



SUMMARY

Caution: Low bases in 2024 which may make some conclusions anecdotal



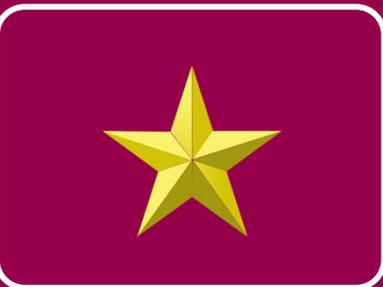
Excellent

- % of respondents rating (4 + 5) = 80%+



Good

- % of respondents rating (4 + 5) = 60% - <80%

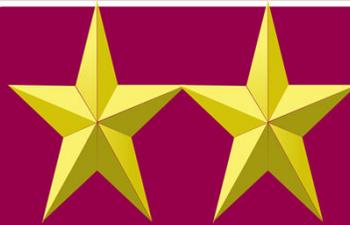


Review

- % of respondents rating (4 + 5) = <60%

SUMMARY: ALL TEAMS 2024:

Overall level of service - CAUTION WHEN DRAWING CONCLUSIONS. LOW BASES



- Vaccine batch release (100%; n=5)
- Pharmacovigilance (100%, n=10)
- Finance (100%, n=7)
- GMP/GDP Inspections (86%, n=7)
- Quality Defect Reporting (84%, n=6)

- Validation (69%, n=13)
- Pharmaceuticals (69%, n=13)
- Biologicals (76%, n=8)
- Product & Batch recall (66%, n=6)

- Application Management (45%, n=20)
- Joint Labelling (13%, n=8)
- Mock-ups (20%, n=5)
- Enforcement (33%, n=3)
- Parallel Applications (0% - 50%, bases n=2 to 13)

APPLICATION MANAGEMENT (n=20)

By Application Management we mean the team that provides:

- Advice on regulatory issues
- Advice on application procedures and processes including submission
- Validation of renewal applications and administrative variations
- Issuing of marketing authorisation documentation.

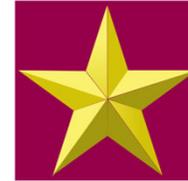
We are not referring to validation enquiries, validation documentation or safety, quality, efficacy questions at this point.

SUMMARY: APPLICATION MANAGEMENT 2024:

Half of the parameters rated “GOOD”, half “REVIEW”



Overall level of service



SUMMARY: APPLICATION MANAGEMENT 2022 - 2024:

An apparent decrease in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Helpfulness of staff	-19%	Good
Consistency of advice given between staff	-20%	Review
Approachability	-21%	Good
Usefulness of advice given	-24%	Good
Speed of response to enquiries	-34%	Review
Overall level of service	-43%	Review
Knowledge of staff responding to enquiries	-46%	Review

VALIDATION PERFORMED BY APPLICATION MANAGEMENT

The next two questions refer to the checking process undertaken following the receipt of an application at the VMD. It relates to pharmaceutical and biological applications and specifically to new marketing authorisations and most variations.

(n=13)

SUMMARY: VALIDATION 2024:

All areas “EXCELLENT ”or “GOOD”



Overall level of service



- Flexibility of approach/willingness to listen to a reasoned argument
- Approachability of staff

- Consistency of advice given
- Speed of response to enquiries
- Usefulness of advice given
- Ease of identifying the correct person to speak to in this area
- Knowledge of staff responding to enquiries
- Helpfulness of staff
- Clarity of the points included in validation deferral letters

SUMMARY: VALIDATION 2022 - 2024:

An apparent decrease in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Approachability of the staff	1%	Excellent
Ease of identifying the correct person to speak to	-7%	Good
Usefulness of advice given	-7%	Good
Flexibility of approach / willingness to listen to a reasoned argument	-16%	Excellent
Speed of response to enquires	-17%	Good
Helpfulness of staff	-19%	Good
Clarity of the points included in validation deferral letters	-25%	Good
Knowledge of staff responding to enquiries	-26%	Good
Overall level of service	-26%	Good
Consistency of advice given	-27%	Good

JOINT LABELLING

(n=8)

Joint-Labeling' is the term used to describe the process for obtaining a single label for use on the UK and Irish markets. A joint-label may be obtained at the end of a European procedure, as a stand-alone variation for mutually recognised products, or via a harmonisation variation for nationally authorised products. To note, HPRA only participate in a joint assessment prior to initial marketing of a product or subject to there being significant changes to the design and readability of the label. Please provide comments on the UK's performance only in relation to the joint-labelling process

Overall satisfaction with the process



- Clarity of the process
- Consistency of advice given
- Timescales for the process

MOCK-UPS WITHIN THE LAST 12 MONTHS (n=5)

Overall satisfaction with the process of mock-up assessment



- Clarity of the process



- Consistency of advice given
- Timescales for the process



PHARMACEUTICALS (n=13)

