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Autoridade Nacional do Medicamento
e Produtos de Saúde I.P.

Decentralised Procedure

RMS Final Assessment Report

OVERVIEW

Bicalutamida Generis

50 mg, 150 mg, Film-coated tablet

(Bicalutamide)

PT/H/2569/001-002/DC

Applicant: Eugia Pharma (Malta) Limited

Reference Member State	PT
Start of the procedure:	23/06/2023
Date of this report:	31/07/2024

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ADMINISTRATIVE INFORMATION

Proposed name of the medicinal product in the RMS	Bicalutamida Generis
Name of the drug substance (INN name):	Bicalutamide
Pharmaco-therapeutic group (ATC Code):	L02BB03; HORMONE ANTAGONISTS AND RELATED AGENTS, Anti-androgens
Pharmaceutical form(s) and strength(s):	Film-coated tablet, 50 mg, 150 mg
Reference Number(s) for the Decentralised Procedure	PT/H/2569/001-002/DC
Reference Member State:	PT
Concerned Member States:	• PT/H/2569/001/DC: BE, DE, ES, FR, IT, NL • PT/H/2569/002/DC: BE, DE, ES, IT, NL
Legal basis of application:	Article 10(1) generic application
Applicant (name and address)	Eugia Pharma (Malta) Limited Valletta Waterfront 14 Vault 2 Level Floriana FRN 1914 Malta
Names and addresses of all manufacturer(s) responsible for batch release in the EEA	**APL Swift Services (Malta) Limited** Hf26, Hal Far Industrial Estate Qasam Industrijali Hal Far Birzebbuga BBG 3000 Malta (GMP – 21-04-2021) **Generis Farmaceutica S.A.** Rua Joao De Deus N 19 Venda Nova, Amadora 2700-487 Portugal (GMP – 20-10-2021) **Arrow Generiques** 26 Avenue Tony Garnier

	Lyon 69007 France (GMP- ~~08-12-2021~~ 15-02-2024)
Names and addresses of all manufacturer(s) of the medicinal products	[redacted]

[redacted]

	[redacted]
Names and addresses of all manufacturers of the active substance	[redacted]
Names and addresses of all ASMF holders (if different from manufacturer of active substance)	
Names and addresses of all CEP holders (if different from manufacturer of active substance)	[redacted]
Names and addresses of contract companies used for clinical trials (CRO(s))	**Eugia Pharma Specialities Limited** Survey No 550 551 And 552 Kolthur Village Shamirpet Mandal Medchal Malkajgiri District Hyderabad Telangana 500101 India *(Sponsor)* **Axis Clinicals Limited** 1-121/1 Survey No 66 (part) & 67 (part) Serilingampally Hyderabad 500049 India *(Clinical, Bioanalytical and Pharmacokinetic centres)*
RMS contact person	**Name:** [redacted] **Tel:** [redacted] **Email:** rms.procedures@infarmed.pt
Names of the assessors:	**Quality**: [redacted] **Non-clinical**: [redacted] **Clinical**: [redacted] **BE**: [redacted] **ERA**: [redacted]

I RECOMMENDATION

Based on the review of the data on quality, safety and efficacy, the RMS considers that the application for Bicalutamida Generis 50 mg and 150 mg, film-coated tablets:

Bicalutamide 150 mg:
is indicated as monotherapy or as adjuvant to radical prostatectomy or to radiotherapy in patients with locally advanced prostate cancer at high risk for disease progression (see section 5.1).
Monotherapy treatment of patients with metastatic prostate cancer, for whom the whom surgical castration or other medical intervention is not considered appropriate or acceptable.

Bicalutamide 50 mg:
Combination therapy with <Invented name> 50 mg:
Treatment of advanced prostate cancer in combination with luteinizing hormone-releasing hormone (LHRH) analogue therapy or surgical castration.
Monotherapy with 3 tablets of <Invented name> 50 mg (150 mg bicalutamide): [Invented name] at a dose of 150 mg is indicated either alone or as adjuvant to radical prostatectomy or radiotherapy in patients with locally advanced prostate cancer at high risk for disease progression (see section 5.1).

is approvable.

II EXECUTIVE SUMMARY

II.1 Problem statement

For generic application this section is not applicable.

