg and 75 mg eltrombopag olamine as active substance. The pharmaceutical form of the different strengths can be distinguished by their colour, shape, and debossing and are as follows:

25 mg: almost white to pale yellow, round, biconvex film-coated tablet with a breaking notch on one side, dark red to brown at the break, with a diameter of approximately 7 mm

50 mg: brown, round, biconvex film-coated tablet with a breaking notch on one side, dark red to brown at the break, with a diameter of approximately 9 mm.

75 mg: pink, round, biconvex film-coated tablet, with a diameter of approximately 10 mm.

The excipients are:
Tablet core – microcrystalline cellulose, mannitol, povidone K90, sodium starch glycolate (type A), and magnesium stearate.
Tablet coating – polyvinyl alcohol, titanium dioxide (E171), macrogol, talc, iron oxide yellow (E172) (50 mg only), and iron oxide red (E172) (50 mg and 75 mg only).

The tablet strengths are dose proportional.

The film-coated tablets are packed in an oriented polyamide/aluminium/polynivylchloride//aluminium (oPA/Alu/PVC//Alu) blister or oPA/Alu/PVC//Alu perforated unit dose blister.

III.2. Active Substance

The structure of the active substance has been adequately proven and its physico-chemical properties are sufficiently described. The active substance is eltrombopag olamine, an established active substance described in the European Pharmacopoeia (Ph.Eur.). The active substance is a dark purple crystalline powder and is insoluble in water.

Eltrombopag olamine exhibits polymorphism, for this product, the same polymorphic form is consistently produced.

Manufacturing process
The manufacture of the active substance has been adequately described. The used starting materials, solvents and reagents are considered acceptable. Adequate tests and acceptable specifications have been adopted for these.

Quality control of the active substance
The active substance specification includes relevant tests and the limits for impurities and degradation products have been justified in accordance with the applicable ICH Guidelines for impurities in new Drug Substances. The analytical methods applied are suitably described and non-compendial methods have adequately been validated. The active substance specification is considered adequate to control the quality and meets the requirements of the monograph in the Ph.Eur. and in-house. Batch analytical data demonstrating compliance with this

specification have been provided for three batches from supplier I and two batches from supplier II.

Stability of the active substance
Stability data have been submitted for several production scaled batches (supplier I) and three production scaled batches (supplier II) of the active substance in accordance with the applicable European guidelines. Based on the data submitted, the re-test period for the active substances was confirmed for 3 years/18 months when stored under the stated conditions. This is acceptable.

III.3. Medicinal Product

Pharmaceutical development
The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines. The choice of the excipients is justified, and their functions explained.

The main development studies were the characterisation of the reference products, dissolution method development and performance of formulation optimization studies. The choice of the QC dissolution method has been justified. A bioequivalence (BE) study has been performed with the 75 mg product versus the respective reference product strength. The test batch used in the BE study was manufactured according to the finalised formulation and manufacturing process at a representative scale. Comparative dissolution testing at 3 pHs (0.1N HCl, pH 4.5 and pH 6.8 media) has been successfully studied in support of the bioequivalence study and biowaiver for the additional 25 mg and 50 mg strengths.

Manufacturing process
The manufacturing process has been sufficiently described and critical steps identified. The manufacturing process has been validated according to relevant European/ICH guidelines.

Process validation data on the product have been presented for five pilot scale batches in accordance with the relevant European guidelines.

The product is manufactured using conventional manufacturing techniques. Process validation for full-scale batches will be performed post authorisation.

Control of excipients
The excipients comply with the current version of the Ph.Eur. monograph. With additional in-house specifications for the ready-to-use film-coating materials. These specifications are acceptable.

Quality control of the medicinal product
The medicinal product specifications are adequate to control the relevant parameters for the dosage form. The specification includes tests for appearance, average mass, identity, uniformity of dosage units, assay, related substances, microbial limits, dissolution and nitrosamine impurities. The release and shelf-life tests and limits are identical are for all test parameters with the exception of nitrosamines. Limits in the specification have been justified and are considered appropriate for the adequate quality control of the product.