SUMMARY: PHARMACEUTICALS 2024: “MIXED”



Overall level of service



- Usefulness of advice
- Pragmatism / willingness to listen to a reasonable alternative view



- Ease of identifying the correct person to speak to in this area
- Knowledge of staff responding to enquiries
- Helpfulness of staff
- Relevance of questions asked by pharmaceutical quality assessors
- Relevance of q's asked by pharmaceutical efficacy assessors



- Approachability
- Relevance of q's asked by pharmaceutical safety assessors
- Speed of response to enquiries
- Relevance of q's asked by pharmaceutical eco-tox assessors
- Consistency of approach between assessors

SUMMARY: PHARMACEUTICALS 2022 - 2024:

An apparent decrease in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Consistency of approach between assessors	-43%	Review
Approachability	-42%	Review
Relevance of q's asked by pharmaceutical eco-tox assessors	-32%	Review
Overall level of service	-31%	Good
Relevance of q's asked by pharmaceutical safety assessors	-31%	Review
Speed of response to enquiries	-30%	Review

SUMMARY: PHARMACEUTICALS 2022 - 2024:

An apparent decrease in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Knowledge of staff responding to enquiries	-25%	Good
Ease of identifying the correct person to speak to in this area	-21%	Good
Relevance of questions asked by pharmaceutical quality assessors	-20%	Good
Helpfulness of staff	-19%	Good
Pragmatism / willingness to listen to a reasonable alternative view	-11%	Excellent
Usefulness of advice	-10%	Excellent
Relevance of q's asked by pharmaceutical efficacy assessors	-10%	Good

BIOLOGICALS (n=8)

SUMMARY: BIOLOGICALS 2024:

All “EXCELLENT” or “GOOD”



Overall level of service



- Helpfulness of staff
- Ease of identifying the correct person to speak to in this area
- Usefulness of advice

- Relevance of questions asked by immunological assessors
- Consistency of approach between assessors
- Pragmatism / willingness to listen to a reasonable alternative view
- Approachability
- Knowledge of staff responding to enquiries
- Speed of response to enquiries

SUMMARY: BIOLOGICALS 2022 - 2024:

Performance maintained or improved for a few



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Helpfulness of staff	0%	Excellent
Relevance of questions asked by immunological assessors	3%	Good
Ease of identifying the correct person to speak to in this area	8%	Excellent
Usefulness of advice	25%	Excellent

SUMMARY: BIOLOGICALS 2022 - 2024:

Some apparent decreases in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Speed of response to enquiries	-12%	Good
Consistency of approach between assessors	-12%	Good
Overall level of service	-6%	Good
Approachability	-3%	Good
Pragmatism / willingness to listen to a reasonable alternative view	-2%	Good
Knowledge of staff responding to enquiries	-1%	Good

SUMMARY: VACCINE BATCH RELEASE 2024: “EXCELLENT”



Overall level of service



Quality of issued documentation

Advice provided

Timescales for the process

SUMMARY: VACCINE BATCH RELEASE 2022 - 2024:

Satisfaction maintained at “excellent”



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Quality of issued documentation	0%	Excellent
Advice provided	9%	Excellent
Timescales for the process	8%	Excellent



PHARMACOVIGILANCE (n=10)

SUMMARY: PHARMACOVIGILANCE 2024:

All parameters “EXCELLENT”



Overall level of service



- Relevance of questions relating to Adverse Event reports Knowledge of staff responding to enquiries
- Pragmatism/willingness to listen to a reasonable alternative view
- Consistency of advice given
- Usefulness of advice
- Approachability
- Helpfulness of staff
- Consistency of approach between assessors
- Relevance of questions asked by PSUR assessors
- Speed of response to enquiries
- Ease of identifying the correct person to speak to in this area
- Relevance of questions asked by assessors during applications/renewals
- Knowledge of staff responding to enquiries

SUMMARY: PHARMACOVIGILANCE 2022 - 2024:

Maintained or increased in satisfaction in several areas since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