II.2 About the product

The product contains the active ingredient Bicalutamide, which belongs to the Pharmacotherapeutic Group: Anti-androgens (ATC code: L02BB03).
Bicalutamide is a non-steroidal antiandrogen, devoid of other endocrine activity. It binds to androgen receptors without activating gene expression, and thus inhibits the androgen stimulus. Regression of prostatic tumours results from this inhibition. Clinically, discontinuation of bicalutamide can result in antiandrogen withdrawal syndrome in a subset of patients.
Bicalutamide is a racemate with its antiandrogenic activity being almost exclusively in the (R)-enantiomer.

II.3 General comments on the submitted dossier

This decentralised application concerns a generic version, under Directive 2001/83/EC Article 10 (1) for Bicalutamide 50 mg and 150 mg, film-coated tablet, with the trade name Bicalutamida Generis 50 mg and 150 mg, film-coated tablets.

The originator product is Casodex; 50 mg and 150 mg, Film-coated tablet, by Laboratoires Juvisé Pharmaceuticals which is currently approved in several European countries.

With PT as Reference Member State in this Decentralized Procedure, *Eugia Pharma (Malta) Limited* is applying for the Marketing Authorisation for

- *Bicalutamida Generis 50 mg film-coated tablets* in BE, DE, ES, FR, IT and NL as CMS (PT/H/2569/001/DC)
- *Bicalutamida Generis* 150 *mg film-coated tablets in* BE, DE, ES, IT and NL as CMS (PT/H/2569/002/DC)

The current formulation has the same qualitative and quantitative composition, in terms of active substance, and the same pharmaceutical form than the reference product marketed throughout Europe.

Assessment of similarity with authorised orphan medicinal product(s) under market exclusivity
Potential similarity with orphan medicinal products
According to the application form and a check of the Community Register of orphan medicinal products there is no medicinal product designated as an orphan medicinal product for a condition relating to the indication proposed in this application.

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 finished product and batch release situated in the EU.

III SCIENTIFIC OVERVIEW AND DISCUSSION

III.1 Quality aspects

[redacted]

[redacted]

III.2 Non clinical aspects

Pharmacodynamic, pharmacokinetic and toxicological properties of bicalutamide are well known. As bicalutamide is a widely used, well-known active substance, the applicant has not submitted additional studies and further studies are not required. An overview based on literature review is, thus, appropriate.

The non-clinical overview has been written by Dr Sebastian V. J., graduate in Veterinary Pharmacology and Toxicology, and Director of Development Consulting and Scientific Affairs at PharmaLex India Pvt. Ltd. since 2019. Report is dated March 2023 and refers 42 publications up to year 2022.

Assessor's comment:
The non-clinical overview on the pre-clinical pharmacology, pharmacokinetics and toxicology is adequate.
Concerning the SmPC proposed for Bicalutamide 150 mg film-coated tablets, the non-clinical safety findings are considered adequately mentioned in sections 4.6 and 5.3. Notwithstanding, the SmPC/5.3 content for Bicalutamide 50 mg film-coated tablets should be harmonized in line with the content proposed for Bicalutamide 150 mg film-coated tablets.

Environmental Risk Assessment (ERA)
The presented justification for the absence of ERA is prepared according to Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use (EMEA/CHMP/SWP/4447/00 corr 2, EMA 2006) and Questions and answers on Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use (EMA/CHMP/SWP/44609/2010 Rev. 1, 2016) and is based on the generic substitution of the product.
According the guidelines each applicant is required to submit an ERA also for applications under Art 10-generic medicinal products. However, the ERA dossier may consist of an adequate justification for the absence of specific study data, the Q&A document EMA/CHMP/SWP/44609/2010 Rev. 1, 2016, offers the possibility of the following justification for the absence of a complete ERA. And “In certain cases, consumption data of the active ingredient in Kg/year over the time, preferably for at least the last 4 years in several Member States, might be helpful in this respect.”
Applicant supplied sale data for the last 3 years (2020-2022) of Bicalutamide reflecting a decreasing trend in the involved member states. Moreover, since is intended for a generic replacement it will not lead to increased exposure to the environment, but rather to replace part of the current market.