An adequate risk evaluation report on nitrosamines has been submitted. Appropriate routine control with acceptable limits for nitrosamine impurities are performed on the medicinal product.

Satisfactory validation data for the non-compendial analytical methods have been provided. Batch analytical data for three pilot scaled batches of the 25 mg and 50 mg strengths and two pilot scaled batches of the 75 mg strength from the proposed production site have been provided, demonstrating compliance with the specification.

Stability of the medicinal product
Stability data on the product have been provided for two (25 mg and 50 mg) and three (75 mg) production scale batches stored at 25°C/ 60% RH (24 months) and 40°C/75% RH (6 months). The stability was tested in accordance with applicable European guidelines. Photostability studies were performed in accordance with ICH recommendations. The results showed that the product is stable when exposed to light. Based on the data submitted, a shelf life of 3 years was granted. The labelled storage conditions are: This medicinal product does not require any special storage conditions.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies
There are no substances of ruminant animal origin present in the product nor have any been used in the manufacturing of this product, so a theoretical risk of transmitting TSE can be excluded.

III.4. Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the Member States consider that Eltrombopag STADA has a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the active substance and medicinal product.

IV. NON-CLINICAL ASPECTS

IV.1. Introduction

Pharmacodynamic, pharmacokinetic and toxicological properties of eltrombopag olamine are well known. As eltrombopag olamine is a widely used, well-known active substance, the MAH has not provided additional studies and further studies are not required. The submitted overview based on literature is appropriate.

IV.2. Ecotoxicity/environmental risk assessment (ERA)

For the ecotoxicity / environmental risk assessment, the MAH has submitted the following study results:

Phase I of the ERA was resolved by obtaining right to reference from the MAH of the originator product. The default Fpen was used for the reference product, resulting in a PECsw above the trigger requiring a Phase II assessment. Risk assessment of phase I is thereby satisfactorily resolved and concluded.

With regard to the Phase II assessment, the MAH refers to the ERA of the reference product Revolade. Although this is acceptable, the MAH was asked to justify that the scientific conclusion reached in the previous ERA is complete and in line with the revised ERA guideline. It is noted that the revised guideline contains additional requirements, especially with regard to soil, sediment, groundwater and secondary poisoning, which might require additional studies. In addition, the MAH was asked to conduct a literature search to identify studies conducted after the innovator studies were submitted and assessed. In response, the PNEC/PEC calculations (Risk Characterisation ratios/ Risk Quotients) for the different environmental compartments have been added in order to demonstrate that the scientific conclusions reached for the previous ERA are also applicable to the generic product, also with regard to the slightly changed guidance set in the revised ERA guideline (EMEA/CHMP/SWP/4447/00 Rev. 1 – Corr.). No risk has been identified. Furthermore, an exhaustive review of the public literature has been performed, and no additional studies of scientific value have been found.

As the Eltrombopag Octanol-water partition coefficient was higher than the limit of 4.5, a further PBT assessment was conducted. It was concluded that Eltrombopag is persistent and toxic but not bioaccumulative. The PBT assessment is thereby satisfactorily resolved and concluded.

Conclusions on studies:
The MAH demonstrated applicability of the previous (innovator) ERA for this generic application. Literature does not suggest increased or new risks.

IV.3. Discussion on the non-clinical aspects

This product is a generic formulation of Revolade which is available on the European market. Reference was made to the preclinical data obtained with the reference medicinal product. A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which was based on up-to-date and adequate scientific literature. The overview justifies why there is no need to generate additional non-clinical pharmacology, pharmacokinetics and toxicology data. Therefore, the Member States agreed that no further non-clinical studies are required.

V. CLINICAL ASPECTS

V.1. Introduction

Eltrombopag olamine is a well-known active substance with established efficacy and tolerability. A clinical overview has been provided, which is based on scientific literature. The Member States agreed that no further clinical studies are required, besides the one bioequivalence study discussed below. Bioequivalence has been investigated in line with the EMA Guideline on the Investigation of Bioequivalence (CPMP/EWP/QWP/1401/98 Rev. 1/Corr**).