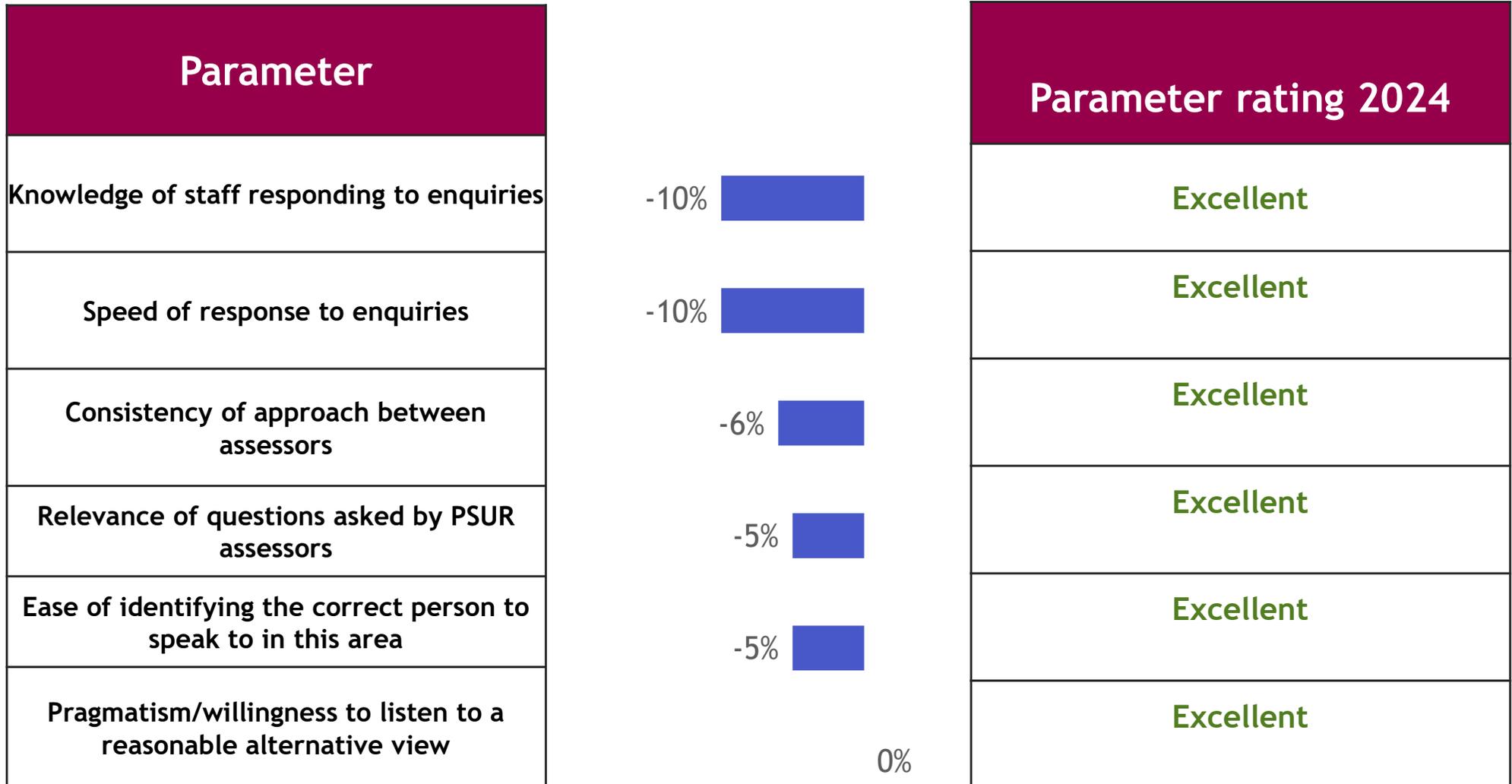
Parameter		Parameter rating 2024
Relevance of questions relating to Adverse Event reports	0%	Excellent
Helpfulness of the staff	5%	Excellent
Approachability	5%	Excellent
Usefulness of advice	5%	Excellent
Overall level of service	5%	Excellent
Relevance of questions asked by assessors during applications/renewals	17%	Excellent

SUMMARY: PHARMACOVIGILANCE 2022 - 2024:

Maintained or decreased in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024





QUALITY DEFECT REPORTING AND BATCH RECALL

SUMMARY: QUALITY DEFECT REPORTING 2024: “EXCELLENT”



Overall satisfaction with the
resolution of the reported
defect case



SUMMARY: PRODUCT & BATCH RECALL 2024::

All parameters “EXCELLENT”