Furthermore, as Bicalutamida Generis 50 mg and 150 mg, film-coated tablets are intended to substitute the reference product in the involved member states where the reference product is already present, no change to the environmental exposure is anticipated following approval of the Marketing Authorisation for the proposed product.

In line with EMA/CHMP/SWP/44609/2010 Rev. 1, 2016, an increase in environmental exposure is expected only when the following conditions are fulfilled: "An increase in environmental exposure is generally expected when the patient population is increased. Examples are: the addition of a new indication, the inclusion of a new patient population or an increase of the maximum recommended therapeutic dose." None of these three criteria is fulfilled in the proposed generic application, therefore no increase in environmental exposure due to the registration of proposed generic product is expected.

Bicalutamida Generis 50 mg and 150 mg, film-coated tablets are a generic product intended to substitute the reference and fulfils the Q&A criterion for the justification/absence of a complete ERA:
1. No new indication is added.
2. The same patient population will be treated.
3. No increase in the maximum recommended therapeutic dose.
Bicalutamide has restricted therapeutic indications and a well-defined posology, under supervision of a physician experienced in the treatment of cancer patients.
Considering the above mentioned the information presented is considered satisfactory and acceptable for absence of ERA studies.
4. The product will be marketed only in the member states where the reference product is already present.
Based on the above no further assessment is necessary. Bicalutamida Generis 50 mg and 150 mg, film-coated tablets approval will not lead to an increase in environmental exposure.
According to the Q&A on Guideline on the Environmental Risk Assessment of Medicinal Products for Human Use, EMA/CHMP/SWP/44609/2010 Rev. 1, 2016, criteria for the absence of a complete ERA are thus justified.

The precautionary and safety measures taken in order to reduce any risk to the environment by including the general statement on the SmPC and PL, according to "Guideline on the environmental risk assessment of medicinal products for human use" EMEA/CHMP/SWP/4447/00, 2006, have been applied by the applicant.

Assessor´s comments:
Applicant's justification for the omission of the Environmental Risk Assessment (ERA) is accepted and it is line with EMA/CHMP/SWP/44609/2010 Rev. 1, 2016. An increased exposure to the environment is not expected. Thus, no environmental risk is foreseen.

III.3 Clinical aspects

This assessment report represents an evaluation of the key elements of the information provided by the company in the dossier. For more details, the reader should refer to the company´s clinical overview and summary and to the clinical file.

The clinical overview was written by *Dr.* [redacted], *M.D.*, medically qualified and currently Professor (Pharmacology) at Hamdard University, New Delhi, and Consultant to Lifesciences Industry.

The clinical overview is dated March 2023 and refers to 70 publications up to year 2022.

The clinical efficacy and safety of bicalutamide are sufficiently known, in which bicalutamide-containing medicinal products have been marketed in several countries for several years.

Assessor's comment:
Proposed PI texts for Bicalutamide Generis, 150 mg, film-coated tablet, are in line with PI texts of reference medicinal product, Casodex, 150 mg, film-coated tablet (see section 5). Proposed PI texts for Bicalutamide Generis, 50 mg, film-coated tablet, are in line with PI texts of Bicalutamide Sandoz 50 mg, film-coated tablet (approved through DC procedure NL/H/0738/001/DC in 15.02.2007) with the contained information in accordance with reference product, Casodex, 50 mg, film-coated tablet.

Assessor's comment:

A Clinical Overview was submitted, containing a review of published clinical data on pharmacokinetic and pharmacologic properties of bicalutamide.

In particular, the overview of biopharmaceutical issues is provided concerning the basis for the application, the biopharmaceutical grounds for the product development and a summary of the in vivo bioequivalence studies performed with the 50 mg strength and the 150 mg strength, fulfilling the requirements for in vivo bioequivalence testing of immediate release formulations, according to the Guideline on the Investigation of Bioequivalence.