V.2. Pharmacokinetics

To support the application, the MAH has submitted one bioequivalence study comparing the pharmacokinetic profiles of the test product Eltrombopag 75 mg, STADA Arzneimittel AG, Germany and the reference medicinal Revolade Eltrombopag 75 mg, Novartis Europharm Limited, Ireland. A biowaiver was requested for the lower strengths 25 mg and 50 mg. The formula and manufacturing process of the bioequivalence batch was identical to the formula proposed for marketing.

Biowaiver

According to the EMA bioequivalence guideline, the following general requirements must be met where a waiver for additional strength is claimed:

a. the pharmaceutical products are manufactured by the same manufacturing process,
b. the qualitative composition of the different strengths is the same,
c. the composition of the strengths are quantitatively proportional, i.e. the ratio between the amount of each excipient to the amount of active substance(s) is the same for all strengths (for immediate release products coating components, capsule shell, colour agents and flavours are not required to follow this rule),
d. appropriate *in vitro* dissolution data should confirm the adequacy of waiving additional *in vivo* bioequivalence testing.

These requirements are met.

The dissolution tests at pH 1.2, 4.5 and 6.8 show for the various strengths of the medicinal product that more than 85% of the active substance is released within 15 minutes. Therefore, the profiles can be considered as similar. As the conditions for the biowaiver criteria are met, a biowaiver for the lower strengths has been granted.

Bioequivalence study, C1B01303

Design

A single-dose, randomised, open label, three-treatment, three-period, two-sequence, crossover, balanced, oral comparative bioequivalence study was carried out under fasted conditions in 15 healthy male subjects, aged 21-38 years. Each subject received a single dose (75 mg) of one of the eltrombopag olamine formulations. The tablet was orally administered with 240 mL water after an overnight fasting period of at least 10 hours. There were three dosing periods, separated by a washout period of 14 days.

The plasma concentration time curve was used to assess the rate and extent of absorption. Blood samples were collected pre-dose and at 0.5, 1, 1.5, 2, 2.5, 3, 3.5, 4, 4.5, 5, 5.5, 6, 7, 8, 10, 12, 16, 24, 36, 48 and 72 hours after administration of the products.

The SmPC recommends administering the product at least two hours before or four hours after any products containing polyvalent cations (e.g. iron, calcium, magnesium, aluminium, selenium and zinc), such as antacids, dairy products (or other calcium containing food products), or mineral supplements.

The design of the study was considered acceptable as according to the SmPC eltrombopag olamine may be administered without reference to food intake. The bioequivalence study under fasting conditions is in accordance with CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** Note for Guidance on the investigation of bioavailability and bioequivalence.

Bioanalytical/statistical methods
The bioanalytical method has been adequately validated according to current guidelines (ICH M10) and is considered acceptable for analysis of the plasma samples. The methods used in this study for the pharmacokinetic calculations and statistical evaluation are considered acceptable.

Results
15 subjects enrolled in the study. One subject withdrew from period I due to personal reasons, and was replaced. A total of 15 subjects were eligible for pharmacokinetic analysis.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean, t_{max} (median, range)) of eltrombopag olamine, 75 mg under fasted conditions.

Treatment N= 15	AUC_{0-t} (µg.h/mL)	$AUC_{0-\infty}$ (µg.h/mL)	C_{max} (µg/mL)	t_{max} (h)
Test	81.0	118	6.80	3.0 (2.0 - 5.5)
Reference	77.5	110	6.90	3.5 (2.5 - 4.5)
***Ratio (90% CI)**	1.05 (0.97 – 1.13)	1.07	0.99 (0.92 – 1.07)	-

$AUC_{0-\infty}$	Area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t}	Area under the plasma concentration-time curve from time zero to t = 72 hours
C_{max}	Maximum plasma concentration
t_{max}	Time after administration when maximum plasma concentration occurs
CI	Confidence interval
*	Back-transformed from ln-transformed least-squares mean values

Conclusion on bioequivalence study:
The 90% confidence intervals calculated for AUC_{0-t}, and C_{max} are within the conventional bioequivalence acceptance range of 80% – 125%. Based on the submitted bioequivalence study Eltrombopag STADA 75 mg is considered bioequivalent with Revolade 75 mg under fasted conditions.