Overall level of service



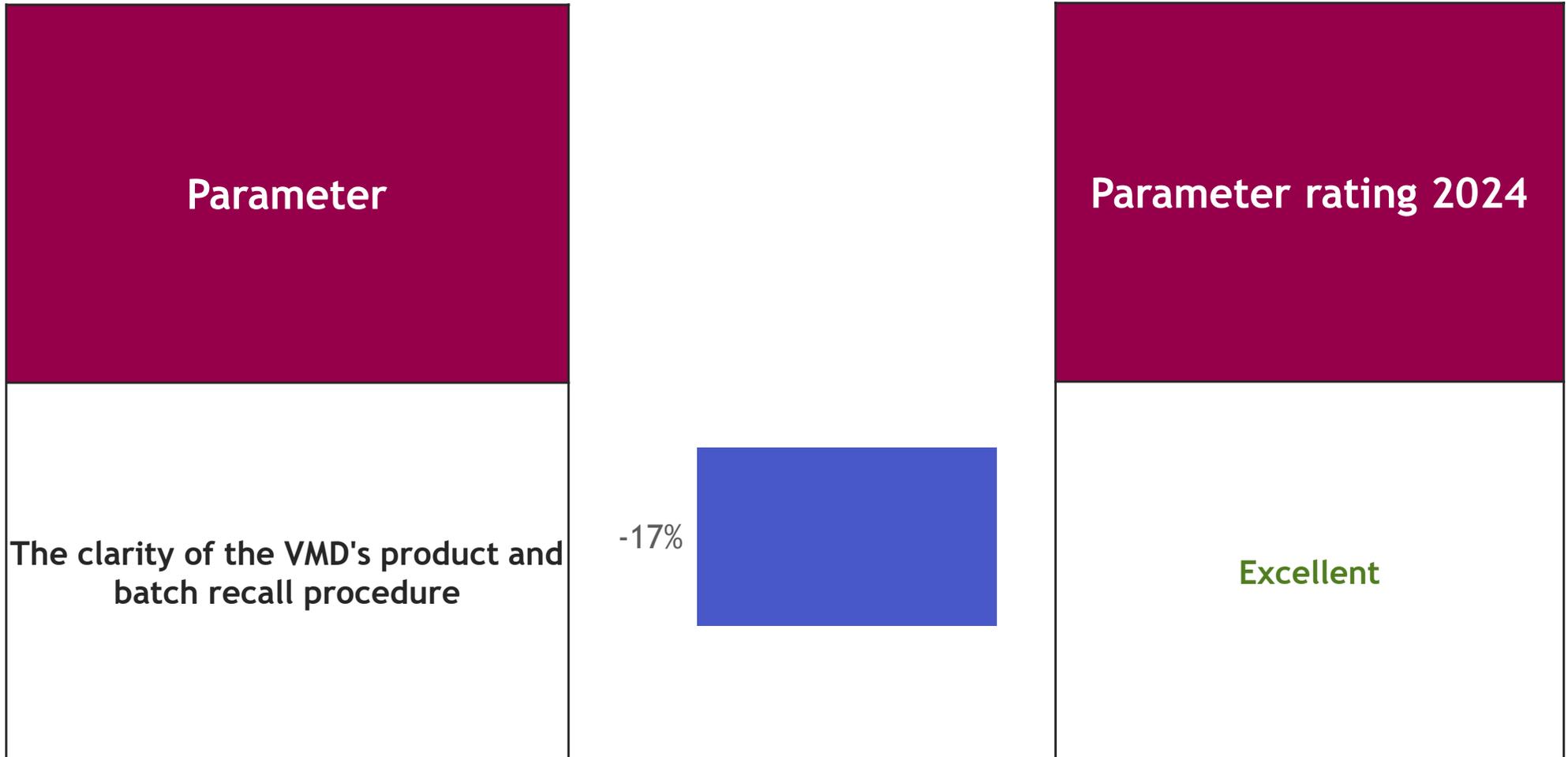
- The clarity of the VMD’s quality defects recall procedure
- Ease of reporting quality defects
- Communication during the reporting process

SUMMARY: PRODUCT AND BATCH RECALL 2022 - 2024:

Some apparent decreases in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024



GMP OR GDP INSPECTIONS (n=9)

Thinking now of Good Manufacturing Practice (GMP) or Wholesale Dealer (GDP) inspections performed by the VMD's inspectors including Schedule 6 inspections (Exemptions for Small Pet Animals):

SUMMARY: GMP & GDP INSPECTIONS 2022:

All parameters “EXCELLENT”