The applicant has conducted two bioequivalence studies against both the strengths as below:

- **Study no: 028-21**: *An open label, balanced, randomised, two-treatment, two-sequence, two-period, cross-over, single-dose, oral bioequivalence study of Bicalutamide Tablets 50 mg (Test) of Eugia Pharma Specialities Limited, India and Casodex® (Bicalutamide) Tablets 50 mg (Reference) of AstraZeneca GmbH, Germany in 60 healthy, adult, male, human subjects under fasting conditions.*
- **Study no: 001-21**: *An open label, balanced, randomised, two-treatment, two sequence, two-period, crossover, single-dose, oral bioequivalence study of Bicalutamide Tablets 150 mg (Test) of Eugia Pharma Specialities Limited, India and Casodex® (Bicalutamide) Tablets 150 mg (Reference) of AstraZeneca GmbH, Germany in 60 healthy, adult, male, human subjects under fasting conditions.*

Assessor's comment:

For immediate release tablets, bioequivalence can be assessed based on a single dose study. According to the current guideline, the bioequivalence studies submitted (with both 50 mg & 150 mg strengths) are sufficient to support the application.

Assessor's comment:

In principle, the submitted bioequivalence studies are considered adequate and sufficient to support registration of Bicalutamida 50 mg and 150 mg tablets.

The overall design in both studies is similar and acceptable. GCP and GLP aspects are stated and the CRO was recently inspected by EU regulatory Authorities.

CoA of biobatches, containing the required information on test and reference products are provided. The reference product is appropriate. Test product batch size (120 000 tablets) is acceptable.

The drug assay (% of label claim) of test and reference products show that they differ less than 5%.

Pharmacokinetic conclusion

Bioequivalence was adequately demonstrated between the proposed generic products *Bicalutamide Generis 50mg/150mg tablets* and the reference products of bicalutamide in the market, *Casodex®.*

Before approval can be recommended, the Applicant should solve the issues addressed in the LoQ.

Summary Pharmacovigilance system

The RMS considers that the Pharmacovigilance systems as described by the applicant fulfil the requirements and provides adequate evidence that the applicant has the services of a qualified person responsible for pharmacovigilance and has the necessary means for the notification of any adverse reaction suspected of occurring either in the Community or in a third country.

Assessor's comment:
The applicant provided a Summary of the Pharmacovigilance System for RMS (PT) dated 31 January 2023 (version SPS/EUGIA-PT/003) that includes a set of documents, namely: a signed statement appointing a European Union Qualified Person Responsible for Pharmacovigilance (EU-QPPV), Ludka Fyles (Medical Degree in General Medicine. Charles University, Prague); contact details of the EU-QPPV: Birzebbuga, Malta; a statement indicating that the QPPV resides in Malta and operate where the Pharmacovigilance System Master File (PSMF) for the medicinal product is located (Birzebbuga, Malta) - PSMF code assigned by the eXtended EudraVigilance Medicinal Product Dictionary: MFL18867; a signed statement confirming the necessary means to fulfil the tasks and responsibilities listed in the Title IX of Directive 2001/83/EC.
Similar set of documents were submitted for CMS (version SPS/EUGIA-MI/001 dated 31 October 2022).

Risk Management Plan

The Applicant submitted a Risk Management Plan for Bicalutamide (version 1.0) dated 13 March 2023.
Upon request, the Applicant submitted an updated Risk Management Plan for Bicalutamide (version 1.1) dated 22 December 2023, that comply with current EU legislation.
On Day 198, the Applicant submitted an updated Risk Management Plan for Bicalutamide (version 1.2) dated 21 Jun 2024, that comply with current EU legislation.

The table below summarizes the proposed identified safety concerns for the product:

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

No additional pharmacovigilance activities or additional risk minimisation measures are being proposed.

Assessor's comment:
The applicant has provided description of the risk management system (version 1.1) for Bicalutamide. No additional pharmacovigilance activities or risk minimisation measures are being proposed, which is supported.

The MAH shall perform the required pharmacovigilance activities and interventions detailed in the agreed RMP presented in Module 1.8.2 of the Marketing Authorisation and any agreed subsequent updates of the RMP.

An updated RMP should be submitted:

- At the request of the RMS;
- Whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important (pharmacovigilance or risk minimisation) milestone being reached.

If the dates for submission of a PSUR and the update of a RMP coincide, they can be submitted at the same time, but via different procedures.

Periodic Safety Update Report (PSUR)

Active substance is currently listed in the published EURD list
With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.
- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
- In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.