As a biowaiver has been granted, the results of study C1B01303 with the 75 mg formulation can be extrapolated to the lower strengths 25 mg and 50 mg, in accordance with the conditions in the Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/ Corr **.

V.3. Summary Pharmacovigilance system

The MAH has submitted a signed Summary of the MAH's and/or Proposed Future MAH's Pharmacovigilance System. Provided that the Pharmacovigilance System Master File fully complies with the legal requirements as set out in the Commission Implementing Regulation and as detailed in the GVP module, the RMS considers the Summary acceptable.

V.4. Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to

Eltrombopag STADA. At the time of approval, the accepted version of the RMP was version 0.2 with sign-off date 20 March 2026.

Table 2. Summary table of safety concerns as approved in the RMP

Important identified risks	**Adult ITP, Paediatric ITP, HCV-associated thrombocytopenia and severe aplastic anaemia** • Hepatotoxicity • Thromboembolic events **HCV-associated thrombocytopenia** • Hepatic decompensation
Important potential risks	**Adult ITP, Paediatric ITP, HCV-associated thrombocytopenia and severe aplastic anaemia** • Increased Bone Marrow Reticulin Formation • Haematological malignancies **Severe aplastic anaemia** • Cytogenic abnormalities
Missing information	**Adult ITP, Paediatric ITP, HCV-associated thrombocytopenia and severe aplastic anaemia** • Patients with hepatic impairment

The Member States agreed that routine pharmacovigilance activities and routine risk minimisation measures are sufficient for the risks and areas of missing information.

As part of routine pharmacovigilance activities and in line with the RMP of the reference product, the MAH proposed the following Specific Adverse Reaction Follow-up checklists:

- Hepatobiliary laboratory abnormalities
- Hepatic decompensation
- Thrombotic and thromboembolic events
- Worsening thrombocytopenia and bleeding
- Hematological malignancy
- Bone Marrow Reticulin / Bone Marrow Fibrosis

V.5. Discussion on the clinical aspects

For this authorisation, reference is made to the clinical studies and experience with the reference medicinal product Revolade. No new clinical studies were conducted. The MAH demonstrated through a bioequivalence study that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of this reference medicinal product. Risk management is adequately addressed. This generic medicinal product can be used instead of the reference medicinal product.

VI. USER CONSULTATION

The package leaflet (PL) has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC. The language used for the purpose of user testing the PL was English.

A user consultation with target patient groups on the package leaflet (PL) has been performed based on a bridging report making reference to Revolade, EU/1/10/612 and Ofloxacin, AT/H/0748/001. The bridging report submitted by the MAH has been found acceptable; bridging is justified for both content (Revolade) and layout (Ofloxacin) of the leaflet.

VII. POST-APPROVAL COMMITMENTS (PAC's)

Post-approval commitments: not applicable.

VIII. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Eltrombopag STADA 25 mg, 50 mg and 75 mg film-coated tablets have a proven chemical-pharmaceutical quality and are generic forms of Revolade 25 mg, 50 mg and 75 mg film-coated tablets. Eltrombopag olamine is a well-known medicinal product with an established favourable efficacy and safety profile.

Bioequivalence has been shown between the test and reference medicinal products, in line with the requirements of European guidance documents.

The Board followed the advice of the assessors.

There was no discussion in the CMD(h). Agreement between Member States was reached during a written procedure. The Member States, based on the data submitted, considered that essential similarity has been demonstrated for Eltrombopag STADA with the reference medicinal product, and have therefore granted a marketing authorisation. The decentralised procedure was finalised with a positive outcome on 4 July 2026.

IX. RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

IX.1. List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC

N.A.

IX.2. List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC

N.A

STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Procedure number	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
N.A.	N.A.	N.A.	N.A.	N.A.	N.A.