Overall level of service



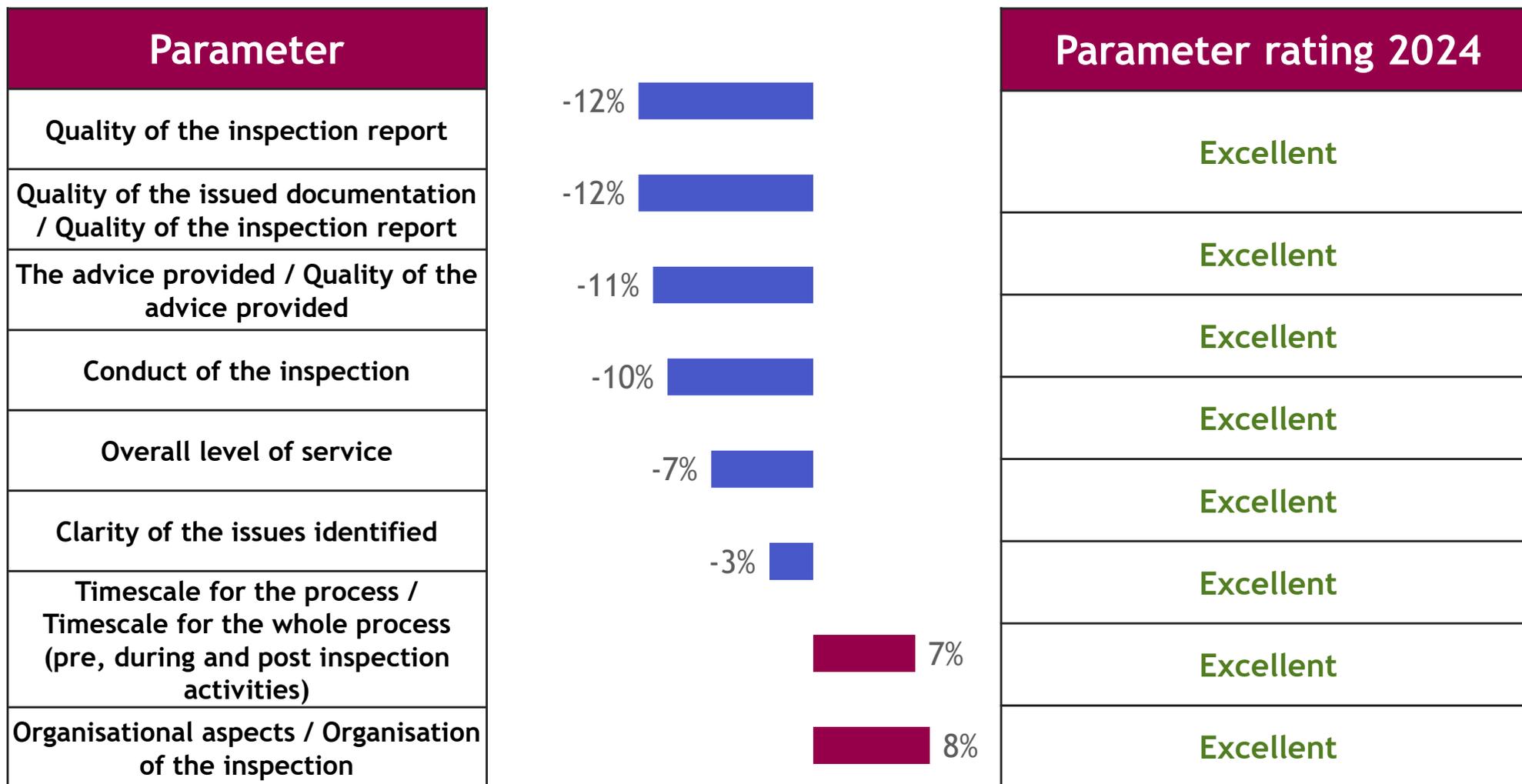
- Organisation of the inspection
- Conduct of the inspection
- Quality of the advice provided by the inspectors
- Timescale for the whole process
- Quality of the inspection report
- Clarity of the issues identified
- The extent to which the inspection met your needs

SUMMARY: GMP / GDP INSPECTIONS 2022 - 2024

Some apparent decreases and increases in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024



FINANCE (n=17)

SUMMARY: FINANCE 2024:

Mostly “EXCELLENT”



Overall level of service



- Approachability
- Helpfulness of staff
- Knowledge of staff responding to enquiries
- Speed of response to enquiries
- How easy is it to identify the correct person to speak to in this area

- Transparency of fee structure for all applications

SUMMARY: FINANCE 2022 - 2024

Some apparent increases in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
How easy is it to identify the correct person to speak to in this area	24%	Excellent
Speed of response to enquiries	18%	Excellent
Knowledge of staff responding to enquiries	12%	Excellent
Helpfulness of staff	12%	Excellent
Approachability	12%	Excellent
Overall level of service	3%	Excellent
Transparency of fee structure for all applications	2%	Good

VMRs (n=27)

SUMMARY: VMRs 2024: “MIXED”



- VMD consultation on VMRs



- Direct communications from the VMD on the GB VMRs



COMMUNICATIONS

VMD's Service Standards for enquiries

Enquiries and requests for information

We aim to:

- respond to enquiries and complaints within 15 working days
- reply to Freedom of Information requests within 20 working days

Sometimes we may need longer to respond, for example if you are asking for complex information or if we need to involve a third party. If we are unable to respond within these timescales, we will let you know.

We will always try to answer your telephone calls promptly and respond to questions arising from them within 5 working days. If we cannot provide a complete answer within that time, we will let you know why.

Where the first person you speak to cannot answer your query, we will ensure that someone who can deal with it calls you back, within 2 working days.

If we are away from the office when you call us, we will ensure that you are told:

- * when we will be back; and
- * who you can contact in our absence.