Common renewal date
The common renewal date will be set 5 years after the EoP.

IV BENEFIT RISK ASSESSMENT

Based on the review of the data on quality, safety and efficacy, the RMS considers that the application for Bicalutamida Generis, is approvable.

V LIST OF QUESTIONS as proposed by RMS

V.1 Quality aspects

Major objections
None

Other concerns
None

V.2 Non clinical aspects

Major objections
None

Other concerns
None

V.3 Clinical aspects

Major objections

None

Other concerns

None

V.4 Module 1

Major objections
None

Other concerns
None

VI RECOMMENDATIONS AND CONDITIONS FOR MARKETING AUTHORISATION AND PRODUCT INFORMATION

VI.1 Legal Status

POM restricted

VI.2 List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC

N/A

VI.3 List of conditions pursuant to Article 21a or specific obligations pursuant to Article 22 of Directive 2001/83/EC

N/A

VI.4 Module I – Application related comments (including product name)

Product name

The proposed product name in PT, Bicalutamida Generis (INN+"Generis"; MAH is Eugia Pharma (Malta) Limited) is acceptable. A declaration from Generis was submitted allowing the use of the brand name "Generis" by Eugia Pharma (MAH).

VI.5 Summary of Product Characteristics (SmPC)

Proposed PI texts for Bicalutamide Generis, film-coated tablet, are in line with PI texts of reference medicinal product, Casodex.

SmPC is attached.

VI.6 Package Leaflet (PL)

VI.6.1 Package Leaflet

Proposed PI texts for Bicalutamide Generis, film-coated tablet, are in line with PI texts of reference medicinal product, Casodex.

PL is attached.

VI.6.2 Assessment of User Testing

Assessment of the User Testing is attached in the 'QRD Guidance and Checklist for the Review of User Testing Results'.

VI.7 Labelling

Labelling is attached.

VII APPENDIX

QRD GUIDANCE AND CHECKLIST FOR THE REVIEW OF USER TESTING RESULTS

QRD GUIDANCE AND CHECKLIST FOR THE REVIEW OF USER TESTING RESULTS

[Disclaimer: This guidance has been set up to provide practical information on how to evaluate user testing reports which are based on the readability testing method as described in Annex 1 of the EC Readability Guideline. This does not exclude the submission and evaluation of user testing reports based on other methods than the one outlined above, for which specific assessment guidance may be issued once experience has been gained

Useful links: More detailed practical guidance can be found in the following documents:

- *EC Readability Guideline http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-2/c/2009_01_12_readability_guideline_final.pdf*
- *"Operational procedure on Handling of "Consultation with target patient groups" on Package Leaflets (PL) for Centrally Authorised Products for Human Use http://www.emea.europa.eu/htms/human/qrd/qrdplt/27737805en.pdf* "Consultation with Target Patient Groups-meeting the requirements of Article 59(3) without the need for a full test-Recommendations for Bridging" http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Consulation_PatientsGroups/CMDh_100_2007_Rev1_clean_April09.pdf
- "Position paper on user testing of package leaflets" http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/Consulation_PatientsGroups/CMDh_234_2011.pdf
- *[MRP/DCP relevant document – link to be inserted]*

PRODUCT INFORMATION

Name of the medicinal product:	Bicalutamida Generis
Name and address of the applicant:	Eugia Pharma (Malta) Limited Valletta Waterfront 14 Vault 2 Level Floriana FRN 1914 Malta
Name of company which has performed the user testing:	Eugia Pharma (Malta) Limited
Type of Marketing Authorisation Application:	Article 10(1) generic application
Active substance:	Bicalutamide
Pharmaco-therapeutic group (ATC Code):	L02BB03; HORMONE ANTAGONISTS AND RELATED AGENTS, Anti-androgens
Therapeutic indication(s):	*Bicalutamide 150 mg is indicated either alone or as adjuvant to radical prostatectomy or radiotherapy in patients with locally advanced prostate cancer at high risk for disease progression. Bicalutamide 150 mg is also indicated for the management of patients with locally advanced, non-metastatic prostate cancer for whom surgical castration or other medical intervention is not considered appropriate or acceptable.* *Bicalutamide 50 mg is indicated in the treatment of advanced prostate cancer in combination with luteinising hormone-releasing hormone (LHRH) analogue therapy or surgical castration*

- Full user testing report provided	☐ yes	☒ no
- Bridging report provided	☒ yes	☐ no

(In case of bridging report, multiple bridging is, in principle, not acceptable. However, a maximum of 3 bridging procedures could be accepted for one product: e.g. first bridging to address the scientific content, a second one to address the device and a last one to address the layout of the PL).