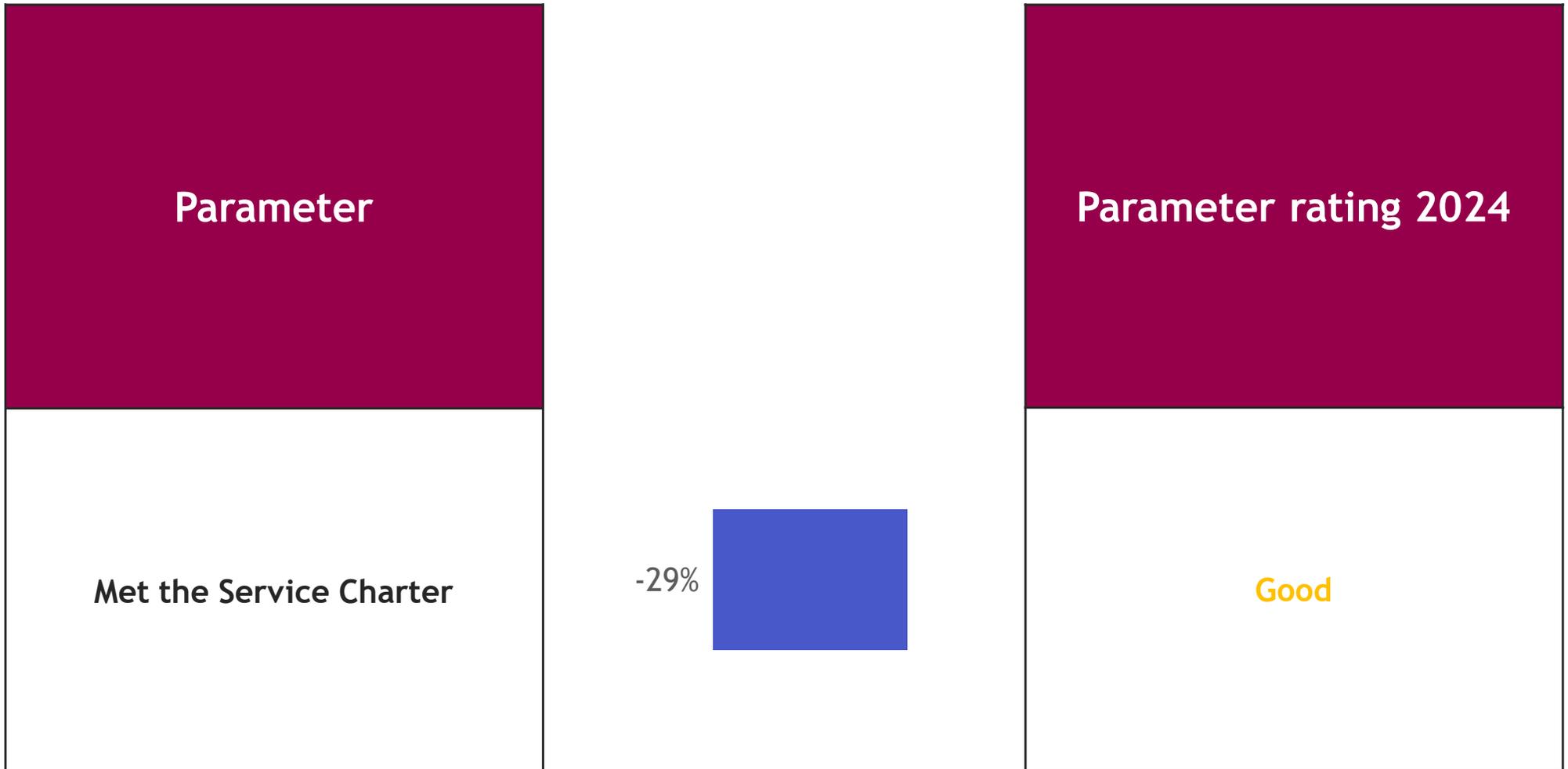
When you leave a message, we will call you back, or ensure that someone able to deal with your query calls you, within two working days of our return to the office.

SUMMARY: THE SERVICE CHARTER

An apparent decrease in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024



SUMMARY: COMMUNICATIONS INFORMATION SHARING ACTIVITIES

2024: "MIXED"



Overall usefulness of the information sharing activities



- Via NOAH
- Monthly update bulletin email

- Gov.uk news items
- Direct communications

- Annual open information event
- Quarterly MAVIS
- The Information Hub
- Linked In

SUMMARY: COMMUNICATIONS 2024: “MIXED”



- Keeps you informed of new or emerging issues

- Makes you aware of relevant new information in a timely fashion
- (-13% cf 2022)

SUMMARY: COMMUNICATIONS WEBSITE 2022: “MIXED”



Overall level of satisfaction with
the VMD's material on GOV.UK



- Accuracy
- Usefulness
- Being up to date



- Ease of finding what you are looking for
- Accessibility

SUMMARY: COMMUNICATIONS: WEBSITE 2022 - 2024:

Some apparent decreases in satisfaction since the previous wave



% rating 4 or 5, ranked by % change 2022 - 2024

Parameter		Parameter rating 2024
Accessibility	-25%	Review
Ease of finding what you are looking for	-22%	Review
Accuracy of information on the website	-19%	Good
Overall level of satisfaction	-16%	Review
Being up to date	-6%	Good
Usefulness	-6%	Good

Q36 How would you rate the VMD in terms of ...Scale of 1 to 5, 1=Very poor, 5=Excellent. Bases on chart exclude “don’t know” and “not applicable”

INTERNATIONAL (n=19)

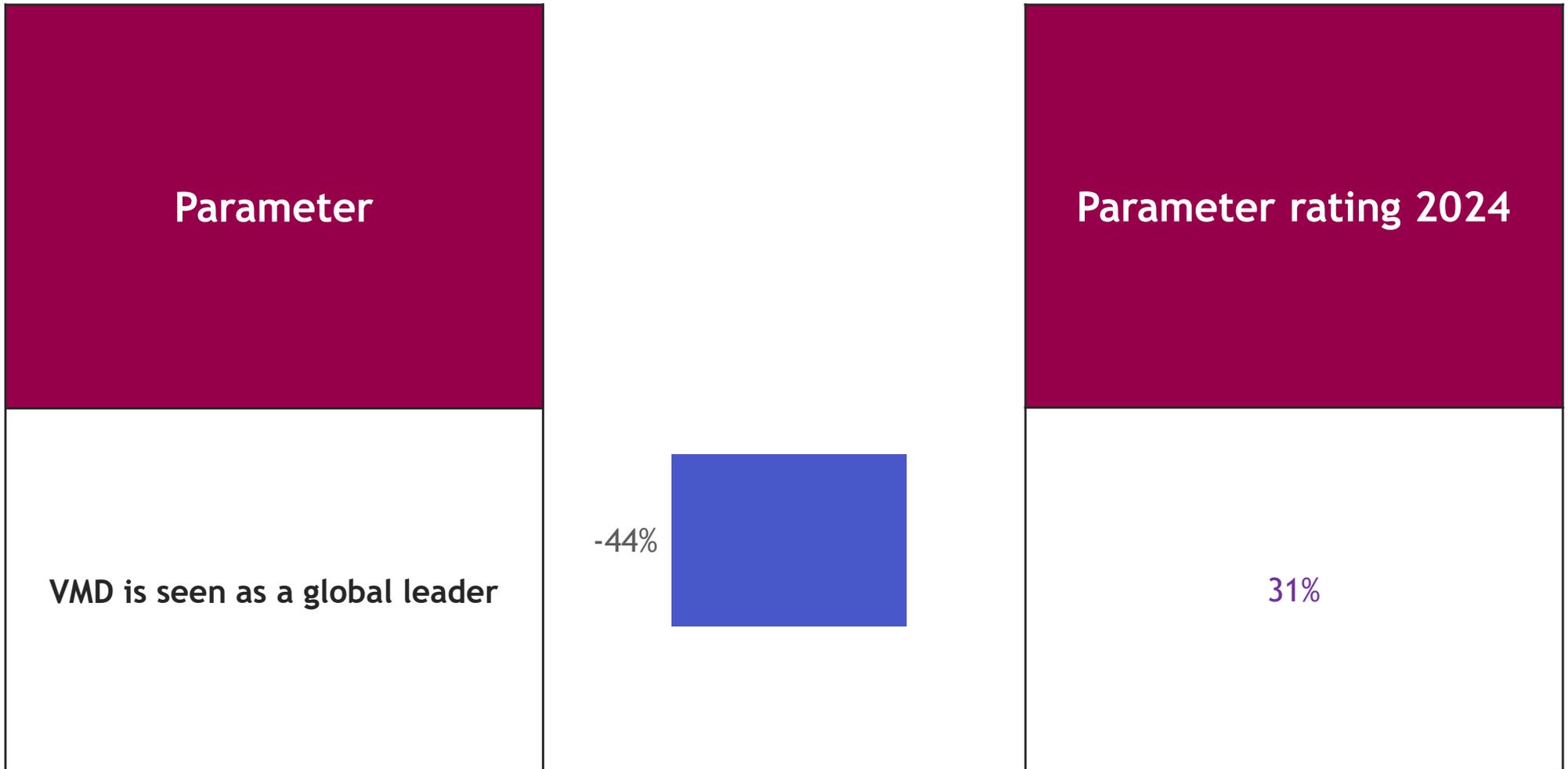
All who have interacted with another national authority within the last 2 years

SUMMARY: GLOBAL LEADER 2024:

A decrease in the % of customers who see the VMD as a global leader



% rating 4 or 5, ranked by % change 2022 - 2024





OVERALL SATISFACTION WITH VMD

SUMMARY: OVERALL LEVEL OF SATISFACTION WITH THE VMD (maintained or increased compared with a year ago): “GOOD”



Overall level of satisfaction

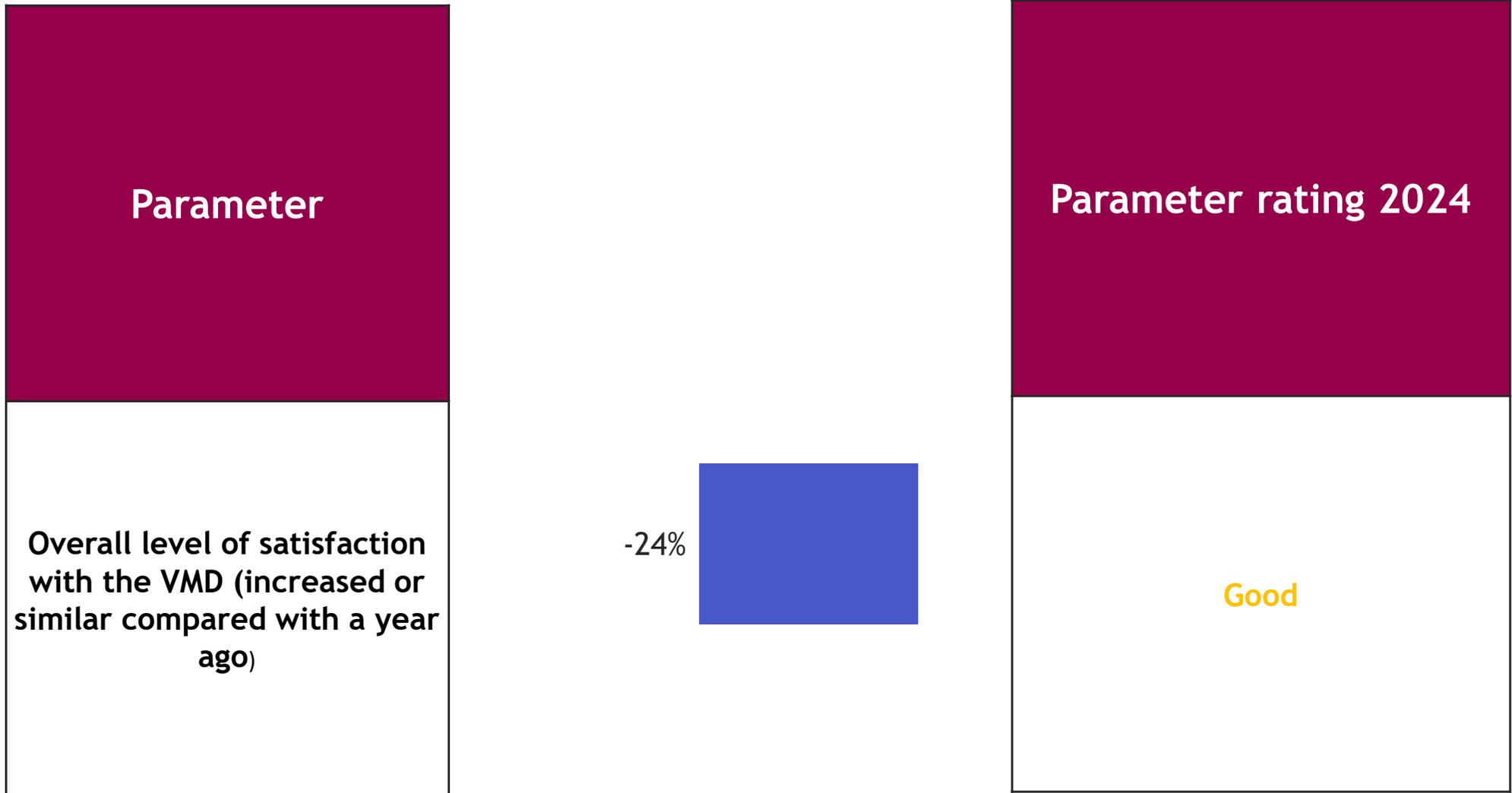


SUMMARY: OVERALL LEVEL OF SATISFACTION WITH THE VMD

A decrease in the % of customers whose overall satisfaction with the VMD has been maintained or increased compared with a year ago



% rating 4 or 5, ranked by % change 2022 - 2024



Feedback was also collected on the following. Details are presented in the main report.

- ❖ The Product Literature Standard (PLS)
- ❖ Parallel Applications
- ❖ The VMD when acting as CMS in MRP/DCP on behalf of NI
- ❖ Joint Review Applications



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