- Grounds for bridging based on a sound justification:
  - ☐ extensions for the same route of administration

☒ reference to test on same class of medicinal product
☐ reference to test with same safety issues
☐ other _____

Is the justification for bridging acceptable? ☒ yes ☐ no

(In case no full user testing or bridging report has been provided, a justification should be submitted.)

- Is the justification for not submitting a report acceptable? ☐ yes ☐ no

Reasons

The Applicant requested a waiver based on bridging statements for conducting a user testing on the proposed PL for Bicalutamide Generis, 50 mg & 150 mg, film-coated tablet. Therefore, it submitted the following documents:
- Statements confirming the Daughter PL design and layout is similar with that of Aurobindo's design & layout; also, the Applicant submitted a formally bridging to compare the design and layout of Bicalutamida Generis, 50 mg & 150 mg, film-coated tablet (Daughter PL) with Metoprolol Aurobindo, 50 mg & 100 mg, film-coated tablets (Parent design & layout PL) assessed and approved during DC Procedure SE/H/120l/001-002/DC, which are considered identical;

The details of the technical readability as compared as following,

	Metoprolol Aurobindo 50 mg & 100 mg film-coated tablets (Parent PIL -Design & layout)	<Invented name> 50 mg film-coated tablet (Daughter PIL)
Font	Arial	Arial
Font size	9 pt	9 pt
Paper size	210 x 360 mm	150 x 320 mm
Weight of the paper	40-45 g/m^2	40-45 g/m^2
Colour of the paper	White	White
Colour of the text	Black	Black

- The PAR of Metoprolol Aurobindo, 50 mg & 100 mg, film-coated tablets (SE/H/1201/001-002/DC), confirming that the PL was approved via a valid user consultation study;
- A statement confirming proposed PL text for Bicalutamida Generis, 50 mg, film-coated tablet (Daughter PL), is inline to the text of Bicalutamide Sandoz 50 mg, film-coated tablet (Parent content PL) which was approved through DC procedure NL/H/0738/001/DC and the date of issue of the marketing authorization is 15.02.2007; the important key messages for safe use are similar in both Daughter and Parent content PL;
- A statement confirming proposed PL text for Bicalutamida Generis, 150 mg, film-coated tablet (Daughter PL), is inline to the text of Bicalutamide Accord 150 mg, film-coated tablet (Parent content PL) which was approved through DC procedure NL/H/4485/001/DC and the date of issue of the marketing authorization is 22.01.2020 and also inline with the reference product, Casodex; the important key messages for safe use are similar in both Daughter and Parent content PL;
- The PAR of Bicalutamide Sandoz, 50 mg, film-coated tablet (NL/H/738/001/DC dated 25 June 2009) confirming that its PL has been accepted via a sucessful user consultation study;
- The PAR of Bicalutamide Accord, 150 mg, film-coated tablet (NL/H/4485/001/DC dated 07 May 2020), in which its PL has been accepted via a on the basis of a bridging report making reference to the content of Bicalutamide Fresenius Kabi 150 mg (UK/H/3982/001/DC).
RMS agrees that the design and layout of the PL of Bicalutamida Generis is similar to Metoprolol Aurobindo, which ensures the readability and traceability of the information in Daughter PL. As the content of the PL for Bicalutamida Generis 150 mg is inline with the reference product, Casodex 150 mg, and the content of the PL for Bicalutamida Generis 50 mg is in line with the PL of Bicalutamide Sandoz 50 mg, which was approved via a successful user consultation study, RMS may accept the waiver and that proposed leaflet for Bicalutamida Generis, 50 mg & 150 mg, film-coated tablet, complies with the CMDh Guideline "Consultation with target patient groups - Meeting the requirements of article 59(3) without the need for a full test - Recommendations for Bridging" (April, 2009).